APPENDIX

APPENDIX
TABLE OF CONTENTS

Page

APPENDIX A

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

2024-1864

APPLE INC., CISCO SYSTEMS, INC., GOOGLE LLC,
INTEL CORPORATION,
Plaintiffs-Appellants,

EDWARDS LIFESCIENCES CORPORATION,
EDWARDS LIFESCIENCES LLC,
Plaintiffs

v.

JOHN A. SQUIRES, UNDER SECRETARY OF COMMERCE FOR INTELLECTUAL PROPERTY AND DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE,
Defendant-Appellee

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

Decided: February 13, 2026

---

* * *

Before LOURIE, TARANTO, and CHEN, *Circuit Judges*.

TARANTO, *Circuit Judge*.

This case returns to us after a decision by the district court rendered on remand from our decision in

Apple Inc. v. Vidal, 63 F.4th 1 (Fed. Cir. 2023) (*2023 CAFC Decision*). The subject of the case, brought in 2020, was a challenge by Apple Inc. and four other companies (collectively, Apple) to certain instructions that the Director of the Patent and Trademark Office (PTO or Office) had given to the Patent Trial and Appeal Board (Board) to govern how the Board, as the Director's delegatee, would exercise the Director's statutory, discretionary authority to decline to institute inter partes review (IPR) proceedings under 35 U.S.C. ch. 31 (§§ 311-19), added to the Patent Act by the America Invents Act (AIA), Pub. L. No. 112-29, 125 Stat. 284 (2011). Seeking relief under the Administrative Procedure Act (APA), 5 U.S.C. § 706, Apple asserted that the instructions led to too many non-institution decisions (denying too many IPR opportunities to challenge patents asserted against it in court) and were legally defective in three respects: they were contrary to 35 U.S.C. ch. 31, arbitrary and capricious, and issued without formal notice-and-comment rulemaking as defined by the APA, 5 U.S.C. § 553. After the district court held all of Apple's challenges to be judicially unreviewable, we held in 2023 that the first two challenges were unreviewable but the third was not, and we therefore remanded for consideration of the rulemaking-process (§ 553) challenge. *2023 CAFC Decision*, at 11-18. On remand, the district court rejected the challenge, holding that the instructions did not have to be issued through notice-and-comment rulemaking. *Apple Inc. v. Vidal*, No. 20-CV-06128, 2024 WL 1382465 (N.D. Cal. Mar. 31, 2024) (*2024 District Court Decision*). Apple appeals.

We hold, in agreement with the district court, that the Director's instructions are a "general statement of policy" exempted from notice-and-comment rulemaking procedures by the express terms of § 553(b). Congress provided no legal right to institution of an IPR, which is just one of several mechanisms for adjudicating challenges to patents. The challenged pronouncements at issue are simply instructions to the Board for how, as the Director's delegatee, it should exercise in the first instance the Director's statutory discretionary authority not to institute an IPR. The non-institution authority of the Director is statutorily insulated from judicial review, at least when, as relevant here, no constitutional claim is presented. And the instructions do not even purport to bind the Director, who has always retained the authority to make the non-institution decision even after an initial Board decision as delegatee. Based on those characteristics taken together, we affirm the district court's decision that notice-and-comment rulemaking was not required for the challenged instructions.

I

We rehearse pertinent legal and factual background set forth more fully in *2023 CAFC Decision*, at 6-11.

A

In the AIA, Congress authorized the Director to institute an IPR, upon petition by a challenger, of claims of an already-issued patent to determine whether they actually failed to meet certain patentability requirements (based on specified kinds of prior art) and should be cancelled. 35 U.S.C. §§ 311, 316-318. Importantly for present purposes, it is the Director that Congress gave the authority to decide whether to institute an IPR. 35 U.S.C. § 314(a). Even if certain statutory preconditions for institution are met, non-institution remains within the Director's discretion: No law compels institution. *2023 CAFC Decision*, at 6-7; *see id. at* 6 ("'The Director is permitted, but never compelled, to institute an IPR[, a]nd no petitioner has a right to such institution.' *Mylan Laboratories Ltd. v. Janssen Pharmaceutica, N.V.*, 989 F.3d 1375, 1382 (Fed. Cir. 2021)."); *id.* at 7 (quoting the Supreme Court's statement, based on § 314(a), that there is "no mandate to institute review," *Cuozzo Speed Technologies, LLC v. Lee*, 579 U.S. 261, 273 (2016)). Congress reinforced the Director's discretion by broadly precluding review of its exercise at least where no constitutional ground is asserted. *2023 CAFC Decision*, at 7; *see United States v. Arthrex, Inc.*, 594 U.S. 1, 8-9 (2021) (stating that "Congress [ ] committed the decision to institute inter partes review to the Director's *unreviewable* discretion") (emphasis added); *Thryv, Inc. v. Click-To-Call Technologies, LP*, 590 U.S. 45, 60 (2020); *Cuozzo*, 579 U.S. at 271-76.

"From the outset of the IPR program," the Director authorized the Board to institute an IPR as the Director's delegatee. *2023 CAFC Decision*, at 7; 37 C.F.R. § 42.4(a). The Director, as the possessor of the statutory authority, always retained full power to reverse an initial Board decision on institution or to make the decision personally in the first instance. *2023 CAFC Decision*, at 7, 13.

At issue in the present case is a trio of related instructions the Director issued to the Board for its exercise of delegated non-institution authority (where the threshold statutory preconditions are present), addressing the common situation where the IPR petitioner and patentee are already involved in district-court litigation over the patent at issue. Two of the instructions were in the form of precedential Board decisions to govern later Board decisions, exercising the Director's authority under Patent Trial and Appeal Board, Standard Operating Procedure 2 (now Revision 11) at 1 (2023) (*SOP 2*). *NHK Spring Co. v. IntriPlex Technologies, Inc.*, IPR2018-

00752, 2018 WL 4373643 (P.T.A.B. Sept. 12, 2018) (made precedential on May 7, 2019) (NHK); *Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, 2020 WL 2126495 (P.T.A.B. Mar. 20, 2020) (modifying NHK, made precedential on May 5, 2020) (*Fintiv*). The *NHK-Fintiv* instructions identified six nonexclusive factors that the Board must assess, with the factors weighing in favor of or against institution. *See 2023 CAFC Decision*, at 8-10 (quoting and describing the instructions). The *NHK-Fintiv* instructions, as Board precedent, bind only the Board, not the Director or, therefore, the PTO.

After this case began (and was decided the first time by the district court), the Director issued a third instruction, citing the Director's authority to "provid[e] policy direction and management supervision for the Office" under 35 U.S.C. § 3(a)(2)(A) as well as *SOP 2*. *See* Memorandum from Katherine K. Vidal, Under Secretary of Commerce for Intellectual Property and Director of the PTO, to Members of the Board, Interim Procedure for Discretionary Denials in AIA Post-Grant Proceedings with Parallel District Court Litigation at 2-3 (June 21, 2022) (*June 2022 Memo*). This instruction somewhat modified the first two instructions and likewise applied only to the Board, not purporting to bind the Director. No party has suggested that the *June 2022 Memo* changes the analysis of the issue before us, so, like the parties and the district court, we address the *NHK-Fintiv* instructions generally without separate mention of the June 2022 instruction.

B

In our 2023 decision, we ruled that "at least Apple has standing to press the challenge to the Director's instructions as invalid for want of notice-and-comment rulemaking." *2023 CAFC Decision*, at 15. We also ruled that the rulemaking-process challenge was reviewable. *Id.* at 14-15. On remand, the district court conducted the review, addressing the basic legal distinction that is at issue here.

It is undisputed that the instructions come within the capacious notion of "rule" under the APA, 5 U.S.C. § 551(4). But, as is also undisputed, not all rules require notice-and-comment procedures under § 553, which states such a requirement, § 553(b)-(d), while taking pains to identify exclusions. Thus, in two provisions not at issue here, § 553(a) excludes rules addressing certain topics, and § 553(b) permits agencies to make exceptions based on, *e.g.*, findings of impracticability. What is at issue here, and in most of the relevant case law, is § 553(b)'s additional express exclusion of "interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice," unless another statute requires notice-and-comment procedures. 5 U.S.C. § 553(b).

The Supreme Court long ago recognized: "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." *Chrysler Corp. v. Brown*, 441 U.S. 281, 301 (1979). The Court also summarized: "The notice-and-comment requirements apply … only to so-called 'legislative' or 'substantive' rules." *Lincoln v. Vigil*, 508 U.S. 182, 196 (1993). In the present case, the particular dispute is whether the instructions are a substantive/legislative rule or, instead, a "general statement [ ] of policy." *2024 District Court Decision*, at *5 n.3 (internal quotation marks omitted). The Supreme Court has explained that a general statement of policy is a pronouncement "issued by an agency to advise the public prospectively of the manner in which the agency proposes to exercise a discretionary power." *Chrysler*, 441 U.S. at 302 n.31 (internal citation and quotation marks omitted); *Lincoln*, 508 U.S. at 197.

The district court in this case held that the instructions are "a general statement of policy, rather than a substantive or legislative rule, [and] the Director was not required to conduct notice-and-comment rulemaking prior to designating the *NHK* and *Fintiv* decisions as precedential, and the lack of such rulemaking does not render the *NHK-Fintiv* standard unlawful." *2024 District Court Decision*, at *13 (cleaned up). Apple timely filed an appeal that is within our jurisdiction under 28 U.S.C. § 1295(a)(1).

C

The PTO announced several changes of relevance after the briefs on appeal were filed. In February 2025, the Acting Director rescinded the *June 2022 Memo*.[1] On October 17, 2025, the Director took two additional actions of note.

First, the Director announced that, for now, the Board would not be making initial institution decisions and, instead, he (with advice) would directly be making institution decisions: "[T]he Director, in consultation

[1] *USPTO rescinds memorandum addressing discretionary denial procedures*, USPTO.GOV (Feb. 28, 2025), https://www.uspto.gov/about-us/news-updates/uspto-rescinds-memorandum-addressing-discretionary-denial-procedures; *see also* Chief Admin. Patent Judge, Guidance on PTO's recission of "Interim Procedure for Discretionary Denials in AIA Post-Grant Proceedings with Parallel District Court Litigation" (Mar. 24, 2025), https://www.uspto.gov/sites/default/files/documents/guidance_memo_on_interim_procedure_recission_20250324.pdf.

with at least three [Board] judges, will determine whether to institute trials in all IPR[s] … . [W]here the Director determines [that] detailed treatment of issues raised in a petition is appropriate … , the Director may refer the decision on institution to one or more members of the [Board]." Memorandum from John A. Squires, Under Secretary of Commerce for Intellectual Property and Director of the PTO, to All Board Judges at 1-2 (Oct. 17, 2025), https://www.uspto.gov/sites/default/files/documents/Director_Institution_of_AIA_Trial_Proceedings.pdf.

Second, the PTO published a notice of proposed rulemaking, the proposals consisting of "modifications to the rules of practice for [IPR] before the [Board] that the [Director] and, by delegation, the [Board] will use in instituting IPR." Revision to Rules of Practice Before the Patent Trial and Appeal Board, 90 Fed. Reg. 48335, 48335 (Oct. 17, 2025) (to be codified at 37 C.F.R. pt. 42). If finally adopted as proposed, the institution standard would bind the PTO itself, not merely the Board. *Id.* Specifically, the PTO proposed to modify 37 C.F.R. § 42.108 by adding the following provision to address parallel pending proceedings:

> (f) Parallel Litigation—Inter partes review *shall not be instituted* or maintained if, more likely than not, any of the following will occur, with respect to a challenged claim or an independent claim from which a challenged claim depends, before the due date for the final written decision pursuant to 35 U.S.C. [§] 316(a)(11):
>
> > (1) U.S. District Court—A district court trial in which a party challenges the patent under 35 U.S.C. [§§] 102 or 103 … .

90 Fed. Reg at 48341 (emphasis added). The proposal does not expressly revoke the precedential status of the *NHK* and *Fintiv* decisions. *See* 90 Fed. Reg at 48336.

II

It is undisputed that whether the Director was obligated to use notice-and-comment procedures when issuing the challenged instructions presents an issue of law that we resolve de novo. Moreover, neither side has suggested that there is any material difference on this issue between our circuit's own law and the law of the regional circuit of the district court (the Ninth Circuit), and both sides, in addressing the issue, also draw on other circuits' decisions, including but not only those of the D.C. Circuit. We follow suit.

A

We begin with several preliminaries to our discussion of the main issue.

1

We agree with the parties that the new announcements of the PTO do not render the dispute before us moot. To begin with, as already noted, the issues before us are not altered by the inclusion of the *June 2022 Memo* in the case. The February 2025 rescission of that memorandum does not moot the case. And the October 2025 announcements likewise leave the dispute here a live one.

As to the Director's announcement that he will for now be making the institution decisions himself (with advice), the Director has explained to this court why that action does not moot the case. The Director has not repealed the regulation, 37 C.F.R. § 42.4(a), that allows "[t]he Board [to] institute[ ] the [proceeding] on behalf of the Director," *see Arthrex*, 594 U.S. at 9, and while "[Board] panels do not now exercise the Director's discretion to institute," he "has left those decisions as precedential" and "if [Board] panels were to again exercise the Director's discretion to institute, *NHK* and *Fintiv* would remain precedent." Letter from Weili J. Shaw, Attorney for the United States, to Jarrett B. Perlow, Clerk of Court (Jan. 2, 2026), ECF No. 104 at 1-2. In these circumstances, the high standard for finding mootness based on "voluntary cessation" is not met, *West Virginia v. Environmental Protection Agency*, 597 U.S. 697, 720 (2022) ("[V]oluntary cessation does not moot a case unless it is absolutely clear that the allegedly wrongful behavior could not reasonably be expected to recur.") (internal citation and quotation marks omitted), and we see no other basis for a determination of mootness.

As to the notice of proposed rulemaking, the agency action is just a proposal. It has no current effect, and it cannot be reliably predicted what, if any, effect it will come to have. That is enough to avoid mootness based on the proposal. *See Chafin v. Chafin*, 568 U.S. 165, 172 (2013); *see also Vanscoter v. Sullivan*, 920 F.2d 1441, 1448 (9th Cir. 1990) (reasoning that "[t]he protracted nature of agency proceedings and the uncertainty as to whether and when the proposed regulation may be adopted preclude a finding of mootness").

2

Apple suggests that our 2023 holding that Apple had standing to press its rulemaking-process claim must be understood to have decided that the challenged instructions constitute substantive/legislative rules. Apple Opening Br. at 25, 35-36. We reject Apple's contention that our standing holding establishes that the challenged instructions meet that standard. We did not purport to do so, and our standing result did not necessarily do so.

In 2023, in reversing the grant of a motion to dismiss regarding the rulemaking-process claim, we held that, for standing purposes, the injury was concrete and particularized and not unduly speculative and was to a "legally protected interest" based on a one-step-removed effect on Apple's interest as a defendant in infringement suits. *2023 CAFC Decision*, at 16-17. That conclusion logically does not answer the question whether an agency pronouncement about its own enforcement policies meets the core standard for a measure being substantive/legislative under § 553, which, in one judicial statement (similar to others, capturing essentially the same idea), requires that the measure "alter the landscape of individual rights and obligations, binding parties with the force and effect of law." *Stupp Corp. v. United States*, 5 F.4th 1341, 1352 (Fed. Cir. 2021). Indeed, to equate the Article III notion of legally protected interest, *see* Charles A. Wright, et al., Federal Practice and Procedure § 3531.4 & nn.15-16 (3rd ed. 2025) (discussing the uncertain scope of that notion), with the binding-law standard for triggering a notice-and-comment duty under § 553 would run counter to the many decisions that reject § 553 challenges on the merits, *i.e.*, on the ground that the statutory duty did not apply in the case, not for want of Article III standing. In any event, our standing conclusion in 2023 involved a motion to dismiss, and "where the plaintiff presents a nonfrivolous legal challenge, alleging an injury to a protected right … , the federal courts may not dismiss for lack of standing on the theory that the underlying interest is not legally protected." *Initiative & Referendum Inst. v. Walker*, 450 F.3d 1082, 1093 (10th Cir. 2006). Thus, our standing ruling in 2023 does not control the resolution of the merits issues now before us.

3

We also reject Apple's contention that the statutory provision contemplating the Director's issuance of IPR regulations, 35 U.S.C. § 316, compels notice-and-comment rulemaking, Apple Opening Br. at 53-55. Section 316 provides that, as to various topics, "[t]he Director shall pre-scribe regulations," including ones "establishing and governing inter partes review under [chapter 31] and the relationship of such review to other proceedings under [title 35]." 35 U.S.C. § 316(a)(4). That provision does not impose a notice-and-comment rulemaking requirement for the contemplated "regulations." Any requirement of notice-and-comment procedures is not implicit in the word "regulations," and so must come from another source of law, such as 5 U.S.C. § 553, which depends on the particular type of regulation.

Apple cannot properly read more into § 316's use of the word "regulation." For one thing, "by 1987 courts had commonly referred to both substantive and interpretative rules as 'regulations,'" *Azar v. Allina Health Services*, 587 U.S. 566, 578 (2019) (emphasis in original), and, as already noted, "interpretative rules" are expressly exempt from notice-and-comment requirements under 5 U.S.C. § 553(b). Relatedly, as the D.C. Circuit long ago explained, "[c]ourts and Congress treat the terms 'regulation' and 'rule' as interchangeable and synonymous," *National Treasury Employees Union v. Weise*, 100 F.3d 157, 160 (D.C. Cir. 1996), and, as already noted, the term "rule," 5 U.S.C. § 551(4), extends to statements of general policy as well as interpretative pronouncements that are expressly exempt from notice-and-comment requirements under 5 U.S.C. § 553(b).

Moreover, the Patent Act itself provides that the PTO may "establish *regulations* … in accordance with section 553 of title 5," 35 U.S.C. § 2(b)(2)(B) (emphasis added), and that reference covers both regulations for which § 553 requires notice-and-comment procedures and regulations for which § 553 says there is no notice-and-comment requirement, *see In re Chestek PLLC*, 92 F.4th 1105, 1110 (Fed. Cir. 2024).

Accordingly, Apple's challenge depends on whether the instructions are a substantive/legislative rule or, instead, are a general statement of policy under 5 U.S.C. § 553(b).

B

Although courts' formulations vary in their precise wording, we have summarized the governing standard for a substantive/legislative rule as follows: "Legislative rules alter the landscape of individual rights and obligations, binding parties with the force and effect of law[.]" *Stupp*, 5 F.4th at 1352 (quoted and applied in *Xi'an Metals & Minerals Import & Export Co. v. United States*, 50 F.4th 98, 105-06 (Fed. Cir. 2022)); *see also Chrysler*, 441 U.S. at 295-96, 301-02 (stressing force and effect of law); *Disabled American Veterans v. Secretary of Veterans Affairs*, 859 F.3d 1072, 1077 (Fed. Cir. 2017) (stressing binding effect and force of law), *overruled regarding a § 552 issue by National Organization of Veterans' Advocates, Inc. v. Secretary of Veterans Affairs*, 981 F.3d 1360 (Fed. Cir. 2020) (en banc); *National Mining Association v. McCarthy*, 758 F.3d 243, 251 (D.C. Cir. 2014). In contrast, general statements of policy are pronouncements that "do not have the force and effect of law," *Chrysler*, 441 U.S. at 302 n.31, and are merely "'statements issued by an agency to advise the public prospectively of the manner in which the agency proposes to exercise a discretionary power,'" *id*. (quoting Tom C. Clark, United States Attorney General, Attorney General's Manual on the Administrative Procedure Act 30 n.3 (1947)). *See also Sacora v. Thomas*, 628 F.3d 1059, 1069 (9th Cir. 2010); *Mada-Luna v. Fitzpatrick*, 813 F.2d 1006, 1014 (9th Cir. 1987); *National Mining Association*, 758 F.3d at 251; *Syncor International Corp. v. Shalala*, 127 F.3d 90, 94 (D.C. Cir. 1997); *Brock v. Cathedral Bluffs Shale Oil Co.*, 796 F.2d 533, 537 (D.C. Cir. 1986) (Scalia, J.); *Batterton v. Marshall*, 648 F.2d 694, 706 (D.C. Cir. 1980); *Guardian Federal Savings & Loan Association v. Federal Savings & Loan Insurance Corp.*, 589 F.2d 658, 666 (D.C. Cir. 1978); *Pacific Gas & Electric Co. v. Federal Power Commission*, 506 F.2d 33, 38-39 (D.C. Cir. 1974).

We apply that distinction to the *NHK-Fintiv* instructions at issue here. We conclude that they are on the statement-of-general-policy side of the line.[2]

To begin with, whether an agency pronouncement has binding effect on the agency is central to the § 553 inquiry. *See Xi'an Metals*, 50 F.4th at 105-06; Stupp, 5 F.4th at 1352; Disabled American Veterans, 859 F.3d at 1077; *see also Syncor*, 127 F.3d at 94; *Professionals & Patients for Customized Care v. Shalala*, 56 F.3d 592, 595 (5th Cir. 1995); *Pacific Gas*, 506 F.2d at 38. "The

---

[2] There is no contention, or basis for a contention, that the *NHK-Fintiv* instructions are made substantive/legislative by virtue of modifying a pre-existing rule that was itself separately conceded or established to be substantive/legislative. *Compare United States Telecom Association v. Federal Communications Commission*, 400 F.3d 29, 34-35 (D.C. Cir. 2005), *with Hemp Industries Association v. Drug Enforcement Administration*, 333 F.3d 1082, 1088 (9th Cir. 2003). No such substantive/legislative pre-existing rule has been identified.

critical factor to determine whether a directive announcing a new policy constitutes a 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." *Mada-Luna*, 813 F.2d 1013 (internal citation omitted and cleaned up); *Guardian*, 589 F.2d at 666 (same). But the *NHK-Fintiv* instructions are not binding on the agency, *i.e.*, on the statutory decisionmaker—the Director.

The instructions challenged by Apple do not even purport to bind the Director. The Director, who is the statutory decisionmaker on the matter, always could make the non-institution (or institution) decision personally, whether or not the Board has made an initial decision. *See 2023 CAFC Decision*, at 7, 13. The Director's "flexibility and [his] opportunity to make individualized determinations" when "exercising [his] discretionary power" to institute is fully preserved. *Sacora*, 628 F.3d at 1070 (cleaned up).

The challenged instructions, besides leaving much initial discretion to the Board, simply inform the Board how, as delegatee, it should "exercise [the Director's] discretionary power in specific cases." *Mada-Luna*, 813 F.2d at 1013 (internal citations removed). But "they are only binding [on] the initial adjudicat[ory]" decisionmaker. *Erringer v. Thompson*, 371 F.3d 625, 630-31 & n.10 (9th Cir. 2004). These instructions are best understood as merely "advis[ing] the public prospectively of the manner in which the agency proposes to exercise a discretionary power," *Chrysler*, 441 U.S. at 302 n.31; *Lincoln*, 508 U.S. at 197—here, through a delegatee's initial decision that the Director is free to displace.

As Apple observes, the Director has (in the past) generally not displaced the initial decisions of the Board as delegatee. Apple Opening Br. at 27, 34. But that fact does not mean that the Director has effectively treated those instructions as binding on the Director, who is the statutory grantee of institution authority–although the Director could do so in the future. *See* 90 Fed. Reg. 48335, 48335 (proposing institution standards applicable to the PTO). It means only that the Board's implementation of existing instructions in a particular case has reflected the Director's judgment at the time, which could have been altered in any given case as a matter of unreviewable discretion. *Syncor*, 127 F.3d at 94 ("[A general policy statement] merely represents an agency position with respect to how it will treat … the governing legal norm … . The agency retains the discretion and the authority to change its position—even abruptly—in any specific case because a change in its policy does not affect the legal norm."); *see also Guardian*, 589 F.2d at 666 (observing that a binding norm did not exist when the agency decisionmaker possessed the "discretion to accept a non-conforming [ ] report" under the challenged regulation).

In this important respect, the present case differs critically from a variety of cases in which the challenged pronouncement did have a binding effect on the agency itself. *See, e.g., Coalition for Common Sense in Government Procurement v. Secretary of Veterans Affairs*, 464 F.3d 1306, 1318 (Fed. Cir. 2006) (determining that the Secretary "intended" its changes to its refund system "to be binding … on itself"); *W.C. v. Bowen*, 807 F.2d 1502, 1505 (9th Cir.), *opinion amended on denial of rehearing*, 819 F.2d 237 (9th Cir. 1987) (holding that the administrative law judges' "final [Social Security disability benefit] decisions bind[ ] both the Secretary [of

Health and Human Services] and claimant[s]" because the challenged agency "program limits the Secretary's discretion not to review an [administrative law judge's] decision"); *Mendoza v. Perez*, 754 F.3d 1002, 1024 (D.C. Cir. 2014) (determining that the challenged guidance letters established procedures for how the "Department [of Labor] will evaluate H-2A applications, [and] … what employers must do to obtain approval," binding both the ultimate decisionmaker and "substantively affect[ing] the regulated public"); *General Electric Co. v. Environmental Protection Agency*, 290 F.3d 377, 384 (D.C. Cir. 2002) (determining that EPA guidance facially purported to apply to both regulated entities as well as the agency itself).

The nature and statutory treatment of the decision that is the subject of the challenged instructions, insofar as the instructions allegedly harm Apple, further confirm that the instructions are not on the notice-and-comment side of the § 553 line at issue. Apple complains of "an institution standard that *reduces* the likelihood that IPR will be instituted." Apple Opening Br. at 36 (emphasis added); *see id.* at 25, 34-36. That is, it challenges pronouncements concerning the Director's decision *not* to initiate an agency adjudicatory proceeding.

But, as we have explained, Apple has "no right to an IPR." *Mylan Laboratories*, 989 F.3d at 1383; *see supra* p.4. To the contrary, the Director has broad and protected discretion not to launch an IPR, even when the statutory pre-conditions are present. For one thing, decisions not to launch enforcement actions are a category of agency decisions that the courts "traditionally have regarded as 'committed to agency discretion'" and are "presumptively unreviewable under [the APA, 5 U.S.C.] § 701(a)(2)." *Lincoln*, 508 U.S. at 191 (internal citations omitted). The Supreme Court invoked that recognition when stating that "the agency's decision to deny a petition is a matter committed to the Patent Office's discretion." *Cuozzo*, 579 U.S. at 273; *see Thryv*, 590 U.S. at 60. And in any event, the exercise of such discretion is statutorily protected from judicial review by 35 U.S.C. § 314. *See supra* p.4. These confirmations of unreviewable discretion strongly indicate that the instructions concerning such non-institution are properly considered "'statements issued by [the PTO] 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 (internal citation omitted)).

Finally, as previously discussed, the "touchstone for distinguishing" substantive rules from general statements of policy is that the former must have the "force and effect of law" and do so with respect to "individual rights and obligations." *Chrysler*, 441 U.S. at 301-02 (internal citation and quotation marks omitted); *Stupp*, 5 F.4th at 1352. That is how we understand what it must mean to "affect" "individual rights and obligations" in this area. *See Chrysler*, 441 U.S. at 301-02. That understanding follows from the requirement that a substantive/legislative rule have the force and effect of law binding the agency and from the § 553(b) *exclusion* of statements of policy about the expected exercise of discretion—which, if exercised one way, could often end up modifying an individual's legal position.[3]

[3] Apple quotes a portion of a sentence from *Batterton v. Marshall*, 648 F.2d 694 (D.C. Cir. 1980), in support of a suggested standard that would allow for a looser connection to legal rights or obligations—loose enough to encompass the present challenged instructions, which are not binding on the agency. *See* Apple Opening Br. at 32. But Apple's suggestion relies on an overreading of the cited *Batterton* phrase even on its own terms and is inconsistent

A non-institution decision, which is protected as a matter of unreviewable discretion (constitutional issues aside), leaves a patent challenger's actual legal rights and obligations unchanged—what they would be if Congress had not enacted the IPR regime (which it enacted only with protected Director discretion about institution). A non-institution decision has no legal effect on the underlying patent rights and obligations. Challengers are "free to litigate [a challenged patent's] claims' validity in [their] own district court case." *Mylan Laboratories*, 989 F.3d at 1383. And they may seek reexamination in the PTO under 35 U.S.C. ch. 30, §§ 301-07.

C

The § 553 distinction at issue here involves terms and concepts having a good deal of imprecision to them,

---

with *Chrysler* (which *Batterton* does not cite) and all the case law we have discussed. In *Batterton*, after stating that notice-and-comment rulemaking is "required for those actions that carry the force of law," taken pursuant to power to "promulgate binding regulations," the D.C. Circuit observed that such rules "thus implement congressional intent" and "effectuate statutory purposes," and it then added: "In so doing, they grant rights, impose obligations, or *produce other significant effects on private interests*." 648 F.2d at 701-02 (footnotes omitted) (emphasis added). Apple points to the italicized phrase and treats it as if it stood alone and stated an independently sufficient basis for an agency action to qualify as a substantive/legislative rule. Apple Opening Br. at 32, 33, 41. It should not be so understood. The "[i]n so doing" sentence does not purport to be declaring independently sufficient conditions; rather, it is identifying effects that a substantive/legislative rule, so qualifying under the just-described force-of-law and binding-effect criteria, has. And *Batterton*, which involved a change in existing rights (to certain federal money), does not rely for its result on the broad notion Apple suggests; Apple itself relies on *Batterton* only for its phrase, not for its result (on facts far different from those present here).

so the case-specific facts involved in cited judicial opinions, not just the language used in those opinions, matter in analyzing the present case against the background of pertinent case law. Apple has placed particular reliance on several decisions in which the D.C. Circuit held that an agency violated § 553 by not using notice-and-comment procedures. But those decisions involved issues or circumstances that differed materially from those present in this case. They therefore do not alter our conclusion here.

Apple cites *American Federation of Labor and Congress of Industrial Organizations v. National Labor Relations Board*, in which the D.C. Circuit determined that three (of five) challenged provisions of a rule announced by the National Labor Relations Board had to be promulgated through notice-and-comment rulemaking. 57 F.4th 1023, 1036-43 (D.C. Cir. 2023) (*AFL-CIO*); *see* Apple Opening Br. at 37. But there was no issue in *AFL-CIO* about a "statement of general policy" or a pronouncement not binding on the agency and concerning the agency's unreviewable non-enforcement discretion. Rather, the Board's only argument was that the three provisions were excused from notice-and-comment rulemaking as "rules of agency organization, procedure, or practice," 5 U.S.C. § 553(b), and the D.C. Circuit rejected that argument. *AFL-CIO*, 57 F.4th at 1036. It held that the three provisions ("those regarding employers' production of voter lists, the delayed certification of election results, and who may serve as election observers") altered employees' statutory "right[s] to elect representatives of their choice" and to "bargain in good faith," 29 U.S.C. §§ 158, 159, because they "trench[ed] on the union's substantive interest in campaigning on equal footing with the employer," "delay[ed] certification [thus] cut[ting] back on an employer's legal duty to postelection to bargain in good faith," and "directly affect[ed] regulated parties' interests in fair elections." *AFL-CIO*, 57 F.4th at 1027-29, 1035. The present case, involving no legal entitlement to the desired institution, a pronouncement not binding on the statutory decisionmaker, unreviewable discretion in the relevant authority, and the "statement of general policy" (not the "agency organization, procedure, or practice") portion of § 553, is properly distinguished from *AFL-CIO*.

Apple also points to *General Electric Co. v. Environmental Protection Agency*, in which the D.C. Circuit held that the Environmental Protection Agency (EPA) had to use notice-and-comment procedures to promulgate a guidance document defining legal obligations of private parties concerning EPA-regulated disposal of a certain chemical compound. 290 F.3d at 385; *see* Apple Opening Br. at 37. The D.C. Circuit concluded that the guidance document on its face purported "to bind the [EPA]" and "require[ ] [regulated entities] to conform" to cleanup plan criteria. *Id.* at 384-85. The court held that "the commands of the Guidance Document indicate that it has the force of law." *Id.* at 385. For reasons we have explained, the present case is far different.

Apple points in addition to *Reeder v. Federal Communications Commission*, 865 F.2d 1298, 1305 (D.C. Cir. 1989). *See* Apple Opening Br. at 37. But in *Reeder*, the D.C. Circuit noted that the government did not dispute on appeal that the Federal Communications Commission's order at issue, which changed its "longstanding policy" for commercial FM frequency channel substitutions, was subject to notice-and-comment procedures. 865 F.2d at 1304, 1305. Even aside from evident differences in facts, *see also supra* p.14 n.2, that is reason enough to conclude that *Reeder* does not alter our conclusion here.

Finally, Apple relies on *Pickus v. United States Board of Parole*, 507 F.2d 1107 (D.C. Cir. 1974), stating that "the rule altering the [P]arole [B]oard's standards was subject to notice and comment not because inmates had an existing right to parole—they did not—but because the rule was calculated to have a substantial effect on ultimate parole decisions." Apple Opening Br. at 38 (internal citations and quotation marks omitted); *see also id.* at 45-46. Apple's reliance on *Pickus* is misplaced. In *Pickus*, federal prisoners challenged the Parole Board's adopted criteria for granting parole, and the D.C. Circuit held that the criteria should have been promulgated pursuant to notice-and-comment because the criteria were "self imposed controls over the manner and circumstances in which the *agency will* exercise its plenary power. They have the effect of law and are not reviewable *except for* arbitrariness." 507 F.2d at 1113 (emphases added). In contrast to the present case, *Pickus* itself recognized that it involved pronouncements found to bind the agency with the effect of law, and parole decisions under the criteria that were reviewable, albeit deferentially. Indeed, perhaps because a decision to deny parole is rather different from a decision simply to stay out of a requester's way (it is a decision to keep detaining the requester), a parole denial was not committed to the Parole Board's discretion by law, but was reviewable (deferentially) in habeas. *See Furnari v. Warden, Allenwood Federal Correctional Institution*, 218 F.3d 250, 254 (3d Cir. 2000); *Ruviwat v. Smith*, 701 F.2d 844, 844-45 (9th Cir. 1983); *Sutherland v. McCall*, 709 F.2d 730, 732 (D.C. Cir. 1983); *Izsak v. Sigler*, 604 F.2d 1205, 1206 n.1 (9th Cir. 1979). The present case is materially different for purposes of § 553.

III

For the foregoing reasons, we affirm the district court's judgment rejecting Apple's challenges to the Director's instructions as having improperly been issued without notice-and-comment rulemaking procedures.

AFFIRMED

APPENDIX B

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN JOSE DIVISION

Case No. 20-cv-06128-EJD
Re: ECF Nos. 153, 157

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

Filed March 31, 2024

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

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] 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*,

---

[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.*

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 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.*

A. 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 crossmotions 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

[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.

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,

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)

---

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

(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 *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 918.

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 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.

[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)).

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* I*nc. 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." *Hefgott*, 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); s*ee 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 nonexclusive 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. S*ee 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 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

[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.

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

[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.

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 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

[Signature]
EDWARD J. DAVILA
United States District Judge

APPENDIX C

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

2022-1249

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

v.

KATHERINE K. VIDAL, UNDER SECRETARY OF COMMERCE FOR INTELLECTUAL PROPERTY AND DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE,
Defendant-Appellee.

Decided: March 13, 2023

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

---

* * *

Before LOURIE, TARANTO, and STOLL, *Circuit Judges*. TARANTO, *Circuit Judge*.

Plaintiffs are Apple Inc. and four other companies that have repeatedly been sued for patent infringement and thereafter petitioned the Director of the Patent and Trademark Office (PTO) to institute inter partes reviews (IPRs), under 35 U.S.C. §§ 311-319, so that the PTO's Patent Trial and Appeal Board could adjudicate the petitions' unpatentability challenges to patent claims that had been asserted against them in court. In the present action, brought against the Director in district court under the Administrative Procedure Act (APA), 5 U.S.C. §§ 701-706, plaintiffs challenge instructions the Director issued to the Board to inform it how to exercise, under delegation by the Director, the Director's discretion whether to institute a requested IPR. Plaintiffs assert that the instructions are likely to produce too many denials of institution requests. The district court dismissed the APA action on the ground that the Director's instructions were made unreviewable by the IPR provisions of the patent statute.

We affirm in part and reverse in part. We affirm the unreviewability dismissal of plaintiffs' challenges to the instructions as being contrary to statute and arbitrary and capricious. No constitutional challenges are presented. But we reverse the unreviewability dismissal of plaintiffs' challenge to the instructions as having been improperly issued because they had to be, but were not, promulgated through notice-and-comment rulemaking under 5 U.S.C. § 553. That challenge, we also hold, at least Apple had standing to present. We remand for further proceedings on the lone surviving challenge. Like the district court, we do not reach the merits of that challenge.

I

A

In the America Invents Act (AIA), Pub. L. No. 112-29, 125 Stat. 284 (2011), Congress authorized the filing of a petition asking the PTO to conduct an IPR of whether identified claims in an issued patent comply with certain patentability requirements of novelty or obviousness over prior art. 35 U.S.C. § 311(a)-(b). The Board is the PTO component assigned to perform the IPR adjudication if a review is instituted, *id.* §§ 6(b)(4), 316-318, with the Board's "final written decision" in the IPR subject to appeal to this court, *id.* § 319; *see id.* § 141. But it is the PTO's Director to whom Congress assigned the task of determining whether to institute a review in the first place. *Id.* § 314(b); *see Thryv, Inc. v. Click-To-Call Technologies, LP*, 140 S. Ct. 1367, 1370-71 (2020).

For the Director to institute, certain preconditions must be met. One prerequisite, for all petitions, is the crossing of a merits "threshold": "The Director may not authorize an [IPR] to be instituted unless the Director determines that the information presented in the petition ... and any response ... shows 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). Another prerequisite, applicable in the predictably common situation where the patent owner has already sued the petitioner (or a real party in interest or privy) for infringement of the patent, is compliance with a timing limit: The petition must be filed within one year after service of the infringement complaint. *Id.* § 315(b).

Even when such requirements are met, however, the statute uses no language commanding institution. "The Director is permitted, but never compelled, to institute an IPR[, a]nd no petitioner has a right to such institution." *Mylan Laboratories Ltd. v. Janssen Pharmaceutica, N.V.*, 989 F.3d 1375, 1382 (Fed. Cir. 2021). The Supreme Court explained in *SAS Institute, Inc. v. Iancu*: "§ 314(a) invests the Director with discretion on the question *whether* to institute review." 138 S. Ct. 1348, 1356 (2018); *see also Cuozzo Speed Technologies,* *LLC v. Lee*, 579 U.S. 261, 273 (2016) (citing § 314(a) and stating: "no mandate to institute review").

Congress not only left the discretion to the Director but also protected its exercise from judicial review, even regarding the mandatory threshold conditions for institution, at least where, as here, the court challenge is not on a constitutional ground. *See Cuozzo*, 579 U.S. at 275 (noting that it was not addressing challenges that implicate constitutional questions, which present distinct issues regarding congressional preclusion of judicial review).[1] Thus, Congress declared: "The determination by the Director whether to institute an inter partes review under [§ 314] shall be final and nonappealable." 35 U.S.C. § 314(d). Based on that provision, whose terms apply whether the determination is negative or positive, the Supreme Court has held that the institution decision is unreviewable, even in a proper appeal of a final written decision reached by the Board after a positive institution determination: "Congress has committed the decision to institute inter partes review to the Director's unreviewable discretion." *United States v. Arthrex, Inc.*, 141 S. Ct. 1970, 1977 (2021); *see Thryv*, 140 S. Ct. at 1372-73 (relied on by *Arthrex* for above statement); *Cuozzo*, 579 U.S. at 271-75.[2]

---

[1] Because the present case does not involve a constitutional challenge, we hereafter generally refrain from noting that the unreviewability principle at issue has not been extended to constitutional challenges.

[2] In SAS, the Supreme Court held that § 318, whose subject is not institution but the scope of a required final written decision, requires the Board, in its final written decision, to decide the patentability of all patent claims challenged in the petition. 138 S. Ct. at 1354-57. It follows, as a corollary, that the institution determination must be an all-or-nothing one, a "binary" one, *id.* at 1355, regarding the claims to be reviewed. It is that institution determination which

From the outset of the IPR program, the Director delegated the institution authority to the Board. 37 C.F.R. § 42.4(a); *see Arthrex*, 141 S. Ct. at 1977; *Thryv*, 140 S. Ct. at 1371. We have upheld that delegation, recognizing "the longstanding rule that agency heads have implied authority to delegate to officials within the agency," that "Congress regularly gives heads of agencies more tasks than a single person could ever accomplish, necessarily assuming that the head of the agency will delegate the task to a subordinate officer," and that, in particular, "Congress assigned the Director the decision to institute, necessarily assuming that the popularity of inter partes review and the short time frame to decide whether to institute inter partes review would mean that the Director could not herself review every petition." *Ethicon Endo-Surgery, Inc. v. Covidien LP*, 812 F.3d 1023, 1031-32 (Fed. Cir. 2016) (footnote omitted). We have also made clear that any institution decision made by the Board as delegatee of the Director is subject to reversal by the Director. *In re Palo Alto Networks, Inc.*, 44 F.4th 1369, 1375 & n.3 (Fed. Cir. 2022) (stating that "the Director plainly has the authority to revoke the delegation or to exercise her review authority in individual cases despite the delegation"); *see Arthrex*, 141 S. Ct. at 1980 ("The Director ... controls the decision whether to institute inter partes review ... .").

B

The one-year time limit of § 315(b), already mentioned, makes clear that Congress recognized the likelihood of parallel pending proceedings in the PTO and in the courts. Being sued for infringement provides a defendant a distinct motivation to seek cancellation,

---

is the subject of the unreviewability principle of *Arthrex*, *Thryv*, and *Cuozzo*.

through an IPR, of patent claims asserted against it in court.[3] The existence of such overlapping proceedings raises self-evident issues of efficiency and interbranch relations. But Congress generally left the two branches to exercise their available discretion to address such issues. Congress enacted no provision for this scenario that directs the court to stay its case in light of a pending request for IPR or an instituted IPR. Nor did Congress enact a provision prescribing how the Director is to address such an overlapping pending court case in exercising the discretion whether to institute an IPR.

1

The Director addressed this topic in 2019 and 2020 by exercising the authority to "designate[] past PTAB decisions as 'precedential' for future panels." *Arthrex*, 141 S. Ct. at 1980 (citing § 316(a)(4), quoted *supra* n.2, and § 3(a)(2)(A), which states that "[t]he Director shall be responsible for providing policy direction and management supervision for the Office"); *see* Trial and Appeal Board, Standard Operating Procedure 2 (Revision 10) at 1-2 (Standard Procedure 2). Specifically, the Director designated as precedential, and hence binding on Board panels (Standard Procedure 2 at 11), two Board decisions that had denied IPR petitions: *NHK Spring Co. v. Intri-Plex Technologies, Inc.*, IPR2018-00752, 2018 WL 4373643 (P.T.A.B. Sept. 12, 2018) (designated

[3] Other provisions also reflect Congress's expectation that the same patent claims might well be at issue in both an IPR proceeding and a court case. *See*, *e.g.*, 35 U.S.C. § 315(e)(2) (estoppel bar); *id.* § 315(a)(2) (addressing situation of petitioner initiation of both court and agency proceeding); *id.* § 316(a)(4) (providing that "[t]he Director shall prescribe regulations— ... establishing and governing inter partes review under this chapter and the relationship of such review to other proceedings under this title," the latter including actions in court, *see id.* § 281).

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). Both decisions address the role, in the decision whether to institute an IPR, of the pendency of district-court infringement litigation involving the same patents. The decisions, designated as precedential, constitute instructions from the Director regarding how the Board is to exercise the Director's institution discretion.

The decisions articulate "a discretionary standard for denying IPR petitions based on pending parallel litigation." Plaintiffs' Notice of Motion and Motion for Summary Judgment at 5, *Apple Inc. v. Iancu*, No. 20-cv-06128, 2021 WL 5232241, (N.D. Cal. Nov. 10, 2021), ECF No. 65, 2020 WL 8339428 (heading, capitalization removed except for "IPR"). In *NHK*, the Board relied on "the advanced state of the district court proceeding" involving the same patent to deny institution, reasoning that, given the projected trial date in the parallel court case, conducting an IPR would be an inefficient use of agency resources. 2018 WL 4373643, at *7. In *Fintiv*, the Board elaborated on *NHK*, enumerating six factors—the last one open-ended—to be assessed in deciding whether to institute an IPR in parallel with an overlapping court case:

> 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.

2020 WL 2126495, at *2. The Board explained how certain facts on the enumerated topics tend to weigh for or against institution, *id.* at *3-7, and how the "concerns of inefficiency and the possibility of conflicting decisions were particularly strong" in *NHK*, *id.* at *5. The Board stated generally 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. The Board summarized: "[I]n evaluating the factors, the Board takes a holistic view of whether efficiency and integrity of the system are best served by denying or instituting review." *Id.*

2

The above instructions (the *Fintiv* instructions) were the subject of this case when it was filed in district court, when it was decided by the district court, and when plaintiffs filed their brief as appellants in this court. Thereafter, on June 21, 2022, the Director updated the instructions. On that day, having issued a request for comments, *see* Request for Comments on Discretion to Institution Trials Before the Patent Trial and Appeal Board, 85 Fed. Reg. 66,502 (Oct. 20, 2020), and having received hundreds of comments, the Director announced (without publication in the Federal Register) "several clarifications" to the *Fintiv* instructions "under the Director's authority to issue binding agency guidance to govern the PTAB's implementation of various statutory provisions." Memorandum from PTO Director to PTAB, Interim Procedure for Discretionary Denials in AIA Post-Grant Proceedings with Parallel District Court Litigation at 2-3 (June 21, 2022) (*June 2022 Memo*).

The Director described Congress's aim "to establish a more efficient and streamlined patent system that will improve patent quality and limit unnecessary and counterproductive litigation costs," June 2022 Memo at 1 (quoting H.R. Rep. No. 112-98, pt. 1, at 40 (2011)), and its own experience with cost-increasing inefficiency and gamesmanship when parallel PTO proceedings and court cases exist, *id.* The Director now instructed the Board that it should not "rely on the *Fintiv* factors to discretionarily deny institution in view of parallel district court litigation where a petition presents compelling evidence of unpatentability." *Id.* at 2. The Director further stated that the *Fintiv* analysis does not apply when the parallel proceeding is not a district-court case but a proceeding within the International Trade Commission. *Id.* at 2-3. The Director added that no *Fintiv*-based institution denial would occur "where a petitioner presents a stipulation not to pursue in a parallel proceeding the same grounds or any grounds that could have reasonably been raised before the [Board]." *Id.* at 3. Finally, the Director announced that, in the application of the *Fintiv* instructions, "when other relevant factors weigh against exercising discretion to deny institution or are neutral, the proximity to trial should not alone outweigh all of those other factors," *id.* at 8, and that, even as to that factor, a particular "scheduled trial date" was not a reliable indicator of proximity, which instead should be assessed based "the most recent statistics on median time-to-trial for civil actions in the district court" hearing the parallel case, *id.*

The Director stated that the new instructions would apply to all pending proceedings in the PTO and "remain in place until further notice." *Id.* at 9. But the Director added that "[t]he Office expects to replace this interim guidance with rules after it has completed formal rule-making." *Id.*

The current challenge seeks prospective relief only, and the June 2022 instructions are part of the current operative instruction set regarding institution decisions by the Board as delegatee of the Director.[4] It would seem proper, therefore, were it important, to consider the updated instructions rather than the *Fintiv* instructions alone. *See National Treasury Employees Union v. Von Raab*, 489 U.S. 656, 661 n.1 (1989) (deciding case based on agency program as altered after court of appeals decision). But none of our conclusions in this appeal depend on whether we consider the *Fintiv* instructions or the updated instructions.

C

On August 31, 2020, Apple and three other companies filed suit in the Northern District of California, seeking to challenge the *Fintiv* instructions on three grounds under the APA: (1) that the Director acted contrary to the IPR provisions of the patent statute, *see* 5 U.S.C. § 706(2)(C); (2) that the *Fintiv* instructions are

---

[4] For subsequent clarifications from the Director, see *OpenSky Industries, LLC v. VLSI Tech. LLC*, IPR2021-01064, 2022 WL 4963049, at *20 (P.T.A.B. Oct. 4, 2022) (precedential) (Director's Decision on Determining Abuse of Process), and *CommScope Technologies LLC v. Dali Wireless, Inc.*, IPR2022-01242, 2023 WL 2237986, at *2 (P.T.A.B. Feb. 27, 2023) (Director's Decision on Rehearing).

arbitrary and capricious, see 5 U.S.C. § 706(2)(A); and (3) that the *Fintiv* instructions were issued without compliance with the notice-and-comment rulemaking requirements of 5 U.S.C. § 553, as assertedly required by that APA provision and by 35 U.S.C. § 316. *Apple*, 2021 WL 5232241, at *3. An amended complaint added a fifth plaintiff but asserted the same challenges. The government moved to dismiss the case, arguing that plaintiffs lacked standing and, in the alternative, that APA review was unavailable both because (1) "statutes preclude judicial review" of the matters presented and (2) the challenges are to "agency action [that] is committed to agency discretion by law," 5 U.S.C. § 701(a)(1)-(2). Briefing on that motion followed—on the same schedule as briefing on plaintiffs' own motion for summary judgment, which the court ruled, at plaintiffs' urging, was sufficiently "intertwined" with the dismissal motion to warrant parallel briefing. Order on Defendants' Motion for Administrative Relief Requesting a Stay of Briefing on Plaintiffs' Motion for Summary Judgment at 1, *Apple*, No. 20-cv-06128, 2021 WL 5232241, ECF No. 70; Plaintiffs' Opposition to Defendant's Motion for Administrative Relief Requesting a Stay of Briefing on Plaintiffs' Motion for Summary Judgment at 2, *Apple*, No. 20-cv-06128, 2021 WL 5232241, ECF No. 69.

On November 10, 2021, the district court granted the government's motion to dismiss. *Apple*, 2021 WL 5232241, at *1-6. The district court first concluded that plaintiffs had standing. *Id.* at *4-5. The court then concluded that their challenges were to Director actions that were not reviewable. *Id.* at *5–6. The court reasoned that 35 U.S.C. § 314(d), together with *Cuozzo* and *Thryv*, precluded review because, to rule on the challenges, the court "would have to analyze questions that are closely tied to the application and interpretation of statutes" governing institution decisions. *Id.* at *6 (internal quotation marks, for quote from *Cuozzo* and *Thryv*, omitted). The court therefore dismissed the case and "terminate[d] [p]laintiffs' motion for summary judgment." *Id.* Like the parties before us, we treat this dismissal as invoking the exclusion from the APA applicable where "statutes preclude judicial review." 5 U.S.C. § 701(a)(1).

Plaintiffs appealed on December 8, 2021, and that appeal ripened when the district court entered final judgment on December 13, 2021. We have jurisdiction over the timely appeal under 28 U.S.C. § 1295(a)(1) because plaintiffs' claims, at least in part, are based on the patent statute.

II

Plaintiffs argue on appeal that the district court erred when it held that the IPR provisions of the patent statute "preclude judicial review" of the challenged agency actions, bringing the case within the APA exclusion stated in 5 U.S.C. § 701(a)(1). The government, in response, defends the district court's § 701(a)(1) ruling and argues, in the alternative, that affirmance is separately required because the challenged agency action is "committed to agency discretion by law," § 701(a)(2), and because plaintiffs lack standing. We may consider the § 701(a)(1) unreviewability issue first and need not consider § 701(a)(2) and standing unless we find a challenge to lie outside the § 701(a)(1) exclusion from APA review. *See Block v. Community Nutrition Institute*, 467 U.S. 340, 353 n.4 (1984). We decide the issues presented, which are entirely legal, de novo. *See Alarm.com Inc. v. Hirshfeld*, 26 F.4th 1348, 1354 (Fed. Cir. 2022); *Digitalis Education Solutions, Inc. v. United States*, 664 F.3d 1380, 1384 (Fed. Cir. 2012).

We begin with plaintiffs' first two challenges (urging that the Director's instructions violate the IPR statute and are arbitrary and capricious), which we consider together. We affirm the § 701(a)(1) dismissal of those challenges and so need not consider § 701(a)(2) or standing. We then address the remaining challenge (concerning the absence of notice-and-comment rulemaking). We hold that neither § 701(a)(1) nor § 701(a)(2) bars review of the third challenge and that at least Apple has standing to press it. We therefore reverse the dismissal as to the third challenge and remand.

A

Plaintiffs' first two counts in their amended complaint challenge the content of the Director's institution instructions. The statutory challenge is that the instructions allow, and encourage or even require, denial of institution contrary to proscriptions plaintiffs draw from the IPR statute. Most concretely, plaintiffs assert that § 315(b)'s setting of an outer time limit on filing a petition, where the petitioner or its privy or the real party in interest has been sued on the patent in court, implies that the Director is forbidden, when determining whether to institute, to consider the timing of the petition within that limit and the stage of development of the court case. The arbitrary-and-capriciousness challenge is that the *Fintiv* instructions are not "reasonable and reasonably explained." *Federal Communications Commission v. Prometheus Radio Project*, 141 S. Ct. 1150, 1158 (2021) ("The APA's arbitrary-and-capricious standard requires that agency action be reasonable and reasonably explained."); *Snyder v. McDonough*, 1 F. 4^{th} 996, 1005 (Fed. Cir. 2021). Plaintiffs assert that the *Fintiv* instructions' directive to consider the time to trial in the parallel court case disregards the unreliability of court-set trial dates, which are frequently moved forward. For both challenges, plaintiffs invoke some of the policies articulated in the legislative process leading to the creation of the IPR program in the 2011 AIA.

These two challenges have institution as their direct, immediate, express subject. In this respect, the challenges are critically different from the challenge the Supreme Court agreed with in SAS, a decision on which plaintiffs rely. There, the subject of the challenge was the interpretation of § 318, which prescribes the scope of the final written decision required of the Board in an IPR. The Court held that § 318 requires the final written decision to "resolve *all* of the claims in the case." 138 S. Ct. at 1353. That holding was not precluded by the unreviewability of institution decisions already articulated in *Cuozzo*, even though the § 318 holding had, as a corollary, the effect of requiring the Director's decision whether to institute a requested review to be essentially an all-or-nothing one. *Id.* at 1358-60. As the Court explained in *Thryv*, the merely collateral effect of a provision concerning "the manner in which the agency's review 'proceeds' once instituted" did not bring SAS within the principle of unreviewability of "whether the agency should have instituted review at all." 140 S. Ct. at 1376.

SAS thus does not alter the principle of unreviewability governing "application and interpretation of statutes related to the [PTO's] decision to initiate inter partes review.'" *Id.* at 1373 (internal quotation marks omitted) (quoting *Cuozzo*, 579 U.S. at 275); *see id.* at 1376 n.8. Plaintiffs' statutory and arbitrary-and-capriciousness challenges in this case focus directly and expressly on institution standards, nothing else. The Supreme Court in *Cuozzo* and *Thryv* did not exclude any challenge from the reviewability bar where the invoked provisions of law directly govern institution—as the Court understood was the case for the pleading provision that was at issue in *Cuozzo* (§ 312(a)(3) (a petition "may be considered only if ...")) and the timing provision that was at issue in *Thryv* (§ 315(b) (an IPR "may not be instituted if ...")). *See Thryv*, 140 S. Ct. at 1373, 1376 n.8.[5]

In *Arthrex*, the Supreme Court confirmed the principle of unreviewability of the Director's decision whether to institute. 141 S. Ct. at 1977. The Court relied indirectly on *Cuozzo*'s holding that the IPR statute's text, legislative history, and structure supplied the clear and convincing evidence required to overcome the strong presumption in favor of reviewability generally, 579 U.S. at 273, and on *Cuozzo*'s application of the unreviewability principle even in a case in which a review was instituted and completed and a proper appeal was taken to this court of the Board's final written decision, *id.* at 271-75. The Court in *Arthrex* directly relied on *Thryv*, in which the Court, as in *Cuozzo*, applied the

[5] The Court in *Cuozzo* recognized, as SAS was soon to illustrate, that some statutory provisions addressed to other matters might have an indirect bearing on institution, and for that reason the *Cuozzo* Court said that it was not deciding "the precise effect of § 314(d) on appeals that implicate constitutional questions, that depend on other less closely related statutes, or that present other questions of interpretation that reach, in terms of scope and impact, well beyond" § 314. 579 U.S. at 275. The Court in *Cuozzo* further stated that its holding did not "enable the agency to act outside its statutory limits by, for example, canceling a patent claim for 'indefiniteness under § 112' in an inter partes review." *Id.* The example given is the PTO's "canceling a patent claim" in an IPR (*after* institution, *see* § 318(b)), not an aspect of the institution determination. *Id.* The Court in *Thryv* subsequently noted, without elaboration, that it was not "decid[ing] whether mandamus might be available in an extraordinary case." 140 S. Ct. at 1374 n.6. The case before us is not a mandamus case. *See also Mylan*, 989 F.3d at 1382 (holding mandamus standard not met for challenge to denial based on *Fintiv* instructions).

unreviewability principle in a proper appeal and made clear that the principle bars judicial resolution of even run-of-the-mill statutory interpretation issues inherent in an institution determination by the Director as long as the statutory provision is one sufficiently focused on institution itself, as the Court held was true of § 315(b), *Thryv*, 140 S. Ct. at 1372-73. Nothing in the unreviewability principle repeatedly affirmed by the Supreme Court in this setting, moreover, turns on whether the Director has provided an explanation (as the Board, as delegatee, typically does). That is hardly surprising, as the Supreme Court has rejected the notion that "if the agency gives a 'reviewable' reason for otherwise unreviewable action, the action becomes reviewable." *Interstate Commerce Commission v. Brotherhood of Locomotive Engineers*, 482 U.S. 270, 283 (1987).

The present case, unlike *Thryv* and *Cuozzo*, does not involve a petition-specific challenge, i.e., a challenge to a Director determination whether to institute a review requested in an individual petition. Rather, it involves a challenge to the Director's instructions to the Board, as delegatee, regarding how to exercise the Director's institution discretion. But we conclude that the IPR statute's preclusion of review, as now settled by the Supreme Court based on statutory text, legislative history, and structure, must encompass preclusion of review of the content-focused challenges to the instructions at issue here.

This conclusion rests on what we already confirmed in *Ethicon*, namely, the inevitability and congressional expectation of the Director's delegation of the institution decision, given the large number of institution decisions the Director would otherwise have to make personally, in highly technical matters involving significant records, while fulfilling many other responsibilities. *See Ethicon*, 812 F.3d at 1031-32. Given the need for delegation, and the Director's "political responsibility of determining which cases should proceed," *Saint Regis Mohawk Tribe v. Mylan Pharmaceuticals Inc.*, 896 F.3d 1322, 1327-28 (Fed. Cir. 2018), the Director 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. Such guidance is crucial for ensuring that such determinations will overwhelmingly be made in accordance with the policy choices about institution she would follow if she were making the determinations herself and, relatedly, for minimizing the number of occasions on which she has to reverse such determinations, as she may do, *see Palo Alto Networks*, 44 F.4th at 1375. If the congressional preclusion of review of the decision to institute is to be respected in the inevitable system of delegation, it must extend to the substance of such instructions.

If the Director personally made an institution decision accompanied by an explanation containing the same reasoning as appears in the instructions here at issue, then the decision would be unreviewable for being contrary to statute or arbitrary and capricious. For the IPR system to function with the delegations that are inevitable and congressionally expected, the same conclusion must follow for the instructions given by the Director to the Board as delegatee. We therefore affirm the district court's dismissal of plaintiffs' first two challenges under 5 U.S.C. § 701(a)(1).[6]

---

[6] In the first two challenges, plaintiffs assert that the instructions, because of their content, will likely lead to non-institution determinations that will harm them. Non-institution determinations are a species of non-enforcement decisions, which are among the few recognized categories of agency action that are generally

B

Plaintiffs' third challenge is that the Director was required, by 35 U.S.C. § 316 together with 5 U.S.C. § 553, to promulgate the institution instructions through notice-and-comment rulemaking procedures. This challenge, we conclude, may be pressed under the APA. We also hold that at least Apple has standing to press it.

1

Whether 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. *Lincoln v. Vigil*, 508 U.S. 182, 195 (1993); *see American Medical Association v. Reno*, 57 F.3d 1129, 1134 (D.C. Cir. 1995) ("[U]nder the APA the ultimate availability of substantive judicial review is *distinct* from the question of whether the basic rulemaking strictures of notice and comment and reasoned

---

"committed to agency discretion by law," 5 U.S.C. § 701(a)(2). *See Cuozzo*, 579 U.S. at 273 ("[T]he agency's decision to deny a petition is a matter committed to the Patent Office's discretion." (citing § 701(a)(2))); *Department of Homeland Security v. Regents of University of California*, 140 S. Ct. 1891, 1905-06 (2020); *Department of Commerce v. New York*, 139 S. Ct. 2551, 2565 (2019); *Lincoln v. Vigil*, 508 U.S. 182, 191 (1993); *Heckler v. Chaney*, 470 U.S. 821, 831-32 (1985). Some court decisions from outside the Supreme Court suggest that certain agency announcements of non-enforcement policy may fall outside the § 701(a)(2) exclusion from APA review. *See, e.g., Crowley Caribbean Transport, Inc. v. Pena*, 37 F.3d 671, 676 (D.C. Cir. 1994). The Supreme Court in *Regents*, when presented with an argument along those lines, did not reach the argument, because it held that the policy at issue was not a mere non-enforcement policy. 140 S. Ct. at 1906-07. We do not reach it either, as we affirm dismissal of plaintiffs' first two challenges based on § 701(a)(1) and so need not decide whether § 701(a)(2) would independently support dismissal.

explanation apply. ... The APA's procedural requirements are enforceable apart from the reviewability of the underlying action, and, indeed, support several important functions wholly distinct from judicial review." (omission of internal *Lincoln* citation and quote)); *Story v. Marsh*, 732 F.2d 1375, 1381, 1384 (8th Cir. 1984); *Natural Resources Defense Council v. U.S. Department of Energy*, 362 F. Supp. 3d 126, 147 (S.D.N.Y. 2019); *Batalla Vidal v. Duke*, 295 F. Supp. 3d 127, 148 (E.D.N.Y. 2017). Given this recognized distinction, we reject a conclusion of unreviewability, under § 701(a)(1) or (2), for plaintiffs' third challenge.

Here, as discussed above, the Supreme Court has held that clear and convincing evidence establishes a congressional protection from judicial review of the substance of the Director's institution discretion. That holding does not cover, and we see no basis for extending it to protect as well, the Director's choice of whether to use notice-and-comment rulemaking to announce instructions for the institution decision. The government here has not shown that anything in § 314(d) or elsewhere in the IPR statute supplies clear and convincing evidence that there was to be no judicial review of the choice of announcement procedure, a matter for which generally applicable standards exist. *See, e.g., Lincoln*, 508 U.S. at 196; *Xi'an Metals & Minerals Import & Export Co. v. United States*, 50 F.4th 98, 105-06 (Fed. Cir. 2022). In these circumstances, we have been shown no sufficient justification for a conclusion that the high standard of § 701(a)(1) for inferring a preclusion of review is met for this distinct issue.

Nor have we been presented a persuasive justification for concluding that the use or non-use of notice-and-comment rulemaking procedures is a matter "committed to agency discretion by law," 5 U.S.C. § 701(a)(2). The general rule that non-enforcement choices are committed to agency discretion by law, *see supra* n.5, does not mean that the choice of announcement procedure for issuing instructions for the making of choices is also committed to agency discretion by law. And at least because of the developed standards under 5 U.S.C. § 553, this is not a case where there is "no meaningful standard" by which to judge the process choice. *Department of Commerce v. New York*, 139 S. Ct. 2551, 2568 (2019) (considering whether matter was "one of those areas traditionally committed to agency discretion" and, then, whether there was "no meaningful standard" to use the judge the agency action).

The Supreme Court's decision in *Lincoln* supports our conclusion about reviewability regarding plaintiffs' third challenge. The Court there held that § 701(a)(2) barred review of the substance of an agency's choice of how to allocate a lump-sum appropriation, because allocation under a lump-sum appropriation was a recognized category of action committed to the agency's discretion. *Lincoln*, 508 U.S. at 191-95. But the Court was not asked to and did not hold unreviewable, for compliance with 5 U.S.C. § 553, the agency's choice not to use notice-and-comment rulemaking; instead, it decided, on the merits, that § 553 did not require notice-and-comment rulemaking for the agency decision at issue. *Id.* at 195-99. The government in *Lincoln* explained this distinction, stating: "The rulemaking provision of the APA, 5 U.S.C. 553, may itself provide 'law to apply' for reviewing agency procedures, even if there is otherwise no jurisdiction to review the substance of an agency decision." Brief for Petitioners, *Lincoln*, 508 U.S. 182 (No. 91-1833), 1992 WL 547219, at *10 n.8 (citing *Story*, 732 F.2d at 1381, 1384). We conclude that the distinction applies here.

We also conclude that at least Apple has standing to press the challenge to the Director's instructions as invalid for want of notice-and-comment rulemaking. We so conclude without aggregating the plaintiffs' asserted threatened harms, an approach taken by plaintiffs without arguing for its propriety. *See, e.g.*, *Summers v. Earth Island Institute*, 555 U.S. 488, 494-97 (2009) (analyzing individual plaintiffs separately); *ASARCO Inc. v. Kadish*, 490 U.S. 605, 615 (1989) ("[T]he doctrine of standing to sue is not a kind of gaming device that can be surmounted merely by aggregating the allegations of different kinds of plaintiffs, each of whom may have claims that are remote or speculative taken by themselves."); *Valley Forge Christian College v. Americans United for Separation of Church & State, Inc.*, 454 U.S. 464, 489 (1982) ("The law of averages is not a substitute for standing."). We will focus on Apple alone, and our conclusion that it has standing to press the remaining challenge permits us to reverse the dismissal and remand for the merits of that challenge to be addressed (along with any question about standing of other plaintiffs available for decision on remand if necessary). *See, e.g.*, *Little Sisters of the Poor Saints Peter & Paul Home v. Pennsylvania*, 140 S. Ct. 2367, 2379 n.6 (2020); *Rumsfeld v. Forum for Academic & Institutional Rights, Inc.*, 547 U.S. 47, 52 n.2 (2006).

In reviewing a standing determination made on a motion to dismiss a complaint, like the standing determination before us in this appeal, we assess standing de novo. *Ford Motor Co. v. United States*, 688 F.3d 1319, 1323 (Fed. Cir. 2012). We ask if the standard at the complaint stage, requiring allegations of fact plausibly indicating satisfaction of the legal requirement, is met. *See TransUnion LLC v. Ramirez*, 141 S. Ct. 2190, 2208

(2021); *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560–61 (1992); *James v. J2 Cloud Services, LLC*, 887 F.3d 1368, 1372 (Fed. Cir. 2018). We focus on the allegations of the complaint, but, under the regional circuit's law we apply, we may also consider, at least, matters of which we may properly take judicial notice. *See Lee v. City of Los Angeles*, 250 F.3d 668, 689–90 (9th Cir. 2001).

For a plaintiff to have standing, the plaintiff must show (1) an "injury in fact," (2) "a causal connection between the injury and the conduct complained of," and (3) a likelihood that "the injury will be redressed by a favorable decision." *Lujan*, 504 U.S. at 560–61 (internal quotation marks omitted). An injury in fact is "a legally protected interest which is (a) concrete and particularized" and "(b) actual or imminent, not conjectural or hypothetical." *Id.* at 560 (internal quotation marks omitted). The Court has found an assertion of future injury insufficient where it "involve[d] a significant degree of guesswork." *Trump v. New York*, 141 S. Ct. 530, 536 (2020). On the other hand, "[a]n allegation of future injury may suffice if the threatened injury is certainly impending, or there is a substantial risk that the harm will occur." *Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 159 (2014) (internal quotation marks omitted) (quoting *Clapper v. Amnesty International USA*, 568 U.S. 398, 414 n.5 (2013)); *Department of Commerce*, 139 S. Ct. at 2566. Of particular significance for this case, when a plaintiff asserts an entitlement to a rulemaking, the redressability requirement for standing is relaxed: It is enough for that element to be met that "there is some possibility that the requested relief," namely, notice-and-comment rulemaking, would "prompt the [agency] to reconsider the decision that allegedly harmed" the plaintiff. *Massachusetts v. Environmental Protection Agency*, 549 U.S. 497, 518 (2007); *see Summers*, 555 U.S. at 496-97;

Lujan, 504 U.S. at 572 n.7; *Iowa League of Cities v. Environmental Protection Agency*, 711 F.3d 844, 871 (8th Cir. 2013); *Sierra Club v. Environmental Protection Agency*, 699 F.3d 530, 533 (D.C. Cir. 2012).

Apple is non-speculatively threatened with harm to a legally protected interest from the challenged instructions. The complaint asserts harm with only brief elaboration. *See* Amended Complaint, ¶¶ 23, 28, *Apple*, No. 20-cv-06128, 2021 WL 5232241, ECF No. 54; J.A. 1134; J.A. 1136. But that is enough in this case. We may take judicial notice that Apple is a repeat player, in the relevant respect, on a very large scale. On a regular basis, for many years, it has been sued for infringement (giving it a concrete stake) and then petitioned for an IPR of patent claims at issue in that suit. Some of the petitions have been denied—for Apple, at least in *Fintiv* itself—based on the institution instructions at issue.

Given that history, it is far from speculative that this sequence will be repeated in the future, considering Apple's size and use of a wide variety of technologies and the realistically perceived 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. *See Jibril v. Mayorkas*, 20 F.4th 804, 815 (D.C. Cir. 2021) (concluding that "extensive" history supporting "future plans" can establish injury in fact); *N.B. ex rel. Peacock v. District of Columbia*, 682 F.3d 77, 84 (D.C. Cir. 2012) ("[A]lthough 'past ... conduct does not in itself show a present case or controversy regarding injunctive relief,' 'past wrongs' may serve as 'evidence bearing on whether there is a real and immediate threat of repeated injury.'" (cleaned up) (quoting *City of Los Angeles v. Lyons*, 461 U.S. 95, 102 (1983))). It is not unduly conjectural, but "the predictable effect" of the instructions, *Department* *of Commerce*, 139 S. Ct. at 2566, that the challenged instructions, which are plausibly alleged to cause more denials of institution than might otherwise occur, will continue causing harm in the form of denial of the benefits of IPRs linked to the concrete interest possessed by an infringement defendant—even though Apple cannot specify in advance individual IPR requests (filed with an infringement suit pending) that will be denied. These facts, we conclude, mean that "there is a substantial risk that the harm will occur" in the future because of the instructions. *Susan B. Anthony List*, 573 U.S. at 159 (internal quotation marks omitted) (quoting *Clapper*, 568 U.S. at 414 n.5). The injury is concrete and legally protected, because of the infringement suit, so the injury and causation requirements for standing are met.

The applicable standard for redressability here is also met. There is a genuine possibility that the instructions would be changed in a way favorable to Apple in a notice-and-comment rulemaking. That possibility is confirmed by the fact that the Director, in response to comments, announced favorable clarifications in the June 2020 Memo.

For those reasons, we conclude that Apple has standing to press the claim that the challenged instructions were improperly put in place without notice-and-comment rulemaking.[7]

---

[7] Neither side has suggested mootness of this challenged based on the June 2022 Memo or subsequent clarifications, *see supra* n.4, which, like their predecessors, were not put in place through notice-and-comment rulemaking (including publication in the Federal Register). A challenge might not be mooted by a change in challenged conduct if the alteration is itself subject to the same asserted deficiency as its predecessor. *See, e.g., Davenport v. Washington Education Association*, 551 U.S. 177, 182 n.1 (2007); *Northeastern Florida Chapter of Associated General Contractors of America v. City*

III

For the foregoing reasons, we affirm the district court's judgment dismissing plaintiffs' challenges to the Director's instructions as substantively contrary to statute and as arbitrary and capricious. We reverse the district court's dismissal for unreviewability of plaintiffs' challenge to the Director's instructions as having improperly been issued without notice-and-comment rulemaking, a challenge that we also conclude at least Apple has standing to press. We remand for consideration of this one challenge on the merits.

The parties shall bear their own costs.

AFFIRMED IN PART, REVERSED IN PART, AND REMANDED

---

of Jacksonville, 508 U.S. 656, 661–63 (1993); 13C Charles A. Wright & Arthur R. Miller, Federal Practice and Procedure § 3533.6 at n.63 (3d ed. 2022). The post-*Fintiv* clarifications do not appear to moot plaintiffs' third challenge, the only one remaining after our unreviewability holding regarding the first two challenges. Any further exploration of the effect of the post-*Fintiv* clarifications is left to the district court on remand.

APPENDIX D

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN JOSE DIVISION

Case No. 5:20-cv-06128-EJD
Re: Dkt. Nos. 64, 65

APPLE INC., ET AL.,

Plaintiffs,

v.

ANDREI IANCU,

Defendant.

ORDER GRANTING MOTION TO DISMISS; TERMINATING MOTION FOR SUMMARY JUDGMENT

Under the Leahy-Smith America Invents Act ("AIA"), 35 U.S.C. § 100 *et seq.*, a party may ask the U.S. Patent and Trademark Office ("the PTO") to review and potentially cancel claims in an already-issued patent that the PTO finds to be unpatentable in light of prior art. *See* 35 U.S.C. §§ 102, 103. This process, called "inter partes review" ("IPR"), is widely used to determine the patentability of patent claims that are the subject of pending patent infringement litigation. Plaintiffs challenge two PTO decisions that establish non-exclusive factors to aid in the PTO's determination of whether to institute IPR and argue that these decisions violate the Administrative Procedure Act ("APA") because they are arbitrary, capricious, and unlawful under the AIA.

Defendant contends that the Court cannot reach Plaintiffs' challenge, both because Plaintiffs lack standing and because the issue is not justiciable. The Court must agree with Defendant—while Plaintiffs have standing to pursue their claims, the Court is bound by *Cuozzo Speed Technlogies, LLC v. Lee*, 579 U.S. 261 (2016) and *Thryv, Inc. v. Click-To-Call Tehcnologies*, 140 S. Ct. 1367 (2020), which require the Court to dismiss this action for lack of jurisdiction.

I. BACKGROUND

A. The Inter Partes Review Process

The Constitution grants Congress the power "[t]o promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries." U.S. Const. art. I, § 8, cl. 8. Pursuant to this power, Congress created a patent system that grants inventors rights over the manufacture, sale, and use of their inventions. *See* 35 U.S.C. § 100 *et seq*. Inventors can secure a patent by filing an application with the PTO that includes "claims" that describe the invention. A patent examiner then reviews the patent claims, considers the prior art, and determines whether each claim meets the applicable patent law requirements. *See id*. §§ 101, 102, 103, 112. The examiner then accepts the claim or rejects it and explains why. *See id*. § 132(a).

"Sometimes, though, bad patents slip through." *SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1353 (2018). To remedy this problem, Congress allows parties to challenge the validity of patent claims in federal court. *See* 35 U.S.C. § 282(b)(2)-(3). Congress also has created an administrative process that allows a patent challenger to ask the PTO to reconsider the validity of an earlier granted patent claim. Specifically, in 2011, Congress enacted the AIA, which modified the "inter partes reexamination" system in favor of "inter partes review." *See* H.R. Rep. No. 112-98, pt. 1, pp. 46-47 (2011) (H.R. Rep.), codified at 35 U.S.C. §§ 311-19.

The IPR regime functions like civil litigation. A party must first file "a petition to institute an inter partes review of [a] patent. 35 U.S.C. § 311(a). The petition "may request to cancel as unpatentable 1 or more claims of [the] patent" on the ground that the claims are obvious or not novel. *Id.* § 311(b). The petition must identify "each claim challenged," the grounds for the challenge, and the evidence supporting the challenge. *Id.* § 312(a)(3). After a petition is filed, the patent owner may respond with "a preliminary response to the petition" to explain "why no inter partes review should be instituted." *Id.* § 313. With the parties' submissions, the Director of the PTO ("the Director") then decides "whether to institute an inter partes review … pursuant to [the] petition." *Id.* § 314(b). Before instituting review, the Director must determine "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 Director has delegated this authority to the Patent Trial and Appeal Board ("the PTAB") to exercise on his behalf. 37 C.F.R. § 42.4(a) (2017). The PTAB-patent judges are appointed by the Secretary of Commerce and must be "persons of competent legal knowledge and scientific ability." 35 U.S.C. § 6(a), (c). Once the Director institutes IPR, the case proceeds before the PTAB "with many of the usual trappings of litigation." *SAS Inst.*, 138 S. Ct. at 1354. For example, the parties conduct discovery, issue briefing, and appear before the PTAB for an oral hearing. 35 U.S.C. § 316(a)(5), (6), (8), (10), (13). The parties also may settle the action and end IPR. *Id.* § 317.

If, however, IPR is instituted and the action is not settled, the PTAB must "issue a final written decision with respect to the patentability of any patent claim challenged by the petitioner." *Id.* § 318(a).

35 U.S.C. §§ 315 and 316(a)(11) establish time limits for the institution and completion of IPR. For instance, IPR may not be instituted if the "petition requesting the proceeding is filed more than 1 year after the date on which the petitioner, real party in interest, or privy of the petitioner is served with a complaint alleging infringement of the patent." 35 U.S.C. § 315(b). As a result, the "life-span" of an IPR from the filing of a petition to a final written decision is typically only 18 months. *See* 35 U.S.C. § 316(a)(11); C.F.R. § 42.107(b); Amended Complaint for Declaratory and Injunctive Relief ("Compl."), Dkt. No. 54.

Finally, while the AIA authorizes judicial review of a "final written decision" canceling a patent claim, it does not allow for review of the Director's initial decision whether to institute IPR. *Compare* 35 U.S.C. § 319 (allowing a party dissatisfied with the PTAB's final written decision to appeal the decision), *with id.* § 314(d) ("The determination by the Director whether to institute inter partes review under this section shall be final and appealable.").

B. The *NHK/Fintiv* Decisions

By default, the PTAB's decisions in IPR proceedings have no precedential force in future cases. Patent Trial and Appeal Board, Standard Operating Procedure 2 (Rev. 10) ("SOP-2"), at 3, 8-9 (Sept. 20, 2018). However, the PTO has established a procedure for designating select PTAB decisions as "precedential." SOP-2 at 1-2, 8-12. Specifically, the Director decides whether to designate a Board decision as precedential. SOP-2 at 11.

This procedure does not allow for public notice of or public comment on the PTAB's decision to designate an IPR decision as precedential. SOP-2 at 8-11. Decisions designated as precedential are "binding" on the PTAB "in subsequent matters involving similar factors or issues." SOP-2 at 11.

Two recent, precedential PTAB decisions are at issue: *NHK Spring Co., Ltd. v. Intri-Plex Techs., Inc.*, No. IPR2018-00752, 2018 WL 4373643 (P.T.A.B. Sept. 12, 2018) ("*NHK*") and *Apple Inc. v. Fintiv, Inc.*, No. IPR2020-00019, 2020 WL 2126495 (P.T.A.B Mar. 20, 2020) ("*Fintiv*").

In *NHK*, the PTAB exercised its discretion under both 35 U.S.C. §§ 314(a) and 325(d)(6) to deny institution of IPR, in part due to a parallel district court trial that was scheduled six months away. After Intri-Plex Technologies, Inc. sued NHK International and its parent company, NHK Spring, for infringement of U.S. Patent No. 6,183,841 in the Northern District of California, NHK Spring petitioned for IPR. *Intri-Plex Techs., Inc. v. NHK Int'l Corp.*, No. 3-17-cv-1097 (N.D. Cal. 2017). The PTAB denied institution because of the parallel district court proceedings. . The PTAB found that "the advance state of the district court proceeding[s] … weigh[ed] in favor of denying [IPR] under § 314(a)" because the petitioner asserted the arguments in both its petition for IPR and before the district court proceeding. *Id.*

In *Fintiv*, the PTAB clarified how it would consider parallel litigation when deciding whether to institute IPR. 2020 WL 2126495. There, Apple sought IPR of patent claims that had been asserted against the company in an infringement suit in federal court. Apple filed the petition less than ten months after the parallel infringement suit began. Building on *NHK*, the PTAB stated that in the interests of "system efficiency, fairness, and patent quality," it would "weigh" six factors under 35 U.S.C. § 314(a) when deciding whether to institute IPR. *Id.* at *3 (hereinafter "the *NHK-Fintiv* rule"). Those factors are:

1. Whether the district court granted a stay or evidence exists that a stay may be granted if IPR proceedings are instituted;
2. The proximity of the court's trial date to the PTAB's projected statutory deadline for a final written decision;
3. The investment by the parties and district court in the parallel proceeding;
4. The overlap between the issues raised in the petition and the parallel proceeding;
5. Whether the IPR 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 of the challenge to patentability.

C. Plaintiffs' Lawsuit

Plaintiffs allege that the PTAB has applied *NHK-Fintiv* rule to unlawfully deny numerous IPR petitions, including petitions filed by Plaintiffs. Compl. ¶ 54. Plaintiffs filed this action to challenge the Director's authority to reject petitions for IPR using the *NHK-Fintiv* rule. Compl. ¶¶ 65-71. Plaintiffs assert three claims, each arising under the Administrative Procedure Act ("APA"). First, Plaintiffs argue that pursuant to 5 U.S.C. § 706(2)(C), this Court must "hold unlawful and set aside" the Director's use of the *NHK-Fintiv* rule because the Director exceeded his statutory authority in adopting it. Compl. ¶¶ 82-86 (Count I). Second, Plaintiffs argue that pursuant to 5 U.S.C. § 706(2)(A), this Court must "hold unlawful and set aside" the *NHK-Fintiv* rule because it is is arbitrary, capricious, and violates the AIA. Compl. ¶¶ 87-91 (Count II). Finally, Plaintiffs argue that pursuant to 5 U.S.C. § 706(2)(D), this Court must "hold unlawful and set aside" the *NHK-Fintiv* rule because it is a final, binding rule that was issued without notice and comment. Compl. ¶¶ 92-95 (Count III).

Defendant has moved to dismiss the Amended Complaint under Federal Rule of Civil Procedure 12(b)(1) on the grounds that Plaintiffs lack standing or, in the alternative, that Plaintiffs claims are not justiciable under the APA. Plaintiffs have moved for summary judgment. The Court only reaches Defendant's motion to dismiss.

II. LEGAL STANDARD

Federal Rule of Civil Procedure 12(b)(1) requires dismissal when the plaintiff fails to meet his or her burden of establishing subject-matter jurisdiction. *St. Clair v. City of Chico*, 880 F.2d 199, 201 (9th Cir. 1989). Dismissal on this basis is appropriate when a plaintiff fails to establish standing, *Oregon v. Legal Servs. Corp.*, 552 F.3d 965, 969 (9th Cir. 2009), *abrogated on other grounds by Bonds v. United States*, 564 U.S. 211 (2011), or brings a non-cognizable claim under the APA, *Fairbanks North Star Borough v. U.S. Army Corps of Engineers*, 543 F.3d 586, 591 (9th Cir. 2008).

A defendant may either challenge jurisdiction "facially" by arguing the complaint "on its face" lacks jurisdiction or "factually" by presenting extrinsic evidence that demonstrates the lack of jurisdiction. *Wolfe v. Strankman*, 392 F.3d 358, 362 (9th Cir. 2004); *Safe Air* *for Everyone v. Meyer*, 373 F.3d 1035, 1039 (9th Cir. 2004). "In a facial attack, the challenger asserts that the allegations contained in a complaint are insufficient on their face to invoke federal jurisdiction. By contrast, in a factual attack, the challenger disputes the truth of the allegations that, by themselves, would otherwise invoke federal jurisdiction." *Safe Air for Everyone*, 373 F.3d at 1039.

III. DISCUSSION

A. Article III Standing

To satisfy Article III's standing requirements, "a plaintiff must show (1) it has suffered an 'injury in fact' that is (a) concrete and particularized and (b) actual or imminent, not conjectural or hypothetical; (2) the injury is fairly traceable to the challenged action of the defendant; and (3) it is likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision." *Friends of the Earth, Inc. v. Laidlaw Envtl. Servs. (TOC), Inc.*, 528 U.S. 167, 180-81 (2000). As the party invoking federal jurisdiction, the plaintiff bears the burden of establishing that all three requirements are met. *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561 (1992). "At the pleading stage, general factual allegations of injury resulting from the defendant's conduct may suffice." *Id.* Because Plaintiffs seek prospective relief, they must show that "the threatened injury is 'certainly impending,' or there is a 'substantial risk' that the harm will occur." *Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 158 (2014) (quoting *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 414 n.5 (2013)).

1. Injury-in-Fact

To demonstrate an "injury in fact," a plaintiff must allege that it has sustained "an invasion of a legal protected interest" that is "concrete and particularized" and "actual or imminent." *Lujan*, 504 U.S. at 560 (citations omitted). When, as in this case, a suit challenges the legality of government action or inaction, the nature and extent of facts that must be averred at the pleading stage to establish standing depends upon whether the plaintiff is "himself an object of the action (or foregone action) at issue." *Id*. at 561. If he is, "there is ordinarily little question that the action or inaction has caused him injury, and that a judgment preventing or requiring the action will redress it." *Id*. 561-62.

Defendant argues that Plaintiffs cannot establish an injury-in-fact because under the AIA they have no protected right to IPR. *See* Motion to Dismiss Plaintiffs' Complaint ("MTD") at 9, Dkt. No. 64. In the Defendant's view, because the Director possesses unreviewable discretion over the initiation decision, Plaintiffs cannot allege that they are harmed by the *NHK-Fintiv* rule. But Plaintiffs do not argue that they are harmed by the *denial* of IPR. Instead, Plaintiffs identify harms that result from the Director's allegedly unlawful use of the *NHK-Fintiv* rule. Specifically, Plaintiffs allege that (1) because the AIA prescribes the factors that the Director can consider during the initiation decision process and allows for IPR during parallel litigation, the *NHK-Fintiv* rule violates the APA as it requires the PTAB to consider factors outside the considerations prescribed in the AIA; (2) the use of the *NHK-Fintiv* rule imposes an unlawful obstacle to IPR because it increases the risk that an IPR petition (including ones submitted by Plaintiffs) will be denied; (3) which deprives Plaintiffs of the benefits of IPR. *See* Compl. ¶¶ 80-95. Thus, contrary to Defendant's position, Plaintiffs' alleged injury is not that they were denied IPR, but that the Director is using unlawful considerations that increase the risk of denial, thereby depriving them of the *benefits* of IPR. *See* Compl. ¶¶ 31-32, 54-61 (naming benefits of IPR).

Plaintiffs have established that the *NHK-Fintiv* rule have harmed or present a "substantial risk" of harming them. This is a sufficient injury-in-fact. *See Susan B. Anthony*, 573 U.S. at 158; *see also E. Bay Sanctuary Covenant v. Biden*, 993 F.3d 640, 665 (9th Cir. 2021) ("An injury-in-fact is 'an invasion of a legally protected interest,' but this means an interest that is only concrete and particularized and actual or imminent—*not* an interest protected by statute. This distinction prevents Article III standing requirements from collapsing into the merits of a plaintiff's claim … ."). Indeed, as courts have previously found, the denial of an opportunity to obtain a benefit is itself an injury-in-fact. *See, e.g., Abboud v. I.N.S.*, 140 F.3d 843, 847 (9th Cir. 1998) (holding that a "lost opportunity represents a concrete injury"), *superseded by statute as stated in Hsiao v. Scalia*, 821 F. App'x 680, 683-84 (9th Cir. 2020); *Settles v. U.S. Parole Comm'n*, 429 F.3d 1098, 1101-03 (D.C. Cir. 2005) (holding that the plaintiff had standing to challenge a regulation that made it more difficult for him to gain the benefit of parole); *Robertson v. Allied Sols., LLC*, 902 F.3d 690, 697 (7th Cir. 2018) ("Article III's strictures are met not only when a plaintiff complains of being deprived of some benefit, but also when a plaintiff complains that she was deprived of a chance to obtain a benefit.").

2. Causation

There must be a causal connection between the injury and the conduct complained of—"the injury has to be 'fairly … trace[able] to the challenged action of the defendant, and not … th[e] result [of] the independent action of some third party not before the court." *Lujan*, 504 U.S. at 560 (alterations in original) (quoting *Simon v. E. Ky. Welfare Rights Org.*, 426 U.S. 26, 41-42 (1976)).

Plaintiffs have met the causation requirement. Their Amended Complaint demonstrates that the *NHK-Fintiv* rule (the conduct complained of) diminishes their opportunity to experience the benefits of IPR (the injury asserted). Compl. ¶¶ 52–62.

3. Redressability

It must be "likely," as opposed to merely "speculative," that the injury will be "redressed by a favorable decision." *Lujan*, 504 U.S. at 561. Plaintiffs ask the Court to enjoin the Director from applying the *NHK-Fintiv* rule. *See* Compl. at 20. If Plaintiffs prevail, this Court could enjoin the use of the *NHK-Fintiv* rule, which would redress the Plaintiffs' injuries. *See Nat'l Wildlife Fed'n v. Espy*, 45 F.3d 1337, 1343 (9th Cir. 1995). Plaintiffs have thus established redressability and have met their obligation to establish standing.

B. Justiciability

Before reaching the question of whether the use of the *NHK-Fintiv* rule violates the APA, this Court must first ensure that this issue is reviewable considering the Supreme Court's analysis of 35 U.S.C. § 314(d) in *Cuozzo Speed Technologies, LLC v. Lee*, 136 S. Ct. 2131 (2016). Under 35 U.S.C. 314(d), "[t]he determination by the Director whether to institute an inter partes review under this section shall be final and nonappealable."

In *Cuozzo*, the Supreme Court analyzed this "no appeal" provision in the context of a challenge to the Director's decision to institute IPR of two claims. 136 S. Ct. at 2138. There, the Director agreed to reexamine three claims, even though the petition for IPR only expressly challenged one of the claims. *Id.* As in this case, Cuozzo argued that the Directors acted outside his legal authority and violated the APA by instituting IPR with respect to the two unchallenged claims because 35 U.S.C. § 312(a)(3) requires the petition for IPR to identify "in writing and with particularity, each claim challenged." In finding the Director's institution decision unreviewable, the Court determined that § 314(d) applies where the grounds for challenging the Director's institution decision "consist of questions that are closely tied to the application and interpretation of statutes related to [the Director's] decision to initiate inter partes review." *Cuozzo*, 136 S. Ct. at 2141. However, the Court emphasized that its holding did not decide "the precise effect of § 314(d) on appeals that implicate constitutional questions, that depend on other less closely related statutes, or that present other questions of interpretation that reach, in terms of scope and impact, well beyond [§ 314(d)]." *Id.* The Court explained that institution decisions that implicate due process concerns or jurisdictional violations are not "categorically precluded" from judicial review under § 314(d). *Id.* at 2141-42.

More recently, in *Thryv, Inc. v. Click-to-Call Technologies, LP*, 140 S. Ct. 1367, 1373 (2020), the Supreme Court held that the Director's application of 35 U.S.C. § 315(b)'s time bar is "final and nonappealable" under 35 U.S.C. § 314(d). Relying on *Cuozzo*, the Court determined that the Director's application of the time bar is "closely related to its decision whether to institute inter partes review and is therefore rendered nonappealable by § 314(d)." *Thryv*, 140 S. Ct. at 1370. The Court explained that § 315(b)'s "time limitation is integral to, indeed a condition on, institution" and concluded that "[a] challenge to a petition's timeliness under § 315(b) thus raises an 'ordinary dispute about the application of' an institution-related statute." *Id.* at 1373 (quoting *Cuozzo*, 136 S. Ct. at 2139).

Much like *Thryv*, the *NHK-Fintiv* rule establishes factors that are "closely related to [the Director's decision] whether to institute inter partes review." *Thryv*, 140 S. Ct. at 1370. Plaintiffs' challenge does not fit within the categories of non-precluded review. *See Cuozzo*, S. Ct. at 2141-42 (stating that constitutional challenges or jurisdictional violations are not "categorically precluded"). Thus, in view of *Cuozzo* and *Thryv*, this Court cannot deduce a principled reason why preclusion of judicial review under § 314(d) would not extend to the Director's determination that parallel litigation is a factor in denying IPR. *See Saint Regis Mohawk Tribe v. Mylan Pharms. Inc.*, 896 F.3d 1322, 1327 (Fed. Cir. 2018) ("If the Director decides not to institute [IPR], *for whatever reason*, there is no review.") (emphasis added)). To inquire into the lawfulness of the *NHK-Fintiv* rule, the Court would have to analyze "questions that are closely tied to the application and interpretation of statutes related to the [Director's] decision to initiate inter partes review." *Cuozzo*, 136 S. Ct. at 2141-42. *Cuozzo* forbids this and so the Court must conclude that Plaintiffs' challenge to the *NHK-Fintiv* rule is barred by § 314(d).

IV. CONCLUSION

The Court **GRANTS** Defendant's motion to dismiss for lack of subject-matter jurisdiction. The Court **TERMINATES** Plaintiffs' motion for summary judgment. The Clerk shall close the file.

IT IS SO ORDERED.

Dated: November 10, 2021

[Signature]
EDWARD J. DAVILA
United States District Judge