

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

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

v.

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

2022-1249

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: March 13, 2023

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

TARANTO, *Circuit Judge*.

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

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

the lone surviving challenge. Like the district court, we do not reach the merits of that challenge.

I

A

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

For the Director to institute, certain preconditions must be met. One prerequisite, for all petitions, is the crossing of a merits “threshold”: “The Director may not authorize an [IPR] to be instituted unless the Director determines that the information presented in the petition . . . and any response . . . shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.” 35 U.S.C. § 314(a). Another prerequisite, applicable in the predictably common situation where the patent owner has already sued the petitioner (or a real party in interest or privy) for infringement of the patent, is compliance with a timing limit: The petition must be filed within one year after service of the infringement complaint. *Id.* § 315(b).

Even when such requirements are met, however, the statute uses no language commanding institution. “The Director is permitted, but never compelled, to institute an IPR[, a]nd no petitioner has a right to such institution.”

Mylan Laboratories Ltd. v. Janssen Pharmaceutica, N.V., 989 F.3d 1375, 1382 (Fed. Cir. 2021). The Supreme Court explained in *SAS Institute, Inc. v. Iancu*: “§ 314(a) invests the Director with discretion on the question *whether* to institute review.” 138 S. Ct. 1348, 1356 (2018); *see also Cuozzo Speed Technologies, LLC v. Lee*, 579 U.S. 261, 273 (2016) (citing § 314(a) and stating: “no mandate to institute review”).

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

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

S. Ct. at 1372–73 (relied on by *Arthrex* for above statement); *Cuozzo*, 579 U.S. at 271–75.²

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

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

141 S. Ct. at 1980 (“The Director . . . controls the decision whether to institute inter partes review . . .”).

B

The one-year time limit of § 315(b), already mentioned, makes clear that Congress recognized the likelihood of parallel pending proceedings in the PTO and in the courts. Being sued for infringement provides a defendant a distinct motivation to seek cancellation, through an IPR, of patent claims asserted against it in court.³ The existence of such overlapping proceedings raises self-evident issues of efficiency and interbranch relations. But Congress generally left the two branches to exercise their available discretion to address such issues. Congress enacted no provision for this scenario that directs the court to stay its case in light of a pending request for IPR or an instituted IPR. Nor did Congress enact a provision prescribing how the Director is to address such an overlapping pending court case in exercising the discretion whether to institute an IPR.

1

The Director addressed this topic in 2019 and 2020 by exercising the authority to “designate[] past PTAB decisions as ‘precedential’ for future panels.” *Arthrex*, 141 S. Ct. at 1980 (citing § 316(a)(4), quoted *supra* n.2, and § 3(a)(2)(A), which states that “[t]he Director shall be

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

responsible for providing policy direction and management supervision for the Office”); *see* Trial and Appeal Board, Standard Operating Procedure 2 (Revision 10) at 1–2 (Standard Procedure 2). Specifically, the Director designated as precedential, and hence binding on Board panels (Standard Procedure 2 at 11), two Board decisions that had denied IPR petitions: *NHK Spring Co. v. Intri-Plex Technologies, Inc.*, IPR2018-00752, 2018 WL 4373643 (P.T.A.B. Sept. 12, 2018) (designated precedential on May 7, 2019), and *Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, 2020 WL 2126495 (P.T.A.B. Mar. 20, 2020) (designated precedential on May 5, 2020). Both decisions address the role, in the decision whether to institute an IPR, of the pendency of district-court infringement litigation involving the same patents. The decisions, designated as precedential, constitute instructions from the Director regarding how the Board is to exercise the Director’s institution discretion.

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

1. whether the court granted a stay or evidence exists that one may be granted if a proceeding is instituted;

2. proximity of the court's trial date to the Board's projected statutory deadline for a final written decision;
3. investment in the parallel proceeding by the court and the parties;
4. overlap between issues raised in the petition and in the parallel proceeding;
5. whether the petitioner and the defendant in the parallel proceeding are the same party; and
6. other circumstances that impact the Board's exercise of discretion, including the merits.

2020 WL 2126495, at *2. The Board explained how certain facts on the enumerated topics tend to weigh for or against institution, *id.* at *3–7, and how the “concerns of inefficiency and the possibility of conflicting decisions were particularly strong” in *NHK*, *id.* at *5. The Board stated generally that the factors “relate to whether efficiency, fairness, and the merits support the exercise of authority to deny institution in view of an earlier trial date in the parallel proceeding,” *id.* at *3. The Board summarized: “[I]n evaluating the factors, the Board takes a holistic view of whether efficiency and integrity of the system are best served by denying or instituting review.” *Id.*

2

The above instructions (the *Fintiv* instructions) were the subject of this case when it was filed in district court, when it was decided by the district court, and when plaintiffs filed their brief as appellants in this court. Thereafter, on June 21, 2022, the Director updated the instructions. On that day, having issued a request for comments, *see* Request for Comments on Discretion to Institution Trials Before the Patent Trial and Appeal Board, 85 Fed. Reg. 66,502 (Oct. 20, 2020), and having received hundreds of

comments, the Director announced (without publication in the Federal Register) “several clarifications” to the *Fintiv* instructions “under the Director’s authority to issue binding agency guidance to govern the PTAB’s implementation of various statutory provisions.” Memorandum from PTO Director to PTAB, Interim Procedure for Discretionary Denials in AIA Post-Grant Proceedings with Parallel District Court Litigation at 2–3 (June 21, 2022) (*June 2022 Memo*).

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

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

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

C

On August 31, 2020, Apple and three other companies filed suit in the Northern District of California, seeking to challenge the *Fintiv* instructions on three grounds under the APA: (1) that the Director acted contrary to the IPR provisions of the patent statute, see 5 U.S.C. § 706(2)(C); (2) that the *Fintiv* instructions are arbitrary and capricious, see 5 U.S.C. § 706(2)(A); and (3) that the *Fintiv* instructions were issued without compliance with the notice-and-comment rulemaking requirements of 5 U.S.C. § 553,

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

as assertedly required by that APA provision and by 35 U.S.C. § 316. *Apple*, 2021 WL 5232241, at *3. An amended complaint added a fifth plaintiff but asserted the same challenges. The government moved to dismiss the case, arguing that plaintiffs lacked standing and, in the alternative, that APA review was unavailable both because (1) “statutes preclude judicial review” of the matters presented and (2) the challenges are to “agency action [that] is committed to agency discretion by law,” 5 U.S.C. § 701(a)(1)–(2). Briefing on that motion followed—on the same schedule as briefing on plaintiffs’ own motion for summary judgment, which the court ruled, at plaintiffs’ urging, was sufficiently “intertwined” with the dismissal motion to warrant parallel briefing. Order on Defendants’ Motion for Administrative Relief Requesting a Stay of Briefing on Plaintiffs’ Motion for Summary Judgment at 1, *Apple*, No. 20-cv-06128, 2021 WL 5232241, ECF No. 70; Plaintiffs’ Opposition to Defendant’s Motion for Administrative Relief Requesting a Stay of Briefing on Plaintiffs’ Motion for Summary Judgment at 2, *Apple*, No. 20-cv-06128, 2021 WL 5232241, ECF No. 69.

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

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

II

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

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

A

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

These two challenges have institution as their direct, immediate, express subject. In this respect, the challenges are critically different from the challenge the Supreme Court agreed with in *SAS*, a decision on which plaintiffs rely. There, the subject of the challenge was the interpretation of § 318, which prescribes the scope of the final written decision required of the Board in an IPR. The Court held that § 318 requires the final written decision to "resolve *all* of the claims in the case." 138 S. Ct. at 1353. That holding was not precluded by the unreviewability of institution decisions already articulated in *Cuozzo*, even though

the § 318 holding had, as a corollary, the effect of requiring the Director’s decision whether to institute a requested review to be essentially an all-or-nothing one. *Id.* at 1358–60. As the Court explained in *Thryv*, the merely collateral effect of a provision concerning “the manner in which the agency’s review ‘proceeds’ once instituted” did not bring SAS within the principle of unreviewability of “whether the agency should have instituted review at all.” 140 S. Ct. at 1376.

SAS thus does not alter the principle of unreviewability governing “application and interpretation of statutes related to the [PTO’s] decision to initiate inter partes review.” *Id.* at 1373 (internal quotation marks omitted) (quoting *Cuozzo*, 579 U.S. at 275); *see id.* at 1376 n.8. Plaintiffs’ statutory and arbitrary-and-capriciousness challenges in this case focus directly and expressly on institution standards, nothing else. The Supreme Court in *Cuozzo* and *Thryv* did not exclude any challenge from the reviewability bar where the invoked provisions of law directly govern institution—as the Court understood was the case for the pleading provision that was at issue in *Cuozzo* (§ 312(a)(3) (a petition “may be considered only if . . .”) and the timing provision that was at issue in *Thryv* (§ 315(b) (an IPR “may not be instituted if . . .”). *See Thryv*, 140 S. Ct. at 1373, 1376 n.8.⁵

⁵ The Court in *Cuozzo* recognized, as SAS was soon to illustrate, that some statutory provisions addressed to other matters might have an indirect bearing on institution, and for that reason the *Cuozzo* Court said that it was not deciding “the precise effect of § 314(d) on appeals that implicate constitutional questions, that depend on other less closely related statutes, or that present other questions of interpretation that reach, in terms of scope and impact, well beyond” § 314. 579 U.S. at 275. The Court in

In *Arthrex*, the Supreme Court confirmed the principle of unreviewability of the Director’s decision whether to institute. 141 S. Ct. at 1977. The Court relied indirectly on *Cuozzo*’s holding that the IPR statute’s text, legislative history, and structure supplied the clear and convincing evidence required to overcome the strong presumption in favor of reviewability generally, 579 U.S. at 273, and on *Cuozzo*’s application of the unreviewability principle even in a case in which a review was instituted and completed and a proper appeal was taken to this court of the Board’s final written decision, *id.* at 271–75. The Court in *Arthrex* directly relied on *Thryv*, in which the Court, as in *Cuozzo*, applied the unreviewability principle in a proper appeal and made clear that the principle bars judicial resolution of even run-of-the-mill statutory interpretation issues inherent in an institution determination by the Director as long as the statutory provision is one sufficiently focused on institution itself, as the Court held was true of § 315(b), *Thryv*, 140 S. Ct. at 1372–73. Nothing in the unreviewability principle repeatedly affirmed by the Supreme Court in this setting, moreover, turns on whether the Director has provided an explanation (as the Board, as delegatee, typically does). That is hardly surprising, as the Supreme

Cuozzo further stated that its holding did not “enable the agency to act outside its statutory limits by, for example, canceling a patent claim for ‘indefiniteness under § 112’ in an inter partes review.” *Id.* The example given is the PTO’s “canceling a patent claim” in an IPR (*after* institution, *see* § 318(b)), not an aspect of the institution determination. *Id.* The Court in *Thryv* subsequently noted, without elaboration, that it was not “decid[ing] whether mandamus might be available in an extraordinary case.” 140 S. Ct. at 1374 n.6. The case before us is not a mandamus case. *See also Mylan*, 989 F.3d at 1382 (holding mandamus standard not met for challenge to denial based on *Fintiv* instructions).

Court has rejected the notion that “if the agency gives a ‘reviewable’ reason for otherwise unreviewable action, the action becomes reviewable.” *Interstate Commerce Commission v. Brotherhood of Locomotive Engineers*, 482 U.S. 270, 283 (1987).

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

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

congressional preclusion of review of the decision to institute is to be respected in the inevitable system of delegation, it must extend to the substance of such instructions.

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

⁶ In the first two challenges, plaintiffs assert that the instructions, because of their content, will likely lead to *non*-institution determinations that will harm them. Non-institution determinations are a species of non-enforcement decisions, which are among the few recognized categories of agency action that are generally "committed to agency discretion by law," 5 U.S.C. § 701(a)(2). *See Cuozzo*, 579 U.S. at 273 ("[T]he agency's decision to deny a petition is a matter committed to the Patent Office's discretion." (citing § 701(a)(2))); *Department of Homeland Security v. Regents of University of California*, 140 S. Ct. 1891, 1905–06 (2020); *Department of Commerce v. New York*, 139 S. Ct. 2551, 2565 (2019); *Lincoln v. Vigil*, 508 U.S. 182, 191 (1993); *Heckler v. Chaney*, 470 U.S. 821, 831–32 (1985). Some court decisions from outside the Supreme Court suggest that certain agency announcements of non-enforcement policy may fall outside the § 701(a)(2) exclusion from APA review. *See, e.g., Crowley Caribbean Transport, Inc. v. Pena*, 37 F.3d 671, 676 (D.C. Cir. 1994). The Supreme Court in *Regents*, when presented with an argument along those lines, did not reach the argument, because it held

B

Plaintiffs’ third challenge is that the Director was required, by 35 U.S.C. § 116 together with 5 U.S.C. § 553, to promulgate the institution instructions through notice-and-comment rulemaking procedures. This challenge, we conclude, may be pressed under the APA. We also hold that at least Apple has standing to press it.

1

Whether notice-and-comment rulemaking procedures had to be employed for an agency action presents a matter “quite apart from the matter of substantive reviewability” of the action for being contrary to statute or arbitrary and capricious. *Lincoln v. Vigil*, 508 U.S. 182, 195 (1993); see *American Medical Association v. Reno*, 57 F.3d 1129, 1134 (D.C. Cir. 1995) (“[U]nder the APA the ultimate availability of substantive judicial review is *distinct* from the question of whether the basic rulemaking strictures of notice and comment and reasoned explanation apply. . . . The APA’s procedural requirements are enforceable apart from the reviewability of the underlying action, and, indeed, support several important functions wholly distinct from judicial review.”) (omission of internal *Lincoln* citation and quote); *Story v. Marsh*, 732 F.2d 1375, 1381, 1384 (8th Cir. 1984); *Natural Resources Defense Council v. U.S. Department of Energy*, 362 F. Supp. 3d 126, 147 (S.D.N.Y. 2019); *Batalla Vidal v. Duke*, 295 F. Supp. 3d 127, 148 (E.D.N.Y. 2017). Given this recognized distinction, we reject a conclusion of unreviewability, under § 701(a)(1) or (2), for plaintiffs’ third challenge.

that the policy at issue was not a mere non-enforcement policy. 140 S. Ct. at 1906–07. We do not reach it either, as we affirm dismissal of plaintiffs’ first two challenges based on § 701(a)(1) and so need not decide whether § 701(a)(2) would independently support dismissal.

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

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

The Supreme Court’s decision in *Lincoln* supports our conclusion about reviewability regarding plaintiffs’ third challenge. The Court there held that § 701(a)(2) barred

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

2

We also conclude that at least Apple has standing to press the challenge to the Director's instructions as invalid for want of notice-and-comment rulemaking. We so conclude without aggregating the plaintiffs' asserted threatened harms, an approach taken by plaintiffs without arguing for its propriety. *See, e.g., Summers v. Earth Island Institute*, 555 U.S. 488, 494–97 (2009) (analyzing individual plaintiffs separately); *ASARCO Inc. v. Kadish*, 490 U.S. 605, 615 (1989) (“[T]he doctrine of standing to sue is not a kind of gaming device that can be surmounted merely by aggregating the allegations of different kinds of plaintiffs, each of whom may have claims that are remote or speculative taken by themselves.”); *Valley Forge Christian College v. Americans United for Separation of Church & State, Inc.*, 454 U.S. 464, 489 (1982) (“The law of averages is not a substitute for standing.”). We will focus on Apple alone, and our conclusion that it has standing to press the remaining challenge permits us to reverse the

dismissal and remand for the merits of that challenge to be addressed (along with any question about standing of other plaintiffs available for decision on remand if necessary). *See, e.g., Little Sisters of the Poor Saints Peter & Paul Home v. Pennsylvania*, 140 S. Ct. 2367, 2379 n.6 (2020); *Rumsfeld v. Forum for Academic & Institutional Rights, Inc.*, 547 U.S. 47, 52 n.2 (2006).

In reviewing a standing determination made on a motion to dismiss a complaint, like the standing determination before us in this appeal, we assess standing *de novo*. *Ford Motor Co. v. United States*, 688 F.3d 1319, 1323 (Fed. Cir. 2012). We ask if the standard at the complaint stage, requiring allegations of fact plausibly indicating satisfaction of the legal requirement, is met. *See TransUnion LLC v. Ramirez*, 141 S. Ct. 2190, 2208 (2021); *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560–61 (1992); *James v. J2 Cloud Services, LLC*, 887 F.3d 1368, 1372 (Fed. Cir. 2018). We focus on the allegations of the complaint, but, under the regional circuit’s law we apply, we may also consider, at least, matters of which we may properly take judicial notice. *See Lee v. City of Los Angeles*, 250 F.3d 668, 689–90 (9th Cir. 2001).

For a plaintiff to have standing, the plaintiff must show (1) an “injury in fact,” (2) “a causal connection between the injury and the conduct complained of,” and (3) a likelihood that “the injury will be redressed by a favorable decision.” *Lujan*, 504 U.S. at 560–61 (internal quotation marks omitted). An injury in fact is “a legally protected interest which is (a) concrete and particularized” and “(b) actual or imminent, not conjectural or hypothetical.” *Id.* at 560 (internal quotation marks omitted). The Court has found an assertion of future injury insufficient where it “involve[d] a significant degree of guesswork.” *Trump v. New York*, 141 S. Ct. 530, 536 (2020). On the other hand, “[a]n allegation of future injury may suffice if the threatened injury is certainly impending, or there is a substantial risk that the harm will occur.” *Susan B. Anthony List v. Driehaus*, 573

U.S. 149, 159 (2014) (internal quotation marks omitted) (quoting *Clapper v. Amnesty International USA*, 568 U.S. 398, 414 n.5 (2013)); *Department of Commerce*, 139 S. Ct. at 2566. Of particular significance for this case, when a plaintiff asserts an entitlement to a rulemaking, the redressability requirement for standing is relaxed: It is enough for that element to be met that “there is some possibility that the requested relief,” namely, notice-and-comment rulemaking, would “prompt the [agency] to reconsider the decision that allegedly harmed” the plaintiff. *Massachusetts v. Environmental Protection Agency*, 549 U.S. 497, 518 (2007); see *Summers*, 555 U.S. at 496–97; *Lujan*, 504 U.S. at 572 n.7; *Iowa League of Cities v. Environmental Protection Agency*, 711 F.3d 844, 871 (8th Cir. 2013); *Sierra Club v. Environmental Protection Agency*, 699 F.3d 530, 533 (D.C. Cir. 2012).

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

Given that history, it is far from speculative that this sequence will be repeated in the future, considering Apple’s size and use of a wide variety of technologies and the realistically perceived advantages of the IPR process, including the applicability of a lighter burden of persuasion to prevail in challenging a patent claim than the burden applicable in district court. See *Jibril v. Mayorkas*, 20 F.4th 804, 815 (D.C. Cir. 2021) (concluding that “extensive” history

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

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

For those reasons, we conclude that Apple has standing to press the claim that the challenged instructions were

improperly put in place without notice-and-comment rule-making.⁷

III

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

The parties shall bear their own costs.

**AFFIRMED IN PART, REVERSED IN PART, AND
REMANDED**

⁷ Neither side has suggested mootness of this challenged based on the June 2022 Memo or subsequent clarifications, *see supra* n.4, which, like their predecessors, were not put in place through notice-and-comment rulemaking (including publication in the Federal Register). A challenge might not be mooted by a change in challenged conduct if the alteration is itself subject to the same asserted deficiency as its predecessor. *See, e.g., Davenport v. Washington Education Association*, 551 U.S. 177, 182 n.1 (2007); *Northeastern Florida Chapter of Associated General Contractors of America v. City of Jacksonville*, 508 U.S. 656, 661–63 (1993); 13C Charles A. Wright & Arthur R. Miller, *Federal Practice and Procedure* § 3533.6 at n.63 (3d ed. 2022). The post-*Fintiv* clarifications do not appear to moot plaintiffs' third challenge, the only one remaining after our unreviewability holding regarding the first two challenges. Any further exploration of the effect of the post-*Fintiv* clarifications is left to the district court on remand.