

No. 23-135

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IN THE  
**Supreme Court of the United States**

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INTEL CORPORATION, EDWARDS LIFESCIENCES  
CORPORATION, EDWARDS LIFESCIENCES LLC,  
*Petitioners,*

*v.*

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

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ON PETITION FOR A WRIT OF CERTIORARI TO THE  
UNITED STATES COURT OF APPEALS  
FOR THE FEDERAL CIRCUIT

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**REPLY BRIEF FOR PETITIONERS**

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Flouting statutory text and the presumption of reviewability, the decision below gives the PTO a blank check to adopt rules governing institution of inter partes review that are substantively immune from judicial scrutiny, no matter how arbitrary or unlawful. The Federal Circuit’s decision not only shields the *Fintiv* rule and its “disastrous consequences” from any challenge to its substantive unlawfulness, *Leading Innovators Br. 3*, but signals to the PTO that it may rewrite the institution standards Congress wrote and face no judge but itself.

The Director barely addresses the text of 35 U.S.C. §314(d), which limits the judicial-review bar to individual “determination[s] whether to institute” IPR, or the many decisions holding that statutes precluding judicial review of specific agency decisions do not bar review of rules governing those decisions. The Director suggests the America Invents Act differs from the statutes in those cases because the Director cannot make all institution decisions herself. But the PTO is not the only agency in which delegation is a practical necessity. The cases petitioners rely on similarly concerned delegations of discretion to make unreviewable determinations, and in none of those cases did this Court conclude that judicial review of standards governing the exercise of delegated discretion would “subvert” Congress’s decision to shield the individual determinations from review. *Opp. 13-14*. This Court instead recognized that stretching a judicial-review bar beyond its text would subvert the presumption of reviewability and the critical role it plays in ensuring that agencies “obey [their] statutory commands.” *Bowen v. Michigan Acad. of Family Physicians*, 476 U.S. 667, 681 (1986). The Federal Circuit’s “unreviewability principle” is the antithesis of that presumption and endorses the very argument this Court

rejected in *SAS Institute, Inc. v. Iancu*, 138 S. Ct. 1348, 1359 (2018).

None of the Director’s alternative arguments refutes the need for review. The standing arguments have been rejected repeatedly. And the argument that institution decisions are committed to agency discretion ignores that this case—unlike the previously denied petitions for certiorari that the Director hides behind, Opp. 10—involves no challenge to any institution decision. The issue is whether relief is available under the APA when the Director adopts unlawful rules governing all institution decisions. The Director does not dispute the broad and pressing implications of that question. And the prospect that the Director—emboldened by the decision below—might initiate rulemaking to adopt even more unlawful institution standards makes it more urgent, not less, for this Court to grant review.

## ARGUMENT

### I. THE DECISION BELOW CONFLICTS WITH PRECEDENT INTERPRETING ANALOGOUS JUDICIAL-REVIEW BARS

This Court has repeatedly held that statutes barring review of specific agency actions do not bar review of agency standards governing those actions. Pet. 14-20; *e.g.*, *Bowen*, 476 U.S. 667; *Department of Homeland Sec. v. Regents of Univ. of Cal.*, 140 S. Ct. 1891 (2020); *McNary v. Haitian Refugee Ctr., Inc.*, 498 U.S. 479 (1991). The decision below cannot be reconciled with that precedent. Tellingly, the Director barely tries. Opp. 14-15 & n.4.

That *Bowen*, *Regents*, and *McNary* “constru[ed] statutory schemes other than the AIA,” Opp. 14, in no way renders them inapposite. As in those cases, the AIA’s “text, structure, and purpose” indicate that

Congress did not intend to preclude review of rules governing institution. *Id.* (quotation marks omitted). As to text, §314(d) bars review only of “[t]he determination ... whether to institute an [IPR]” in a particular case. As to structure, Congress gave the PTO no authority to establish institution rules through adjudications of IPR petitions—instead requiring such rules to be made through regulations, 35 U.S.C. §316(a)—and so would never have expected §314(d) to bar review of rules. Pet. 16. As to purpose, Congress adopted §314(d) “to avoid the significant costs ... of nullifying a thoroughgoing determination about a patent’s validity” in a particular IPR based on a defect in the institution decision, *Thryv, Inc. v. Click-to-Call Techs., LP*, 140 S. Ct. 1367, 1376 (2020)—a purpose unrelated to review of rules governing institution. As in *Bowen, Regents*, and *McNary*, the AIA contains no evidence—let alone clear-and-convincing evidence—that Congress intended §314(d) to extend beyond its targeted language. Pet. 14.

Instead of answering these points, the Director emphasizes the “practical necessity” of delegating institution decisions to the Board subject to rules governing that delegated function. Opp. 13-14. But delegation is a universal feature of administrative agencies, and agency heads routinely adopt rules to ensure that delegated power is wielded in accordance with their policy choices. *Cf. United States v. Arthrex, Inc.*, 141 S. Ct. 1970, 1978-1979 (2021). Petitioners’ cases are no different.

*Bowen*, for example, involved a delegation of authority to insurance carriers to make unreviewable Medicare-benefit determinations. 476 U.S. at 674-675, 678. Congress recognized delegation was necessary and expected the HHS Secretary to issue standards governing that delegated authority. 42 U.S.C. §1395u(a) (1986). Although the statute precluded judicial review of the

carriers' determinations, this Court held that a challenge to the Secretary's "instructions" to carriers on how to make those determinations was reviewable. *Bowen*, 476 U.S. at 678. That decision did not "subvert Congress's decision to shield individual [determinations]" from review, Opp. 13-14, but adhered to the statutory text and recognized the difference between challenges to individual determinations (which Congress would have had good reason to preclude) and challenges to the rules governing the administration of Medicare (which Congress would not plausibly have foreclosed). *Bowen*, 476 U.S. at 675-678. The same analysis applies here.

Similarly, *Regents* involved a challenge to the Secretary of Homeland Security's "instruct[ions]" to Immigration and Customs Enforcement (ICE) as to how it should exercise enforcement discretion on the agency's behalf. 140 S. Ct. at 1902; *see* No. 18-587 Pet. App. 97a-101a, 112a-119a. As here, those instructions sought to align ICE's removal decisions with the policies the Secretary would follow if performing the delegated function herself. *Cf.* Opp. 13. Review of those instructions did not "subvert" Congress's decision to make individual removal actions unreviewable. Opp. 13-14. Rather, it was "implausible" to read the targeted provisions barring review of individual removal proceedings to establish a more "general jurisdictional limitation." *Regents*, 140 S. Ct. at 1907. The same is true here.<sup>1</sup>

The Director also cannot reconcile this case with *McNary*, which held that a plain reading of a judicial-review bar precluded review only of determinations regarding certain applications for status adjustment. 498

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<sup>1</sup> The Director's sole reference to *Regents* addresses the wrong section of the opinion. Opp. 15 n.4 (citing 140 S. Ct. at 1906); *cf.* Pet. 16-18 (discussing 140 S. Ct. at 1907).



U.S. at 491-492. Likewise, a plain reading of §314(d) precludes judicial review only of “[t]he determination ... whether to institute an [IPR].” Pet. 18. While surrounding provisions in *McNary* confirmed that stretching the judicial-review bar beyond its text would have “ma[de] no sense,” Opp. 15 n.4, the same is true here, Pet. 16.

Other courts construe judicial-review bars narrowly. Pet. 19-20. The Director’s efforts to dispel that conflict again fail. As to *American Clinical Laboratory Association v. Azar*, 931 F.3d 1195 (D.C. Cir. 2019), while the statute there “‘separate[d] the ‘data collection process’” (which was reviewable) “‘from the ‘establishment of payment amounts’” (which was not reviewable), Opp. 18, the same is true here. The AIA distinguishes individual institution decisions, which are subject to §314(d), from the adoption of rules governing institution, see 35 U.S.C. §316(a)(2), (4), which are not. The judicial-review bar in *Hyatt v. OMB*, 908 F.3d 1165 (9th Cir. 2018), “was ‘demonstratively narrow in scope,’” Opp. 19, but so is §314(d), shielding only “[t]he determination ... whether to institute an [IPR].” Although *Lepre v. Department of Labor*, 275 F.3d 59 (D.C. Cir. 2001), involved a constitutional claim, the court relied on *Bowen* in holding that the “practice or procedure used in making [unreviewable] decisions” was reviewable. *Id.* at 64-65. And the Director has no answer to *Sharkey v. Quarantillo*, 541 F.3d 75 (2d Cir. 2008), except to mischaracterize petitioners’ claims as challenging a decision “whether ... to institute inter partes review.” Opp. 19.

## **II. THE DECISION BELOW CONFLICTS WITH SAS**

The Federal Circuit held that §314(d) bars “any challenge ... where the invoked provisions of law directly govern institution.” Pet. App. 14a. That is the argument this Court rejected in *SAS*, 138 S. Ct. at 1359.

In *SAS*, this Court held that §314(d) did not preclude a challenge to the Board’s practice of partial institution. 138 S. Ct. at 1354, 1359. Emphasizing the presumption of reviewability, the Court rejected the argument that §314(d) “foreclos[es] judicial review of any legal question bearing on ... institution.” *Id.* at 1359. Rather, where a party does not challenge an institution decision, “judicial review remains available consistent with the [APA].” *Id.* The Federal Circuit’s holding—that §314(d) applies whenever a challenge “focus[es] directly and expressly on institution standards,” Pet. App. 14a—reads §314(d) to do exactly what *SAS* held it did not: “enable the [PTO] to act outside its statutory limits.” 138 S. Ct. at 1359.

Like the Federal Circuit, Pet. App. 14a, the Director reimagines *SAS* as a case about the scope of the Board’s final written decision under 35 U.S.C. §318. Opp. 14. That is wrong. *SAS* decided the permissibility of “institut[ing] review on only some [claims] ... and den[ying] review on the rest,” 138 S. Ct. at 1354—an issue that had “institution as [its] direct, immediate, express subject” and would be nonjusticiable under the holding below, Pet. App. 14a. Although *SAS* “located th[e] rule [forbidding partial institution] in §318(a),” *Thryv*, 140 S. Ct. at 1376, the parties and the Court extensively “invoked provisions of law directly govern[ing] institution,” Pet. App. 14a, belying the Federal Circuit’s conclusion that an atextual “unreviewability principle” arises whenever an issue implicates institution-related provisions. *See SAS*, 138 S. Ct. at 1354-1356.

Neither *Thryv* nor *Cuozzo Speed Technologies, LLC v. Lee*, 579 U.S. 261, 273 (2016), supports the decision below. *Cf.* Opp. 11-13. Each concerned a “decision whether to institute an [IPR]” and had no occasion to suggest that §314(d) extends to rules governing institution. Opp. 11 (quotation marks omitted); *see Cuozzo*, 579 U.S. at 269-

271; *Thryv*, 140 S. Ct. at 1371-1373. *Cuozzo* construed §314(d) consistent with the presumption of reviewability and cited the existence of a “close[] tie[]” to institution-related statutes as a potential limit beyond which §314(d) might not apply, even in cases directly “attacking [a] decision to institute [IPR]”—not, as the Director suggests (at 11), as a basis for expanding §314(d) to cases presenting no such attack. 579 U.S. at 273-275. The decision below upends that reasoning.

### **III. THE ISSUE’S IMPORTANCE IS UNDISPUTED AND REVIEW IS WARRANTED NOW**

The Director concedes the decision below establishes a broad “principle of unreviewability” that will preclude review not just of *Fintiv*, but of any PTO rule “focus[ed] ... on institution standards.” Opp. 8 (quotation marks omitted). Petitioners and amici explained the significant harms that decision threatens for the patent system and IPR’s central role in effectuating the AIA’s reforms, to the detriment of leading technology companies like petitioners and smaller businesses and more vulnerable innovators alike. Pet. 5-8, 24-31; Leading Innovators Br. 4-21; ACT Br. 3-15, 19; CCIA Br. 2, 4-5. The Director disputes none of that and identifies no good reason to delay review.

#### **A. The Alternative Argument For Affirmance Lacks Merit**

The Director’s contention (at 15-18) that “[t]he decision whether to institute [IPR]” is “committed to the USPTO’s discretion by law” and therefore unreviewable under 5 U.S.C. §701(a)(2) does not support the judgment below and would not weigh against review anyway.

This Court routinely grants review to resolve important questions even when other arguments that

might support the judgment remain to be decided on remand. *See, e.g., NCAA v. Smith*, 525 U.S. 459, 462 (1999); *Department of Transp. v. Association of Am. Railroads*, 575 U.S. 43, 55-56 (2015); *Fitzgerald v. Barnstable Sch. Comm.*, 555 U.S. 246, 260 (2009). There is no reason to depart from that practice. The Federal Circuit declined to reach this argument, Pet. App. 17a-18a n.6, and this Court does “not decide in the first instance issues not decided below,” *NCAA*, 525 U.S. at 470.

In any event, the Director’s reliance on §701(a)(2) fails because this case does not involve any “decision whether to institute [IPR].” Opp. 15. Even assuming an institution decision is comparable to a non-enforcement decision in a particular case that is committed to agency discretion by law, Opp. 16, this case is about something different: judicial review of institution standards that change the rules for all cases in a legislative manner.<sup>2</sup> As to that issue, there are undoubtedly “meaningful standard[s] against which to judge” those rules. *Id.* (quoting *Heckler v. Chaney*, 470 U.S. 821, 830 (1985)). Petitioners claim the AIA prohibits the Director from denying institution based on parallel litigation. Pet. 2. The AIA’s text, structure, and purpose provide the “meaningful standard” to judge that claim. It is “almost ludicrous to suggest that there is ‘no law to apply’ in reviewing whether an agency” acted contrary to “a law.” *International Union, United Auto., Aerospace & Agric. Implementation Workers of Am. v. Brock*, 783 F.2d 237, 246 (D.C. Cir. 1986). Petitioners also claim *Fintiv* is arbitrary and capricious. Pet. 2. The APA’s well-established requirements of reasoned decisionmaking provide the

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<sup>2</sup> *Chaney* involved no such rule. *Cf.* Opp. 18. There, plaintiffs challenged the agency’s refusal to take specific enforcement actions. 470 U.S. at 824-825.

“meaningful standard” to judge that claim. This case is not the “rare instance” in which “there is no law to apply.” *Chaney*, 470 U.S. at 830 (quotation marks omitted).

### **B. The Standing Argument Lacks Merit**

Both courts below rejected the Director’s standing challenge, which need not detain this Court either. As the district court explained, petitioners alleged an injury-in-fact that is fairly traceable to the *Fintiv* rule and that will be redressed by its invalidation. Namely, “the Director is using unlawful considerations that increase the risk of denial [of IPR], thereby depriving [petitioners] of the *benefits* of IPR.” Pet. App. 35a. As the Federal Circuit put it, *Fintiv* is “plausibly alleged to cause more denials of institution than might otherwise occur,” and its “predictable effect” will be to “continue causing harm in the form of denial of the benefits of IPRs linked to the concrete interest possessed by an infringement defendant” in the opportunity to seek cancellation of the asserted patent through IPR. Pet. App. 23a-24a.

Contrary to the Director’s insinuation (at 20), the Federal Circuit never suggested petitioners’ standing differs from Apple’s, and the Director identifies no reason why it would. The Federal Circuit limited its discussion to Apple only to avoid “aggregating” alleged injuries; and having done so, its conclusion that Apple has standing made it unnecessary to address others’ standing. Pet. App. 21a.

The Federal Circuit’s standing analysis readily applies to Intel and Edwards. Like Apple, petitioners are “non-speculatively threatened with harm to a legally protected interest.” Pet. App. 23a. They too are “repeat player[s]” that have been “regularly sued for infringement ... and then petitioned for an IPR of patent claims at issue” and had petitions denied based on *Fintiv*. *Id.*;

see C.A.J.A. 1140-1144. And it “is ... the predictable effect,” that the *Fintiv* rule “will continue causing harm in the form of denial of the benefits of IPRs.” Pet. App. 23a-24a (quotation marks omitted). This is not a mere “deprivation of a procedural right.” *Summers v. Earth Island Inst.*, 555 U.S. 488, 496 (2009); cf. Opp. 21. *Fintiv* restricts patent-infringement defendants’ access to the opportunity to obtain cancellation of the asserted patent through IPR. Pet. App. 23a-24a. The loss of an opportunity to obtain a benefit is a concrete injury, even without any guarantee the benefit will materialize. See, e.g., *Czyzewski v. Jevic Holding Corp.*, 580 U.S. 451, 463-464 (2017) (creditors had standing to challenge bankruptcy order that cost them “the power to bring their own lawsuit,” even though a lawsuit “might [have] prove[d] fruitless”). The “injury and causation requirements for standing are met” for the same reasons. Pet. App. 24a.

The redressability requirement is satisfied because enjoining the *Fintiv* rule would prevent the Board from relying on it to deny petitioners’ IPR petitions. While the Director implies (at 20) the redressability requirement for the claims here is more stringent than for the notice-and-comment claim addressed by the Federal Circuit, the Director articulates no reason why redressability is not met for any of petitioners’ claims. As the district court recognized, Pet. App. 37a, there is none.

### **C. Review Is Warranted Without Delay**

Interlocutory status is “no impediment to certiorari” here because “the court below has decided an important issue, otherwise worthy of review.” Shapiro et al., *Supreme Court Practice* §4.18 (11th ed. 2019). Resolution of petitioners’ notice-and-comment claim on remand will not affect or obviate the need for review. Pet. 33 n.5. The Director suggests (at 20) that “[i]f petitioners

prevail on remand, the agency could undertake a notice-and-comment process,” which might result in changes to *Fintiv*. But this petition does not seek review of the *Fintiv* rule. The issue is whether institution standards are subject to judicial review. The events the Director hypothesizes would not eliminate the need for review of that question, even if the Director withdrew *Fintiv* altogether. Indeed, the Director does not deny that any regulation resulting from a future rulemaking would be substantively unreviewable under the decision below.

This Court should not wait to see if the Director’s speculation materializes. More than three years into the claimed “continuing evaluation” of a possible rulemaking (Opp. 20), the Director has issued only an advance notice, while adopting increasingly stringent rules constricting access to IPR without notice and comment. Pet. 10-11, 30, 32. The manifest illegality of several proposals in the advance notice (Pet. 28-30) suggests the PTO understands the Federal Circuit’s decision for exactly what it is: a green light to adopt substantively unlawful institution standards with impunity. This Court should intervene to preserve the role of IPR in the patent system and the presumption that courts are available to check unlawful agency action.

### **CONCLUSION**

The petition should be granted.

Respectfully submitted.

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