No. 23-1298

In the Supreme Court of the United States

UNITED THERAPEUTICS CORPORATION,

Petitioner,

v.

LIQUIDIA TECHNOLOGIES, INC.,

Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

REPLY BRIEF FOR THE PETITIONER

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REPLY BRIEF FOR THE PETITIONER

Liquidia cannot meaningfully deny the existence of a split in the Federal Circuit concerning the standard of review in appeals challenging decisions in excess of an agency's statutory authority. In one line of cases, the Federal Circuit routinely abdicates determining the agency's compliance with statutory limits on its power to the agency. In another line of cases, the Federal Circuit polices the agency's statutory compliance *de novo*, as it must. The correct standard of review is important: the more cases in the mistaken line of authority, the more likely the next case is to join that mistaken line—a snowball effect of ill-conceived precedent. Here, the agency decided to cancel valuable property rights without statutory authority. This case presents an ideal vehicle to resolve the split and vindicate the Article III courts' mandate to decide key legal questions without deference.

The decision below falls on the wrong side of the split. This Court recently reaffirmed that "[c]ourts *must* exercise their independent judgment in deciding whether an agency has acted within its statutory authority, as the APA requires." *Loper Bright Enters. v. Raimondo*, 144 S. Ct. 2244, 2273 (2024) (emphasis added). That makes sense: the APA expressly states that reviewing courts "shall decide all relevant questions of law." 5 U.S.C. § 706. As this Court made clear in *SAS* in the context of the same agency and same procedure at issue here, 35 U.S.C. § 312 ("Requirements of Petition") precludes relying on grounds not preserved "in writing and with particularity" in the petition, or not based on "copies" of the printed publications "provide[d]" with the petition. 35 U.S.C. § 312(a)(3)(A), (5). The agency's compliance with those legal requirements must be reviewed without deference to the agency.

Liquidia does not seriously disagree with this proposition, so it takes another tack: arguing that the question presented is not really presented at all. But the record

speaks for itself. The legal question is whether the Board decided to cancel UTC's patent based on "grounds and printed publications" that were "new," not presented as Section 312 requires, and therefore beyond its statutory authority. And on that point, the Federal Circuit's abdication was clear: it "conclude[d] that the Board *did not abuse its discretion* in considering the arguments" because "[a]s the Board observed, Liquidia's arguments were not inconsistent with, and therefore not new over, the grounds raised in its IPR petition." Pet.App. 8a (emphasis added). To support this holding, the Court relied on one side of the intra-circuit split which reviews for only an abuse of discretion "when a reply contention crosses the line from the responsive to the new." *Id.* (quoting *Ericsson Inc. v. Intell. Ventures I LLC*, 901 F.3d 1374, 1380 (Fed. Cir. 2018)).

Liquidia also argues that the "grounds and printed publications" on which it prevailed are not really new. That is not the question presented here, although it is the question the Federal Circuit wrongly failed to answer. But Liquidia's backfilling is incorrect in any event. The statute required that "copies" of the printed publications relied on by the Board be "includ[ed]" with the initial IPR petition. The Board relied instead on hypothesized "abstract books" that Liquidia never submitted and neither the Board nor the court below has ever seen. Plainly there is a substantial question whether the Board relied on a ground that is "new" and, thus, "whether [the] agency has acted within its statutory authority" (*Loper Bright*, 144 S. Ct. at 2273); that question should be reviewed *de novo*, as some panels of the Federal Circuit do. That did not happen here.

Loper Bright is not "irrelevant," as Liquidia argues. Opp. 13. It clarifies the judiciary's role in ensuring that agency action does not transgress statutory limits. That review must be "independent," without deference to the agency. At minimum, the Court should grant, vacate, and remand the case in light of *Loper Bright*.

A. The intra-Federal Circuit split causes ongoing confusion, conflicts with two statutes, and warrants this Court's explicit correction.

The Federal Circuit has two irreconcilable lines of cases that apply different standards of review to the same question: whether an agency decision to cancel a patent relied on grounds beyond the agency's statutory authority. Pet. 14-17. Some review that question for only an abuse of discretion—as the court below did; others apply plenary review, as two statutes (35 U.S.C. § 312; 5 U.S.C. § 706) and this Court's *SAS* and *Loper Bright* decisions require.

Liquidia attempts to recharacterize *some* of the cases applying *de novo* review as those that "concern the procedural requirements" of the APA. Opp. 13. That claim is overly ambitious—its APA distinction does not hold up on its own terms, as discussed below. But even Liquidia only claims that this argument explains away "*nearly* all" of the decisions in the split. Opp. 20, 23 n.4 (emphasis added). Liquidia thus acknowledges, as it must, that this distinction fails to reconcile several key cases creating the split.

Those cases expressly accept that whether the agency relied on a "new" ground, not raised in the petition, must be reviewed *de novo*—not just as a matter of fair notice, but as a matter of the statutory constraints on the agency's authority. The leading decision on that side of the split expressly acknowledges this:

> The APA, the IPR statute, the Board's regulations, and our precedents collectively impose two separate, but related, restrictions on what a petitioner may include in its reply. First, the arguments and evidence in the reply must not be part of a *new* theory of unpatentability. Second, the arguments and evidence in the reply must be *responsive* to the patent owner's contentions or the Board's institution decision. . . . Our standard of review of the Board's

> application of the newness and responsiveness restrictions differs.

Corephotonics, Ltd. v. Apple Inc., 84 F.4th 990, 1008 (Fed. Cir. 2023). Under this line of cases, the question of "newness" (which implicates Section 312) is reviewed "de novo" while the question of "responsiveness" (which implicates the Board's regulations) is reviewed for an "abuse of discretion." *Id.*; *accord Wildcat Licensing WI LLC v. Atlas Copco Tools & Assembly Sys. LLC*, No. 2022-1304, 2024 WL 89395, at *2 (Fed. Cir. Jan. 9, 2024) ("Whether post-petition argument and evidence presents a new invalidity theory implicates the Board's statutory authority and is subject to de novo review.").

These cases cannot be explained away as relying on some procedural requirement specific to the APA. Each of them recognized the statutory basis of the rule against reliance on new grounds, and each of them applied *de novo* review to that issue, whether or not there was *also* an APA issue in the case. *Compare, e.g.*, *Corephotonics*, 84 F.4th at 1008 ("The newness restriction stems from the statutory mandate that the petition govern the IPR proceeding, so whether a ground the Board relied on [i]s new . . . is a question of law we review de novo." (citation omitted)), *with id.* at 1001-02 ("Any marked departure from the grounds identified with particularity in the petition would . . . violate both the APA and the IPR statute."). Liquidia has no real response to *Corephotonics* or *Wildcat Licensing* except to argue (Opp. 22) that they somehow show that the court did not defer here. That the Federal Circuit did not "mention" or "rely" upon the APA (Opp. 23 n.4), despite UTC having identified the APA violation (*infra* p. 5), further exposes the problem. Without correction, the court is free to characterize the same agency action as an APA or Section 312 violation (requiring *de novo* review) *or* as grounded in agency regulations (permitting an abuse-of-discretion standard).

Thus, Liquidia fails to explain away the split between decisions like *Corephotonics*—reviewing "newness" *de novo*—and decisions like the one below—treating "newness" as purely a matter of the Board's own rules, reviewed deferentially. What is more, the *Corephotonics* side of the split is weightier than Liquidia acknowledges, because its "APA"/"non-APA" distinction does not hold up. Before *SAS* confirmed Section 312's role in constraining the Board, the Federal Circuit regularly grounded the obligation not to switch grounds in the APA. And the line of cases applying *de novo* review treats the points as largely interchangeable where the standard of review is concerned. For instance, in *Corephotonics*, the court was quite clear that "[t]he newness restriction stems from the statutory mandate" of Section 312, but based *de novo* review on *NuVasive*, which Liquidia characterizes as an APA case. 84 F.4th at 1008.

Liquidia also claims that cases invoking the APA are inapposite because UTC did not invoke the APA, but that is wrong for multiple reasons. UTC explicitly raised APA violations below (Pet. 11-12) and in the Petition (Pet. 19-20). And as UTC explained, in this context there is no real distinction between a statutory violation and an APA violation: by its own terms, any agency action "not in accordance with law" or "in excess of statutory jurisdiction, authority, or limitations" is an APA violation *per se*. 5 U.S.C. § 706(2)(A), (C). And under the APA, agency interpretations of statutes are not entitled to deference. *Loper Bright*, 144 S. Ct. at 2261.

Accordingly, even if UTC did not challenge the agency's decision as an APA violation entitled to *de novo* review—which it demonstrably did (Pet. 11-12, 19-20)—the decision below still requires "independent" *de novo* review "in deciding whether an agency has acted within its statutory authority, as the APA requires." *Loper Bright*, 144 S. Ct. at 2273. Where the Federal Circuit decides more agency

appeals than nearly any other appellate court,[1] this fundamental question of federal law concerning its standard of review should be unquestionably clear.

B. This case is a suitable vehicle to address the question presented.

Liquidia attempts to distinguish this case from the intra-circuit split by arguing that there are no "new" grounds or "new" printed publications. This argument assumes the conclusion: if the Board found that the "grounds and printed publications" are not "new" and the Federal Circuit reviews that determination only for an abuse of discretion, the statutory limits of Section 312 are never independently policed by the reviewing court. Here, *de novo* review of Section 312's "Requirements of Petition" would be dispositive in UTC's favor.

This case presents an ideal vehicle to give teeth to independent *de novo* agency review because the facts are so stark. The Board decided that the '793 patent should be cancelled based on "abstract books" that are not in evidence and have never been seen by any party, declarant, or adjudicative body in direct violation of Section 312(a)(3)(A)-(B), (5) (and the APA). Just as UTC has never seen these "abstract books," neither will this Court. They were never included in the initial petition—as Section 312(a)(3)(A) requires—nor were they ever produced in reply. To the extent the "abstract books" exist, there is zero evidence that they contain the same text or disclosure as the JESC and JAHA "journal supplements" relied on by the agency.[2]

Remarkably the petition contained *none* of the safeguards to ensure that the hypothetical "abstract books" complied with the statute. The petition never mentioned

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[1] *Lex Machina*, https://law.lexmachina.com/ (last visited Sept. 6, 2024) (reviewing the second most agency appeals since Jan. 1, 2012).

[2] Notably, the agency did not accept that the JESC and JAHA journal supplements included with the petition qualified as prior art. Pet. 10.

the "abstract books" and so could not identify the "grounds on which the challenge to each claim is based" "in writing and with particularity." § 312(a)(3). The petition certainly did not "includ[e]" "copies" of the "abstract books" which Liquidia now alleges qualify as "printed publications." Liquidia does not have them. Nor were "copies" *ever* provided to the patent owner. § 312(a)(3)(A). And no "affidavits or declarations" were "includ[ed]" with the petition mentioning "abstract books." As a result, this case presents the straightforward issues of (a) whether the IPR statute and *SAS* require the Federal Circuit to review *de novo*, or only for an abuse of discretion, the Patent Office's reliance on new grounds and new printed publications—not raised in the initial petition—when deciding to cancel patent claims; and (b) whether the Court should vacate and remand the decision below in light of this Court's decision in *Loper Bright*.

Liquidia's response to these clear statutory violations is that nothing can be done based on the agency's "factual finding reviewed only for substantial evidence," never mind the statute. Opp. 2-3.[3] The court charged with policing the agency's actions only made things worse.

The Federal Circuit affirmed the agency's reliance on never-seen hypothetical abstract books in deciding to cancel a patent. Specifically, UTC argued that "the Board's theory would have been adequately supported only if Liquidia had provided 'evidence of *actual* existence or

[3] Because the "abstract books" are not in evidence, Liquidia has attempted to manufacture "substantial evidence" in its Opposition. For example, footnote 3 asserts that the "abstracts attached to the petition include[d] specific dates and locations of the conferences." Opp. 18 n.3 (quoting C.A. App. 2684, 7597-7613). Liquidia is wrong. The "abstracts attached to the petition" were not the "abstract books"; rather, they were the JESC and JAHA "journal supplements" that the Board determined were not publicly accessible and therefore not prior art. *Supra* footnote 2.

dissemination' of the [abstract] books." Pet.App. 8a (quoting UTC C.A. Br. 37 (C.A. Dkt. 39)). Without acknowledging Section 312's requirement that the "printed publication" used to challenge the patent *must* be included in the petition, the court glibly stated "that is not the proper standard." *Id.* But under Section 312, that *is* the proper legal standard.

This case does not "turn[] on highly case-specific questions about scientific journals and the availability of the abstracts at certain conferences two decades ago" (Opp. 3)—it turns on whether the plain language of Section 312 controls.

C. *Loper Bright* provides a basis for the Court to grant, vacate, and remand.

At minimum, *Loper Bright* justifies granting the petition, vacating the decision below, and remanding to the Federal Circuit for reconsideration in light of this Court's recent decision. Such a GVR would require the Federal Circuit to consider, without deference to the agency, whether the Board's reliance on new grounds and new printed publications—not raised in the initial IPR petition—was proper under Section 312.

This Court has broad authority to GVR, and such action "is appropriate when intervening developments" disturb "a premise that the lower court would reject . . . where it appears that such a redetermination may determine the ultimate outcome." *Wellons v. Hall*, 558 U.S. 220, 225 (2010) (quoting *Lawrence v. Chater*, 516 U.S. 163, 167 (1996)). *Loper Bright* is plainly such an intervening development in this case.

The fact that the Federal Circuit did not explicitly rely on *Chevron* does not render *Loper Bright* "irrelevant." Opp. 29. This Court's mandate in *Loper Bright* requires that courts exercise "independent judgment in deciding whether an agency has acted within its statutory authority"—

precisely the issue in this case. *See, e.g.*, Pet. 21-23; *Loper Bright*, 144 S. Ct. at 2247.

There is at least a "reasonable probability" that the Federal Circuit's decision "rest[ed] upon a premise" it would reject if considered under *Loper Bright*. The decision below, like the line of cases it follows, rests on the notion that the Board's rules expand the scope of permissible grounds beyond what the statute permits: those cases take the view that the agency can allow in matters made in "'legitimate reply,'" as long as they are "not inconsistent with" the petition. Pet.App. 7a-8a (citation omitted). That is substituting the agency's view of the statutory framework for this Court's, and treating what should be a statutory claim reviewed *de novo* as if it were a matter of agency discretion reviewed deferentially. *See id.*

Analysis of this case under *Loper Bright* would be dispositive. A document not in evidence would not survive *de novo* review to stand in the place of the "printed publications" required to form the basis of, and be included with, the petition under Section 312. This is especially true when compliance with the statute cannot be abdicated to mere review of the agency's procedural rules. *See Loper Bright*, 144 S. Ct. at 2273 ("[W]hen a particular statute delegates authority to an agency consistent with constitutional limits, courts must respect the delegation, while ensuring that the agency acts within it.").

Liquidia's argument boils down to "this is not a *Chevron* case." Opp. 29-32. But that misses the point. The relevant question is: "Does the statute authorize the challenged agency action?" *Loper Bright*, 144 S. Ct. at 2269. In this case, the answer is decidedly "no," and the Board exceeded its authority by going outside the bounds of Section 312. The Federal Circuit did not have a chance to consider this case under *Loper Bright*. It should do so now.

As a last-ditch effort to undermine *Loper Bright* as intervening authority, Liquidia contends that UTC "waived"

Chevron. Opp. 32. Not so. During the pendency of UTC's appeal to the Federal Circuit, UTC has maintained that it is entitled to the protections of the APA. *E.g.*, UTC C.A. Br. 30, 32 (C.A. Dkt. 39) (arguing that the Board "exceeded its statutory authority in relying on a theory . . . not preserved by Liquidia's Petition" and that "[g]oing beyond the petition's theories violated not just the IPR statute but the Administrative Procedure Act"). *Loper Bright* makes clear that those are the very provisions that rule out deference to agencies on legal questions. UTC could not have done more in the court of appeals, because at that time (and, indeed, until after the petition was filed), *Chevron* was still binding precedent. Waiver cannot apply to an issue that a party was foreclosed from raising in the proceedings below. The change in the law is precisely the reason why a GVR is warranted.

CONCLUSION

The Court should grant the petition.

Respectfully submitted.

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