

**United States Court of Appeals
for the Federal Circuit**

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

**EDWARDS LIFESCIENCES CORPORATION,
EDWARDS LIFESCIENCES LLC,**
Plaintiffs

v.

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

2024-1864

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

MARK CHRISTOPHER FLEMING, Wilmer Cutler Pickering
Hale and Dorr LLP, Boston, MA, argued for all plaintiffs-
appellants. Plaintiffs-appellants Apple Inc., Cisco Sys-
tems, Inc., Intel Corporation also represented by GARY M.

FOX, ALYSON ZUREICK, New York, NY; MARK D. SELWYN, Palo Alto, CA. Plaintiff-appellant Google LLC also represented by NATHAN K. KELLEY, Perkins Coie LLP, Washington, DC; ANDREW DUFRESNE, Madison, WI.

WEILI J. SHAW, Appellate Staff, Civil Division, United States Department of Justice, Washington, DC, argued for defendant-appellee. Also represented by BRIAN M. BOYNTON; MICHAEL S. FORMAN, Office of the Solicitor, United States Patent and Trademark Office, Alexandria, VA.

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 *un-reviewable* 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. Intri-Plex 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 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

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.

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/Direct_or_Institution_of_AIA_Trial_Proceedings.pdf.

Second, the PTO published a notice of proposed rule-making, 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 prescribe 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

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*

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 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,

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.

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 preconditions 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

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

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 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).

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, 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 post-election 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