No. 2024-1864

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

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

Plaintiffs-Appellants,

EDWARDS LIFESCIENCES CORPORATION, EDWARDS LIFESCIENCES LLC,

Plaintiffs,

v.

KATHERINE K. VIDAL, Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office,

Defendant-Appellee.

On Appeal from the United States District Court for the Northern District of California in Case No. 5:20-cv-06128-EJD, Judge Edward J. Davila

BRIEF FOR PLAINTIFFS-APPELLANTS

NATHAN K. KELLEY
PERKINS COIE LLP
700 Thirteenth Street NW, Suite 800
Washington, DC 20005
(202) 654-3343

ANDREW T. DUFRESNE
PERKINS COIE LLP
33 East Main Street, Suite 201
Madison, WI 53703
(608) 663-7492

Attorneys for Plaintiff-Appellant Google LLC

CATHERINE M.A. CARROLL
GARY M. FOX
WILMER CUTLER PICKERING HALE AND DORR LLP
2100 Pennsylvania Avenue NW
Washington, DC 20037
(202) 663-6000

MARK D. SELWYN
WILMER CUTLER PICKERING HALE AND DORR LLP
2600 El Camino Real, Suite 400
Palo Alto, CA 94306
(650) 858-6000

Attorneys for Plaintiffs-Appellants Apple Inc., Cisco Systems, Inc., and Intel Corporation

August 5, 2024

ADDITIONAL COUNSEL LISTED ON INSIDE COVER

ALYSON M. ZUREICK
WILMER CUTLER PICKERING
HALE AND DORR LLP
7 World Trade Center
250 Greenwich Street
New York, NY 10007
(212) 230-8800

Counsel for Plaintiffs-Appellants Apple Inc., Cisco Systems, Inc., and Intel Corporation

CERTIFICATE OF INTEREST

Counsel for Plaintiffs-Appellants Apple Inc., Cisco Systems, Inc., and Intel Corporation certifies the following:

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

Apple Inc., Cisco Systems, Inc., and Intel Corporation.

2. Real Party in Interest. Fed. Cir. R. 47.4(a)(2). 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.

None.

3. Parent Corporations and Stockholders. Fed. Cir. R. 47.4(a)(3). 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.

None.

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).

WILMER CUTLER PICKERING HALE AND DORR LLP: Jane E. Kessner, Rebecca M. Lee (former), David M. Lehn (former)

5. Related Cases. Other than the originating case(s) for this case, are there related or prior cases that meet the criteria under Fed. Cir. R. 47.5(a)?

[X] Yes (file separate notice; see below) [ ] No [ ] N/A (amicus/movant)

If yes, concurrently file a separate Notice of Related Case Information that complies with Fed. Cir. R. 47.5(b). Please do not duplicate information. This separate Notice must only be filed with the first Certificate of Interest or, subsequently, if information changes during the pendency of the appeal. Fed. Cir. R. 47.5(b).

Already filed.

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: August 5, 2024

/s/ Catherine M.A. Carroll

CATHERINE M.A. CARROLL
WILMER CUTLER PICKERING
HALE AND DORR LLP
2100 Pennsylvania Avenue NW
Washington, DC 20037
(202) 663-6000

CERTIFICATE OF INTEREST

Counsel for Plaintiff-Appellant Google LLC certifies the following:

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Google LLC

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None.

3. Parent Corporations and Stockholders. Fed. Cir. R. 47.4(a)(3). 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.

XXVI Holdings Inc.; Alphabet 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).

PERKINS COIE LLP: Daniel T. Shvodian, Theresa Nguyen

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None.

Dated: August 5, 2024

/s/ Nathan K. Kelley

NATHAN K. KELLEY
PERKINS COIE LLP
700 Thirteenth Street NW, Suite 800
Washington, DC 20005
(202) 654-3343

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STATEMENT OF RELATED CASES

This case was previously before this Court in a prior appeal. *Apple Inc. v. Vidal*, 63 F.4th 1 (Fed. Cir. Mar. 13, 2023) (No. 2022-1249) (Taranto, J., joined by Lourie & Stoll, JJ.). The U.S. Supreme Court declined to review this Court's decision in that appeal. *Intel Corp. v. Vidal*, 144 S. Ct. 548 (2024) (Mem.). There have been no other appeals in this case to any other appellate court.

Counsel for Appellants are not aware of any case pending in this Court or before any other tribunal that will directly affect or be directly affected by the Court's decision in this appeal.

JURISDICTIONAL STATEMENT

The district court had jurisdiction under 28 U.S.C. § 1331. The Director has waived sovereign immunity. 5 U.S.C. § 702.

The district court denied Appellants' motion for summary judgment and granted the Director's motion for summary judgment on March 31, 2024. Appx1-23. The district court entered final judgment in favor of the Director on April 1, 2024. Appx24.

Appellants timely filed a notice of appeal on May 15, 2024. Appx1738. This Court has jurisdiction under 28 U.S.C. § 1295(a)(1), as the action initially arose in part under the America Invents Act ("AIA"), 35 U.S.C. §§ 311 *et seq*., an "Act of Congress relating to patents," 28 U.S.C. § 1295(a)(1).

INTRODUCTION

The "*NHK-Fintiv* Rule" is unlawful because the Director of the Patent and Trademark Office ("PTO") adopted it without notice-and-comment rulemaking required under the Administrative Procedure Act ("APA"). *NHK-Fintiv* establishes a binding standard governing whether the Patent Trial and Appeal Board ("PTAB" or "Board") will institute IPR when parallel district court litigation exists. The district court initially held that Appellants' notice-and-comment claim is not judicially reviewable, but this Court reversed in relevant part. *Apple Inc. v. Vidal*, 63 F.4th 1, 14-15 (Fed. Cir. 2023). On remand, the district court concluded that *NHK-Fintiv* is not a "substantive" rule and therefore not subject to APA notice-and-comment requirements. That was legal error.

The APA requires notice-and-comment rulemaking for any rule that affects parties' legal rights and interests and binds agency decisionmakers. As applied to such "substantive" rules, notice-and-comment serves vital interests in fairness and good government by giving affected parties an opportunity to be heard and requiring agencies to consider their input. *NHK-Fintiv* is such a rule: It changes the Board's institution standards to implement the Director's policy judgments by making institution less likely when there is parallel litigation, depriving infringement defendants of the opportunity to seek cancellation of patents through IPR. As this Court has explained, due to the Director's precedential designations,

the Rule binds the Board to follow that policy choice so that the Board exercises institution discretion in the same way the Director would if she were making the institution decisions herself. *See Apple*, 63 F.4th at 13.

The district court erred in concluding that *NHK-Fintiv* is a "general statement of policy" exempt from notice-and-comment. *See* 5 U.S.C. § 553(b). The court erroneously accepted the Director's litigation position that, so long as the Board merely considers the Rule's factors, the Board may exercise its own judgment as to whether and when parallel litigation warrants denial of institution. That position cannot be squared with the Director's actual instructions to the Board. Nor can it be squared with the Board's application of the Rule in practice or its harmful effects on infringement defendants seeking the benefits of IPR. The AIA underscores that *NHK-Fintiv* is the type of rule that Congress required to be adopted through notice-and-comment. *See* 35 U.S.C. § 316(a)(2), (4).

The district court's contrary decision allows the Director to eliminate the last check against institution standards that bind the Board and remove the IPR alternative Congress intended. Such rules cannot be challenged under the APA as contrary to law or arbitrary and capricious. *Apple*, 63 F.4th at 11-14. They cannot be challenged before the Board, which has disclaimed any discretion to depart from *NHK-Fintiv*. *Infra* pp. 13-16. And an infringement defendant whose IPR petition is denied under such a rule has no recourse in the courts. *See Mylan Labs.*

Ltd. v. Janssen Pharmaceutica, N.V., 989 F.3d 1375, 1378 (Fed. Cir. 2021), *cert. denied*, 142 S. Ct. 874 (Jan. 18, 2022) (Mem.). Enforcing notice-and-comment requirements in these circumstances is thus vital to ensure that affected parties are heard and that the agency confronts the legal and policy flaws in its approach.

STATEMENT OF THE ISSUES ON APPEAL

Whether, by adopting the *NHK-Fintiv* Rule without notice-and-comment rulemaking, the Director violated (1) the APA, 5 U.S.C. § 553, and (2) the AIA, 35 U.S.C. § 316(a)(2), (4).

STATEMENT OF THE CASE AND FACTS

A. Inter Partes Review

The U.S. patent system's success depends on both providing robust protections for meritorious patents and ensuring that "questionable" patents cannot be exploited in litigation to inhibit innovation. *See* H.R. Rep. No. 112-98, at 39 (2011) ("House Report"). IPR plays a vital role by allowing any person, including an accused infringer, to ask the PTO to reconsider the patentability of previously granted patent claims in view of prior art that the PTO may not have fully considered during its initial examination. *See* 35 U.S.C. § 311.

Congress established IPR out of a "growing sense that questionable patents" were "too easily obtained" and "too difficult to challenge" through existing procedures. House Report 39-40; *see also SAS Inst. Inc. v. Iancu*, 138 S. Ct. 1348,

1353 (2018). IPR benefits parties—especially those facing patent-infringement suits in district court—by providing a "cost effective alternative[] to litigation" for resolving invalidity issues. House Report 40, 48; *see also, e.g.*, House Report 40; 157 Cong. Rec. 3403 (2011) (Statement of Sen. Udall) (IPR "limit[s] unnecessary and counterproductive litigation costs"). As two of the original sponsors of the AIA recently explained, the "intention … was to provide … an efficient, less costly alternative for businesses, and inventors of every type and size." Leahy & Goodlatte, *Flawed* Fintiv *Rule Should Be Deemed Overreach in Tech Suit*, Law360 (June 20, 2024); Appx1750-1752.

Consistent with that goal, IPR offers numerous advantages over district court litigation. Unlike a general verdict, the Board's final written decision facilitates more informed appellate review. IPR is also more streamlined than litigation: An IPR petitioner may challenge a patent only on limited grounds, 35 U.S.C. § 311(b); discovery is limited, *id.* § 316(a)(5); 37 C.F.R. § 42.51; and strict deadlines generally result in the resolution of an IPR within 18 months after the petition is filed, 35 U.S.C. §§ 314(b), 316(a)(11); 37 C.F.R. §§ 42.100, 42.107. Moreover, while questionable patents survive in litigation unless the defendant proves invalidity by clear and convincing evidence, *see Microsoft Corp. v. i4i Ltd. P'ship*, 564 U.S. 91, 95 (2011), in IPR, questionable patent claims will be canceled if the petitioner proves unpatentability by a preponderance of the evidence, 35 U.S.C.

§ 316(e). Finally, IPRs are decided by administrative patent judges ("APJs") with "technical expertise and experience," who "contribute to the public confidence by providing more consistent and higher quality final written decisions" on patentability. *Arthrex, Inc. v. Smith & Nephew, Inc.*, 941 F.3d 1320, 1336 (Fed. Cir. 2019), *vacated on other grounds*, 141 S. Ct. 1970 (2021); *see also* 35 U.S.C. § 6(a) (APJs "shall be persons of competent legal knowledge and scientific ability").

The AIA gives the Director discretion to institute or not to institute IPRs. *See* 35 U.S.C. § 314(a); *Apple Inc. v. Vidal*, 63 F.4th 1, 6-7 (Fed. Cir. 2023). The Director in turn has delegated that authority to the Board. 37 C.F.R. § 42.4(a); *see also id.* §§ 42.2, 42.108; *Apple*, 63 F.4th at 7. The Director's—and hence the Board's—discretion is bounded by the AIA, which establishes "certain preconditions [that] must be met" before IPR may be instituted. *Apple*, 63 F.4th at 6. As this Court previously explained, "[o]ne prerequisite, for all petitions, is the crossing of a merits 'threshold.'" *Id.* Specifically, IPR cannot be instituted "unless" the Director finds that there is "a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314(a). The AIA also sets forth filing deadlines and content requirements for IPR petitions. *E.g.*, *id.* §§ 311(c)(1)-(2), 312(a)(1)-(5), 315(a)(1)-(2), 315(b). And the AIA specifies grounds on which the Director may decide not

to institute IPR even when the preconditions are met. *E.g.*, *id.* § 325(d) (Director may "reject the petition … because[] the same or substantially the same prior art or arguments previously were presented" to the PTO). The Director's (and thus the Board's) institution decision in any particular IPR proceeding is "final and nonappealable." 35 U.S.C. § 314(d).

Congress "recognized the likelihood" that IPR would often proceed in parallel with district-court litigation in which the same patent is at issue, particularly where an infringement defendant challenges the asserted patent through IPR. *Apple*, 63 F.4th at 8. Several provisions of the AIA reflect that expectation. Most significantly, the Director may not institute an IPR challenging a patent asserted in district court unless the IPR petition is filed within "1 year after the date on which the petitioner … is served with a complaint alleging infringement." 35 U.S.C. § 315(b). That provision thus permits IPR with respect to patent claims asserted in a parallel infringement suit so long as that "timing limit" is met. *Apple*, 63 F.4th at 6; *see id.* at 8 n.3 (citing several other AIA provisions "reflect[ing] Congress's expectation that the same patent claims might well be at issue in both an IPR proceeding and a court case").

In an agency like the PTO, where the adjudicative body (the Board) is distinct from the rulemaking body (the Director), "adjudication may not operate as an appropriate mechanism for the exercise of rulemaking." *Facebook, Inc. v.*

Windy City Innovations, LLC, 973 F.3d 1321, 1352 (Fed. Cir. 2020) (additional views of Prost, C.J., and Plager, O'Malley, JJ.); *see id.* at 1349-1351. Rather, to establish generally applicable rules implementing the new IPR proceedings, Congress authorized the Director to "prescribe regulations" governing the conduct of IPRs. 35 U.S.C. § 316(a); *see SoftView LLC v. Apple Inc.*, __ F.4th __, 2024 WL 3543902, at *4-5 (Fed. Cir. July 26, 2024). Regulations required under § 316(a) include those setting forth institution standards, 35 U.S.C. § 316(a)(2), and those "establishing and governing" the relationship between IPR and infringement actions in district court, *see id.* § 316(a)(4). Congress also identified specific considerations the Director must evaluate when promulgating such rules, including the proposed rule's effects on "the economy, the integrity of the patent system, the efficient administration of the [PTO], and the ability of the [PTO] to timely complete [AIA] proceedings." *Id.* § 316(b).

The Director exercised this rulemaking authority in 2012 by promulgating regulations governing IPR proceedings after conducting notice-and-comment procedures. *See* 77 Fed. Reg. 48,680 (Aug. 14, 2012). In subsequent years, the Director continued to follow notice-and-comment procedures when adopting other rules governing IPR. *E.g.*, 80 Fed. Reg. 50,720 (Aug. 20, 2015). As the PTO has explained, the agency has "used the federal rulemaking process to its fullest extent to inform its stakeholders and the public about all aspects of implementation" and

to "collect their feedback." PTO, *Study and Report on the Implementation of the Leahy-Smith America Invents Act* 16 (Sept. 15, 2015).

B. The *NHK-Fintiv* Rule

1. The Rule's adoption

This case involves one generally applicable rule, known as the *NHK-Fintiv* Rule, that the Director adopted to instruct the Board how to exercise the Director's institution discretion in cases where parallel patent-infringement litigation is pending in district court. *Apple*, 63 F.4th at 8. That rule establishes a standard the Board must apply in making institution decisions on the Director's behalf and addresses the relationship between IPR and the pending litigation—*i.e.*, matters within the scope of the Director's authority to "prescribe regulations," 35 U.S.C. § 316(a)(2), (4). And in adopting the Rule, the agency invoked the efficiency considerations that Congress instructed the Director to consider in carrying out her rulemaking authority. *See* Appx1182 (citing 35 U.S.C. § 316(b)). Yet the Director did not adopt the *NHK-Fintiv* Rule by "prescrib[ing] regulations," and it is undisputed the Director did not follow notice-and-comment procedures. Instead, the Director adopted the rule by designating two institution decisions of the Board as "precedential" and thus binding on the Board in all future cases.

In the first Board decision, *NHK Spring Co. v. Intri-Plex Technologies, Inc.*, 2018 WL 4373643 (P.T.A.B. Sept. 12, 2018) (Appx1154-1174), the Board

declared that instituting IPR when parallel litigation involving the same patent had reached an "advanced state" "would be an inefficient use of Board resources." *NHK*, 2018 WL 437643, at *7. The "advanced state of … district court proceeding[s]" therefore "weighs in favor of denying" institution. *Id.*

In the second decision, *Apple Inc. v. Fintiv, Inc.*, 2020 WL 2126495 (P.T.A.B. Mar. 20, 2020) ("*Fintiv I*") (Appx1177-1193), the Board elaborated on *NHK* by articulating six factors it would weigh under 35 U.S.C. § 314(a) to determine whether pending parallel litigation warrants denial of an IPR petition:

- The first factor is "whether the court granted a stay or evidence exists that one may be granted if [an IPR] proceeding is instituted." *Fintiv I*, 2020 WL 2126495, at *2. A stay "strongly weigh[s] against exercising the authority to deny institution," while denial of a stay "weigh[s] in favor of exercising authority to deny institution." *Id.* at *3.

- The second factor is "proximity of the court's trial date to the Board's projected statutory deadline for a final written decision." *Id.* at *2. If trial will occur before the Board's deadline for the final written decision, this factor favors denial of institution. *Id.* at *4.

- The third factor is "investment in the parallel proceeding by the court and the parties." *Id.* at *2. If the court "has issued substantive orders related to the patent," then "this fact favors denial." *Id.* at *4. If the court has not issued such orders, then the third factor favors institution. *Id.*

- The fourth factor is "overlap between issues raised in the petition and in the parallel proceeding." *Id.* at *2. This factor favors denial if the IPR petition "includes … substantially the same claims, grounds, arguments, and evidence as presented in the parallel" litigation. *Id.* at *5. Materially different grounds "weigh against exercising discretion to deny institution." *Id.*

- The fifth factor is "whether the petitioner and the defendant in the parallel proceeding are the same party." *Id.* at *2. If the IPR petitioner "is unrelated to a defendant in an earlier court proceeding," this factor favors institution. *Id.* at *6.

- The sixth factor is "other circumstances that impact the Board's exercise of discretion, including the merits." *Id.* at *2. This factor considers whether the petition's merits are strong enough to "outweigh" the other factors. *Id.* at *6. If "the merits of a ground raised in the [IPR] petition seem particularly strong," this factor favors institution, but if the merits are a "closer call," then this factor favors denial. *Id.*

Fintiv I thus explained whether and when each factor weighs for or against institution. *Id.* at *2-6. The Board explained that "evaluating the[se] factors" is how it would decide the ultimate question whether "efficiency, fairness, and the merits" warrant denial of institution based on the parallel proceeding. *Id.* at *3.

"[B]y default," the Board's decisions have no precedential force in later cases. PTAB, *Standard Operating Procedure 2 (Revision 11)*, at 2-3 (July 24, 2023) ("SOP-2"); Appx1742-1749. The Director has authority, however, to designate Board decisions as "precedential," Appx1742-1744; Appx1747-1748, which makes them "binding" on the Board "in subsequent matters involving similar facts or issues," Appx1748; *see Apple*, 63 F.4th at 8. Other than allowing members of the public to nominate Board decisions for precedential designation, Appx1744-1745, the PTO's designation procedure does not entail any advance public notice or opportunity for comment. Instead, the Director may designate

Board decisions as precedential "at any time, in his or her sole discretion." Appx1747.

The Director designated *NHK* as precedential on May 7, 2019, Appx1154, and designated *Fintiv I* as precedential on May 5, 2020, Appx1177. The precedential designations made the *NHK-Fintiv* Rule "binding" on the Board in all IPR institution decisions where district-court infringement litigation involving the same patent claims is pending. *See* Appx1748. As this Court has explained, *NHK-Fintiv* embodies "instructions from the Director regarding how the Board is to exercise the Director's institution discretion." *Apple*, 63 F.4th at 8. Such instructions, the Court observed (and the Director has agreed), are "crucial for ensuring" that institution decisions "will overwhelmingly be made in accordance with the policy choices" the Director "would follow if she were making the determinations herself," *id.* at 13; *see also* Resp. Br. in Opp. 13, *Intel Corp. v. Vidal*, No. 23-135 (U.S. Nov. 9, 2023) ("Director Br. in Opp."), thereby serving to "preserve [the Director's] effective control over the agency in circumstances where delegation is a practical necessity," Director Br. in Opp. 13.

2. The Board's application of the Rule

Following the precedential designations, the Board applied the *NHK-Fintiv* Rule to deny hundreds of timely IPR petitions even where the petition presented meritorious challenges to the patents at issue. *See* Unified Patents, Portal,

https://tinyurl.com/xwmajkyx; *see also* Appx1140-1143 (collecting cases). Following adoption of the Rule, the percentage of cases raising parallel litigation as a ground for denying institution nearly doubled. *See* PTO, *Patent Trial and Appeal Board Parallel Litigation Study* 12, 16 (June 2022).

In cases involving parallel district-court litigation, the Board has followed the Rule by evaluating and assigning weight to each factor as dictated by the Rule and denying institution where the factors collectively weigh against IPR. The Board's decision in *Apple Inc. v. Fintiv Inc.*, 2020 WL 2486683 (P.T.A.B. May 13, 2020) ("*Fintiv II*"), illustrates the Board's approach: Following the Director's adoption of the Rule, the Board applied it by weighing each factor as directed and concluding based on the factors that IPR would be "inefficient" and should therefore be denied. *Id.* at *5-7. The Rule has been similarly dispositive in numerous cases. *See also, e.g.*, *Vector Flow, Inc. v. HID Global Corp.*, IPR2023-00353, Paper 8 at 18-25 (P.T.A.B. July 17, 2023) (applying the Rule to deny institution); *IBM Corp. v. Digital Doors, Inc.*, IPR2023-00969, Paper 8 at 13 (P.T.A.B. Dec. 5, 2023) (same); *Samsung Elecs. Co. v. California Inst. of Tech.*, 2023 WL 5157594 (P.T.A.B. May 4, 2023) (same); *see also* Appx1140-1143 (collecting cases).

The Board has consistently treated the Rule as dispositive even when IPR petitioners have contended that doing so would result in unreasonable

consequences or require speculation about when trial might occur in the parallel district court litigation. For example, the Board has frequently applied the Rule to deny IPR based on the scheduled trial date only for trial to be rescheduled—often after it is too late for the IPR petitioner to seek reconsideration of the Board's decision. Appx1140-1143; *see, e.g.*, *Intel Corp. v. VLSI Tech. LLC*, 2020 WL 2201828, at *3 (P.T.A.B. May 5, 2020) (acknowledging that trial could not possibly begin on the scheduled date but applying the Rule to deny institution based on the scheduled trial date anyway); Dufresne et al., *How Reliable Are Trial Dates Relied on by the PTAB in the* Fintiv *Analysis?*, 1600 PTAB & Beyond (Oct. 29, 2021) (finding the Board's predictions of trial dates were incorrect in 95 percent of cases). Similarly, until the Director instructed the Board not to do so, the Board for years applied the *NHK-Fintiv* Rule in cases involving parallel investigations before the International Trade Commission ("ITC"), even though the ITC cannot issue binding invalidity decisions. *E.g.*, *Google LLC v. EcoFactor, Inc.*, 2022 WL 945681, at *5 (P.T.A.B. Mar. 18, 2022); *Intel Corp. v. Koninklijke Philips N.V.*, IPR2021-00328, Paper 16 at 3 (P.T.A.B. Mar. 29, 2022).

In many such cases, IPR petitioners have raised legal and policy arguments against applying the *NHK-Fintiv* Rule. The Board has consistently responded that it must follow the Rule and deny IPR when the factors weigh against institution. In *Supercell Oy v. GREE, Inc.*, 2020 WL 3455515 (P.T.A.B. June 24, 2020), for

example, the IPR petitioner argued that several of the Rule's factors were inapt for the case or should not be given the weight the Rule assigns, but the Board repeatedly stated that its discretion was "constrained" by *NHK-Fintiv*, which "dictates that [it] consider [each] factor in this manner." *Id.* at *5-6. Even as to the sixth factor, addressing "other circumstances," the Board stated that the *NHK-Fintiv* Rule "do[es] not allow [it] to accord dispositive weight to Petitioner's argument regarding the practicalities of challenging, through [IPR], those patents that have been asserted in lawsuits filed in fast-moving jurisdictions." *Id.* at *7. The petitioner's policy arguments for departing from the Rule, the Board explained, were simply "not within [the Board's] purview to consider, in light of binding precedent." *Id.* Similarly, in *Apple Inc. v. Maxell, Ltd.*, 2020 WL 3662522 (P.T.A.B. July 6, 2020), the petitioner made "extensive policy arguments" against application of the Rule, but the Board again disclaimed any power to consider them because the Director had designated *NHK-Fintiv* as binding precedent. *Id.* at *7. And in *Koninklijke Philips*, IPR2021-00328, Paper 16 at 9, when the IPR petitioner argued that the Board should not apply the *NHK-Fintiv* Rule in cases involving co-pending ITC investigations, the Board responded again that *NHK-Fintiv* established the precedential standard governing the Board's exercise of institution discretion and that nothing in that Rule "would countenance [the petitioner's] alternate approach" to institution decisions. *Id.*; *see also, e.g.*,

Fintiv II, 2020 WL 2486683, at *4 (declining to consider petitioner's "policy arguments" against applying the Rule because the Rule already "addresses" them); *EcoFactor*, 2022 WL 945681, at *5 n.7 (petitioner's arguments that the *NHK-Fintiv* Rule is "incorrect" could not be considered by the Board but must be made to the now-defunct Precedential Opinion Panel).

3. The Director's refinements to the Rule

In October 2020, several months after adopting the *NHK-Fintiv* Rule, the Director solicited comments "on considerations for instituting trials" under the AIA, including the *NHK-Fintiv* Rule. 85 Fed. Reg. 66,502 (Oct. 20, 2020). Reflecting the significant impact of the PTO's institution standards, the agency received 822 comments. *See* PTO, *Public Views on Discretionary Institution of AIA Proceedings* 2 (Jan. 2021). None of those commenters had received any notice or opportunity to comment before the *NHK-Fintiv* Rule was adopted. The October 2020 request for comments did not result in any rulemaking.

More than a year and a half later, without proposing rules or conducting notice-and-comment procedures, the Director issued "binding" guidance "clarif[ying]" what the Board "will" or "will not" consider in applying the *NHK-Fintiv* Rule. *See* Memorandum from PTO Director to PTAB, *Interim Procedure for Discretionary Denials in AIA Post-Grant Proceedings with Parallel District Court Litigation* 3 (June 21, 2022) ("June 2022 Guidance"). Most notably, the

Director instructed the Board to continue applying the *NHK-Fintiv* Rule to deny institution of IPR based on parallel litigation in district court unless the petition passes a heightened institution threshold. *See id.* at 1. Although, as the Director acknowledged, the AIA requires an IPR petitioner to establish only a "reasonable likelihood" that at least one challenged claim is unpatentable, 35 U.S.C. § 314(a), the Director instructed the Board to deny institution of IPR in accordance with the *NHK-Fintiv* Rule unless the petition presents "compelling evidence" that "would plainly lead to a conclusion" that the challenged claims are unpatentable. June 2022 Guidance 3-5. The Director also instructed the Board to stop applying *NHK-Fintiv* to cases involving parallel ITC investigations. *Id.* at 5-7. And the Director instructed the Board not to deny institution if the "petitioner stipulates not to pursue in a parallel district court proceeding the same grounds as in the petition or any grounds that could have reasonably been raised in the petition." *Id.* at 7 (citing *Sotera Wireless, Inc. v. Masimo Corp.*, IPR2020-01019, Paper 12 at 18-19 (P.T.A.B. Dec. 1, 2020)). The Director stated that the "the [PTO] expects to replace this interim guidance with rules after it has completed formal rulemaking," *id.* at 9, but again undertook no rulemaking at that time.

The Director further tightened the *NHK-Fintiv* institution standard in *CommScope Techs. LLC v. Dali Wireless, Inc.*, 2023 WL 2301719, at *1 (P.T.A.B. Feb. 27, 2023). In that case, after the Director issued the June 2022 Guidance, the

Board determined that the merits of the IPR petition were compelling enough that the Board granted institution without analyzing the first five *NHK-Fintiv* factors. *See id.* Reviewing the Board's decision *sua sponte*, the Director rejected the Board's approach. *Id.* at *1, *3. The Director explained that the "compelling merits" standard announced in the June 2022 Guidance cannot "substitute for a *Fintiv* analysis," which the Board remains bound to apply. *Id.* at *2. Specifically, the Director instructed that "in circumstances where the Board determines that … *Fintiv* factors 1-5 do not favor discretionary denial, the Board shall decline to discretionarily deny under *Fintiv* without reaching the compelling merits analysis" under the sixth factor. *Id.* But if the first five *NHK-Fintiv* factors favor denial, then the Board must make a compelling-merits determination under the sixth factor. *See id.* Again, the Director issued these standards without notice and comment.

In April 2023—three years after adopting the *NHK-Fintiv* Rule—the Director issued an Advance Notice of Proposed Rulemaking "proposing rules to install" the *NHK-Fintiv* Rule with "additional proposed reforms" and seeking feedback on the proposals. 88 Fed. Reg. 24,503, 24,505 (Apr. 21, 2023). Although an advance notice does not initiate rulemaking, engagement with the advance notice nevertheless "was extensive." 89 Fed. Reg. 28,693, 28,695 (Apr. 19, 2024). "[D]iverse stakeholders submitted over 14,500 comments, reflecting

the nation's deep interest in shaping the future of the patent system." *Id.* Yet in April 2024, when the PTO issued a notice of proposed rulemaking, it proposed rules for only a subset of the issues raised in the advance notice and did not address the *NHK-Fintiv* Rule.

Thus, to date, the Director has not undertaken notice-and-comment rulemaking on the *NHK-Fintiv* Rule. In the meantime, the number of cases in which the Board has applied the *NHK-Fintiv* Rule to deny IPR petitions—which had fallen after the June 2022 Guidance as petitioners increasingly resorted to stipulations forgoing key arguments in an effort to avoid the Rule, *supra* pp. 16-17—has been back "on the rise" since *CommScope*, as the Board "continu[es] to rely on [*NHK*-]*Fintiv* to reject petitions." Li & Armond, Fintiv *Denials Are on the Rise at PTAB*, Law360 (Apr. 24, 2024) (finding five-fold increase in *NHK-Fintiv* denials after *CommScope* compared with the period between the June 2022 Guidance and *CommScope*)).

C. Procedural History

As both patent owners and frequent targets of lawsuits for patent infringement, Appellants regularly appear in IPR proceedings and regularly file IPR petitions that relate to overlapping infringement litigation. Appx1131; Appx1140-1143. But since the adoption of the *NHK-Fintiv* Rule, Appellants have

had numerous IPR petitions denied under that Rule based on the pendency of parallel infringement litigation. Appx1140-1143; *see Apple*, 63 F.4th at 16-17.

In 2020, Appellants brought this APA suit challenging the *NHK-Fintiv* Rule as unlawful and seeking to set it aside. Appx1132. Appellants asserted that the *NHK-Fintiv* Rule violates the AIA, is arbitrary and capricious, and was adopted without observance of procedure required by law because it did not go through notice-and-comment rulemaking. Appx1144-1150. Appellants sought prospective relief holding the *NHK-Fintiv* Rule unlawful, setting the Rule aside, and enjoining the Director (and thus the Board) from relying on the Rule or its non-statutory factors to deny institution of IPRs. Appx1150; *see* 5 U.S.C. § 706(2).

The Director moved to dismiss the amended complaint, Appx1223, and the district court granted the Director's motion, Appx1546-1556. The court held that Appellants have Article III standing to pursue their claims. Appx1551-1554. But the court dismissed the complaint under 35 U.S.C. § 314(d), which provides that the "determination by the Director whether to institute an inter partes review under this section shall be final and nonappealable." *See* Appx1554-1556.

In a first appeal, this Court affirmed in part and reversed in part. It affirmed the dismissal of Appellants' claims challenging the *NHK-Fintiv* Rule as contrary to law and arbitrary and capricious, holding that § 314(d) precludes judicial review of the substantive legality of rules relating to institution standards. *Apple*, 63 F.4th at

11-14. The Court's "conclusion rest[ed] on … the inevitability and congressional expectation of the Director's delegation of the institution decision." *Id.* at 13. Because the Director cannot make every institution decision herself, the Court emphasized that she "must be able to give guidance in the form of instructions to her delegatee(s)—the Board (or Board panels)—about how to make the institution determinations on her behalf." *Id.*

As to Appellants' notice-and-comment claim, however, this Court reversed. *Apple*, 63 F.4th at 14-15. The Court held that "[w]hether notice-and-comment rulemaking procedures had to be employed for an agency action presents a matter 'quite apart from the matter of substantive reviewability' of the action for being contrary to statute or arbitrary and capricious." *Id.* at 14 (quoting *Lincoln v. Vigil*, 508 U.S. 182, 195 (1993)). Nothing in the AIA, the Court explained, precludes review of the procedures the Director follows in announcing institution standards. *Id.* at 14-15. The fact that institution decisions are committed to the Director's discretion does not give the Director discretion over the "choice of … procedure" for announcing generally applicable institution standards for the Board to follow. *Id.* at 15.

This Court also held that Appellants have Article III standing to raise the notice-and-comment claim. *Apple*, 63 F.4th at 15. Focusing on Apple, the Court explained that "Apple is non-speculatively threatened with harm to a legally

protected interest" by the *NHK-Fintiv* Rule. *Id.* at 16. In particular, the Court observed that Apple is a "repeat player … on a very large scale," in that Apple has frequently been sued for infringement and then petitioned for IPR of the asserted patent claims and had numerous IPR petitions denied under the *NHK-Fintiv* Rule. *Id.* at 16-17. The Court found it "far from speculative that this sequence will be repeated in the future, acknowledging that Apple will continue to pursue IPRs given the "advantages of the IPR process, including the applicability of a lighter burden of persuasion to prevail in challenging a patent claim than the burden applicable in district court." *Id.* at 17. Thus, it is "not unduly conjectural, but 'the predictable effect'" of the *NHK-Fintiv* Rule—which is "plausibly alleged to cause more denials of institution than might otherwise occur"—that the Rule will "continue causing harm in the form of denial of the benefits of IPRs linked to the concrete interest possessed by an infringement defendant." *Id.* (quoting *Department of Commerce v. New York*, 588 U.S. 752, 768 (2019)). This Court remanded the case to the district court for consideration of the notice-and-comment claim on the merits. *Id.* at 18.[1]

[1] Noting that "[n]either side ha[d] suggested mootness" based on the June 2022 Guidance or other developments, the Court explained that the case is not moot because the Director's subsequent clarifications suffer from "the same asserted deficiency" as the original Rule. *Apple*, 63 F.4th at 17 n.7.

On remand, the parties renewed their cross-motions for summary judgment. Appellants contended that the APA required notice and comment because the *NHK-Fintiv* Rule is a "substantive" rule. They further contended that the AIA reinforces that conclusion by requiring rules that set institution standards or govern the relationship between IPR and parallel litigation to be adopted by "prescrib[ing] regulations." Appx1591. The Director responded that *NHK-Fintiv* is not a "substantive" rule but a "general statement of policy" that is exempt from APA rulemaking requirements. In support, the Director argued that while the Board must "consider" the *NHK-Fintiv* factors, Appx1619, it need not "obey" them, Appx1622. The Director did not attempt to reconcile that position with her June 2022 Guidance or her decision in *CommScope*, both of which reiterated the Rule's limits on how the Board may exercise discretion in instituting IPRs. Nor did the Director explain how the Rule could "preserve her effective control" over the Board's institution decisions, *supra* p. 12, if the Board were free to depart from the Rule by substituting its own policy judgments about the efficiency of conducting IPR alongside overlapping litigation.

The district court denied Appellants' motion for summary judgment and granted the Director's motion. Appx1-23. The court held that *NHK-Fintiv* is not a substantive rule but rather a general statement of policy that is exempt from notice-and-comment requirements. The court first concluded that the *NHK-Fintiv* Rule

does not "alter, create, or impose any individual rights or obligations" because the Director is never required to institute IPR, petitioners do not have a right to IPR, and the Rule does not "require[] any action on the part of a petitioner." Appx15-17. Although the court acknowledged this Court's holding that Appellants had "plausibly alleged," for purposes of Article III standing, that the *NHK-Fintiv* Rule "caused harm by denying IPR benefits linked to an infringement defendant's legally protected interests in the infringement suit," the district court declined to follow that analysis in evaluating whether the Rule is subject to notice and comment. Appx16; *see also Apple*, 63 F.4th at 15-17. The district court then concluded that the *NHK-Fintiv* Rule does not limit the Board's discretion in a binding or "outcome-determinative" way. Appx17-23. Rather, the court accepted the Director's litigation position that, so long as the Board merely "considers" the Rule's factors, the Board retains "genuine discretion" to give effect to its own policy choices by instituting IPR even where the Director's policy judgment as articulated in the Rule indicates that institution should be denied. *Id.* According to the court, "[n]othing in [*NHK-Fintiv*] would prevent" the Board from instituting IPR if institution is the Board's "preferred disposition," even if following the Rule would lead to denial. Appx21.

The district court entered final judgment against Appellants, Appx24, and they timely appealed, Appx1738.

SUMMARY OF THE ARGUMENT

I. The *NHK-Fintiv* Rule is a substantive rule that had to be promulgated through notice-and-comment rulemaking under the APA. The Rule embodies the Director's policy choice that, when certain factors relating to parallel litigation are present, conducting IPR would in the Director's view be "inefficient" and thus IPR should not be instituted. The *NHK-Fintiv* Rule sets a binding standard the Board must apply when evaluating IPR petitions. That standard is calculated to alter the Board's decisions by aligning them with the Director's policy judgment, and it hurts petitioners by making it less likely that IPR will be instituted.

That Rule has both of the key attributes that courts have identified in substantive rules requiring notice and comment: the Rule affects private interests, and it is binding on the Board.

First, the *NHK-Fintiv* Rule affects private interests. In particular, the Rule reduces the likelihood that IPR will be instituted when there is co-pending litigation in district court. *NHK-Fintiv* thus deprives infringement defendants of opportunities to seek cancellation of questionable patents through IPR. That conclusion follows directly from this Court's prior analysis of Article III standing, which recognized that a rule like *NHK-Fintiv* that makes it less likely IPR will be instituted harms the legally protected interests of infringement defendants in obtaining the benefits of IPR.

In concluding that the *NHK-Fintiv* Rule does not affect private interests, the district court declined to follow this Court's standing analysis and determined instead that denying an opportunity to obtain a benefit cannot harm private interests where the benefit, like IPR, is discretionary or uncertain. Numerous decisions of this Court and others hold, however, that rules altering the standards an agency applies in evaluating applications for relief are substantive rules subject to notice and comment even if the relief sought is discretionary. The purposes of notice-and-comment rulemaking likewise apply with full force when a rule restricts access to a discretionary benefit.

Second, the *NHK-Fintiv* Rule is binding on the Board, in that the Board not only must consider the Rule's factors, but also must treat the factors as weighing for or against institution in the specific manner dictated by the Rule and conclude that IPR would be "inefficient" and deny institution when the factors on balance point against it. As this Court previously emphasized, the purpose of that Rule is to ensure that the Board exercises institution discretion in the same way the Director would if she were making institution decisions herself. Each *NHK-Fintiv* factor points in a particular direction, and when the factors collectively point toward denial, the Board has no discretion to institute IPR. If it did, the Rule could not function to preserve the Director's control over institution decisions.

Evidencing the Rule's chokehold on the Board's discretion, *NHK-Fintiv* has been dispositive in hundreds of cases in which the Board has denied institution for no reason other than the Director's assessment of the purported "inefficiency" of allowing IPR to proceed alongside parallel litigation. And although the Director could change her mind and apply a different policy if she were making the institution decision herself, the Board has repeatedly disclaimed any authority to do so—repeatedly telling IPR petitioners that the *NHK-Fintiv* Rule does not allow it even to consider arguments that the Rule should not be followed in particular cases. In making further refinements to the Rule, the Director has never told the Board otherwise (despite the Director's position in this litigation), instead continually tightening the Rule's restrictions on the Board's discretion. As a result, notice-and-comment rulemaking provides the only opportunity for affected parties to challenge the wisdom and legality of the Rule.

In concluding that the *NHK-Fintiv* Rule does not bind the Board's exercise of discretion, the district court accepted the Director's litigation position that the Board must merely consider the Rule and need not obey it. That characterization is irreconcilable with the Rule's operation in practice. The Director has not identified a single case in which the Board instituted IPR even though the Rule pointed toward denial. Indeed, when the Board in *CommScope* attempted to circumvent the *NHK-Fintiv* factors by preliminarily analyzing the merits of the IPR petition,

the Director vacated the Board's institution decision for failing to adhere to the Rule.

II. The AIA confirms that the *NHK-Fintiv* Rule required notice-and-comment rulemaking. The AIA reflects Congress's expectation that rules addressing institution standards and the relationship between IPR and district-court litigation would be promulgated through notice-and-comment rulemaking. The district court never addressed Appellants' statutory arguments.

III. Finally, the *NHK-Fintiv* Rule's flaws illustrate why the Rule should have been subject to notice and comment. If stakeholders had been able to comment on the Rule before its adoption, they would have pointed out the Rule's many legal and policy defects. Instead, the Director imposed a binding rule on the Board without warning that harms IPR petitioners and thwarts the purposes of the AIA. Particularly where every other possible avenue for obtaining judicial review of the Rule has seemingly been foreclosed, the Director should not be permitted to evade statutory notice-and-comment requirements intended to ensure a measure of public accountability.

STANDARD OF REVIEW

Under the APA, a court "shall … hold unlawful and set aside agency action" taken "without observance of procedure required by law." 5 U.S.C. § 706(2).

This Court reviews the district court's grant of summary judgment de novo. *Hyatt v. USPTO*, 48 F.4th 1347, 1350-1351 (Fed. Cir. 2022); *Gill v. DOJ*, 913 F.3d 1179, 1184 (9th Cir. 2019).

Whether an agency has complied with the APA's notice-and-comment requirements is also reviewed de novo. *EmeraChem Holdings, LLC v. Volkswagen Grp. of Am., Inc.*, 859 F.3d 1341, 1345 (Fed. Cir. 2017); *Gill*, 913 F.3d at 1186.

ARGUMENT

Under the Administrative Procedure Act, an agency may adopt rules—other than policy, interpretative, or procedural rules—only through notice-and-comment rulemaking. 5 U.S.C. § 553. That procedure requires the agency to "give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments" before the rule is adopted and to consider and respond to significant comments received during the comment period. *Id.* § 553(c); *see also Citizens to Pres. Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416 (1971).

The notice-and-comment process reflects Congress's "judgment that notions of fairness and informed administrative decisionmaking require" agency decisions to be made "only after affording interested persons notice and an opportunity to comment." *Chrysler Corp. v. Brown*, 441 U.S. 281, 316 (1979). "[N]otice and the opportunity to be heard are an essential component of fairness to affected parties."

Small Refiner Lead Phase-Down Task Force v. EPA, 705 F.2d 506, 547 (D.C. Cir. 1983) (quotation marks omitted); *see also Ivy Sports Med., LLC v. Burwell*, 767 F.3d 81, 87-88 (D.C. Cir. 2014). Moreover, notice and comment "ensur[es] that agency regulations will be tested by exposure to diverse public comment," *Small Refiner*, 705 F.2d at 547 (quotation marks omitted), thereby "afford[ing] the agency a chance to avoid errors and make a more informed decision," *Azar v. Allina Health Servs.*, 587 U.S. 566, 582 (2019). Public feedback thus yields an "'improved'" final rule, *Veterans Just. Grp., LLC v. Secretary of Veterans Affs.*, 818 F.3d 1336, 1344 (Fed. Cir. 2016), by ensuring that "the agency has all pertinent information before it," *Electronic Privacy Info. Ctr. v. DHS*, 653 F.3d 1, 6 (D.C. Cir. 2011).

It is undisputed that the Director did not follow those procedures before adopting the *NHK-Fintiv* Rule. But as set forth below, the Rule is exactly the type of rule to which notice-and-comment requirements apply.

I. THE APA REQUIRED NOTICE-AND-COMMENT RULEMAKING BECAUSE *NHK-FINTIV* IS A SUBSTANTIVE RULE

The APA defines a "rule" as an "agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy." 5 U.S.C. § 551(4). The Director has never disputed that *NHK-Fintiv* qualifies as a "rule" under the APA's definition. *See* Appx1614-1615. And for good reason: *NHK-Fintiv* fits comfortably within that definition. *NHK-Fintiv*

applies generally to any IPR petition when parallel litigation involving the same patent is pending in district court; *NHK-Fintiv* applies prospectively; and *NHK-Fintiv* "implements" and "prescribe[s] … policy" by instructing the Board how to exercise the Director's institution discretion. *See Apple*, 63 F.4th at 8.

The APA requires all "rules" to be adopted through notice-and-comment procedures, except for "interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice." 5 U.S.C. § 553(b). To distinguish between those exceptions and the rules subject to notice-and-comment requirements, courts "generally refer[] to the category of rules to which the notice and comment requirements … apply" as "substantive" or "legislative" rules. *Mendoza v. Perez*, 754 F.3d 1002, 1021 (D.C. Cir. 2014). The Director has never contended that the *NHK-Fintiv* Rule is an interpretive rule or a rule of agency organization, procedure, or practice. Rather, the Director defends *NHK-Fintiv* solely as a "general statement of policy," and the district court ruled solely on that basis. Appx9.[2]

Two characteristics are especially relevant in identifying "substantive" rules and distinguishing them from general statements of policy. First, courts consider

[2] An agency may forgo notice-and-comment procedures upon finding for good cause that conducting rulemaking would be "impracticable, unnecessary, or contrary to the public interest." 5 U.S.C. § 553(b). The Director made no such finding here.

the rule's impact on affected parties. A "substantive" rule is "one that effects a change in existing law or policy which affects individual rights and obligations." *In re Chestek PLLC*, 92 F.4th 1105, 1109 (Fed. Cir. 2024) (quotation marks omitted); *see also Chrysler*, 441 U.S. at 302 (a substantive rule "affect[s] individual rights and obligations"). A substantive rule, in other words, "grant[s] rights, impose[s] obligations, or produce[s] other significant effects on private interests." *Batterton v. Marshall*, 648 F.2d 694, 701-702 (D.C. Cir. 1980). That consideration is relevant to the notice-and-comment requirement because fairness demands notice and an opportunity to be heard when a rule affects private rights and interests. *See Chrysler*, 441 U.S. at 316.

Second, courts ask whether "'the challenged [directive] leaves the agency, or its implementing official, free to exercise discretion to follow, or not to follow, the [announced] policy in an individual case.'" *Mada-Luna v. Fitzpatrick*, 813 F.2d 1006, 1013 (9th Cir. 1987) (alterations in *Mada-Luna*). A substantive rule is "binding" on implementing officials. *Id.*; *see also, e.g.*, *Coalition for Common Sense in Gov't Procurement v. Secretary of Veterans Affs.*, 464 F.3d 1306, 1317 (Fed. Cir. 2006) (a substantive rule is "binding … within the agency"). That consideration is relevant because, when implementing officials are bound to follow the policy judgments embodied in a rule, the notice-and-comment process will be the only opportunity for affected parties to challenge the policy determinations

underlying the rule. *Mada-Luna*, 813 F.2d at 1013.[3] Applying these considerations firmly supports the conclusion that *NHK-Fintiv* is a substantive rule that should have been adopted through notice-and-comment procedures.[4]

A. The *NHK-Fintiv* Rule Affects Private Interests

First, the *NHK-Fintiv* Rule is a substantive rule because it "produce[s] … significant effects on private interests." *See Batterton*, 648 F.2d at 702. In rejecting the Director's challenge to Article III standing, this Court already held that the Rule harms IPR petitioners. *Apple*, 63 F.4th at 16-17. The district court nevertheless held that the Rule is not substantive because the Director is never required to institute IPR—apparently adopting the view that rules altering standards for discretionary decisions cannot be substantive, no matter their effects. Appx16. As explained below, that is incorrect.

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[3] The district court articulated the governing test slightly differently, but only by breaking down these two factors into more granular questions that focused in substance on the same two overarching considerations. Appx15.

[4] Below, the Director contended that this Court applies an additional requirement—unique to this circuit's law—that a rule is not "substantive" under the APA unless it is binding on other tribunals outside the issuing agency. Appx1617. If true, that would require determining what circuit's precedent is controlling; and on that question, the better view is that regional circuit precedent controls because the question whether an agency has violated the APA's notice-and-comment requirements is not a subject "exclusively assigned" to this Court, *Oracle Am., Inc. v. Google Inc.*, 750 F.3d 1339, 1353 (Fed. Cir. 2014). But as the district court correctly concluded, this Court has never held that a rule must be binding on other tribunals to qualify as "substantive." Appx20. It is therefore unnecessary to determine which circuit's law applies.

1. The *NHK-Fintiv* Rule makes it less likely that IPR will be instituted, depriving petitioners of the benefits of IPR

The *NHK-Fintiv* Rule reduces the likelihood that IPR will be instituted when there is parallel litigation, thus restricting infringement defendants' opportunity to seek cancellation of questionable patent claims in IPR. As explained, the Board has applied the *NHK-Fintiv* Rule to deny hundreds of timely IPR petitions, including many filed by Appellants. *See supra* pp. 12-13. Both this Court and the district court have acknowledged that the *NHK-Fintiv* Rule causes "more denials of institution than might otherwise occur," making it more difficult for infringement defendants to challenge dubious patents in IPR. *Apple*, 63 F.4th at 17; *see* Appx1553.

In particular, in the context of rejecting the Director's challenge to Article III standing, this Court explained that the *NHK-Fintiv* Rule "threaten[s] … harm" to the "legally protected interest" of infringement defendants by reducing the likelihood that they can pursue IPR. *Apple*, 63 F.4th at 16. Specifically, the Court found that by predictably "caus[ing] more denials of institution than might otherwise occur," the *NHK-Fintiv* Rule will "continue causing harm in the form of denial of the benefits of IPRs linked to the concrete interest possessed by an infringement defendant." *Id.* at 17.

Those benefits of IPR entail the opportunity for an infringement defendant to seek invalidation of asserted patent claims through the efficient and specialized

alternative to litigation that Congress intended IPR to provide. The opportunity to challenge a patent through IPR offers substantial benefits compared with litigation: reduced litigation costs, deadlines that generally lead to quicker resolution of patentability issues, a lower burden for establishing unpatentability, and review by expert administrative patent judges. *See supra* pp. 5-6. Indeed, this Court has recognized "the realistically perceived advantages of the IPR process." *Apple*, 63 F.4th at 17. The district court here did not—and could not—dispute that the *NHK-Fintiv* Rule has decreased the likelihood that IPRs will be instituted or that this reduction denies prospective petitioners the benefits of IPR. *See* Appx15-17. Given that, this Court's prior analysis compels the conclusion that the *NHK-Fintiv* Rule affects private interests in the requisite manner for the Rule to qualify as substantive.

2. The district court erred in finding no effect on private rights and interests

The district court held the *NHK-Fintiv* Rule does not affect private interests on the ground that IPR is a discretionary form of relief to which plaintiffs have "no existing right"—emphasizing that "there is no set of circumstances under which the Director is required to authorize IPR institution." Appx15-16. That reasoning conflicts not only with this Court's prior opinion, but also with decisions of other courts finding that notice and comment is required for rules that change the

standards governing other types of discretionary relief. And it cannot be squared with the purposes of notice-and-comment rulemaking.

As an initial matter, the district court's reason for disregarding this Court's prior analysis was unsound. Appx16. The district court asserted that adhering to this Court's analysis of the harms inflicted by the *NHK-Fintiv* Rule "would collapse the threshold analysis of standing with that of the merits of the APA claim" and that, at the summary-judgment stage, the district court was "not … required to take Plaintiffs' allegations as true." Appx16 n.5. That misses the point. Appellants did not ask the district court to take as true their mere allegation that the *NHK-Fintiv* Rule reduces the likelihood that IPR will be instituted; they showed at summary judgment—without dispute by the Director—that it would. *See, e.g.*, Appx1580. Rather, the relevant holding in this Court's previous decision is that an institution standard that reduces the likelihood that IPR will be instituted deprives infringement defendants of IPR's benefits and thus qualifies as a harm to a legally protected interest. *Apple*, 63 F.4th at 16. This Court so held even though institution decisions are discretionary, and the district court had no authority to disregard that holding.

Even putting aside this Court's prior opinion, the district court was wrong to conclude that the *NHK-Fintiv* Rule does not affect private interests. *See* Appx15-17. This Court and others have repeatedly recognized that rules "affecting the

substantive … standards by which [an agency] examines a party's application" for a benefit have the requisite effect on rights and interests and are therefore subject to notice-and-comment if they are binding. *Chestek*, 92 F.4th at 1110 (PTO was not required to conduct notice-and-comment rulemaking where the challenged rule did "not alter the substantive standards by which the USPTO evaluates trademark applications"). Among rules held subject to notice-and-comment requirements are a rule changing the "substantive criteria" used by the FCC to allot radio stations, *Reeder v. FCC*, 865 F.2d 1298, 1305 (D.C. Cir. 1989); a guidance document governing how the EPA would assess applications to use non-standard waste-disposal methods, *General Elec. Co. v. EPA*, 290 F.3d 377, 379 (D.C. Cir. 2002); and a rule changing the criteria for selecting union election observers that limited unions' ability to select whomever they wanted, *AFL-CIO v. NLRB*, 57 F.4th 1023, 1041 (D.C. Cir. 2023); *cf. JEM Broad. Co. v. FCC*, 22 F.3d 320, 327 (D.C. Cir. 1994) (distinguishing *Reeder* and finding no notice-and-comment was required for a challenged rule that "did not change the *substantive standards* by which the FCC evaluates license applications" (emphasis in original)).

The same analysis applies to agency rules that make it harder to obtain a benefit even if the benefit is discretionary or uncertain. For example, rules that alter the standards a parole board must apply in a manner that makes it harder to obtain parole have long been described as the "classic example" of a substantive

rule subject to notice and comment, even though parole decisions are imbued with discretion. *American Hosp. Ass'n v. Bowen*, 834 F.2d 1037, 1046 (D.C. Cir. 1987) (citing *Pickus v. United States Bd. of Parole*, 507 F.2d 1107, 1113 (D.C. Cir. 1974)). In *Pickus*, the D.C. Circuit held that guidelines establishing factors for the United States Board of Parole to consider in the "exercise of its discretion to parole eligible federal prisoners," 507 F.2d at 1108, ranked as "substantive agency action" subject to notice-and-comment requirements, *id.* at 1113-1114. That was so despite the board's discretion because the guidelines had "great[] impact on an inmate's chances for parole" and were "likely to produce parole decisions different from those which alternatives would be likely to produce." *Id.* As the D.C. Circuit later explained, the rule altering the parole board's standards was subject to notice and comment not because inmates had an "existing right" to parole, *see* Appx16—they did not—but because the rule was "calculated to have a substantial effect on ultimate parole decisions." *American Hosp. Ass'n*, 834 F.2d at 1046.

Similarly, in *W.C. v. Bowen*, 807 F.2d 1502 (9th Cir. 1987), *amended on denial of reh'g*, 819 F.2d 237 (9th Cir. 1987), the Ninth Circuit considered a program that subjected Administrative Law Judges' decisions to an additional level of review by an agency appellate tribunal if those decisions were favorable to Social Security claimants. 807 F.2d at 1505. Previously, those decisions would not have been subject to further review. *Id.* The court held that the revised

program was a substantive rule "affect[ing] existing rights" because it was "designed to alter ALJ decisions," causing the agency "to deny benefits in close cases where benefits might previously have been granted." *Id.*

Here, too, the *NHK-Fintiv* Rule has a "substantial effect on ultimate" institution decisions and makes it less likely an infringement defendant's IPR petition will be granted. *American Hosp. Ass'n*, 834 F.2d at 1046. The Rule is designed to alter Board decisions by aligning them with the Director's policy choice that access to the benefits of IPR should be denied based on the pendency of parallel litigation in many cases in which IPR might previously have been instituted. And in cases where parallel litigation is pending in a jurisdiction with fast-moving dockets, the Rule effectively truncates the one-year filing window Congress intended to allow. *See* 35 U.S.C. § 315(b). Such a rule affects IPR petitioners' private interests even though petitioners have no entitlement to IPR.

Requiring notice-and-comment rulemaking in such circumstances makes sense in view of the purposes of notice-and-comment procedures. The point of notice-and-comment rulemaking is to ensure that those who will be affected have an opportunity to be heard and that the agency benefits from their perspective and any information they can offer. *See Small Refiner*, 705 F.2d at 547. These considerations plainly apply when a standard is changed in a way that makes it harder to obtain a benefit, even when the affected parties have no entitlement to the

benefit. Yet the district court ignored that IPR petitioners have precisely the type of stake in institution standards that the notice-and-comment process is intended to accommodate. The district court sought to distinguish *W.C.* on the ground that the rule challenged there "affected individuals' 'existing rights' to social security benefits by altering decisions towards benefit denials," whereas IPR petitioners have "no existing right" to IPR. Appx16. That analysis misapprehended *W.C.*, which nowhere suggested that all claimants were entitled to the benefits they sought. *See* 807 F.2d at 1503-1504. While Social Security is an "entitlement" program for purposes of federal budgeting, not everyone who applies for Social Security benefits is entitled—that is, has a right—to them. That is why the agency was determining eligibility in *W.C.* in the first place. *See id.* Moreover, nothing in *W.C.*'s holding turned in any way on whether the benefits at issue were discretionary or certain; what mattered was that the rule altered the agency's decisions, causing the agency "to deny benefits in close cases where benefits might previously have been granted." *Id.* at 1505. The same is true here.

Citing *Mada-Luna*, 813 F.2d at 1016, the district court reasoned that where a requested benefit is discretionary, "the fact that an agency action 'diminishes the likelihood' that the agency will grant relief" does not mean the action is a substantive rule rather than a general statement of policy. Appx16. But that was true in *Mada-Luna* only because the rule at issue was not binding within the

agency. 813 F.2d at 1016-1017. As the Ninth Circuit explained, a "substantial impact" on private rights and interests does not alone suffice to require notice-and-comment rulemaking if the rule is not binding. *See infra* pp. 42-47. But where a rule that is binding on implementing officials within the agency alters the substantive standards those officials apply in a manner that diminishes a party's chances of obtaining relief, rulemaking is required, and *Mada-Luna* nowhere suggests otherwise. 813 F.2d at 1016-1017.

Finally, the district court wrongly suggested that the *NHK-Fintiv* Rule does not "require[] any action on the part of a petitioner." Appx17. The district court's reasoning ignores that petitioners seeking to avoid denial of institution under the Rule have been compelled in many cases to file IPR petitions sooner than the AIA allows or to stipulate that they will not pursue overlapping invalidity arguments in both the district court litigation and the IPR, even though the AIA permits them to do so in many circumstances. *See supra* p. 17. In any event, the relevant question under the APA is not whether a rule "requires … action" by affected parties, Appx17, but whether it "significant[ly] [a]ffects … private interests," *Batterton*, 648 F.2d at 701-702; *see Chestek*, 92 F.4th at 1110. And here, the *NHK-Fintiv* Rule harms the "legally protected interest" of infringement defendants by "caus[ing] more denials of institution than might otherwise occur," thereby denying infringement defendants the benefits of IPR. *Apple*, 63 F.4th at 16-17.

B. The *NHK-Fintiv* Rule Is Binding On The Board

1. The Board has no discretion to depart from the policy choices embodied in the Rule

The "critical factor" distinguishing a substantive rule from a general statement of policy is whether "'the challenged [directive] leaves the agency, or its implementing official, free to exercise discretion to follow, or not to follow, the [announced] policy in an individual case.'" *Mada-Luna*, 813 F.2d at 1013 (alterations in *Mada-Luna*)); *see also Syncor Int'l Corp. v. Shalala*, 127 F.3d 90, 94 (D.C. Cir. 1997). A general statement of policy "advise[s] the public prospectively of the manner in which [an] agency proposes to exercise a discretionary power," *Lincoln v. Vigil*, 508 U.S.182, 197 (1993) (quotation marks omitted)—for example, an announcement of how the agency intends to allocate funds from a lump-sum appropriation, *id.*—but leaves implementing officials free to decide whether to follow that announced policy in individual cases, *Mada-Luna*, 813 F.2d at 1013-1014. The agency retains "the discretion and the authority to change its position—even abruptly—in any specific case." *Syncor*, 127 F.3d at 94. A substantive rule, in contrast, binds implementing officials to follow the policy determination embodied in the rule. *Id.*; *see also Mada-Luna*, 813 F.2d at 1014. Notice-and-comment procedures are required for such rules because the rulemaking proceeding "represent[s] the only opportunity for parties to challenge the policy determinations upon which the new rule is based." *Id.*

Here, the *NHK-Fintiv* Rule is binding on the Board and leaves the Board with no "'discretion to follow, or not to follow'" it in a particular case. *Mada-Luna*, 813 F.2d at 1013. The Director's precedential designations of *NHK* and *Fintiv I* made the Rule "binding" on the Board "in subsequent matters involving similar facts or issues." Appx1748. Under the Rule, when parallel litigation involving the same patent is pending in district court, the Board must (1) consider the Rule's factors, (2) treat each factor as weighing for or against institution in the specific manner dictated by the Rule, and (3) conclude that IPR would be "inefficient" and deny the petition when the factors on balance point against institution. *See supra* pp. 10-11. The Rule thus embodies not just a list of factors the Board must recite, but a binding policy judgment by the Director that when certain facts about the parallel litigation are present, conducting IPR would be inefficient and institution should be denied.

The Board has no discretion to disregard that policy judgment. As this Court has explained, the whole point of the *NHK-Fintiv* Rule is to "ensur[e]" that the Board's institution decisions "will overwhelmingly be made in accordance with the policy choices" the Director "would follow if she were making the determinations herself." *Apple*, 63 F.4th at 13. As the Director herself has put it, the Rule serves to "preserve [the Director's] effective control over the agency in circumstances where delegation is a practical necessity." Director Br. in Opp. 13.

The Rule could not serve that function if it were merely a general statement of policy that left the Board with "the discretion and the authority to change its position" about the efficiency of IPR relative to parallel litigation when considering any specific IPR petition. *Syncor*, 127 F.3d at 94.

The Board's application of the *NHK-Fintiv* Rule confirms that the Rule is binding in the relevant way. *See Professionals & Patients for Customized Care v. Shalala*, 56 F.3d 592, 599 (5th Cir. 1995) (in determining whether a rule is substantive, courts should consider "what the agency does in fact" (quotation marks omitted)). While the Board has adhered to the Rule in denying hundreds of IPR petitions, it has never departed from the Rule by substituting its own policy determinations about the efficiency of litigation relative to IPR or by instituting IPR even where the Rule's factors would lead to denial. *Supra* pp. 12-13. That is because the Board understands it has no discretion to do so. When IPR petitioners have contended that the *NHK-Fintiv* Rule is misguided, or that following it would be illogical in a particular circumstance, the Board has responded that its hands are tied. *See supra* pp. 13-16 (citing cases). The Rule "do[es] not allow [the Board] to accord dispositive weight" to arguments that the circumstances of an individual case warrant a different policy choice than the one embodied in the Rule. *Supercell Oy v. GREE, Inc.*, 2020 WL 3455515, at *7 (P.T.A.B. June 24, 2020).

Such arguments are simply "not within [the Board's] purview to consider, in light of binding precedent." *Id.*

The Director's fine-tuning of the *NHK-Fintiv* Rule further confirms the Rule's binding nature. If the Board were mistaken in thinking it lacks discretion to depart from the Rule, the Director could easily have corrected that misimpression in the June 2022 Guidance, *CommScope*, or any other directive. The Director did not. Instead, every additional guidance the Director has issued addressing *NHK-Fintiv* has reinforced the Rule's binding nature and further circumscribed the Board's discretion. *Supra* pp. 16-19. The result, as recent decisions demonstrate, is that the Board continues to rigidly apply the *NHK-Fintiv* Rule to deny institution of IPR in accordance with the Director's binding policy determinations. *E.g.*, *T-Mobile USA, Inc. v. Cobblestone Wireless LLC*, IPR2024-00136, Paper 18 (P.T.A.B. June 5, 2024); *10x Genomics, Inc. v. President & Fellows of Harvard College*, IPR2023-01299, Paper 15 (P.T.A.B. Mar. 7, 2024); *International Business Machines Corp. v. Digital Doors, Inc.*, IPR2023-00969, Paper 8 (P.T.A.B. Dec. 5, 2023).

Courts have found rules that bind agencies in a manner similar to *NHK-Fintiv* to be substantive rules subject to notice-and-comment requirements. *See, e.g.*, *Syncor*, 127 F.3d at 95-96 (notice-and-comment required where FDA rule bound the agency to a particular regulatory position); *Pickus*, 507 F.2d at 1113

(parole standards requiring board to consider several categories of factors were substantive rules because they "narrow[ed]" the board's "field of vision" to encourage "decisive reliance" on the factors and "define[d] a fairly tight framework to circumscribe the [parole board]'s statutorily broad power"); *W.C.*, 807 F.2d at 1505 (rule that "substantially limit[ed]" the decisionmaker's discretion whether to review ALJ decisions is a substantive rule).

Before the district court, the Director characterized the *NHK-Fintiv* Rule as a mere suggestion of criteria, akin to enforcement priorities, that the Board must think about before making institution decisions but need not "obey." Appx1622. That argument mischaracterizes the *NHK-Fintiv* Rule, which differs from the rules at issue in the cases the Director cited. In *Clarian Health West, LLC v. Hargan*, 878 F.3d 346 (D.C. Cir. 2017), for example, the D.C. Circuit considered criteria adopted by the Department of Health & Human Services for selecting which hospitals' payments and cost reports should be selected for reconciliation review. *Id.* at 349. The criteria constituted a general statement of policy, the court held, because agency decisionmakers "retained discretion to deviate from the[] criteria where [they] determine[d] that doing so would further the aims of the statute." *Id.* at 358; *see id.* at 351 (decisionmaker retains discretion to initiate reconciliation even where the "criteria … are not met" (quotation marks omitted)). Here, in contrast, when parallel litigation has reached a sufficiently advanced stage that

instituting IPR would be "inefficient" according to the Director's Rule, the Board cannot substitute its own judgment that instituting IPR anyway would better "further the aims of the statute." *Id.* at 358. Likewise, in *Professionals & Patients for Customized Care*, 56 F.3d at 597-598, guidelines establishing factors FDA will consider in determining whether to initiate an enforcement action were not subject to notice-and-comment requirements because agency decisionmakers "retain[ed] discretion whether to bring an enforcement action," "even if the factors [we]re present." Conversely, under *NHK-Fintiv*, the Board lacks discretion to institute IPR based on its own policy choices when the Rule's factors—and the Director's determination that the presence of those factors would make IPR "inefficient"—point toward denial. *Supra* pp. 10-11, 13-16. As the Board has acknowledged, nothing in the *NHK-Fintiv* Rule "would countenance such an alternate approach" to institution decisions. *Koninklijke Philips*, IPR2021-00328, Paper 16 at 9.

2. The district court erred in finding that the *NHK-Fintiv* Rule does not bind the Board's discretion

The district court's decision rests on a flawed understanding of the *NHK-Fintiv* Rule. Accepting the Director's litigation position, the court proceeded on the assumption that the Rule requires the Board only to "consider the specified factors" and otherwise leaves the Board free to exercise its own discretion to decide how overlapping litigation should be addressed in any particular case. Appx19; *see also* Appx21. As explained, that view cannot be reconciled with this

Court's explication of the Rule's purposes, with the Board's own application of the Rule, or with the Director's approach to refining the Rule—all of which confirm that the Rule embodies a policy determination by the Director, which the Board is bound to follow, that when the Rule's factors are present, conducting IPR alongside parallel litigation would be "inefficient" and institution should be denied. *Supra* pp. 10-19.

In concluding otherwise, the district court relied in part on the fact that the Rule sets out multiple factors for the Board to consider, under which "various facts may weigh in favor of or against instituting IPR," and no factor is "exclusive" or "outcome-determinative." Appx20-21. But a rule that changes the substantive standards by which an agency evaluates individual applications is subject to notice-and-comment requirements even if there is no single dispositive criterion. *See JEM Broad.*, 22 F.3d at 327 (distinguishing *Reeder*, 865 F.2d at 1305). And while no single factor under *NHK-Fintiv* is necessarily dispositive in every case, the Rule overall has proven dispositive in numerous cases, as evidenced by its repeated use to deny IPR petitions even where the petition presented a meritorious challenge to patentability. Appx1140-1143; *see, e.g.*, *T-Mobile*, IPR2024-00136, Paper 18; *IBM*, IPR2023-00969, Paper 8 at 7-13. Indeed, the Rule is designed to be outcome-determinative, or else it would not effectuate the Director's policy choices for when IPR should be instituted. *See Apple*, 63 F.4th at 13. The Board

has conducted itself accordingly, simply marching through the six factors in a rigid fashion when parallel infringement litigation is pending and disclaiming any authority to look beyond those factors or to treat them differently than the Rule dictates. *E.g.*, *T-Mobile USA*, IPR2024-00136, Paper 18 at 11-26; *10x Genomics*, IPR2023-01299, Paper 15 at 14-22; *IBM*, IPR2023-00969, Paper 8 at 7-13; *see supra* pp. 12-16, 45.

Analogizing to *Mada-Luna*, the district court relatedly misconstrued the Rule's sixth factor, allowing consideration of "other circumstances" including a petition's merits. Appx18-19; *see Fintiv I*, 2020 WL 2126495, at *2. The sixth factor is far from a catch-all. From the outset, the sixth factor has focused on whether the IPR petition's merits are strong enough to "outweigh" the Rule's other factors, or if the merits instead are a "closer call" that favor denial of the petition. *Id.* at *6; *see also Fintiv II*, 2020 WL 2486683, at *6 (explaining that the sixth factor looks at "whether the merits tip the balance one way or another" and denying institution where the merits "d[id] not outweigh other factors"). The Board has thus treated the sixth factor as limited to a preliminary look at the patentability merits. *See, e.g.*, *T-Mobile USA*, IPR2024-00136, Paper 18 at 18-26; *10x Genomics*, IPR2023-01299, Paper 15 at 21-22; *IBM*, IPR2023-00969, Paper 8 at 13. That factor has never been understood as a license for the Board to depart from the policy embodied in the Rule or to override the Rule's instructions on how

the other factors should be weighed. In *Supercell*, for example, the IPR petitioner invoked the sixth factor to argue that the Rule should apply differently when parallel litigation is pending in certain fast-moving jurisdictions, but the Board responded that it is "constrained to follow" the Rule, 2020 WL 3455515, at *4, which "do[es] not allow [the Board] to accord dispositive weight to [such] arguments," even under the sixth factor, *id.* at *7.[5] In doing so, the Board has merely followed the Director's instructions. The June 2022 Guidance directs that the sixth factor encompasses review of whether the petition presents "compelling evidence of unpatentability," in which case that factor will outweigh the others. June 2022 Guidance 3-5. In *CommScope*, the Director further instructed that the sixth factor is limited to analyzing whether the merits seem "compelling" and may be reached only after the Board evaluates the first five factors in accordance with the Rule. *See* 2023 WL 2301719, at *2. Neither the Director nor the district court

[5] The district court posited that even in *Supercell* and cases like it, *see supra* pp. 13-16, the Rule did not prevent the Board from evaluating other facts or circumstances that would weigh in favor of instituting IPR. Appx22. But the Board's decisions say the opposite. On repeated occasions, IPR petitioners have asked the Board to depart from the Rule based on particular circumstances—*e.g.*, the speed to trial in certain fast-moving jurisdictions, limitations on the authority of the ITC, and so on—yet the Board has disclaimed any authority to do so. *Supra* pp. 13-16.

has cited a single case in which the Board invoked the sixth factor as license to deviate from the Rule or to contradict the Rule's treatment of the other factors.[6]

The decision below thus blinks reality in assuming that "[n]othing [in the Rule] would prevent" the Board from giving effect to its "preferred disposition" even when the Rule dictates a different result. Appx21; *see also* Appx23 (asserting that *NHK-Fintiv* "leaves the Board with genuine discretion to evaluate all facts and circumstances relevant to the institution or denial of IPR"). Unlike the rule in *Mada-Luna*, on which the district court relied (*see* Appx18-19), *NHK-Fintiv* does not merely require the Board to "consider the specified factors" while leaving the Board with "great … latitude and discretion" to decide anew what policy choice would be best in a particular case. *See* Appx19; *Mada-Luna*, 813 F.2d at 1017. The Board has no latitude to decide whether to follow the *NHK-Fintiv* Rule, and in weighing each factor, the Board must follow the instructions the Director gave in the Rule and subsequent guidance on her policy choices. *Cf. Mada-Luna*, 813 F.2d

[6] The district court noted that the sixth factor also allows the Board to consider a petitioner's filing of serial or parallel petitions before the PTO or "considerations implicated by 35 U.S.C. § 325(d)." Appx19 (quotation marks omitted); *see Fintiv I*, 2020 WL 2126495, at *6-7. But as the court acknowledged, that simply reflects that there may be reasons for denying a petition that are "unrelated to parallel proceedings" in district court. Appx19. It does not mean the Board has discretion to disobey the Rule when evaluating the considerations that do relate to parallel district court proceedings. That is why *Fintiv I* listed those reasons separately. *See* 2020 WL 2126495, at *6-7.

at 1008 n.1 (describing rules at issue in that case as setting forth capacious factors without dictating how those factors should be evaluated or weighed).

The district court's passing reliance on *Sacora v. Thomas*, 628 F.3d 1059 (9th Cir. 2010), was likewise misplaced. *See* Appx21. In *Sacora*, the court considered a Bureau of Prisons policy regarding inmates' length of placement in a community correctional facility. 628 F.3d at 1064. The policy stated that a placement of six months or less would "'usually'" be sufficient but that a placement could be longer if staff determined that an inmate's particular circumstances justified it. *Id.* The court held that the policy was not a substantive rule subject to notice and comment. *Id.* at 1069-1070. The policy "merely provide[d] guidance" to officials in implementing existing agency regulations while preserving their discretion to make individualized determinations as to the appropriate length of placements in particular cases. *Id.* at 1070 (emphasis omitted). In contrast, *NHK-Fintiv* does not merely provide guidance, but rather obligates the Board to follow the Director's determination that where the factors indicate that IPR would be "inefficient" when weighed as specified in the Rule, the IPR petition should be denied. *Supra* pp. 10-16. The Board has no "discretion to follow, or not to follow" that Rule "in an individual case," and the Rule is therefore substantive. *Sacora*, 628 F.3d at 1069 (quotation marks omitted).

* * *

Throughout this litigation, the Director has sought to avoid notice-and-comment requirements by cloaking the *NHK-Fintiv* Rule in a veneer of discretion in her litigation positions while simultaneously (when speaking out of court) making clear to the Board that it lacks discretion to disobey the Rule. The Director cannot have it both ways. As this Court previously explained, *NHK-Fintiv* binds the Board to follow the Director's policy judgment regarding the "issues of efficiency and interbranch relations" posed by overlapping proceedings. *Apple*, 63 F.4th at 8; *see id.* at 13. Indeed, this Court reached its decision precisely because it understood that individual institution decisions "will overwhelmingly be made in accordance with" the Director's choices. *Id.* at 13. That binding rule harms the legally protected interests of infringement defendants by making it less likely that IPR will be instituted when parallel litigation is pending. *Supra* Part I.A. It is therefore a substantive rule for which the APA requires notice-and-comment rulemaking.

II. THE AIA REINFORCES THAT THE *NHK-FINTIV* RULE SHOULD HAVE BEEN ADOPTED ONLY AFTER NOTICE AND COMMENT

The AIA expressly incorporates the APA's notice-and-comment requirements by providing that the Director adopt certain types of generally applicable rules governing IPR, if at all, by "prescrib[ing] regulations." 35 U.S.C. § 316(a). Congress's use of the term "regulations" generally denotes "legislative [*i.e.*, substantive] rules" rules issued after notice and comment. *United States*

Telecom Ass'n v. FCC, 400 F.3d 29, 38 (D.C. Cir. 2005). The requirement to proceed by "prescrib[ing] regulations" applies specifically to rules "setting forth the standards for the showing of sufficient grounds to institute a review under section 314(a)," 35 U.S.C. § 316(a)(2), and rules "establishing and governing [IPR] … and the relationship of [IPR] to other proceedings" under the relevant statutory title, *id.* § 316(a)(4). With its reference to Title 35 of the U.S. Code, the latter provision encompasses patent-infringement actions brought in district court under 35 U.S.C. § 281. *See Apple*, 63 F.4th at 8 n.3. Together, these provisions evidence Congress's understanding that rules setting institution standards and coordinating the relationship between IPR and parallel litigation are substantive rules beyond the scope of the PTO's pre-existing procedural rulemaking authority. *See SoftView*, 2024 WL 3543902, at *4-5 (holding that, unlike 35 U.S.C. § 2(b)(2)(A), § 316(a)(4) is a source of rulemaking authority for the PTO to issue "'substantive' rules").

NHK-Fintiv is exactly such a rule. The *NHK-Fintiv* Rule modifies "the standards for the showing of sufficient grounds to institute [an IPR] under section 314(a)," 35 U.S.C. § 316(a)(2), by dictating that IPR will not be instituted when the Director would find IPR inefficient in light of parallel litigation in district court. *See NHK*, 2018 WL 4373643, at *7 (describing the Rule as a standard for exercising institution discretion under § 314(a)); *Fintiv I*, 2020 WL 2126495, at

*1-3 (same). Moreover, the *NHK-Fintiv* Rule "establish[es] and govern[s] … the relationship" between IPR and district court infringement litigation, 35 U.S.C. § 316(a)(4), by instructing the Board whether and when to institute IPR when a related infringement action is pending in district court. The PTO itself has thus invoked the rulemaking considerations laid out in § 316 in purporting to justify the *NHK-Fintiv* Rule, *see* Appx1053; 88 Fed. Reg. at 24,506, even while conceding before the district court that the "Director did not adopt the *Fintiv* factors pursuant to … regulatory authority under § 316(b)," Appx1357.

The AIA thus independently demonstrates that Congress would have expected a rule like the *NHK-Fintiv* Rule to be adopted only through notice-and-comment rulemaking. The Director has no discretion to forgo notice-and-comment procedures when they are required by statute. *Apple*, 63 F.4th at 15. Yet the district court's decision allows the Director to "essentially revise [the AIA] and do so without following the basic rulemaking processes, which are supposed to be mandatory, and without accountability to the public." Appx1751.

Although Appellants made these statutory arguments below, *see* Appx1591; Appx1642-1643, the district court failed even to acknowledge them, *see* Appx1-23. This Court should not similarly allow the Director to continue defying the AIA by unilaterally changing the institution standards under *NHK-Fintiv* without warning.

III. THE *NHK-FINTIV* RULE'S FLAWS DEMONSTRATE WHY IT SHOULD HAVE BEEN ADOPTED THROUGH NOTICE-AND-COMMENT RULEMAKING

The Director's flouting of notice-and-comment requirements directly contributed to the Director's adoption of a deeply flawed rule, and the resulting harms illustrate why *NHK-Fintiv* is precisely the type of rule that should have undergone notice-and-comment rulemaking.

As explained, notice-and-comment procedures are intended to promote fairness and improve agency decisionmaking by ensuring that parties whose interests would be harmed by a proposed rule have an opportunity to be heard before those harms are imposed and ensuring that agencies have the full picture of the wisdom and likely consequences of a proposed rule. *See supra* pp. 29-30. Here, following notice-and-comment procedures would have afforded affected parties an opportunity to identify numerous defects in the *NHK-Fintiv* Rule before the Director adopted it. For example, several provisions of the AIA make clear that IPR may proceed alongside overlapping infringement litigation, *see Apple*, 63 F.4th at 8 n.3 (noting "Congress's expectation that the same patent claims might well be at issue in both an IPR proceeding and a court case"), and the Director cannot exercise institution discretion in a manner that violates those provisions and thwarts their purposes. *See* Appx1144-1146; Appx1265-1273. In fact, two former members of Congress—both among the original co-sponsors of the AIA—recently expressed their disappointment that *NHK-Fintiv* has eviscerated the one-year time

limit that Congress had crafted to allow IPR with respect to patent claims at issue in litigation so long as the petition is timely filed. *See* Appx1750-1752. Had the Director followed notice-and-comment procedures, Appellants and other affected parties could have presented their arguments regarding the Rule's conflict with AIA, and the Director would have been obligated to consider those arguments and address the statutory violation, which it has now effectively shielded from judicial review. *See* 5 U.S.C. § 553(c); *Overton Park*, 401 U.S. at 416.

Similarly, notice-and-comment rulemaking would have given Appellants and others an opportunity to explain the *NHK-Fintiv* Rule's irrationality and the arbitrary consequences it would produce, as many did in response to the PTO's belated 2020 request for comments. *See supra* p. 16; Appx1146-1148; Appx1751 (noting that district courts' "aggressive, and frequently fanciful, case timelines" exacerbated the "flawed rule's impact"). Again, the Director would have had to alter the rule to address those defects or else provide a reasoned explanation for refusing to do so. *See* 5 U.S.C. § 553(c); *Overton Park*, 401 U.S. at 416. Instead, the Director acted without warning and entirely failed to grapple with serious questions regarding the Rule's validity and its arbitrary consequences.

As adopted by the Director without notice and comment, the *NHK-Fintiv* Rule has harmed infringement defendants seeking the benefits of IPR, and it has undermined the patent system as a whole. *See* Appx1132; Appx1143-1144. As

things stand, a defendant accused of infringement would understand from the AIA that it has one year to file an IPR petition after being served with a complaint. 35 U.S.C. § 315(b). Consulting the PTO regulations regarding who may file a petition, it would see similar language regarding the one-year period. 37 C.F.R. § 42.101(b). If that defendant were to consult the PTO regulation governing when a petition could be filed, it would see nothing more about the significance of co-pending litigation. *See id.* § 42.102. Further consulting the rules for what to include in the petition, the defendant would find no requirement to discuss any factors related to the timing of parallel litigation. *See id.* § 42.104. Only by consulting the list of Board decisions that the Director has designated as precedential and by reviewing the *NHK* and *Fintiv I* decisions would the defendant learn that, despite the statutory one-year period for filing an IPR petition, time was of the essence and the de facto deadline was far sooner (but how much sooner would depend upon the circumstances of the case). Nor would the petitioner be aware of the possibility that the Director's policies embodied in the *NHK-Fintiv* Rule could change without notice at any time. "Agency rulemaking is not supposed to be a scavenger hunt." *Aqua Products, Inc. v. Matal*, 872 F.3d 1290, 1322 (Fed. Cir. 2017). Conducting notice-and-comment rulemaking, as the APA and AIA require, would have exposed these problems and hopefully averted them.

The notice-and-comment process is now even more crucial to ensuring fairness and sound decisionmaking in the Director's adoption of binding institution standards. Under this Court's prior decision, binding rules that change the standards for institution and make institution less likely will be difficult, if not impossible, to challenge as contrary to law or arbitrary and capricious. *Apple*, 63 F.4th at 11-14. Those rules cannot be challenged in the context of individual institution decisions, because the Board lacks authority to depart from the Rule, *supra* pp. 13-16, and courts lack jurisdiction to intervene, *see, e.g.*, *Mylan Labs. Ltd. v. Janssen Pharmaceutica, N.V.*, 989 F.3d 1375, 1378 (Fed. Cir. 2021), *cert. denied*, 142 S. Ct. 874 (Jan. 18, 2022) (Mem.). As a result, notice-and-comment procedures provide the last remaining check for affected parties against the Director's adoption of unlawful or irrational institution standards that harm parties' legally protected interests. It is all the more necessary, then, to enforce Congress's command that "the interested public should have an opportunity to participate, and the agency should be fully informed, before rules having such substantial impact are promulgated." *Pickus*, 507 F.2d at 1112.

CONCLUSION

The district court's judgment should be reversed.

Respectfully submitted,

/s/ Nathan K. Kelley
NATHAN K. KELLEY
PERKINS COIE LLP
700 Thirteenth Street NW, Suite 800
Washington, DC 20005
(202) 654-3343

ANDREW T. DUFRESNE
PERKINS COIE LLP
33 East Main Street, Suite 201
Madison, WI 53703
(608) 663-7492

Attorneys for Plaintiff-Appellant Google LLC

/s/ Catherine M.A. Carroll
CATHERINE M.A. CARROLL
GARY M. FOX
WILMER CUTLER PICKERING
HALE AND DORR LLP
2100 Pennsylvania Avenue NW
Washington, DC 20037
(202) 663-6000

MARK D. SELWYN
WILMER CUTLER PICKERING
HALE AND DORR LLP
2600 El Camino Real, Suite 400
Palo Alto, CA 94306
(650) 858-6000

ALYSON M. ZUREICK
WILMER CUTLER PICKERING
HALE AND DORR LLP
7 World Trade Center
250 Greenwich Street
New York, NY 10007
(212) 230-8800

Attorneys for Plaintiffs-Appellants Apple Inc., Cisco Systems, Inc., and Intel Corporation

August 5, 2024

STATEMENT OF CONSENT

Pursuant to Federal Circuit Rule 32(g)(3)(B), the undersigned represents that counsel for Google LLC has consented to his signature on this brief.

/s/ Catherine M.A. Carroll
CATHERINE M.A. CARROLL
WILMER CUTLER PICKERING
HALE AND DORR LLP
2100 Pennsylvania Avenue NW
Washington, DC 20037
(202) 663-6000

August 5, 2024

ADDENDUM

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United States District Court
Northern District of California

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

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

Plaintiffs,

v.

KATHERINE K. VIDAL, in her official capacity as Under Secretary of Commerce for Intellectual Property and Director, United States Patent and Trademark Office,

Defendant.

Case No. 20-cv-06128-EJD

ORDER DENYING PLAINTIFFS' RENEWED MOTION FOR SUMMARY JUDGMENT; GRANTING DEFENDANT'S MOTION FOR SUMMARY JUDGMENT

Re: ECF Nos. 153, 157

Plaintiffs Apple Inc., Cisco Systems, Inc., Google LLC, Intel Corp., Edwards Lifesciences Corp., and Edwards Lifesciences LLC (together "Plaintiffs") brought this action against the Director of the United States Patent and Trademark Office ("PTO") alleging three violations of the Administrative Procedure Act ("APA"), 5 U.S.C. § 701 *et seq.*, based on the Director's adoption of a rule (the "*NHK-Fintiv* rule" or "*NHK-Fintiv* standard") concerning the PTO's consideration of petitions to institute *inter partes* review ("IPR"). *See* Am. Compl., ECF No. 54. Following the Court's dismissal of the Amended Complaint for lack of jurisdiction as to all three APA claims, the Federal Circuit affirmed as to two claims and reversed and remanded as to the third. Now pending before the Court are cross-motions for summary judgment on the remaining claim, which challenges the *NHK-Fintiv* standard on the ground that it should have been—but was not—implemented through notice-and-comment rulemaking. *See* Pls.' Renewed Mot. Summ. J. ("Pls.'

MSJ"), ECF No. 153; Def.'s Mot. Summ. J. & Opp'n to Pl.'s MSJ ("Def.'s Opp'n/MSJ"), ECF No. 157.

Based on the parties' written and oral arguments, the Court finds that the *NHK-Fintiv* standard was not a substantive rule requiring notice-and-comment rulemaking.

I. BACKGROUND

The Court has previously set forth the background for the IPR process, as well as the decisions that gave rise to the *NHK-Fintiv* standard, in its order granting the Director's motion to dismiss the Amended Complaint. *See* Order Granting Mot. Dismiss ("MTD Order"), ECF No. 133. Accordingly, the Court here summarizes only the relevant facts for the remaining claim regarding the *NHK-Fintiv* standard's procedural soundness under the APA.

A. PTO Organization and Actions

The powers and duties of the PTO are vested in an individual given the title "Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office" (the "Director"). *See* 35 U.S.C. § 3(a)(1). One of the PTO's organizational offices is the Patent Trial and Appeal Board ("PTAB" or the "Board"). *See* 35 U.S.C. § 6(a). The Board's membership consists of "[t]he Director, the Deputy Director, the Commissioner for Patents, the Commissioner for Trademarks, and the administrative patent judges." *Id.*

The Board's duties include conducting IPRs, which are heard by at least three members of the Board. *See* 35 U.S.C. § 6(c).

1. Standard Operating Procedure 2 ("SOP-2")

By default, decisions issued by the Patent Trial and Appeal Board ("PTAB" or the "Board") in IPR proceedings are "routine" decisions that do not carry any binding authority. Patent Trial and Appeal Board, Standard Operating Procedure 2 (Rev. 11) ("SOP-2"), at 2 (July 24, 2023), https://www.uspto.gov/sites/default/files/documents/20230724_ptab_sop2_rev11_.pdf.[1]

[1] Although the Court here cites to SOP-2, Revision 11, it notes that Revision 10 was the operative version of the document when the Director designated the *NHK* and *Fintiv* decisions as precedential. *See* Def.'s Opp'n/MSJ 3–4 n.2. Revision 11 made no substantive change to the aspects of the precedential designation process relevant to this case. *See id.*

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However, the Director possesses the discretion to designate any decision or part of a decision as "precedential" or "informative." SOP-2, at 6 n.5; *see also United States v. Arthrex, Inc.*, 141 S. Ct. 1970, 1980 (2021) ("The Director also promulgates regulations governing inter partes review . . . and designates past PTAB decisions as 'precedential' for future panels."). "A precedential decision is binding Board authority in subsequent matters involving similar facts or issues." SOP-2, at 7. By contrast, the Director may also designate certain decisions as "informative," meaning that they "set forth Board norms that should be followed in most cases, absent justification, although an informative decision is not binding authority on the Board." *Id.*

2. The *NHK-Fintiv* Standard

At issue in this case are two Board decisions that discretionarily denied instituting IPR petitions: *NHK Spring Co. v. Intri-Plex Technologies, Inc.*, IPR2018-00752, 2018 WL 4373643 (P.T.A.B. Sept. 12, 2018) (designated precedential on May 7, 2019), and *Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, 2020 WL 2126495 (P.T.A.B. Mar. 20, 2020) (designated precedential on May 5, 2020). In both cases, the Board evaluated the argument that it should discretionarily deny IPR institution because a pending district court infringement action involving the same patents was set for trial earlier than the anticipated conclusion of IPR proceedings. *See NHK*, 2018 WL 4373643, at *7 (denying IPR institution due to agreement with patent owner's argument that "the district court proceeding will analyze the same issues and will be resolved before any trial on the Petition concludes") (citation omitted); *Fintiv*, 2020 WL 2126495, at *2 ("When the patent owner raises an argument for discretionary denial under *NHK* due to an earlier trial date, the Board's decisions have balanced the following [six] factors.") (footnote omitted).

The *Fintiv* decision, which expanded on *NHK*, noted that "an early trial date"—as with "other non-dispositive factors considered for [IPR] institution under 35 U.S.C. § 314(a)"—should be "weighed as part of a 'balanced assessment of all relevant circumstances of the case, including the merits.'" *Fintiv*, 2020 WL 2126475, at *2 (quoting Consolidated Trial Practice Guide November 2019 ("TPG"), available at https://www.uspto.gov/TrialPracticeGuideConsolidated). The *Fintiv* Board noted that prior Board decisions had evaluated patent owners' arguments for

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discretionary denials under *NHK* based on a "[p]arellel, co-pending proceeding" by evaluating (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.*

The Board then proceeded to discuss how prior opinions had treated each of these factors—all of which related to the impact of a parallel proceeding, *see id.* at *2–6—before noting that other facts and circumstances separate from the parallel proceedings could impact the Board's decision regarding institution. *See id.* at *7 ("For example, factors unrelated to parallel proceedings that bear on discretion to deny institution include the filing of serial petitions, parallel petitions challenging the same patent, and considerations implicated by 35 U.S.C. § 325(d)." [nn. 34–36]) (citing *Valve Corp. v. Elec. Scripting Prods., Inc.*, IPR2019-00064, Paper 10 (PTAB May 1, 2019) (precedential); *Valve Corp. v. Elec. Scripting Prods.*, Inc., IPR2018-00752, Paper 8 (PTAB Sept. 12, 2018); *Gen. Plastic Indus. Co. v. Canon Kabushiki Kaisha*, IPR2016-01357, Paper 19 (PTAB Sept. 6, 2017) (precedential as to § II.B.4.i); TPG 59–61; *Advanced Bionics, LLC v. MED-EL Elektromedizinische Geräte GmbH*, IPR2019-01469, Paper 6 (PTAB Feb. 13, 2020) (discussing two-part framework for applying discretion to deny institution under 35 U.S.C. § 325(d))). The *Fintiv* Board accordingly concluded by requesting that the parties submit supplemental briefing addressing the various factors discussed by the Board. *See id.* at *7.

The Director designated *NHK* a precedential decision on May 7, 2019, and likewise designated *Fintiv* as precedential on May 5, 2020. As such, "[t]he decisions, designated as precedential, constitute instructions from the Director regarding how the Board is to exercise the Director's institution discretion." *Apple Inc. v. Vidal*, 63 F.4th 1, 8 (Fed. Cir. 2023).

3. June 2022 Interim Procedure for Discretionary Denials

On June 21, 2022, after requesting comments on IPR institution decisions and receiving

822 comments, the Director issued a memorandum (the "June 2022 Memo") indicating that "several clarifications need[ed] to be made to the PTAB's current application of *Fintiv*." Mem., Interim Proc. for Discretionary Denials in AIA Post-Grant Proceedings with Parallel Dist. Ct. Litig. ("June 2022 Mem."), at 2 (June 21, 2022). The June 2022 Memo was issued under the Director's "authority to issue binding agency guidance to govern the PTAB's implementation of various statutory provisions." *Id.* at 3.

The June 2022 Memo clarified three circumstances where the PTAB will *not* deny institution of an IPR under *Fintiv*: (1) when a petition presents "compelling evidence of unpatentability"; (2) when a request for denial is based on a parallel ITC proceeding instead of a district court proceeding; or (3) where a petitioner stipulates not to pursue in a parallel district court proceeding "the same grounds as in the [IPR] petition or any grounds that could have reasonably been raised in the petition." June 2022 Mem. 9. Additionally, when the Board is assessing the second *Fintiv* factor (*i.e.*, comparing the district court's trial date with the Board's projected deadline for a final written IPR decision), the PTAB will consider the district's median time-to-trial. *Id.* The June 2022 Memo lastly reiterated that "even if the PTAB does not deny institution under *Fintiv*, it retains the right to deny institution for other reasons under 35 U.S.C. §§ 314(a), 324(a), and 325(d)." *Id.*

4. Potential for Future Rulemaking

The June 2022 Memo noted that the PTO was "planning to soon explore potential rulemaking on proposed approaches through an Advanced Notice of Proposed Rulemaking," June 2022 Mem. 2, and stated that the office "expect[ed] to replace this interim guidance with rules after it has completed formal rulemaking," *id.* at 9. On April 21, 2023, the PTO published an Advance Notice of Proposed Rulemaking in the Federal Register. *See* Changes Under Consideration to Discretionary Institution Practices, Petition Word-Court Limits, and Settlement Practices for America Invents Act Trial Proceedings Before the Patent Trial and Appeal Board ("Apr. 2023 ANPRM"), 88 Fed. Reg. 24,503 (Apr. 21, 2023). Among various potential changes, the PTO is "proposing rules to install *Apple v. Fintiv* and related guidance, with additional

proposed reforms," where there is "a pending district court action in which a trial adjudicating the patentability of challenged claims has not already concluded at the time of an IPR institution decision." 88 Fed. Reg. at 24,505. It is not clear whether the "additional proposed reforms" would substantially reduce the Board's discretion in applying the *Fintiv* factors. *See id.*

B. Procedural History

On August 31, 2020, Apple and three other companies filed this action, challenging the *NHK-Fintiv* standard on three grounds under the APA. *See* Compl., ECF No. 1. Plaintiffs filed an amended complaint on November 9, 2020. *See* FAC. On November 10, 2021, this Court granted the government's motion to dismiss, finding that Plaintiffs had standing to sue but that their challenges were not reviewable under 35 U.S.C. § 314(d). *See* MTD Order. The Federal Circuit affirmed in part, reversed in part with respect to the reviewability of one claim, and remanded the matter to this Court "for consideration of this one challenge on the merits," referring to Plaintiffs' "challenge to the Director's instructions as having improperly been issued without notice-and-comment rulemaking." *Apple*, 63 F.4th at 18. The circuit court emphasized the distinction between holding a notice-and-comment rule making claim reviewable under the APA and making a decision on the merits as to whether such rule making was required. *See id.* at 15 (discussing Supreme Court decision, *Lincoln v. Vigil*, 508 U.S. 182 (1993), Court did not question APA claim's reviewability, but rather "decided, on the merits, that § 553 did not require notice-and-comment rulemaking for the agency decision at issue"). Additionally, in affirming this Court's finding that Plaintiffs had plausibly alleged an injury-in-fact for the purposes of standing, the Federal Circuit noted that Plaintiffs sufficiently alleged that the *NHK-Fintiv* standard would continue causing harm "harm in the form of denial of the benefits of IPRs linked to the concrete interest possessed by an infringement defendant." *Id.* at 17.

Following remand, the parties proposed a briefing schedule for their anticipated cross-motions for summary judgment. *See* ECF No 145. Pursuant to the Court's scheduling order, Plaintiffs filed their motion for summary judgment on August 17, 2023, *see* Pls.' MSJ; the Director filed her opposition and cross-motion for summary judgment on September 14, 2023, *see*

Def.'s Opp'n/MSJ; Plaintiffs filed their reply in support of their summary judgment motion and opposition to the Director's motion, *see* Pls.' Reply/Opp'n, ECF No. 158; and the Director filed her reply brief, *see* Def.'s Reply, ECF No. 159. The Court heard oral argument on the two summary judgment motions on December 7, 2023. *See* ECF No. 160.

II. LEGAL STANDARDS

A. Governing Law

Federal Circuit law governs the analysis of any issue that is unique to patent law or that presents a substantial question of patent law; any other issue is governed by Ninth Circuit law. *See Alarm.com Inc. v. Hirshfeld*, 26 F.4th 1348, 1354 (Fed. Cir. 2022) ("[A]n issue that presents a substantial question of patent law . . . is governed by our own law, rather than regional circuit law.") (citing *Odyssey Logistics & Tech. Corp. v. Iancu*, 959 F.3d 1104, 1108 (Fed. Cir. 2020)); *Odyssey Logistics*, 959 F.3d at 1108 ("We review procedural rules following 'the rule of the regional circuit, unless the issue is unique to patent law and therefore exclusively assigned to the Federal Circuit.'"); *see also, e.g.*, *Injen Tech. Co., Ltd. v. Advanced Engine Mgmt., Inc.*, 270 F. Supp. 2d 1189, 1192 (S.D. Cal. 2003) (In cases concerning the patent laws, the district court applies the law of the Federal Circuit to patent issues and the law of the circuit in which it sits ('the regional circuit') to nonpatent issues. . . . Thus, as a general rule, procedural issues are governed by the law of the regional circuit.") (internal citations omitted).

"APA claims against the PTO 'raise a substantial question of patent law,'" and substantive legal issues raised in such actions are therefore governed by Federal Circuit law. *Odyssey Logistics*, 959 F.3d at 1108 (internal alternations omitted) (quoting *Exela Pharma Scis., LLC v. Lee*, 781 F.3d 1349, 1352 (Fed. Cir. 2015)); *see also, e.g.*, *Helfgott & Karas, P.C. v. Dickinson*, 209 F.3d 1328, 1334 (Fed. Cir. 2000) (noting that although "[t]he APA is clearly not a patent law," Federal Circuit law governed in APA action brought against PTO because plaintiff's APA claims involved alleged loss of patent-related rights).

B. Summary Judgment

In a district court action challenging an administrative agency's decision under the APA,

"[s]ummary judgment . . . serves as the mechanism for deciding, as a matter of law, whether the agency action is . . . consistent with the APA standard of review." *Gill v. Dep't of Just.*, 246 F. Supp. 3d 1264, 1268 (N.D. Cal. 2017) (citation omitted), *aff'd*, 913 F.3d 1179 (9th Cir. 2019).[2] That is, although the parties and the Court characterize the pending motions as seeking summary judgment, the motions are not brought pursuant to Federal Rule of Civil Procedure 56, and the question before the Court is not whether the movant has shown that there is no genuine dispute as to any material fact. *See id.* at 1267–68; *see also, e.g.*, *Klamuth Siskiyou Wildlands Ctr. v. Gerritsma*, 962 F. Supp. 2d 1230, 1233 (D. Or. 2013) ("'Summary judgment' is simply a convenient label to trigger this court's review of the agency action."), *aff'd*, 638 F. App'x 648 (9th Cir. 2016). "In other words, the district court acts like an appellate court, and the entire case is a question of law." *Gill*, 246 F. Supp. 3d at 1268 (internal quotation marks omitted).

C. APA Review

Under the APA, a "reviewing court shall … hold unlawful and set aside agency action" taken "without observance of procedure required by law." 5 U.S.C. § 706(2)(D). Agency actions can be divided into two broad categories: rule making and adjudication. *See, e.g.*, *Yesler Terrace Cmty. Council v. Cisneros*, 37 F.3d 442, 448 (9th Cir. 1994) (citing 5 U.S.C. §§ 551(4)–(7)). The parties agree that only rule making is relevant here. *See* Pls.' MSJ 14 n.12 (stating *NHK-Fintiv* standard is not adjudication under the APA); *see generally* Def.'s Opp'n/MSJ (no argument that adjudication framework applies to *NHK-Fintiv* standard).

The APA defines "rule" as:

> the whole or a part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy or describing the organization, procedure, or practice requirements of an agency and includes the approval or prescription for the future of rates, wages, corporate or financial structures or reorganizations thereof, prices, facilities, appliances, services or allowances therefor or of valuations, costs, or accounting, or practices bearing on any of the foregoing,

[2] The procedural mechanism of summary judgment in challenging an agency action under the APA does not raise a substantial question of patent law, and is accordingly discussed with reference to Ninth Circuit law.

5 U.S.C. § 551(4), and "rule making" as the "agency process for formulating, amending, or repealing a rule," *id.* § 551(5). In general, when an agency engages in rule making, the APA requires that the agency conduct a notice-and-comment process involving the agency's publication of notice of the proposed rulemaking, the opportunity for interested persons to comment on the proposal, and the agency's response to significant comments. *See* 5 U.S.C. §§ 553(b)–(d). However, the APA expressly excludes three categories of rulemaking from the notice-and-comment requirement: (1) interpretative rules; (2) general statements of policy; and (3) rules of agency organization, procedure, or practice. *Id.* § 553(b)(4)(A).[3] Courts have formulated this distinction to hold that "[t]he notice-and-comment requirements apply . . . only to so-called 'legislative' or 'substantive' rules." *Lincoln v. Vigil*, 508 U.S. 182, 195 (1993) (citations omitted); *see also Chrysler Corp. v. Brown*, 441 U.S. 281, 301 (1979) ("The central distinction among agency regulations found in the APA is that between 'substantive rules' on the one hand and 'interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice' on the other.") (quoting 5 U.S.C. §§ 553(b), (d)).

A rule is "substantive," and therefore subject to the APA's notice-and-comment requirements, if it "effect[s] a change in existing law or policy or . . . affect[s] individual rights and obligations." *Paralyzed Veterans of Am. v. West*, 138 F.3d 1434, 1436 (Fed. Cir. 1998) (citation omitted); *see also Yesler Terrace*, 37 F.3d at 449 ("Substantive rules . . . create rights, impose obligations, or effect a change in existing law pursuant to authority delegated by Congress.") (citation omitted). A "general statement of policy," which is not subject to notice-and-comment rule making, is a statement "issued by an agency to advise the public prospectively of the manner in which the agency proposes to exercise a discretionary power." *Lincoln*, 508 U.S. at 197 (quoting *Chrysler*, 441 U.S. at 302 n.31).

III. DISCUSSION

As noted above, the only remaining claim before the Court is Plaintiffs' challenge to the

[3] The only exception at issue here is for "general statements of policy." *See generally* Def.'s Opp'n/MSJ.

NHK-Fintiv standard as having improperly been issued in violation of the APA due to the lack of notice-and-comment rule making. It is undisputed that the *NHK-Fintiv* standard did not undergo the regular notice-and-comment rule making. The contested issue is thus whether the Director was in fact required to invoke the rule making process to implement the *NHK-Fintiv* standard. Plaintiffs argue that notice-and-comment rule making was required because the adoption of the *NHK-Fintiv* standard was a substantive rule that the Board is bound to follow and that affects private interests. *See* Pls.' MSJ 14–20. The Director argues that notice-and-comment was not required because the *NHK-Fintiv* standard is a general statement of policy that does not affect the rights of private interests and does not replace the Board's discretion. *See* Def.'s Opp'n/MSJ 9–18.

In considering these arguments, the Court first distills the specific agency action at issue before turning to the question of whether that action was the implementation of a substantive rule or the issuance of a general statement of policy.

A. The Nature of the Challenged Action

Plaintiffs' challenge to the *NHK-Fintiv* standard is based on the Director's designation of the *NHK* and *Fintiv* decisions as "precedential" under SOP-2. *See* Pls.' MSJ 7–8; Am. Compl. ¶¶ 49–53, 92–95. Plaintiffs have not challenged SOP-2 itself, or more generally the Director's authority to designate a decision as precedential. *See generally* Am. Compl.; *see also* Dec. 7, 2023 Hr'g Tr. ("Tr.") 40:11–13.[4] Rather, Plaintiffs argue that the specific designations of *NHK* and *Fintiv* have had the effect of creating a substantive rule, which should have been—but was

[4] The Court notes that the Director's authority to designate a decision as precedential is well established. *See, e.g.*, *Facebook, Inc. v. Windy City Innovations, LLC*, 973 F.3d 1321, 1353 (Fed. Cir. 2020) (discussing process under SOP 2 for designating PTAB decision as precedential and noting that *Chevron* deference is not afforded to such decisions). It is also worth noting that other agencies have similar mechanisms through which they may designate a decision as precedential. *See, e.g.*, *ITServe Alliance, Inc. v. U.S. Dep't of Homeland Sec.*, 71 F.4th 1028, 1032 (D.C. Cir. 2023) (Department of Homeland Security designated precedential decision by United States Citizenship and Immigration Services regarding visa eligibility); *Splane v. West*, 216 F.3d 1058, 1065 (Fed. Cir. 2000) ("Written legal opinions [of the General Counsel] designated as precedent opinions [] shall be considered by Department of Veterans Affairs to be subject to the provisions of 5 U.S.C. 552(a)(1).") (quoting 38 C.F.R. § 14.507(b)).

not—subject to notice-and-comment rule making. Accordingly, it is necessary to understand what is required by *NHK* and *Fintiv* before evaluating whether that requirement is properly categorized as a substantive rule or a general statement of policy.

1. When Does the *NHK-Fintiv* Standard Apply?

As a threshold matter, the *NHK-Fintiv* standard applies to the circumstance where the Board is considering a petition to institute IPR, and the patent owner, in opposing the petition, argues that the Board should apply its discretion under 35 U.S.C. § 314(a) to deny institution due to the advanced state of a parallel district court litigation. *See NHK*, 2018 WL 4373643, at *7 (finding, after patent owner argued that IPR would be inefficient where parallel district court proceeding addressing same issues was set for trial five months before IPR would conclude, that "advanced state of the district court proceeding is an additional factor that weighs in favor of denying" IPR); *Fintiv*, 2020 WL 2126495, at *1–2 (aggregating factors that Boards considered where patent owners argued for denial of IPR due to earlier trial date in parallel district court proceeding); *see also Apple Inc. v. Fintiv, Inc.*("*Fintiv II*"), IPR2020-00019, 2020 WL 2486683, at *3 (P.T.A.B. May 13, 2020) (not precedential) ("The recent Precedential Order in this case sets forth factors that balance considerations of system efficiency, fairness, and patent quality when a patent owner raises an argument for discretionary denial due to the advanced state of a parallel proceeding.") (citing *Fintiv*, 2020 WL 2126495, at *2).

2. What Must a Board Do When the *NHK-Fintiv* Standard Applies?

To answer this question, the Court reviews the actual language of *Fintiv*, which expounded on the holding in *NHK* that an early trial date in a parallel proceeding could be a basis for denial of IPR institution. Broadly, the existence of an early trial date in a parallel district court proceeding is a "non-dispositive factor[] considered for institution under 35 U.S.C. § 314(a)" that "should be weighed as part of a 'balanced assessment of all relevant circumstances of the case, including the merits.'" *Fintiv*, 2020 WL 2126495, at *2 (quoting TPG 58). *Fintiv* identified six "factors related to a parallel, co-pending proceeding," *id.*, that Board decisions had balanced following *NHK*, and noted that the "factors relate to whether efficiency, fairness, and the merits support the exercise of

authority to deny institution in view of an earlier trial date in the parallel proceeding," *id.* at *3. In discussing the six identified factors, *Fintiv* noted potential facts that prior Boards had found to weigh for or against—and weakly or strongly—the Board's "exercising the authority to deny institution under *NHK*." *Id.* For example, as to the first factor ("whether a stay exists or is likely to be granted if [an IPR] proceeding is instituted"), a litigation stay "has strongly weighed against exercising authority to deny institution," but a district's court's prior denial of a motion for a stay, and lack of indication that the court would reconsider such a motion, "has sometimes weighed in favor of exercising authority to deny institution under *NHK*." *Id.*

In addition to the six identified factors "related to a parallel, co-pending proceeding"—including the sixth factor of "other circumstances that impact the Board's exercise of discretion, including the merits"—*Fintiv* noted that there may exist facts and circumstances "unrelated to parallel proceedings that bear on discretion to deny institution," including factors such as "the filing of serial petitions, parallel petitions challenging the same patent, and considerations implicated by 35 U.S.C. § 325(d)." *Id.* at *6–7 (footnotes and citations omitted). The precedential *Fintiv* decision ends with a request for supplemental briefing from the parties related to the various enumerated factors and about "whether these or other facts and circumstances exist in their proceeding and the impact of those facts and circumstances on efficiency and integrity of the patent system." *Id.* at *7.

Accordingly, *Fintiv* "articulates [a] set of nonexclusive factors that the PTAB considers . . . in determining whether to institute an [IPR] proceeding where there is parallel district court litigation." June 2022 Mem. 1–2. That is, *Fintiv* summarized various factors that the PTAB had considered in evaluating patent owners' arguments that institution should be denied due to the status of a parallel district court proceeding, and the Director, by designating the decision precedential, required that future Board decisions also consider those identified factors when faced with similar arguments.

B. Classification of the *NHK-Fintiv* Standard

The dispositive question, then, is whether the Director's requirement that Boards consider

the factors enumerated in *Fintiv* constitutes a "substantive rule" that is invalid absent notice-and-comment rule making, or a "general statement of policy" for which the APA does not require such rule making processes. Whether a particular agency action is a "substantive rule" or a "general statement of policy" is a significant question in administrative law. *See, e.g.*, *Nat'l Min. Ass'n v. McCarthy*, 758 F.3d 243, 251 (D.C. Cir. 2014) (describing framework for classification of agency action as "quite difficult and confused," and noting that "among the many complexities that trouble administrative law, few rank with that of sorting valid from invalid uses of so-called 'nonlegislative rules'") (quoting John F. Manning, Nonlegislative Rules, 72 GEO. WASH. L. REV. 893, 893 (2004)). The Court will look primarily to Federal Circuit law in evaluating the classification of the *NHK-Fintiv* standard, as the inquiry here involves the Director's authority and duties under 35 U.S.C. §§ 314 and 316 and thus "can be said to raise a substantial question under the patent laws." *Helfgott*, 209 F.3d at 1333–34; *see also Odyssey Logistics*, 959 F.3d at 1108. However, as indicated below, there is a large degree of overlap between the circuits—including the Federal Circuit and the Ninth Circuit—regarding the classification of agency actions as substantive versus non-substantive rules.

1. Analytical Framework

At base, the Federal Circuit and Ninth Circuit agree that substantive rules "alter the landscape of individual rights and obligations." *Stupp Corp. v. United States*, 5 F.4th 1341, 1352 (Fed. Cir. 2021); *see also Paralyzed Veterans of Am.*, 138 F.3d at 1436 ("[C]ase law has defined 'substantive rules' as those that effect a change in existing law or policy or which affect individual rights and obligations.") (citation omitted); *Yesler Terrace*, 37 F.3d at 449 (Ninth Circuit decision stating that substantive rules "create rights, impose obligations, or effect a change in existing law pursuant to authority delegated by Congress") (citation omitted). By contrast, a "general statement of policy" is a statement "issued by an agency to advise the public prospectively of the manner in which the agency proposes to exercise a discretionary power." *Lincoln*, 508 U.S. at 197 (citation omitted); *see also Stupp*, 5 F.4th at 1351 (same under Federal Circuit law); *Serrato v. Clark*, 486 F.3d 560, 569 (9th Cir. 2007) (same).

The Federal Circuit frequently cites to D.C. Circuit cases when discussing the distinction between substantive and non-substantive rules. *See, e.g.*, *Disabled Am. Veterans v. Sec'y of Veterans Affairs*, 859 F.3d 1072, 1077 (Fed. Cir. 2017) ("The most important factor [in distinguishing substantive rules from general statements of policy] concerns the actual legal effect (or lack thereof) of the agency action in question on regulated entities.") (quoting *Nat'l Min. Ass'n*, 758 F.3d at 252); *id.* (generally describing substantive rulemaking under the APA) (citing *Molycorp, Inc. v. EPA*, 197 F.3d 543, 545 (D.C. Cir. 1999)); *Splane v. West*, 216 F.3d 1058, 1063 (Fed. Cir. 2000) ("The D.C. Circuit has recognized that 'an agency's characterization of its own action, while not decisive, is a factor [to] consider' [in deciding whether a rule is substantive].") (quoting *Am. Hosp. Ass'n v. Bowen*, 834 F.2d 1037, 1047 (D.C. Cir. 1987)). As the D.C. Circuit has noted, its case law "guide[s] the determination of whether an action constitutes a [substantive] rule or a general statement of policy" through two lines of inquiry: the first "considers the effects of an agency's action, inquiring whether the agency has '(1) imposed any rights and obligations, or (2) genuinely left the agency and its decisionmakers free to exercise discretion'"; and the second "looks to the agency's expressed intentions," and particularly as to "whether the action has binding effects on private parties or on the agency." *Clarian Health W., LLC v. Hargan*, 878 F.3d 346, 357 (D.C. Cir. 2017) (citations omitted).

Similarly, under Ninth Circuit law, a general statement of policy (1) must "operate only prospectively," and (2) "must not establish a binding norm or be finally determinative of the issues or rights . . . but must instead leave [agency] officials free to consider the individual facts in the various cases that arise." *Mada-Luna v. Fitzpatrick*, 813 F.2d 1006, 1014 (9th Cir. 1987) (internal quotation marks and citations omitted); *see also Gill v. U.S. Dep't of Just.*, 913 F.3d 1179, 1186 (9th Cir. 2019) ("The critical factor to determine whether a directive announcing a new policy constitutes a legislative rule or a general statement of policy is 'the extent to which the challenged directive leaves the agency, or its implementing official, free to exercise discretion to follow, or not to follow, the announced policy in an individual case.'") (alterations omitted) (quoting *Colwell v. Dep't of Health & Human Servs.*, 558 F.3d 1112, 1124 (9th Cir. 2009)).

2. Application of Analytical Framework

In light of the Court's above discussion of the relevant framework, the Court will evaluate whether the *NHK-Fintiv* standard (1) affects individual rights and obligations; (2) operates prospectively; (3) leaves the PTAB free to exercise discretion and consider the individual facts before it in a given case; and (4) has binding effects, establishes a binding norm, or is otherwise determinative of any issues or rights.

a. Affects Individual Rights and Obligations

Plaintiffs argue that the *NHK-Fintiv* standard affects private interests by increasing the risk of IPR denial and thereby "restricting the ability of infringement defendants to access IPR and its benefits." Pls.' MSJ 18–19. Plaintiffs urge that the Court look to *W.C. v. Bowen*, 807 F.2d 1502 (9th Cir. 1987), *amended on denial of reh'g*, 819 F.2d 137 (9th Cir. 1987), where the circuit held that a Social Security Administration program requiring mandatory screening and review of decisions allowing disability benefits, if those decisions were made by specified administrative law, constituted a substantive rule. *See* Pls.' MSJ 19–20. Plaintiffs argue that the *NHK-Fintiv* standard likewise changes existing policy because it established non-statutory factors that a petitioner "must satisfy to access the benefits of IPR," and was designed to alter the Board's decisionmaking and thereby displaced Board discretion. *See id.* The Director counters that the *Fintiv* factors do not affect any legally protected individual rights or obligations, as IPR petitioners have no right to IPR review, and the institution decision makes no determination regarding the validity of the underlying patent at issue. *See* Def.'s Opp'n/MSJ 10. The Director additionally notes that the Federal Circuit's finding in its remand decision in this case—that Plaintiffs alleged sufficient harm to establish standing—"does not automatically convert to a holding that Plaintiffs' rights are altered by the *Fintiv* factors." *Id.* at 12.

The Court agrees with the Director that the *NHK-Fintiv* standard—*i.e.*, the application of the *Fintiv* factors—does not "alter the landscape of individual rights and obligations," *Stupp*, 5 F.4th at 1352, or "create rights, impose obligations, or effect a change in existing law pursuant to authority delegated by Congress," *Yesler Terrace*, 37 F.3d at 449. Congress has provided that the

Director "may *not* authorize an [IPR] to be instituted unless . . . there is a reasonable likelihood" of success with respect to at least one challenged claim. 35 U.S.C. § 314(a) ("Threshold.") (emphasis added). However, there is no set of circumstances under which the Director is required to authorize IPR institution. *See generally* 35 U.S.C. §§ 311, *et seq.*; *see also, e.g.*, *SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1355 (2018) ("The Director, we see, is given . . . the choice 'whether' to institute an inter partes review."). The *NHK-Fintiv* standard, which requires that the Board consider certain non-exclusive factors in determining whether to institute IPR is therefore distinguishable from the program reviewed in *W.C. v. Bowen*, which affected individuals' "existing rights" to social security benefits by altering decisions toward benefit denials. *See* 807 F.2d at 1505. Where there is no existing right to the action sought by a petitioner, *i.e.*, where a grant of the requested relief is entirely discretionary, the fact that an agency action "diminishes the likelihood," that the agency will grant relief does not require a finding that preclude the action from "constitut[ing] a general statement of policy," even if the agency action "will cause a 'substantial impact' to the rights of a specific class." *Mada-Luna*, 813 F.2d at 1016.[5]

To the extent Plaintiffs argue that the *NHK-Fintiv* standard imposes on the right to bring a petition for IPR within one year of being served with an infringement complaint, *see* Pls.' MSJ 21–22, the Federal Circuit has affirmed this Court's dismissal of Plaintiffs' claim that the *NHK-Fintiv* standard is contrary to the one-year window set by statute. *See Apple*, 63 F.4th at *11–13. Further, there is no statutory language suggesting that Plaintiffs should expect the same likelihood of institution regardless of the time of filing within the one-year window; rather the window

[5] The Federal Circuit, in holding that Plaintiffs had alleged facts sufficient to confer standing, noted that Plaintiffs plausibly alleged that the *NHK-Fintiv* standard caused harm by denying IPR benefits linked to an infringement defendant's legally protected interests in the infringement suit. *See Apple*, 63 F.4th at 17. Plaintiffs argue that this finding should lead to the conclusion that the *NHK-Fintiv* standard is a substantive rule because it alters legal rights, *see* Pls.' MSJ 18, but that argument would collapse the threshold analysis of standing with that of the merits of the APA claim, which is the very distinction between threshold and merits analysis that the Federal Circuit concluded applied to this case. *See Apple*, 63 F.4th at 15 ("The government in *Lincoln* explained this distinction . . . [and] [w]e conclude that the distinction applies here."). The Court is not here required to take Plaintiffs' allegations as true, and makes its finding regarding the merits question based on the analogous case law discussed in this section.

functions to create a time bar in the event the petitioner has been served with a complaint alleging infringement of the patent. *See* 35 U.S.C. § 315(b). Lastly, nothing in the *NHK-Fintiv* standard requires any action on the part of a petitioner or patent owner; rather, the Director's designation of the *NHK* and *Fintiv* decisions as precedential has required action only of the PTAB, as discussed in greater detail below. *See infra*, at Part III(B)(2)(c). Accordingly, the Court finds that the *NHK-Fintiv* factors do not alter, create, or impose any individual rights or obligations.

b. Operates Prospectively

As Plaintiffs note, the general definition of a "rule" is an "agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy." Pls.' MSJ 16 (quoting 5 U.S.C. § 551(4)). Such rules must be adopted through notice-and-comment rule making, except for enumerated exceptions including "general statements of policy." *Id.* (quoting 5 U.S.C. § 553(b)). For an agency action to be a general statement of policy, one requirement is that the action must operate "only prospectively." *Mada-Luna*, 813 F.2d at 1014; *see also Lincoln*, 508 U.S. at 197 (noting that general statements of policy are "statements issued by an agency to advise the public prospectively of the manner in which the agency proposes to exercise a discretionary power") (quoting *Chrysler*, 441 U.S. at 302 n.31).

Here, the parties do not dispute that the Director's designation of the *NHK* and *Fintiv* decisions as precedential had only a prospective effect. *See generally* Pls.' MSJ; Def.'s Opp'n/MSJ; *see also* SOP-2, at 7 (stating that precedential decisions constitute authority for "*subsequent matters* involving similar facts or issues") (emphasis added). Accordingly, the *NHK-Fintiv* standard meets this necessary, though not sufficient, criterion for a general statement of policy.

c. Exercise of Discretion

This next avenue of analysis—whether the *NHK-Fintiv* standard leaves agency officials "free to exercise discretion"—is perhaps the thorniest one presented by this case. *Clarian Health W.*, 878 F.3d at 357; *see also Mada-Luna*, 813 F.2d at 1014 (noting that general statement of policy must "leave [agency] officials free to consider the individual facts in the various cases that

arise"). Plaintiffs argue that the *NHK-Fintiv* standard leaves the Board with no discretion with respect to both (1) considering the *Fintiv* factors and (2) denying institution "where those factors on balance weigh against institution," regardless of any case specific facts. *See* Pls.' MSJ 17–18. The Director agrees that the *NHK-Fintiv* standard requires the Board to consider the enumerated factors, and argues that (1) the Director's complete statutory discretion to deny institution of IPR means that she may instruct the Board on her policy priorities, and (2) the *Fintiv* factors do not require any particular outcome in a given case, but merely guide the Board's attention to certain facts to consider in conducting a holistic analysis. *See* Def.'s Opp'n/MSJ 13–18. The parties' arguments as to whether the *NHK-Fintiv* standard replaces the Board's discretion with respect to the outcome of a petition to institute IPR overlap with the analysis of whether the standard is binding or determinative, and the Court will therefore address those arguments in the following section. *See infra*, at Part III(B)(2)(d). Here, the Court examines whether the *NHK-Fintiv* standard's undisputed requirement that the Board to consider the *Fintiv* factors (when presented with arguments about a parallel district court proceeding) is a substantive rule.

At the outset, to the extent the Director argues that her own complete discretion to deny institution of IPR means that she may set forth instructions that would require the Board to make specific institution decisions in specific circumstances as a general statement of policy, the Court rejects the argument as contrary to the requirement that agency decisionmakers remain free to exercise their discretion. *See Lincoln*, 508 U.S. at 197 (general statements of policy concern "the manner in which the agency proposes to exercise a discretionary power"); *Clarian Health W.*, 878 F.3d at 357 (general statement of policy "genuinely left the agency *and its decisionmakers* free to exercise discretion") (emphasis added) (citation omitted).

The Court finds instructive the Ninth Circuit's reasoning in *Mada-Luna*. There, the Court considered whether two versions of operating instructions issued by the Immigration and Naturalization Service ("INS") were substantive rules or general statements of policy regarding the grant of deferred action status. *See* 813 F.2d at 1017. Both versions of the operating instructions required the agency decisionmakers to consider several enumerated, non-exclusive

factors when determining whether to recommend a case for deferred action, such as the age of the applicant. *See id.* at 1008–09 nn. 1–2. The Ninth Circuit found each version of the operating instruction to be a general statement of policy even though the instructions required the district director to consider the specified factors, reasoning that the instructions "expressly authorize[d]" and left the director free to consider any other individual facts in each case. *See id.* at 1017.

Similarly, here, the *NHK-Fintiv* standard enumerates a set of non-exclusive factors for agency decisionmakers to consider when determining whether to institute an IPR. *See Fintiv*, 2020 WL 2126495, at *2 (noting that *Fintiv* factors relating to early trial date arguments are similar to "other non-dispositive factors considered for institution," all of which "should be weighed as part of a 'balanced assessment of all relevant circumstances of the case'") (quoting TPG 58); *see also* June 2022 Mem. 1–2 ("[*Fintiv*] articulates the following . . . nonexclusive factors."). Further, *Fintiv* not only includes a factor for "other circumstances"—a broad category that makes explicit that the Board should consider "all the relevant circumstances in the case," the decision also expressly notes that "factors unrelated to parallel proceedings [may] bear on discretion to deny institution," such as "the filing of serial petitions, parallel petitions challenging the same patent, and considerations implicated by 35 U.S.C. § 325(d)." *Fintiv*, 2020 WL 2126495, at *6–7 (footnotes and citations omitted). Accordingly, the "language and structure of the directive" not only permit but in fact require that the Board exercise its discretion in consideration of the particular facts presented in each case. *See Mada-Luna*, 813 F.2d at 1015 (citation omitted).

d. Binding or Determinative Effect

The Court lastly considers whether the *NHK-Fintiv* standard establishes a binding norm or has a determinative effect. Plaintiffs argue that the standard is binding because the Board "must grant or deny IPR petitions in accordance with the rule." Pls.' MSJ 10; *see id.* at 18 ("The Board must apply the rule's factors and deny institution in accordance with the *NHK-Fintiv* rule where those factors on balance weigh against institution; the Board has no freedom to consider the individual facts in the various cases that arise and grant an IPR petition where the balancing of the

rule's factors dictates otherwise.") (internal quotation marks omitted) (citing *Mada-Luna*, 813 F.2d at 1014). Plaintiffs additionally argue that the *NHK-Fintiv* rule "overall has proven dispositive, as evidenced by its repeated use to deny IPR petitions." *Id.* at 18 (citing Am. Compl. ¶¶ 54–61); *see id.* at 9 ("[F]ollowing adoption of the rule, the percentage of cases raising parallel litigation as a ground for denying institution nearly doubled. . . [and in] the first half of [2021,] the Board denied institution in 38% of cases in which *NHK-Fintiv* was considered.") (citations omitted). The Director first counters a rule that is binding only within the agency is not a substantive rule. *See* Def.'s Opp'n/MSJ 13–14 (citing *Splane*, 216 F.3d at 1064). The Director further argues that the *Fintiv* factors in any event "do not compel a specific outcome on institution," *id.* at 12, and therefore do not establish a 'binding norm' because "merely guide the Board's decision-making process . . . without dictating any particular outcome," *id.* at 14.

With respect to the Director's first argument—that a rule that is binding within an agency may not be substantive rule—the Court finds the Director's reliance on *Splane* to be misplaced. In *Splane*, the Federal Circuit rejected the argument that a rule's binding effect within the agency meant that the rule "*necessarily* ha[d] the 'force and effect of law,'" such that it could not be anything but a substantive rule. *See* 216 F.3d at 1064 (emphasis added); *see id.* ("Petitioners assert that any agency rule that is binding on an agency tribunal has the 'force and effect of law,' and must therefore be deemed legislative in nature. We disagree."). Any rule—substantive or not—may be "binding on agency officials insofar as any directive by an agency head must be followed by agency employees." *Id.* (citation omitted). However, the Federal Circuit did not hold, as the Director appears to argue, that a rule that binds only the agency may never be a substantive rule. *See id.* Further, the Federal Circuit has since noted that one of the factors relevant to whether an agency action constitutes substantive rule making is "whether the action has binding effect on private parties *or on the agency*." *Disabled Veterans of Am.*, 859 F.3d at 1077 (emphasis added) (quoting *Molycorp*, 197 F.3d at 545).

The Director's next argument—that the *Fintiv* factors are not outcome-determinative—is more persuasive. The language of *Fintiv* repeatedly notes that various facts may weigh in favor of

or against instituting IPR. For example, in considering the first *Fintiv* factor of whether a stay exists or is likely to be granted if an IPR proceeding is instituted, the Board noted that a district court's stay of litigation "has strongly weighed against exercising the authority to deny institution," while a court's lack of indication that it would consider a motion to stay if a PTAB proceeding were instituted "has sometimes weighed in favor of exercising authority to deny institution." *Fintiv*, 2020 WL 2126495, at *3. *Fintiv* itself does not reach a decision on instituting an IPR, but rather only requests briefing consistent with the decision, *see id.* at *7; and the actual decision based on the supplemental briefing has not been designated precedential, *see Fintiv II*, 2020 WL 2486683. Nothing in *Fintiv* would prevent a Board from considering all of the enumerated factors and any others the Board deemed appropriate, finding that the factors related to a parallel proceeding all weighed in favor of denial, but that the merits of the petition were so strong that institution was the preferred disposition. *See Fintiv*, 2020 WL 2126495, at *6–7; *see also* June 2022 Mem. 9 ("[T]he PTAB will *not* deny institution of an IPR . . . when a petition presents compelling evidence of unpatentability.") (emphasis added). For example, in *Commscope Techs. LLC v. Dali Wireless, Inc.*, the Director vacated and remanded the Board's decision instituting IPR without assessing the *Fintiv* factors, holding that on remand:

> The Board should first assess *Fintiv* factors 1–5; if that analysis supports discretionary denial, the Board should engage the compelling merits question. If the Board reaches the compelling merits analysis and finds compelling merits, it shall provide reasoning to explain its determination. By issuing this Order, I express no opinion on whether the Board need reach the compelling merits analysis, nor whether the record as it existed before institution meets the compelling merits standard; I leave these case-specific issues to the sound discretion of the Board.

IPR2022-01242, 2023 WL 2237986, at *3 (P.T.A.B. Feb. 27, 2023) (precedential). Accordingly, the Court finds that the *NHK-Fintiv* standard does not "so fill[] out the statutory scheme that upon application one need only determine whether a given case is within the rule's criterion." *Sacora v. Thomas*, 628 F.3d 1059, 1069 (9th Cir. 2010) (citation omitted).

Plaintiffs' main argument to the contrary relies on what the perceived effects of the *NHK-Fintiv* standard, *i.e.*, an increase in denials of institution where there lies a parallel district court

proceeding. *See* Pls.' MSJ 9, 17–18. Plaintiffs cite to non-precedential decisions in which the Board determined that it could not refuse to consider the *Fintiv* factors for policy reasons. *See id.* (citing, *e.g.*, *Apple Inc. v. Maxell, Ltd.*, No. IPR2020-00203, 2020 WL 3662522, at *7 (P.T.A.B. July 6, 2020); *Supercell Oy v. GREE, Inc.*, No. IPR2020-00513, 2020 WL 3455515, at *7 (P.T.A.B. June 24, 2020)). However, as discussed above, *see supra*, at Part III(B)(2)(c), a requirement to consider a certain subset of factors as part of a holistic analysis is not a substantive rule, and the decisions cited by Plaintiffs do not suggest that there existed other facts or circumstances that would weigh in favor of instituting IPR that the Board was somehow prevented from evaluating. *See generally Apple*, 2020 WL 3662522; *Supercell Oy*, 2020 WL 3455515.

The Court is sympathetic to Plaintiffs' frustration that the Board has placed a greater emphasis on efficiency between the combined PTAB and district court systems. However, although Plaintiffs are doubtless unhappy with the outcomes of their petitions for IPR when those petitions are denied, including where the Board considered the *Fintiv* factors, Plaintiffs' claims based on the allegedly unfair or absurd results have been dismissed, *see Apple*, 63 F.4th at *11–13, and the outcome-based argument does not persuade the Court because the express language of *Fintiv*, as well as the June 2022 Memo and other guidance from the Director, make clear that the Board undertakes a holistic analysis when determining whether to exercise its discretion in denying or instituting IPR. The Director's guidance to the Board regarding her policy priorities of "system efficiency, fairness, and patent quality," *Fintiv*, 2020 WL 2126495, at *2, does not mean that the *NHK-Fintiv* standard creates a "binding norm" or is otherwise outcome determinative.[6] The Court also notes that these policies are entirely consistent with the rationale behind the creation of the IPR process, which, along with other processes, was a corrective measure that relieved the pressure on district courts from an increasing volume of infringement litigation based on "bad patents." *See SAS Inst.*, 138 S. Ct. at 1353; 35 U.S.C. § 282(b)(2)–(3).

Accordingly, based on the Court's foregoing evaluation of the *NHK-Fintiv* standard, it

[6] In fact, counsel for the Director indicated at the hearing on these motions that *Fintiv* denials have dropped significantly. *See* Tr. 37:7–12.

finds the *NHK-Fintiv* standard is a general statement of policy that guides the Board to consider certain enumerated factors related to parallel district court litigation with an eye toward overall system efficiency, but expressly leaves the Board with genuine discretion to evaluate all facts and circumstances relevant to the institution or denial of IPR. Because the *NHK-Fintiv* standard is a general statement of policy, rather than a substantive or legislative rule, the Director was not required to conduct notice-and-comment rule making prior to designating the *NHK* and *Fintiv* decisions as precedential, and the lack of such rule making does not render the *NHK-Fintiv* standard unlawful under the APA, 5 U.S.C. § 706(2)(D).

IV. CONCLUSION

For the foregoing reasons, the Court hereby ORDERS that Plaintiffs' motion for summary judgment is DENIED, and the Director's motion for summary judgment is GRANTED. This order disposes of Plaintiffs' sole remaining claim in this action, and the Court will enter judgment against Plaintiffs and in favor of the Director.

IT IS SO ORDERED.

Dated: March 31, 2024

EDWARD J. DAVILA
United States District Judge

United States District Court
Northern District of California

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

APPLE INC., CISCO SYSTEMS, INC., GOOGLE LLC, INTEL CORPORATION, EDWARDS LIFESCIENCES CORPORATION, and EDWARDS LIFESCIENCES LLC, Plaintiffs, v. KATHERINE K. VIDAL, in her official capacity as Under Secretary of Commerce for Intellectual Property and Director, United States Patent and Trademark Office, Defendant.	Case No.20-cv-06128-EJD **JUDGMENT**

On March 31, 2024, the Court issued an order denying Plaintiffs' renewed motion for summary judgment and granting Defendant's motion for summary judgment. *See* ECF No. 165. Pursuant to Federal Rule of Civil Procedure 58, the Court hereby ENTERS judgment in favor of Defendant and against Plaintiffs. The Clerk of Court shall close the file in this matter.

IT IS SO ORDERED.

Dated: April 1, 2024

EDWARD J. DAVILA
United States District Judge

United States District Court
Northern District of California

CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMITATIONS

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/s/ Catherine M.A. Carroll
CATHERINE M.A. CARROLL
WILMER CUTLER PICKERING
HALE AND DORR LLP
2100 Pennsylvania Avenue NW
Washington, DC 20037
(202) 663-6000

August 5, 2024