No. 2024-1864

**IN THE UNITED STATES COURT OF APPEALS**
**FOR THE FEDERAL CIRCUIT**

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

Plaintiffs-Appellants,

EDWARDS LIFESCIENCES CORPORATION,
EDWARDS LIFESCIENCES LLC,

Plaintiffs,

v.

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

Defendant-Appellee.

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On Appeal from the United States District Court
for the Northern District of California in Case No. 5:20-cv-6128,
Judge Edward J. Davila

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# BRIEF FOR APPELLEE

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## STATEMENT OF RELATED CASES

This Court decided a previous appeal in the present civil action. *See Apple Inc. v. Vidal*, 63 F.4th 1 (Fed. Cir. March 13, 2023) (No. 2022-1249) (Lourie, Taranto & Stoll, JJ.). No other appeal in or from the present civil action has previously been before this or any other appellate court. The government is not aware of any related cases within the meaning of Federal Circuit Rule 47.5.

## STATEMENT OF JURISDICTION

Plaintiffs invoked the jurisdiction of the district court pursuant to 28 U.S.C. § 1331. Appx1133. The district court granted the government's motion for summary judgment on March 31, 2024, Appx23, and entered judgment on April 1, 2024, Appx24. On May 15, 2024, plaintiffs timely filed a notice of appeal to this Court. Appx1739; *see* Fed. R. App. P. 4(a)(1)(B) (60-day time limit). This Court has jurisdiction over the appeal under 28 U.S.C. § 1295(a)(1).

## STATEMENT OF THE ISSUE

Under the Leahy-Smith America Invents Act (AIA), Pub. L. No. 112-29, § 6, 125 Stat. 284, 299-306 (2011), the Director of the U.S. Patent and Trademark Office (USPTO) has unreviewable discretion to determine whether to institute an inter partes review (IPR) proceeding when the petitioner satisfies the statutory prerequisites for institution. The Director has delegated her discretionary institution authority to the Patent Trial and Appeal Board (Board) and provided the Board with guidance about how to exercise that discretion on her behalf. That guidance requires the Board to consider and weigh a list of non-exclusive factors, known as the *Fintiv* factors, in making the discretionary determination whether to institute an IPR in certain types of situations, but it does not require any particular outcome under any particular circumstances.

The issue presented is whether the Administrative Procedure Act (APA), 5 U.S.C. § 551 *et seq.*, or the AIA require the Director to issue such guidance regarding the Board's exercise of her delegated discretion through notice-and-comment rulemaking.

## STATEMENT OF THE CASE

### A. Statutory and Regulatory Background

1. The Patent Act of 1952 (Patent Act), 35 U.S.C. § 1 *et seq.*, charges the USPTO with examining applications for patents and directs the USPTO to issue a patent if the statutory criteria are satisfied. *Id.* § 131. Federal law has also long permitted the USPTO to reconsider the patentability of inventions claimed in previously-issued patents. In the AIA, Congress expanded those procedures in an effort to "establish a more efficient and streamlined patent system." H.R. Rep. No. 112-98, pt. 1, at 39-40 (2011). Among other changes, the AIA established IPR, which "allows a third party to ask the [USPTO] to reexamine the claims in an already-issued patent and to cancel any claim that the agency finds to be unpatentable in light of prior art." *Cuozzo Speed Techs., LLC v. Lee*, 579 U.S. 261, 265 (2016); *see* 35 U.S.C. § 311.

When a petition for IPR is filed, the USPTO Director must determine whether or not to institute an IPR proceeding. That determination has two parts. First, the AIA establishes prerequisites that must be satisfied for the Director to

grant review: "[t]he Director may not authorize an inter partes review to be instituted unless the Director determines that the information presented in the petition . . . shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least [one] of the claims challenged in the petition." 35 U.S.C. § 314(a). The AIA also requires the Director to "prescribe regulations . . . setting forth the standards for the showing of sufficient grounds to institute a review." *Id.* § 316(a)(2). The USPTO has complied with this requirement through notice-and-comment rulemaking. *See* Changes to Implement Inter Partes Review Proceedings, Post-Grant Review Proceedings, and Transitional Program for Covered Business Method Patents, 77 Fed. Reg. 48,680, 48,680 (Aug. 14, 2012). Those rules are not at issue here.

Second, even when a petition meets the statute's prerequisites for institution, the Director nonetheless has discretion to decline to institute review. The AIA contains "no mandate to institute review." *Cuozzo*, 579 U.S. at 273; *see also Mylan Labs. Ltd. v. Janssen Pharmaceutica, N.V.*, 989 F.3d 1375, 1382 (Fed. Cir. 2021) ("The Director is permitted, but never compelled, to institute an IPR."). Nor does the statute specify any criteria that the Director must consider at this step. Instead, "Congress has committed the [institution] decision . . . to the Director's unreviewable discretion." *United States v. Arthrex, Inc.*, 594 U.S. 1, 8-9 (2021); *see also* 35 U.S.C. § 314(a). The AIA contains no requirement that the Director

prescribe regulations with respect to the exercise of this discretion. *See* 35 U.S.C. § 316.

Neither part of the Director's determination is subject to judicial review. The AIA declares that the Director's determination whether to institute review is "final and nonappealable." 35 U.S.C. § 314(d). The Supreme Court has explained that this provision precludes efforts to review the Director's analysis of the statutory prerequisites to an IPR proceeding. *See Thryv, Inc. v. Click-To-Call Techs., LP*, 590 U.S. 45, 53-59 (2020). And as noted, the Supreme Court has also recognized that the Director's exercise of discretion regarding whether to institute IPR proceedings is not subject to judicial review. *See Arthrex*, 594 U.S. at 8-9.[1]

If the Director institutes an IPR proceeding, the Board conducts a trial on the patentability of the challenged claims. *See* 35 U.S.C. §§ 6, 316. Generally, the Board must issue a final written decision on the claims within one year after institution of the proceeding. *See id.* § 316(a)(11); *see also Cuozzo*, 579 U.S. at 268.

Unlike the threshold institution decision, final written decisions affect the substantive legal rights of the parties. Such a decision can cancel patent claims as well as estop the petitioner from asserting in future litigation "that the claim is

[1] This Court has recognized the possibility of mandamus review for "colorable constitutional claims." *Mylan Labs.*, 989 F.3d at 1382.

invalid on any ground that the petitioner raised or reasonably could have raised during" the IPR proceeding. 35 U.S.C. §§ 315(e), 318(a). The AIA authorizes dissatisfied parties to appeal the Board's final written decision on patentability to this Court. *Id.* §§ 318(a), 319. In such appeals, however, parties cannot contend "that the agency should have refused to institute inter partes review." *Thryv*, 590 U.S. at 60.

2. The Director has delegated to the Board her discretionary authority to determine whether IPR proceedings should be instituted. *See* 37 C.F.R. § 42.4(a). However, the Director retains ultimate authority over institution, and "any institution decision made by the Board as delegatee of the Director is subject to reversal by the Director." *Apple Inc. v. Vidal*, 63 F.4th 1, 7 (Fed. Cir. 2023), *cert. denied*, 144 S. Ct. 548 (2024).

The Director also exercises control over institution decisions through additional means. The Director is "responsible for providing policy direction and management supervision for the Office," 35 U.S.C. § 3(a)(2), and does so in various ways, including by publishing guidance materials and issuing memoranda on the handling of recurring issues before the Board. The Director may also designate particular Board opinions as precedential, thus making those opinions "binding Board authority in subsequent matters involving similar facts or issues."

Patent Trial & Appeal Bd., USPTO, *Standard Operating Procedure 2 (Revision 11)*, at 7 (July 24, 2023), https://perma.cc/M4Y8-VSSN (SOP 2).

At issue here is the Director's precedential designation of two Board decisions that identify criteria to be considered in the exercise of the Director's discretion to deny IPR. *See NHK Spring Co. v. Intri-Plex Techs., Inc.*, No. IPR2018-00752, 2018 WL 4373643 (P.T.A.B. Sept. 12, 2018); *Apple Inc. v. Fintiv, Inc.*, No. IPR2020-00019, 2020 WL 2126495 (P.T.A.B. Mar. 20, 2020). In particular, the decisions concern the circumstance when a parallel proceeding is pending in district court. In *NHK*, the Board noted that efficiency weighed in favor of denying review when a "district court proceeding will analyze the same issues and will be resolved before any trial on the [IPR p]etition concludes." 2018 WL 4373643, at *7.

The Board expanded on *NHK* in *Fintiv*, explaining that "an early trial date" is one "non-dispositive factor[]" that "should be weighed as part of a 'balanced assessment of all relevant circumstances of the case, including the merits,'" in determining whether to institute an IPR. 2020 WL 2126495, at *2. *Fintiv* identified six factors the Board had previously considered "relat[ing] 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":

> 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.* at *2-3. The Board explained that "in 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.* at *3. The factors "should be weighed as part of a 'balanced assessment of all relevant circumstances of the case, including the merits.'" *Id.* at *2.

The Director has since issued updated interim guidance altering and refining the *Fintiv* analysis in certain respects. *See* Memorandum from Katherine K. Vidal, Director, USPTO, to Members of the Patent Trial & Appeal Bd. (June 21, 2022), https://perma.cc/ZSV5-ZPZS (June 2022 Guidance). The guidance provides:

> (1) the Board will not discretionarily deny institution under *Fintiv* when a petition presents compelling evidence of unpatentability;
>
> (2) the Board will not discretionarily deny institution under *Fintiv* when the parallel proceeding is before the U.S. International Trade Commission;
>
> (3) the Board will not discretionarily deny institution under *Fintiv* when a petitioner stipulates not to pursue, in a parallel district court

> proceeding, the same grounds as in the petition or any grounds that could reasonably have been raised in the petition; and
>
> (4) when considering the second *Fintiv* factor, the Board will consider evidence presented by the parties regarding the median time-to-trial in the relevant judicial district, as well as other supporting factors.

*See* June 2022 Guidance 3-9.

The Director has also amended and clarified her guidance by exercising her authority to review the Board's institution decisions. *See, e.g.*, *CommScope Techs. LLC, v. Dali Wireless, Inc.*, No. IPR2022-01242, 2023 WL 2237986, at *3 (Dir. Decision Feb. 27, 2023) (precedential) (vacating and remanding for the Board "to revisit its *Fintiv* analysis in view of this Decision"). The Director has reviewed Board institution decisions in at least seven cases involving parallel proceedings since mid-2022. *See* USPTO, *Status of Director Review Requests*, https://perma.cc/BBY3-ASSH (listing cases under "Institution" and "Parallel proceedings").

Finally, the Director is considering comments on a proposed rule regarding criteria for the exercise of her discretionary denial authority. The USPTO began this process in 2020, when the agency issued a request for comment regarding the exercise of the Director's discretionary denial authority. *See* Request for Comments on Discretion to Institute Trials Before the Patent Trial and Appeal Board, 85 Fed. Reg. 66,502 (Oct. 20, 2020). The USPTO then issued an advance notice of proposed rulemaking (ANPRM) identifying, among other topics, possible

future policy changes regarding the exercise of the Director's discretionary denial authority. *See* Changes Under Consideration to Discretionary Institution Practices, Petition Word-Count Limits, and Settlement Practices for America Invents Act Trial Proceedings Before the Patent Trial and Appeal Board, 88 Fed. Reg. 24,503 (Apr. 21, 2023). The USPTO subsequently issued a notice of proposed rulemaking regarding some of the matters discussed in the ANPRM. *See* Patent Trial and Appeal Board Rules of Practice for Briefing Discretionary Denial Issues, and Rules for 325(d) Considerations, Instituting Parallel and Serial Petitions, and Termination Due to Settlement Agreement, 89 Fed. Reg. 28,693, 28,695 (Apr. 19, 2024).[2]

### B. District Court Proceedings

1. Plaintiffs are technology companies that have filed IPR petitions in the past. Appx1134-35. Plaintiffs allege that, in some of those cases, the USPTO declined to institute IPR proceedings after considering the *NHK* and *Fintiv* decisions. Appx1140-43.

Before this lawsuit, plaintiffs repeatedly tried to challenge the *NHK* and *Fintiv* decisions through appeals from Board decisions denying institution of IPR

[2] In this Court's prior decision in this case, the Court found it appropriate to review "the current operative instruction set regarding institution decisions by the Board as delegatee of the Director," including the *NHK* and *Fintiv* decisions themselves as well as the Director's updated guidance. *Apple*, 63 F.4th at 10. For brevity, this brief refers to that collection of guidance as "the *Fintiv* factors."

proceedings. This Court rejected each of those challenges, concluding that the AIA precludes judicial review. *See, e.g.*, *In re Cisco Sys. Inc.*, 834 F. App'x 571, 573 (Fed. Cir. 2020) (unpublished).

Plaintiffs then filed this suit challenging the *NHK* and *Fintiv* decisions on three grounds under the APA. Appx1131. First, plaintiffs alleged that the factors identified in those decisions are contrary to the AIA because the AIA purportedly prohibits the Director from considering parallel district court proceedings when exercising her discretion to deny institution. Appx1148-49. Second, plaintiffs alleged that the *NHK* and *Fintiv* decisions are arbitrary, capricious, and an abuse of discretion because they purportedly create unpredictable, irrational, or inefficient results. Appx1149-50. Third, plaintiffs alleged that the *NHK* and *Fintiv* decisions are unlawful because the Director did not promulgate them through notice-and-comment rulemaking. Appx1150.

2. The district court granted the government's motion to dismiss. Appx1546. The court held that plaintiffs' claims were unreviewable under 35 U.S.C. § 314(d) and *Cuozzo*, which held 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.'" Appx1554-55 (alteration in original) (quoting *Cuozzo*, 579 U.S. at 275).

3. This Court affirmed in part and reversed and remanded in part. *Apple*, 63 F.4th at 18.

a. The Court first held that plaintiffs' statutory-authority and arbitrary-and-capricious claims were unreviewable. *Apple*, 63 F.4th at 11. The Court noted that both claims "focus directly and expressly on institution standards, nothing else," *id.* at 12, and that Supreme Court precedent "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," *id.* at 13. The Court acknowledged that plaintiffs did not challenge "a Director determination whether to institute a review requested in an individual petition," but rather the Director's guidance "regarding how to exercise the Director's institution discretion." *Id.* The Court concluded, however, that the AIA's "preclusion of review . . . must encompass preclusion of review of the content-focused challenges to the instructions at issue here." *Id.*

The Court explained that its holding rested on "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." *Apple*, 63 F.4th at 13. The Court reasoned that, in light of that practical need for delegation and "the Director's 'political

responsibility of determining which cases should proceed,'" guidance from the Director to her delegatee "is crucial for ensuring that [institution] determinations will overwhelmingly be made in accordance with the policy choices about institution [the Director] would follow if she were making the determinations herself." *Id.* (quoting *Saint Regis Mohawk Tribe v. Mylan Pharm. Inc.*, 896 F.3d 1322, 1327 (Fed. Cir. 2018)). The Court observed that, if the Director had invoked the *Fintiv* factors in explaining an institution decision that she had made personally, "the decision would be unreviewable for being contrary to statute or arbitrary and capricious." *Id.* "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." *Id.*

b. This Court reversed as to plaintiffs' notice-and-comment claim and remanded for further consideration. *Apple*, 63 F.4th at 18. The Court found that plaintiff Apple Inc. had standing to press that claim. *Id.* at 17. The Court further concluded that, while the AIA precludes "judicial review of the substance of the Director's institution discretion," that principle does not extend to the procedural issue of "whether to use notice-and-comment rulemaking to announce instructions for the institution decision." *Id.* at 14. The Court did not find "clear and convincing evidence" in the patent statutes "that there was to be no judicial review

of the choice of announcement procedure, a matter for which generally applicable standards exist." *Id.* at 14-15.

4. On remand, the district court granted summary judgment for the government on plaintiffs' notice-and-comment claim. The court concluded that the *Fintiv* factors are not a "legislative rule"—also called a "substantive rule"—that must be promulgated through notice-and-comment rulemaking, but rather a "general statement of policy" that does not require notice-and-comment rulemaking. Appx13, Appx22-23. In distinguishing between the two, the court evaluated four different characteristics the court drew from Federal Circuit and, secondarily, Ninth Circuit case law. Appx13-14. The court concluded that the *Fintiv* factors were a general statement of policy because they (1) do not "alter, create, or impose any individual rights or obligations," Appx17; (2) operate prospectively only, Appx17; (3) leave the Board free to exercise discretion, Appx19; and (4) do not establish a "binding norm" or have "determinative effect." Appx19, Appx21. The court accordingly found that the *Fintiv* factors are "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." Appx23. The court concluded that, because the *Fintiv* factors are "a general statement of policy,

rather than a substantive or legislative rule," notice-and-comment rulemaking was not required. Appx23.

5. Plaintiffs timely appealed to this Court. Appx1739.

## SUMMARY OF ARGUMENT

The district court correctly concluded that the Director was not obligated to issue her guidance regarding the Board's exercise of her delegated discretion through notice-and-comment rulemaking. That guidance is a general statement of policy exempt from the APA's notice-and-comment requirements under 5 U.S.C. § 553(b) because it describes how the USPTO intends to exercise a discretionary power—namely, the Director's unreviewable discretion to grant or deny an IPR petition that meets the statutory prerequisites for institution.

The Director's guidance embodied in the *Fintiv* factors is not, as plaintiffs contend, a legislative rule that requires notice-and-comment rulemaking. The factors do not alter legal rights or obligations, nor do they bind private parties with the force and effect of law. Indeed, the factors are not directed towards private parties at all, but rather towards officials exercising, under the Director's supervision, the Director's authority to make an entirely discretionary decision that does not alter rights or obligations. The *Fintiv* factors also do not establish or modify any legal standards.

Plaintiffs err in arguing that the *Fintiv* factors have the force of law because they channel the Board's discretion and reduce the likelihood of institution in certain cases. It is irrelevant that the Director has instructed the Board to consider the factors, given this Court's precedent holding that such purely intra-agency "binding" does not establish that a directive has the force of law. The fact that a policy statement may have some effect on an agency's discretionary decisions also does not make it a legislative rule. Even if such effects were relevant, the *Fintiv* factors do not have the kind of binding effect that would make them a legislative rule. They have no binding effect on the Director, and they do not require the Board to reach a particular result or otherwise foreclose the Board's ability to exercise genuine discretion and make individualized determinations.

Plaintiffs' argument that the AIA itself requires that the *Fintiv* factors be promulgated through notice-and-comment rulemaking is also unavailing. Plaintiffs rely on 35 U.S.C. § 316(a)(4), which instructs the Director to issue regulations "establishing and governing inter partes review under this chapter and the relationship of such review to other proceedings under this title." However, the Director issued the *Fintiv* factors pursuant to her separate statutory authority to "provid[e] policy direction and management supervision for the Office" under 35 U.S.C. § 3(a)(2), and the rulemaking authority in section 316(a) does not expressly or impliedly repeal the authority in section 3(a)(2).

## ARGUMENT

### I. STANDARD OF REVIEW

This Court "review[s] the district court's grant of summary judgment de novo, applying the same standard as the district court." *Japanese Found. for Cancer Research v. Lee*, 773 F.3d 1300, 1304 (Fed. Cir. 2014); *see Crowe v. Oregon State Bar*, 112 F.4th 1218, 1229 (9th Cir. 2024).

This Court applies its own law, rather than regional circuit law, "to procedural issues that are not themselves substantive patent law issues" if they "(1) pertain to patent law"; "(2) bear an essential relationship to matters committed to [this Court's] exclusive control by statute"; or "(3) clearly implicate the jurisprudential responsibilities of this court in a field within its exclusive jurisdiction." *Madey v. Duke Univ.*, 307 F.3d 1351, 1358 (Fed. Cir. 2002) (quoting *International Nutrition Co. v. Horphag Research Ltd.*, 257 F.3d 1324, 1328 (Fed. Cir. 2001)).

"APA claims against the [USPTO] 'raise[ ] a substantial question of patent law.'" *Odyssey Logistics & Tech. Corp. v. Iancu*, 959 F.3d 1104, 1108 (Fed. Cir. 2020) (second alteration in original) (quoting *Exela Pharma Scis., LLC v. Lee*, 781 F.3d 1349, 1352 (Fed. Cir. 2015) (per curiam)), *abrogated on other grounds by Corner Post, Inc. v. Board of Governors of the Fed. Reserve Sys.*, 144 S. Ct. 2440 (2024); *see also Helfgott & Karas, P.C. v. Dickinson*, 209 F.3d 1328, 1334 (Fed.

Cir. 2000) ("[T]he question of whether the [USPTO] has violated the APA in applying [patent treaty] rules and regulations, as well as its own regulations, raises a substantial question under the patent laws . . . ."). This Court has accordingly applied Federal Circuit precedent in considering APA challenges to USPTO rules. *See, e.g.*, *Cooper Techs. Co. v. Dudas*, 536 F.3d 1330, 1337 (Fed. Cir. 2008); *Mikkilineni v. Stoll*, 410 F. App'x 311, 312 (Fed. Cir. 2010) (per curiam) (unpublished).

## II. THE APA DOES NOT REQUIRE THE DIRECTOR TO UNDERTAKE NOTICE-AND-COMMENT RULEMAKING WHEN ISSUING INSTRUCTIONS REGARDING THE EXERCISE OF HER INSTITUTION DISCRETION

Plaintiffs' sole remaining claim is that the Director was required to set out the guidance to her delegatees embodied in the *Fintiv* factors through notice-and-comment rulemaking. That claim turns on how that guidance is categorized. "The APA divides agency action, as relevant here, into three boxes: legislative rules, interpretive rules, and general statements of policy." *National Mining Ass'n v. McCarthy*, 758 F.3d 243, 251 (D.C. Cir. 2014). "Legislative rules generally require notice and comment, but interpretive rules and general statements of policy do not." *Id.*; 5 U.S.C. § 553(b)(A) (exempting "interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice" from notice-and-comment requirements). A general statement of policy "advise[s] the public prospectively of the manner in which the agency proposes to exercise a

discretionary power." *Lincoln v. Vigil*, 508 U.S. 182, 197 (1993) (quoting *Chrysler Corp. v. Brown*, 441 U.S. 281, 302 n.31 (1979)); *Stupp Corp. v. United States*, 5 F.4th 1341, 1351 (Fed. Cir. 2021). "Legislative rules alter the landscape of individual rights and obligations, binding parties with the force and effect of law . . . ." *Xi'an Metals & Mins. Imp. & Exp. Co. v. United States*, 50 F.4th 98, 106 (Fed. Cir. 2022) (quoting *Stupp*, 5 F.4th at 1352). Interpretive rules "clarify existing duties for affected parties." *Stupp*, 5 F.4th at 1352.

The district court correctly found that the guidance the Director set out through the *Fintiv* factors is a general statement of policy. The *Fintiv* factors are not, as plaintiffs would have it, a legislative rule, because they neither alter individual rights and obligations nor bind parties with the force and effect of law.

### A. The Director's Instructions Regarding the Exercise of Her Institution Discretion Constitute a General Statement of Policy

The *Fintiv* factors are a set of considerations the Director has instructed her delegatees to consider in particular situations as they exercise her purely discretionary authority to grant or deny an IPR petition satisfying the statutory criteria for institution. They also inform the public how the Board is likely to exercise that delegated discretion. As such, they are a quintessential policy statement that "advise[s] the public prospectively of the manner in which the agency proposes to exercise a discretionary power." *Stupp*, 5 F.4th at 1351 (alteration in original) (quoting *Lincoln*, 508 U.S. at 197).

"Congress has committed the [institution] decision . . . to the Director's unreviewable discretion." *United States v. Arthrex, Inc.*, 594 U.S. 1, 8-9 (2021); *see also* 35 U.S.C. § 314(a). "The Director is permitted, but never compelled, to institute an IPR," *Mylan Labs. Ltd. v. Janssen Pharmaceutica, N.V.*, 989 F.3d 1375, 1382 (Fed. Cir. 2021), and the statute specifies no criteria that the Director must consider in exercising that discretion, *see Apple Inc. v. Vidal*, 63 F.4th 1, 8 (Fed. Cir. 2023) ("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."), *cert. denied*, 144 S. Ct. 548 (2024).

The Director delegated that discretion to the Board to exercise in the first instance, although the Director retains ultimate authority over institution decisions and the power to reverse any determination made by the Board. *Apple*, 63 F.4th at 7; *In re Palo Alto Networks, Inc.*, 44 F.4th 1369, 1375 & n.3 (Fed. Cir. 2022). The Director designated the *NHK* and *Fintiv* decisions as precedential and issued her 2022 memorandum providing further guidance on the factors set out in those decisions to "inform [the Board] how to exercise, under delegation by the Director, the Director's discretion whether to institute a requested IPR." *Apple*, 63 F.4th at 6. The *Fintiv* factors therefore guide the Director's delegatees in their exercise of the Director's discretionary institution power. They also inform the public how the Board is likely to approach certain scenarios.

The *Fintiv* factors therefore fit comfortably within the longstanding description of a general statement of policy: 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 Corp.*, 441 U.S. at 302 n.31); *see National Mining Ass'n*, 758 F.3d at 252 (agency action that explains "how the agency . . . will exercise its broad enforcement discretion . . . under some extant statute or rule" is a general statement of policy).

### B. The Director's Instructions Regarding the Board's Exercise of Her Institution Discretion Are Not a Legislative Rule

Plaintiffs contend (at 33) that the Director could give her delegatees the *Fintiv*-factor guidance only through notice-and-comment rulemaking because the guidance constitutes a legislative rule. But the Director's instructions lack the essential features of such a rule: they do not bind parties with the force and effect of law, and they do not alter individual rights and obligations.

#### 1. The Director's instructions do not bind parties with the force and effect of law or alter individual rights and obligations

"Legislative rules alter the landscape of individual rights and obligations, binding parties with the force and effect of law . . . ." *Xi'an Metals*, 50 F.4th at 106 (quoting *Stupp*, 5 F.4th at 1352) (holding that agency action was policy statement, not legislative rule); *see also Paralyzed Veterans of Am. v. West*, 138 F.3d 1434, 1436 (Fed. Cir. 1998); *Animal Legal Def. Fund v. Quigg*, 932 F.2d 920, 927 (Fed.

Cir. 1991). "The most important factor" in determining whether an agency action is a legislative rule is "the actual legal effect (or lack thereof) of the agency action in question on regulated entities." *National Mining Ass'n*, 758 F.3d at 252.

The Director's instructions embodied in the *Fintiv* factors do not alter the legal rights or obligations of private parties. The factors are not directed towards private parties at all. Instead, they are considerations that the Director has deemed relevant to the exercise of her discretionary authority to deny institution in cases involving parallel district court proceedings. And because "Congress has committed the [institution] decision . . . to the Director's unreviewable discretion," *Arthrex*, 594 U.S. at 8-9, no party has a right to have the Director exercise that authority either for or against institution. Nor does the Director's exercise of that authority—whether directly or through delegation—alter legal rights or obligations. If the Director or her delegatee (the Board) declines to institute, both the patent owner's rights and the petitioner's claims of invalidity remain unaffected. If the Director or the Board decides to institute an IPR, the "actual legal effect" comes not from institution, but rather from a final written decision by the Board, which can either cancel patent claims or estop an IPR petitioner from raising claims of invalidity in future litigation. *See* 35 U.S.C. §§ 315(e), 318(a).

Moreover, the *Fintiv* factors neither establish nor modify any legal requirements. They do not "purport[] to impose legally binding obligations or

prohibitions on regulated parties . . . that would be the basis for an enforcement action for violations of those obligations or requirements." *National Mining Ass'n*, 758 F.3d at 251. Nor do the factors "set[] forth legally binding requirements for a private party to obtain a permit or license." *Id.* at 251-52. Instead, the Director has only provided factors to be considered as the Board exercises her unreviewable discretion. Upon consideration of those factors, which leave the Board ample discretion to determine how the factors should be balanced in individual cases, the Board remains free to use that delegated discretion to either grant or deny a statutorily sufficient IPR petition after "a 'balanced assessment of all relevant circumstances of the case, including the merits.'" Appx1052; *see* Appx19; *infra* pp. 37-42. And the Director remains free to change any institution decision or to change or revoke the *Fintiv* factors. *See infra* pp. 35-37. The factors do not alter the statutory prerequisites for institution, nor do they alter the substantive standards by which private rights and obligations will ultimately be determined—that is, the standards for patentability.

**2. Plaintiffs fail to demonstrate that the Director's instructions bind the public**

Plaintiffs contend (at 34) that the *Fintiv* factors are nonetheless a legislative rule because they impact the public by "reduc[ing] the likelihood that IPR will be instituted when there is parallel litigation." That argument misunderstands the law distinguishing legislative rules from policy statements and interpretive rules.

a. The APA expressly provides that a "statement of policy" may "affect[] a member of the public" and be "relied on, used, or cited as precedent by an agency against a party," so long as it was made publicly available or there was actual notice. 5 U.S.C. § 552(a)(2). Thus, the express text of the APA contradicts plaintiffs' argument that a policy statement cannot have an impact on the public.

Courts have likewise held that agency actions lacking legal consequences do not constitute legislative rules even if they have a practical impact on private parties. In *Lincoln*, for example, the Indian Health Service issued a memorandum stating that it was "terminati[ng] . . . all direct clinical services to children in the Albuquerque, Navajo and Hopi reservation service areas" through one of its programs. 508 U.S. at 188 (quotation marks omitted). The Supreme Court concluded that "[w]hatever else may be considered a 'general statemen[t] of policy,' the term surely includes an announcement like the one before us," *id.* at 197 (second alteration in original), even though "discontinuing the Program and reallocating its resources" meant "that [the] respondents would no longer receive certain services," *id.* at 196, 198. The Court noted that the decision did not alter legal standards, "as distinct from affecting the availability of services in a particular geographic area." *Id.* at 198.

The Ninth Circuit has similarly rejected the argument that an agency action "cannot constitute a general statement of policy under section 553 because" the

statement "diminishes the likelihood that [the plaintiff] and other similarly situated aliens will be granted" a discretionary immigration status "and eliminates their opportunity to obtain judicial review." *Mada-Luna v. Fitzpatrick*, 813 F.2d 1006, 1016 (9th Cir. 1987). The court explained that it had "expressly 'rejected the argument that, for the purposes of imposing notice-and-comment requirements on [an] agency for a particular rule, [courts should] look to the "substantial impact" of the rule.'" *Id.* (alterations in original) (quoting *Alcaraz v. Block*, 746 F.2d 593, 613 (9th Cir. 1984)). Likewise, in *National Mining Association*, the D.C. Circuit held that U.S. Environmental Protection Agency (EPA) guidelines "instructi[ng] . . . EPA staff to recommend limitations on mining projects" constituted a general statement of policy even though "the Final Guidance may signal likely future permit denials by EPA" and "regulated parties may feel pressure to voluntarily conform their behavior because the writing is on the wall about what will be needed to obtain a permit." 758 F.3d at 250, 252, 253.

The *Fintiv* factors are no different. The Director's unreviewable discretion to institute IPR proceedings is analogous to the discretionary authority to terminate the provision of services in *Lincoln*, to grant deferred action status in *Mada-Luna*, or to review mining-permit applications in accordance with specified criteria in *National Mining Association*. The fact that the challenged statements in each case bear on how the agency will exercise its discretion does not mean that they "alter

the landscape of individual rights and obligations, binding parties with the force and effect of law." *Stupp*, 5 F.4th at 1352.

Indeed, any new or changed policy is presumably intended to have some impact on the agency's future decisions, and the purpose of publishing the policy is to inform the public of what that impact may be. *See Professionals & Patients for Customized Care v. Shalala*, 56 F.3d 592, 600 (5th Cir. 1995) ("[A]ll statements of policy channel discretion to some degree—indeed, that is their purpose."). But under plaintiffs' argument, that precise impact would mean that the statement must be promulgated through notice-and-comment rulemaking, effectively eliminating the exception to the notice-and-comment requirement for general statements of policy.

That position cannot be squared with longstanding administrative practice. Suppose the Attorney General were to issue guidelines instructing Department of Justice officials to prioritize prosecution of violent crimes—a classic statement "of the manner in which the agency proposes to exercise a discretionary power." *Stupp*, 5 F.4th at 1351 (quoting *Lincoln*, 508 U.S. at 197). The natural outcome of such a statement would be to increase the likelihood that violent offenders would be subject to criminal prosecution. Under plaintiffs' theory, those guidelines would be invalid because they were not the result of notice-and-comment rulemaking, but that result cannot be correct. The Department of Justice has often issued such

guidelines, with the potential to impact private parties, without any court suggesting they run afoul of the APA's rulemaking requirements. *See, e.g.*, U.S. Dep't of Justice, *Justice Manual* § 9-2.031 (Jan. 2020) (setting out "Petite Policy" which "establishes guidelines for the exercise of discretion by appropriate officers of the Department of Justice in determining whether to bring a federal prosecution based on substantially the same act(s) or transactions involved in a prior state or federal proceeding"); *id.* § 9-27.240 (June 2023) (setting out factors government attorneys should weigh when "determining whether prosecution should be declined because the person is subject to effective prosecution in another jurisdiction").

b. Plaintiffs cite cases stating that agency actions that change the substantive standard for adjudicating private parties' rights and obligations require notice and comment, but those cases actually support the government's position. For example, plaintiffs cite (at 32, 37) *In re Chestek PLLC*, 92 F.4th 1105 (Fed. Cir. 2024), *cert. denied*, No. 23-1217, 2024 WL 4426594 (U.S. Oct. 7, 2024). *Chestek* held that "[t]he key distinction here is . . . not whether" the agency action "affects a party's ability to obtain a trademark, but whether the requirement affects the substantive trademark standards by which the [USPTO] examines a party's application." *Id.* at 1109. Such cases are consistent with this Court's precedent holding that legislative rules "bind[] parties with the force and effect of law." *Stupp*, 5 F.4th at 1352. If an agency action alters legal standards for adjudicating

rights and obligations, then that action carries the force of law. The Director's *Fintiv* instructions, in contrast, do not affect the substantive standards by which the USPTO ultimately determines the rights and obligations of patentees or IPR petitioners. They do not affect the law the Board applies in issuing a final written decision. Instead, they affect only the exercise of the Director's unreviewable discretion to institute an IPR, which is akin to an agency's discretion to initiate enforcement proceedings or to commence a prosecution. *See also, e.g.*, *Chestek*, 92 F.4th at 1109-10 ("The critical fact here, however, is that the [challenged] rules did not change the *substantive standards* by which the [Federal Communications Commission] evaluates license applications, *e.g.*, financial qualifications, proposed programming, and transmitter location. This fact is fatal to [the plaintiff]'s claim." (first alteration in original) (emphasis omitted) (quoting *JEM Broad. Co. v. FCC*, 22 F.3d 320, 327 (D.C. Cir. 1994))).

Plaintiffs likewise err in relying (at 38-39) on *W.C. v. Bowen*, 807 F.2d 1502 (9th Cir.), *amended on denial of reh'g*, 819 F.2d 237 (9th Cir. 1987). In *W.C.*, the Department of Health and Human Services enacted a program that targeted Administrative Law Judges (ALJs) for additional review based on how frequently each ALJ allowed Social Security disability benefits. *Id.* at 1503-04. The court held that the program was a legislative rule based in part on a district court factual finding that the program "was designed to alter ALJ decisions" and "caused those

judges to deny benefits in close cases where benefits might previously have been granted." *Id.* at 1505. In other words, the program was intended to substantively alter the agency's adjudication of claimants' rights to cash benefits under the statutory standards of the Social Security Act. Here, in contrast, the *Fintiv* factors do not seek to alter the ultimate adjudication of patentability under the Patent Act. Thus, to the extent this out-of-circuit decision retains persuasive value, it does not apply here.

Plaintiffs' reliance on the out-of-circuit decision in *Pickus v. U.S. Board of Parole*, 507 F.2d 1107, 1113 (D.C. Cir. 1974), is similarly misplaced. To begin, *Pickus* predates the Supreme Court's description of policy statements in *Lincoln* as announcing a manner of exercising a discretionary power, which this Court has correctly since applied. *See, e.g.*, *Stupp,* 5 F.4th at 1351; *see also American Hosp. Ass'n v. Bowen*, 834 F.2d 1037, 1047 (D.C. Cir. 1987) (noting that "[o]ver time, [the D.C. C]ircuit . . . has gradually shifted focus from asking whether a given procedure has a 'substantial impact' on parties" in determining whether a rule is legislative (quoting *Pickus*, 507 F.2d at 1112)). In any event, even plaintiffs read that decision to have found a rule substantive because "the rule was 'calculated to have a substantial effect on ultimate parole decisions.'" Appellants' Br. 38 (quoting *American Hosp. Ass'n*, 834 F.2d at 1046). In other words, the D.C. Circuit relied on the conclusion that the "selection of parole eligibility guidelines

had the intent and effect of changing substantive outcomes" in determinations regarding inmates' release from incarceration. *American Hosp. Ass'n*, 834 F.2d at 1048 (describing *Pickus*). The institution decision to which the *Fintiv* factors are directed, in contrast, involves no ultimate determination as to private parties' rights.

Finally, even if this Court were to adopt a "substantial effect" test of the sort plaintiffs propose (at 39), that test would not be satisfied here. As discussed further below, even as to the limited question of whether an IPR should be instituted, the *Fintiv* factors do not dictate outcomes; they leave the Board with broad discretion to determine whether institution is warranted in a given case and leave the Director free to reverse any decision. *See infra* pp. 35-42. Moreover, those factors are applicable only to the subset of cases involving parallel district court litigation and, even then, affect only the forum in which patentability questions will be litigated (the Board or in district court). The *Fintiv* factors have no application to the ultimate patentability determination. Thus, any incidental effects on patent rights flowing from the Director's guidance regarding the Board's exercise of her discretion are far too remote and attenuated to constitute a "substantial effect."

c. Plaintiffs rely (at 36) on this Court's prior holding in this case that Apple had standing to pursue its notice-and-comment challenge. In assessing standing, the Court found that it was not unduly conjectural "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." *Apple*, 63 F.4th at 17. Plaintiffs contend that this holding establishes a legal effect sufficient to make the *Fintiv* factors a legislative rule, but that argument lacks merit.

The question of whether a plaintiff has adequately alleged harm to a "legally protected interest" to establish standing, *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992), is entirely distinct from the question of whether an agency action "alter[s] the landscape of individual rights and obligations, binding parties with the force and effect of law," *Stupp*, 5 F.4th at 1352. If the rule were otherwise, any plaintiff who established standing for a notice-and-comment challenge to a general statement of policy would automatically prevail on the merits of their challenge, because the existence of standing would mean that the rule has the force and effect of law. Moreover, all of the cases in which courts have upheld agency actions as general statements of policy would be wrongly decided, absent unidentified standing problems, because the existence of standing would mean that the plaintiff should have prevailed on the merits. That result cannot be correct.

Nor is there any suggestion in this Court's prior decision that its standing holding resolved the notice-and-comment claim here. The Court rested its holding

on Apple's liability for infringement, emphasizing that Apple's "injury is concrete and legally protected, because of the infringement suit." *Apple*, 63 F.4th at 17. To the extent the Court discussed the "denial of the benefits of IPRs," it was only because they were "linked to the concrete interest possessed by an infringement defendant." *Id.*; *see also Summers v. Earth Island Inst.*, 555 U.S. 488, 496 (2009) (A "deprivation of a procedural right without some concrete interest that is affected by the deprivation—a procedural right *in vacuo*—is insufficient to create Article III standing."); *ABS Glob., Inc. v. Cytonome/ST, LLC*, 984 F.3d 1017, 1024-25 (Fed. Cir. 2021) (concluding that an IPR petitioner who lost on merits but did not face infringement suit lacked standing to seek judicial review). The Court found standing because the panel believed that the *Fintiv* factors would plausibly "cause more denials of institution than might otherwise occur," which in turn would reduce the likelihood of Apple litigating patentability questions in IPRs, which in turn could increase the likelihood that Apple would ultimately face infringement liability. *Apple*, 63 F.4th at 17. But while that chain of practical effects and predictions relating to infringement liability was sufficient for this Court to find standing, the standard here is whether the *Fintiv* factors "alter the landscape of individual rights and obligations, binding parties with the force and effect of law." *Stupp*, 5 F.4th at 1352. This Court's prior decision does not speak to that question.

### 3. Plaintiffs misunderstand and err in relying on the binding effect of the Director's instructions within the agency

Plaintiffs argue next (at 42) that the Director was required to instruct the Board to consider the *Fintiv* factors through notice-and-comment rulemaking because those instructions bind the Board and remove its discretion. That argument misunderstands both the law and the nature of the factors.

a. Plaintiffs err in contending that an agency official's duty to follow guidance issued by an agency head turns any such guidance into a legislative rule. In *Splane v. West*, 216 F.3d 1058 (Fed. Cir. 2000), this Court expressly considered and rejected the argument 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." *Id.* at 1064. Reviewing Supreme Court precedent, this Court found that a rule does not have the "force and effect of law" merely because it is "binding on agency officials insofar as any directive by an agency head must be followed by agency employees." *Id.* Instead, the "reference to a regulation having the 'force and effect of law' is to the binding effect of that regulation on tribunals *outside* the agency, not on the agency itself." *Id.* (looking to whether an agency general counsel's opinion had "any binding effect whatsoever outside the agency, on the [Court of Appeals for Veterans Claims], or on this court"); *see also Coalition for Common Sense in Gov't Procurement v. Secretary of Veterans Affairs*, 464 F.3d 1306, 1317 (Fed. Cir. 2006) (explaining that "a substantive rule has the 'force and

effect of law'" because "[t]he change in existing law affected by a substantive rule is binding not only within the agency, but is also binding on tribunals outside the agency"), *overruled on other grounds en banc by National Org. of Veterans' Advocates, Inc. v. Secretary of Veterans Affairs*, 981 F.3d 1360 (Fed. Cir. 2020); 1 Richard J. Pierce, Jr., *Administrative Law Treatise* § 6.3, at 420 (5th ed. 2010) ("[C]ourts distinguish between rules and general statements of policy based on whether the agency statement has binding effect on members of the public.").[3]

To the extent Ninth Circuit precedent is persuasive, that court followed a similar approach in *Erringer v. Thompson*, 371 F.3d 625 (9th Cir. 2004). *Erringer* held that the challenged rules were not legislative because, although they "b[ound] . . . Medicare contractors," "our query is whether the rule has a binding effect 'on

[3] In light of such language, it is unclear why the district court declined to rely on *Splane* on the view that it "did not hold . . . that a rule that binds only the agency may never be a substantive rule." Appx20. But even the district court's more limited reading of *Splane*—that binding effects on the agency alone do not suffice to make a rule legislative—is sufficient to reject plaintiffs' argument insofar as they contend that the Director's instructions to consider the *Fintiv* factors are a legislative rule simply because the Board is required to follow those instructions and the instructions channel the Board's discretion.

The district court also cited *Disabled American Veterans v. Secretary of Veterans Affairs* as taking a different approach, Appx20, but that decision expressly stated that "[t]o amount to substantive rulemaking with the force and effect of law, the rule's change in existing law must be 'binding not only within the agency, but [ ] binding on tribunals outside the agency.'" 859 F.3d 1072, 1077 (Fed. Cir. 2017) (second alteration in original) (quoting *Coalition for Common Sense*, 464 F.3d at 1317). In any event, that panel decision could not overrule this Court's prior precedential decision in *Splane*.

tribunals *outside* the agency,'" and "[t]o the extent that the contractors administer Medicare benefits under the supervision of [the Centers for Medicare & Medicaid Services], they are not 'tribunals outside the agency.'" *Id.* at 631 (quoting *Hemp Indus. Ass'n v. DEA*, 333 F.3d 1082, 1088 (9th Cir. 2003)).

This approach is consistent with the purposes of the APA. "An agency's own attempt to regularize and control its own prosecutorial discretion certainly goes a long way toward eliminating the randomness and arbitrariness of individual enforcement decisions by individual agency personnel," and by publishing such policies, "the goals of openness, predictability, and fairness are significantly advanced." Richard M. Thomas, *Prosecutorial Discretion and Agency Self-Regulation:* CNI v. Young *and the Aflatoxin Dance*, 44 Admin. L. Rev. 131, 152 (1992). The contrary approach—prohibiting senior officials from announcing guidelines that agency employees must follow unless the officials undergo notice-and-comment rulemaking—"would create horrible incentives" to either forgo such instructions or refuse to publicly disclose them. 1 Pierce, *supra*, § 6.3, at 424.

Requiring notice-and-comment rulemaking for all binding instructions would also encumber the "clear 'lines of accountability demanded by the Appointments Clause,'" which "allow[] the President to 'attribute [any] failings to those whom he can oversee.'" *In re Palo Alto Networks, Inc.*, 44 F.4th at 1375 (second alteration in original) (quoting *Arthrex*, 594 U.S. at 16-17). The Patent

Act makes the Director "responsible for providing policy direction and management supervision for the [USPTO]" and for performing her "duties in a fair, impartial, and equitable manner." 35 U.S.C. § 3(a)(2)(A). The Director's ability to perform these duties would be significantly hampered if she could not issue guidelines and memoranda directing the officials under her supervision in the performance of their duties, but instead had to direct her many and various subordinates solely by means of notice-and-comment rulemaking—a process that typically takes more than a year per rule to complete, *see* Anne Joseph O'Connell, *Agency Rulemaking and Political Transitions*, 105 NW. U. L. Rev. 471, 513 (2011). Such circumscription of the Director's fundamental tools of management would muddy the President's and the public's ability to hold the Director accountable for the USPTO's performance of its duties.

b. Even if this Court were to consider binding effects of the Director's guidance within the agency, plaintiffs profoundly mistake those effects.

First, although the Director respects the value of precedential decisions, which reflect her own views of considerations relevant to the institution decision, the Director herself is not bound by the *Fintiv* factors. The Director can and does exercise her own discretion "in individual cases despite the delegation" of her institution authority to the Board by, for example, rehearing institution decisions through Director Review. *In re Palo Alto Networks, Inc.*, 44 F.4th at 1375 & n.3;

*see* USPTO, *Revised Interim Director Review Process*, https://perma.cc/V3PV-MXJW; Rules Governing Director Review of Patent Trial and Appeal Board Decisions, 89 Fed. Reg. 79,744 (Oct. 1, 2024); USPTO, *Status of Director Review Requests*, *supra* (listing cases under "Institution" in which the Director has exercised her review authority over Board institution decisions both at the request of parties and *sua sponte*). And when the Director makes or reviews an institution decision herself, she can not only decide how the *Fintiv* factors should apply in the particular case, but also make her decision precedential so as to alter their application in the future. The Director can further de-designate *Fintiv* as precedential, designate other Board decisions as precedential, or issue Director guidance altering the factors as she sees fit. Such retained discretion by the head of the agency undermines any assertion that a policy binds the agency in a manner that makes it a legislative rule. *See Erringer*, 371 F.3d at 631 n.10 (noting that even if the plaintiff challenged certain guidelines, "they are only binding in the initial adjudication and during the preliminary appeals stages"); *Warder v. Shalala*, 149 F.3d 73, 82 (1st Cir. 1998) ("Of course, a rule with the force and effect of law—binding not only the agency and regulated parties, but also the courts—is by definition a substantive rule. However, a rule may lack this force and still bind agency personnel."); *American Hosp. Ass'n*, 834 F.2d at 1047 (noting that the court had previously relied on agency "assertions . . . that the Secretary retained

discretion to supersede [the challenged] guidelines in particular cases" to find a policy statement). The *Fintiv* factors accordingly do not bind the agency and lack the "force and effect of law."

Second, the Director has not required the Board to grant or deny institution in any particular circumstance; the Director has simply instructed the Board to consider a list of non-exclusive factors when it exercises the Director's institution discretion in cases involving parallel district court proceedings. *See* Appx1052 (explaining that factors are to be "weighed as part of a 'balanced assessment of all relevant circumstances of the case, including the merits'"); Appx1053 (expressly instructing that "in 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"); Appx1060 (explaining that "weighing the degree of overlap [with district-court claims] is highly fact dependent"); Appx1061 (noting that the sixth factor incorporates all "other circumstances that impact the Board's exercise of discretion, including the merits"). As the district court explained, "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." Appx22. "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." Appx21.

Given as much, the Director's challenged instructions do not have the type of binding effects other circuits have at times looked to in finding a legislative rule. As the Ninth Circuit explained, a general statement of policy "provides guidance to agency officials in exercising their discretionary powers while preserving their flexibility and their opportunity to make 'individualized determination[s].'" *Mada-Luna*, 813 F.2d at 1013 (alteration in original) (emphasis omitted) (quoting *Guardian Fed. Sav. & Loan Ass'n v. Federal Sav. & Loan Ins. Corp.*, 589 F.2d 658, 667 (D.C. Cir. 1978)) (upholding guidance specifying five factors for immigration officials to consider in determining whether to grant an alien deferred action status). In her *Fintiv*-factor instructions, the Director left the Board room to make precisely those kinds of individualized determinations, eschewing any "'*binding norm*' that 'so fills out the statutory scheme that upon application one need only determine whether a given case is within the rule's criterion.'" *Id.* at 1014 (quoting *Ryder Truck Lines, Inc. v. United States*, 716 F.2d 1369, 1377 (11th Cir. 1983)); *see also Professionals & Patients for Customized Care*, 56 F.3d at 597-601 (concluding that an FDA guidance document identifying nine factors "the agency will consider" "[i]n determining whether to initiate" an enforcement action

was a policy statement because the guidance did not "draw a 'line in the sand' that, once crossed, removes all discretion from the agency").

Plaintiffs insist that despite the clarity with which the Director expressed that her *Fintiv* instructions are not "outcome determinative," Appx22, those instructions are nonetheless "binding," foreclosing the Board's use of "its own judgment" and requiring the Board to deny institution in light of "certain facts." Appellants' Br. 43, 46-47; *see also* Appellants' Br. 48, 52. As discussed, that assertion gravely misunderstands the *Fintiv* factors, which are not a checklist that leads to a deterministic result. Indeed, the sixth factor expressly calls for balancing efficiency considerations relating to parallel litigation against all "other circumstances that impact the Board's exercise of discretion, including the merits." Appx1061. Thus, even if the five factors relating to parallel litigation point toward denial of institution, the Board can still decide to institute based on other circumstances.

Plaintiffs fare no better in relying (at 43, 51) on the Director's instruction that the Board consider certain factors and weigh them either for or against institution. A requirement to take into account certain factors as part of a discretionary balancing exercise does not create the type of binding norm within an agency that some courts have found creates a legislative rule. *See Mada-Luna*, 813 F.2d at 1008 n.1 ("[T]he following factors . . . should be considered . . . ."); 

*Professionals & Patients for Customized Care*, 56 F.3d at 597 (addressing guidance establishing factors "the agency *will* consider" but concluding that despite "the mandatory tone of the factors," they "afford[] an opportunity for individualized determinations" (emphasis added)).

Nor are plaintiffs right (at 44, 48-51) that the *Fintiv* factors are nonetheless deterministic in practice. Plaintiffs suggest (at 44) that the Board has never "institut[ed] IPR even where the Rule's factors would lead to denial." But the sixth *Fintiv* factor calls for consideration of all "other circumstances that impact the Board's exercise of discretion, including the merits." Appx1061. It therefore would make no sense for the Board to hold that the six *Fintiv* factors weigh in favor of denial but then institute because some other compelling circumstance (which should have been reflected in the sixth factor) outweighed the *Fintiv* factors. And to the extent plaintiffs mean that the Board has never reached a decision contrary to the result called for by the first five factors, they are incorrect. *See, e.g.*, *IBM Corp. v. Digital Doors, Inc.*, No. IPR2023-00973, 2024 WL 209905, at *11 (P.T.A.B. Jan. 19, 2024) ("As discussed above, we determine that *Fintiv* factors 1-5 weigh in favor of discretionary denial of institution. Under factor 6, however, we determine that the Petition presents a compelling, meritorious challenge to patentability of claim 1."); *Apple Inc. v. Sonrai Memory Ltd.*, No. IPR2023-00819, 2023 WL 8099286, at *5-6 (P.T.A.B. Nov. 21, 2023).

Moreover, the Board has exhibited flexibility in applying the *Fintiv* criteria, contrary to plaintiffs' contention (at 49) that the Board is required to "march[] through the six factors in a rigid fashion." For example, in *Sotera Wireless, Inc. v. Masimo Corp.*, No. IPR2020-01015, 2020 WL 7049372, at *7 (P.T.A.B. Dec. 1, 2020), the Board considered a novel circumstance under factor four, "overlap between issues raised in the petition and in the parallel proceeding." Although the issues indeed overlapped and the factor would normally have tended to weigh against institution, the Board found that the particular circumstances of the case called for a different result given the petitioner's case-specific stipulation in district court to forgo grounds available in the IPR, if instituted. *Id.*

The Board has also taken into account considerations besides the merits under the sixth factor. For example, in *Kavo Dental Technologies, LLC v. Osseo Imaging, LLC*, No. IPR2020-00671, 2020 WL 3092621, at *10-11 (P.T.A.B. June 10, 2020), the Board considered which party was at fault for "prejudice" the patent owner allegedly suffered due to delay in filing the IPR petition and whether the "Patent Owner has not come forward with clean hands." Similarly, in *TCO AS v. NCS Multistage Inc.*, No. PGR2020-00077, 2021 WL 662165, at *8 (P.T.A.B. Feb. 18, 2021), the Board considered "[d]iscovery [i]ssues" and whether the district court was the better forum to conduct extra-territorial or third-party discovery in evaluating the sixth *Fintiv* factor for a post-grant review petition. And in *Samsung*

*Electronics Co. v. California Institute of Technology*, No. IPR2023-00131, 2023 WL 5166111, at *9 (P.T.A.B. May 4, 2023), the Board considered "the history of *inter partes* reviews against the [challenged] patent and its related patents."

### C. The Purposes of the APA and the AIA Support the Use of Policy Statements in This Context

The Director's *Fintiv* instructions are also consistent with the purposes of the APA and the AIA. As explained, the AIA "committed the [IPR institution] decision . . . to the Director's unreviewable discretion." *Arthrex*, 594 U.S. at 8-9. Congress presumably did so to maximize the Director's flexibility to allocate IPR resources in a manner that best serves the patent system and promotes efficiency. *See* H.R. Rep. No. 112-98, pt. 1, at 40 (explaining that Congress sought to "establish a more efficient and streamlined patent system that will improve patent quality and limit unnecessary and counterproductive litigation costs"). At the same time, delegation was inevitable because Congress "necessarily assum[ed] 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." *Apple*, 63 F.4th at 7 (quoting *Ethicon Endo-Surgery, Inc. v. Covidien LP*, 812 F.3d 1023, 1032 (Fed. Cir. 2016)).

To accomplish Congress's objectives, the Director must be able to direct the Board as to how to exercise her delegated discretion. Use of policy statements that the APA specifically exempts from notice-and-comment requirements allows the

Director to adapt her instructions as circumstances and the needs of the patent system change. Indeed, one of Congress's primary objectives in enacting the AIA was "to accommodate changes in the economy and the litigation practices in the patent realm." H.R. Rep. No. 112-98, pt. 1, at 38-39. Consistent with that goal, the Director has repeatedly issued and modified guidance to the Board as needed based on the needs of the patent system and the USPTO. Thus, for example, in response to concerns that trial dates the Board considered under *Fintiv* were inaccurate, the Director instructed the Board to consider, if presented by a party, "the median time from filing to disposition of the civil trial for the district in which the parallel litigation resides." *See* June 2022 Guidance 3, 8-9. And by publishing those policies, the Director makes it easier for the public to understand how the agency is likely to exercise its discretion. "[T]he publication of a general statement of policy facilitates long range planning within the regulated industry and promotes uniformity in areas of national concern." *Pacific Gas & Elec. Co. v. Federal Power Comm'n*, 506 F.2d 33, 38 (D.C. Cir. 1974). Plaintiffs' theory that the Director is limited to notice-and-comment rulemaking to effectuate and publish policies regarding the use of her own discretion fails to account for either the APA's contemplation of policy statements or the Director's need to respond nimbly to the changing needs of the patent system.

## III. THE AIA DOES NOT REQUIRE THE USPTO DIRECTOR TO ISSUE INSTRUCTIONS TO DELEGATEES EXERCISING HER DISCRETION THROUGH NOTICE-AND-COMMENT RULEMAKING

Plaintiffs' final argument (at 53-55) is that the AIA independently required the Director to promulgate the *Fintiv* instructions to the Board through notice-and-comment rulemaking. Plaintiffs rely on 35 U.S.C. § 316(a), which states that "[t]he Director shall prescribe regulations" on a variety of topics, including regulations "establishing and governing inter partes review under this chapter and the relationship of such review to other proceedings under this title," such as district court infringement suits. 35 U.S.C. § 316(a)(4). They contend (at 53) that Congress's use of the term "regulations" means legislative rules promulgated through notice-and-comment rulemaking. And they infer that Congress intended to preclude the Director from using any other means for articulating policies addressing the topics in section 316(a).

Plaintiffs' argument is wrong on every front. "Regulations" does not always mean legislative rules enacted through notice-and-comment rulemaking. "Courts and Congress treat the terms 'regulation' and 'rule' as interchangeable and synonymous." *National Treasury Emps. Union v. Weise*, 100 F.3d 157, 160 (D.C. Cir. 1996). Thus, when courts "speak of an agency's 'regulation'—a term nowhere mentioned in the Administrative Procedure Act—[courts] have in mind what the APA defines as a 'rule,'" a definition that includes general statements of policy.

*Id.*; *see* 5 U.S.C. § 551(4); *see also Azar v. Allina Health Servs.*, 587 U.S. 566, 578 (2019) ("[B]y 1987 courts had commonly referred to *both* substantive and interpretive rules as 'regulations.'").

This Court has likewise held that the USPTO rulemaking authority in 35 U.S.C. § 2(b)(2)—which provides that the USPTO "may establish *regulations* . . . in accordance with section 553 of title 5," 35 U.S.C. § 2(b)(2) (emphasis added)—does not necessarily require the USPTO to proceed by notice-and-comment rulemaking. *Chestek*, 92 F.4th at 1110. The Court held that, notwithstanding section 2(b)(2)'s use of the term "regulations" and its express reference to the notice-and-comment requirements of 5 U.S.C. § 553, the statute preserved the "exceptions to notice-and-comment rulemaking contained within § 553(b)," *id*, which includes the exception for "interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice," 5 U.S.C. § 553(b)(A). Thus, to the extent a rule issued pursuant to section 2(b)(2) falls within a notice-and-comment exception, that section's reference to "regulations" does not independently require notice-and-comment rulemaking.

Moreover, although section 316(a) gives the Director the power and duty to enact regulations on certain topics, it does not impliedly repeal or limit the Director's other statutory authorities to issue rules and guidance. The Director properly issued the challenged *Fintiv* instructions as an exercise of her power to

"provid[e] policy direction and management supervision for the Office," 35 U.S.C. § 3(a)(2). Nothing in section 316(a) suggests that Congress intended to bar the Director from exercising her section 3(a)(2) supervisory authority whenever the issue falls within the scope of a topic listed in section 316(a). Given that section 316(a)(4) requires regulations "establishing and governing inter partes review," plaintiffs' position would effectively prevent the Director from exercising supervisory authority over the conduct of IPR. The statute does not require that result.

## CONCLUSION

For the foregoing reasons, the Court should affirm the judgment of the district court.

Respectfully submitted,

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## CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limit of Federal Circuit Rule 32(b)(1) because it contains 10,822 words. This brief also complies with the typeface and type-style requirements of Federal Rule of Appellate Procedure 32(a)(5)-(6) because it was prepared using Microsoft Word in Times New Roman 14-point font, a proportionally spaced typeface.

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