IN THE

Supreme Court of the United States

UNITED THERAPEUTICS CORPORATION, *Petitioner*,

v.

 $\begin{array}{c} \text{Liquidia Technologies, Inc.,} \\ Respondent. \end{array}$

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

BRIEF IN OPPOSITION

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QUESTIONS PRESENTED

- 1. Whether the Federal Circuit correctly concluded, in a non-precedential opinion, that the Patent Trial and Appeal Board (PTAB) did not abuse its discretion when it found that the arguments made by Respondent Liquidia Technologies, Inc. in its inter partes review (IPR) reply brief were (a) responsive to arguments raised for the first time in Petitioner United Therapeutics Corp.'s opposition brief, and (b) supported $_{
 m the}$ grounds and printed publications Respondent originally asserted in its IPR petition.
- 2. Whether the Federal Circuit's ruling should be disturbed in light of this Court's recent decision in *Loper Bright Enterprises v. Raimondo*, 603 U.S. ---, 144 S. Ct. 2244 (2024), where, as here, no alleged statutory ambiguity is at issue and no party or tribunal raised or relied on *Chevron* deference below.

CORPORATE DISCLOSURE STATEMENT

Respondent Liquidia Technologies, Inc. is a wholly owned subsidiary of Liquidia Corporation, which is a publicly held corporation.

TABLE OF CONTENTS

			Page
QUES	STION	S PRESENTED	i
CORE	PORAT	E DISCLOSURE STATEMENT	ii
TABL	E OF	AUTHORITIES	v
INTR	ODUC	TION	1
STAT	'EMEN	TOF THE CASE	4
	A.	Statutory and Regulatory Framework	4
	В.	The Parties Conducted <i>Inter</i> Partes Review Based On Liquidia's Claim of Obviousness and the Voswinckel Abstracts	6
	С.	The PTAB Determined that the Challenged Claims Are Unpatentable	9
	D.	The Federal Circuit Unanimously Affirmed in a Non-Precedential Decision	10
REAS	SONS I	FOR DENYING THE PETITION	12
I.	This (orari Should Be Denied Because Case Does Not Present the tion Claimed as a Basis for Review .	14
II.		Identifies No Intra-Circuit Split anting this Court's Review	18

	A.	As UTC's Cases Show, the Federal Circuit Reviews De Novo the PTAB's Compliance with the APA's Procedural Requirements, as Informed by Section 312	9
	В.	As UTC's Cases Also Show, the Federal Circuit Reviews Compliance with the PTAB's IPR Rules, Including Regarding Reply Briefs, for Abuse of Discretion	3
III.	Chevron and Loper Bright Are Irrelevant to This Case		
	A.	This Case Does Not Involve Statutory Ambiguity or Chevron Deference	9
	B.	Loper Bright Has No Bearing On This Case	1
	C.	Any Argument Regarding Chevron Has Been Waived	2
CONC	CLUSI	ON 3:	2

Page(s)
Cases
AIP Acquisition LLC v. Cisco Sys., Inc., 714 F. App'x 1010 (Fed. Cir. 2017)21
Apple Inc. v. Andrea Elecs. Corp., 949 F.3d 697 (Fed. Cir. 2020) 24
Arthrex Inc. v. Smith & Nephew, Inc., 935 F.3d 1319 (Fed. Cir. 2019)
Axonics, Inc. v. Medtronic, Inc., 75 F.4th 1374 (Fed. Cir. 2023)20
Carlson v. Green, 446 U.S. 14 (1980)
Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837 (1984)
Corephotonics Ltd. v. Apple Inc., 84 F.4th 990 (Fed. Cir. 2023)22, 23, 25, 26
Cuozzo Speed Techs., LLC v. Lee, 579 U.S. 261 (2016)
Echevarria v. Astrazeneca Pharm. LP, 856 F.3d 119 (1st Cir. 2017)28
Ericsson Inc. v. Intell. Ventures I LLC, 901 F.3d 1374 (Fed. Cir. 2018)16, 25, 26

,	Page(s)
Flathead-Lolo-Bitterroot Citizen Task Force 98 F.4th 1180 (9th Cir. 2024)	•
Green v. U.S. Anesthesia Partners of Colo., I 2023 WL 7015660 (10th Cir. Oct. 25, 202	•
Halliburton v. Erica P. Johnson Fund., Inc., 573 U.S. 258 (2014)	
Hormel v. Helvering, 312 U.S. 552 (1941)	32
Intelligent Bio-Sys., Inc. v. Illumina Cambri 821 F.3d 1359 (Fed. Cir. 2016)	
Jazz Pharms., Inc. v. Amneal Pharms., LLC 895 F.3d 1347 (Fed. Cir. 2018)	*
Johnson v. Guzman Chavez, 594 U.S. 523 (2021)	30
Kom Software, Inc. v. NetApp, Inc., 2021 WL 5985360 (Fed. Cir. Dec. 17, 202	21)26
Loper Bright Enterprises v. Raimondo, 144 S. Ct. 2244 (2024)	29, 31, 32
Medtronic, Inc. v. Barry, 891 F.3d 1368 (Fed. Cir. 2018)	17
Microsoft Corp. v. IPA Techs. Inc., 2022 WL 989403 (Fed. Cir. Apr. 1, 2022)	26

(00-10-10-10-10)	Page(s)
MModal LLC v. Nuance Commc'ns, Inc., 846 F. App'x 900 (Fed. Cir. 2021)	26
Napleton 1050, Inc. v. NLRB, 976 F.3d 30 (D.C. Cir. 2020)	28
Netflix, Inc. v. DivX, LLC, 84 F.4th 1371 (Fed. Cir. 2023)	26
Nobel Biocare Servs. AG v. Instradent USA, 903 F.3d 1365 (Fed. Cir. 2018)	
In re NuVasive, Inc., 841 F.3d 966 (Fed. Cir. 2016)	21
Parkervision, Inc. v. Vidal, 88 F.4th 969 (Fed. Cir. 2023)	20, 24
Rembrandt Diagnostics, LP v. Alere, Inc., 76 F.4th 1376 (Fed. Cir. 2023)	25
Return Mail, Inc. v. United States Postal Se 587 U.S. 618 (2019)	
SAS Institute, Inc. v. Iancu, 584 U.S. 357 (2018) 2, 4, 11, 14, 20,	, 28, 29, 30
In re Stepan Co., 660 F.3d 1341 (Fed. Cir. 2011)	22
TRUSTID, Inc. v. Next Caller, Inc., 2021 WL 4427918 (Fed. Cir. Sept. 27, 20	021)21

viii

TABLE OF AUTHORITIES

	Page(s)
Uniloc 2017 LLC v. Facebook, Inc., 2021 WL 5370480 (Fed. Cir. Nov. 18, 202	21) 26
United States v. Johnston, 268 U.S. 220 (1925)	17
Wildcat Licensing WI LLC v. Atlas Copco To Assembly Sys. LLC, 2024 WL 89395 (Fed. Cir. Jan. 9, 2024)	
Youakim v. Miller, 425 U.S. 231 (1976)	32
Statutes	
5 U.S.C. § 554(b) § 554(c) § 556(d) § 706(2)(D)	19, 20 20
35 U.S.C. § 311(a)-(b)	11, 14, 20 5, 24, 28 5 28
Leahy-Smith America Invents Act, Pub. L. 125 Stat. 284 (2011)	

	Page(s)
Regulations	
37 C.F.R.	
§ 42.1-80	5
§ 42.23	
§ 42.23(b)	
§ 42.51	
§ 42.65	
§ 42.100-123	
Other Authorities	
H.R. Rep. No.	
112-98 (2011)	4, 5
Rules of the Supreme Court of the U. Rule 10	

INTRODUCTION

United Therapeutics Corporation's (UTC's) Petition is based on a fundamentally false premise: that the Federal Circuit, contrary to 35 U.S.C. § 312(a)(3) (Section 312), deferred to a determination by the Patent Trial and Appeal Board (PTAB) allowing new printed publications" "new grounds and supporting unpatentability to be introduced into the inter partes review (IPR) proceedings brought by Respondent Liquidia Technologies, Inc. (Liquidia). Pet. 1; see 35 U.S.C. § 312(a)(3) (requiring an IPR petition to identify, inter alia, "the grounds on which the challenge to each claim is based" and "printed publications" supporting those grounds). The Federal Circuit did no such thing here. To the contrary, the Federal Circuit determined, without deference to the PTAB, that the grounds and publications asserted by Liquidia in its IPR petition—namely, obviousness based on two abstracts and a previously issued patent—remained the grounds and publications upon which the PTAB relied.

What the Federal Circuit did do—appropriately—was hold that the PTAB did not abuse its discretion in determining that Liquidia's IPR reply arguments were permissible under the PTAB's rules because they appropriately responded to new factual arguments raised for the first time in UTC's IPR opposition. Specifically, Liquidia's reply responded to UTC's new and fact-bound claim with argument and evidence that the same publications identified in Liquidia's petition—in support of the same grounds of unpatentability—were publicly accessible before the relevant cutoff date. The Director of the Patent and Trademark Office is required by statute to set rules for conducting IPR proceedings, see 35 U.S.C. § 316(c),

including as to the proper scope of reply and sur-reply submissions. And consistent with this statutory mandate and longstanding Federal Circuit precedent, the PTAB's application of those rules to specific IPR proceedings is reviewed for abuse of discretion. That is all that happened here.

That the Federal Circuit did not do what UTC claims it did is reason enough to deny the Petition. However, contrary to UTC's claims, there also is no intra-Circuit split. To begin, virtually all of UTC's cases applying a de novo standard were, in fact, considering procedural challenges adjudications under the Administrative Procedure Act (APA), and, in particular, whether the agency had provided notice and an opportunity to be heard. Some of those cases also cite Section 312 as a basis for de On the other hand, the abuse-ofnovo review. discretion cases cited by UTC consider the distinct question of the parties' compliance with the PTAB's rules, including that a reply brief be limited to arguments that respond to an opposition brief. The cases cited by UTC expressly recognize this distinction and are not in disagreement. The Federal Circuit's decision here does not conflict with either line of cases, this Court's decision in SAS Institute, Inc. v. Iancu, 584 U.S. 357 (2018), or otherwise break new ground.

Although UTC attempts to recast the Federal Circuit's opinion in this case and to contrive an intra-Circuit split in a bid for this Court's review, UTC's real complaint is simply about the facts as resolved below—namely, whether the two abstracts upon which Liquidia has relied since the initiation of the IPR were sufficiently accessible to the public before the relevant date. The PTAB's determination that they were is a factual finding reviewed only for

substantial evidence. It also turns on highly casespecific questions about scientific journals and the availability of the abstracts at certain conferences two decades ago. UTC is unhappy with these findings of fact, but its disappointment is no basis for review. *See* Sup. Ct. R. 10 ("A petition for a writ of certiorari is rarely granted when the asserted error consists of erroneous factual findings or the misapplication of a properly stated rule of law.").

Finally, UTC's belated invocation of *Chevron* in an apparent attempt to make this case seem significant in anticipation of this Court's recent ruling in Loper Bright Enterprises v. Raimondo, 603 U.S. ---, 144 S. Ct. 2244 (2024), likewise provides no basis for review, including a grant, vacatur, and remand as requested by UTC. Put simply, this case has nothing to do with *Chevron* or *Loper Bright*: it does not involve any assertion of statutory ambiguity, and it does not involve whether to defer to an agency's statutory construction in light of any such ambiguity. rulings below had nothing to do with *Chevron* either, and even were that not the case, UTC has waived any argument for review based on the overruling of *Chevron*, as it raised that issue for the first time in its Petition.

The Petition should be denied.

STATEMENT OF THE CASE

A. Statutory and Regulatory Framework

"To win a patent, an applicant must (among other things) file 'claims' that describe the invention and establish to the satisfaction of the Patent Office the invention's novelty and nonobviousness." U.S. at 360. "Sometimes, though, bad patents slip through." Accordingly, "Congress has long Id.permitted parties to challenge the validity of patent claims in federal court," and, "[m]ore recently, Congress has supplemented litigation with various administrative remedies." Id.; see Cuozzo Speed Techs., LLC v. Lee, 579 U.S. 261, 267 (2016) ("For several decades, the Patent Office has also possessed the authority to reexamine—and perhaps cancel—a patent claim that it had previously allowed.").

In 2011, Congress passed the Leahy-Smith America Invents Act (AIA). Pub. L. 112-29, 125 Stat. 284 (2011). Congress's chief aim in enacting the AIA was "to establish a more efficient and streamlined patent system that will improve patent quality and limit unnecessary and counterproductive litigation costs." H.R. Rep. No. 112-98, at 39-40 (2011). The AIA created the PTAB within the U.S. Patent and Trademark Office (PTO) and tasked it with overseeing three new types of administrative proceedings to efficiently review the validity of patents post-issuance. See Return Mail, Inc. v. United States Postal Serv., 587 U.S. 618, 623-624 (2019). One of these proceedings is known as *inter partes* review (IPR), which replaced a prior process known as *inter partes* reexamination. SAS, 584 U.S. at 361.

IPR permits "a person," other than the patent owner, to petition for the review of a patent on the ground that one or more of its claims is unpatentable, either because the claim lacks "novelty" or because the claim is "obvious" in light of "patents or printed publications" existing at the time of the patent application. 35 U.S.C. § 311(a)-(b); see id. §§ 102-103. An IPR proceeding begins with the filing of a petition with the PTAB, and under 35 U.S.C. § 312, an IPR petition must "identif[y], in writing and with particularity, each claim challenged, the grounds on which the challenge to each claim is based, and the evidence that supports the grounds for the challenge to each claim." *Id.* § 312(a)(3). Where applicable, a petitioner must include "copies of patents and printed publications that the petitioner relies upon in support of the petition." *Id.* § 312(a)(3)(A).

Under 35 U.S.C. § 316, the Director of the PTO "shall prescribe regulations * * * establishing and governing inter partes review under this chapter and the relationship of such review to other proceedings under this title." 35 U.S.C. § 316(a)(4). Under this provision, Congress authorized the PTO to set rules regarding a range of procedural aspects of an IPR proceeding—including the "discovery of relevant evidence," *id.* § 316(a)(5), the submission of briefs and supporting evidence, *id.* § 316(a)(8), and oral hearings, *id.* § 316(a)(10). As this provision reflects, Congress "intend[ed] for the USPTO to address potential abuses and current inefficiencies under its expanded procedural authority." H.R. Rep. No. 112-98, at 48 (2011).

Implementing Section 316, the PTO issued regulations governing virtually all aspects of PTAB proceedings, including IPRs. 37 C.F.R. §§ 42.1-80, 42.100-123. These regulations provide procedures for, among other things, producing documents and taking testimony, *id.* §§ 42.51-65, submitting briefs and

motions, id. §§ 42.20-25, and conducting oral argument, id. § 42.70.

As relevant here, 37 C.F.R. § 42.23 explicitly addresses the scope of reply briefs submitted in IPR proceedings: a reply "may only respond to arguments raised in the corresponding opposition, patent owner preliminary response, patent owner response, or the decision on institution." *Id.* § 42.23(b). A sur-reply similarly "may only respond to arguments raised in the corresponding reply and may not be accompanied by new evidence other than deposition transcripts of the cross-examination of any reply witness." *Id.*

B. The Parties Conducted *Inter Partes*Review Based On Liquidia's Claim of Obviousness and the Voswinckel Abstracts

UTC owns U.S. Patent 10,716,793 ("the '793 patent"), which describes a method for treating pulmonary hypertension by inhaling a drug called treprostinil. Pet. App. 2a, 17a n.2, 18a.

Liquidia petitioned for *inter partes* review of all claims of the '793 patent on the ground that they would have been obvious to a person of ordinary skill in the art before the relevant date of May 15, 2006. Pet. App. 3a; see Fed. Cir. App. 101-179. Liquidia's petitioned ground asserted obviousness on the basis of one of UTC's then-existing patents, U.S. Patent 6,521,212 ("the '212 patent"), when viewed in light of two previously published journal abstracts, called the Voswinckel abstracts. Pet. App. 3a; see Fed. Cir. App.

¹ References to "Fed. Cir. App." refer to the Joint Appendix below. See United Therapeutics Corp. v. Liquidia Technologies, Inc., No. 2023-1805 (Fed. Cir. Oct. 12, 2023), ECF No. 31.

124. Liquidia attached copies of the '212 patent and the Voswinckel abstracts to its IPR petition. Pet. App. 3a; Fed. Cir. App. 133-135, 141-157 (petition); Fed. Cir. App. 1207-1243 (attached materials).

As Liquidia's IPR petition explained, the '212 patent was published in 2003 and disclosed a method of delivering treprostinil to a patient by inhalation to treat pulmonary hypertension. Pet. App. 3a; see Fed. Cir. App. 130-133, 1207. The petition then explained that the first of the two Voswinckel abstracts, which was published in the Journal of the European Society of Cardiology (JESC) in October 2004, described a study of inhaled treprostinil that was presented at the European Society of Cardiology Congress in Munich. Pet. App. 3a, 21a, 23a; see Fed. Cir. App. 133-135, 1234-1240. Liquidia's petition further explained that the second Voswinckel abstract, which was published in the Journal of the American Heart Association (JAHA), described another study of patients who received inhaled treprostinil and was presented at the American Heart Association's Scientific Sessions in New Orleans in 2004. Pet. App. 3a, 21a, 23a; see Fed. Cir. App. 135-136, 1241-1243.

UTC opposed the institution of IPR. Its Patent Owner Preliminary Response did not, however, dispute that the Voswinckel abstracts qualified as prior art, despite contesting the prior art status of other art cited in the petition. Pet. App. 7a; see Fed. Cir. App. 237-251.

In August 2021, the PTAB instituted an IPR on all grounds set forth in Liquidia's petition. Pet App. 16a. UTC then, for the first time in its IPR response, challenged the sufficiency of the Voswinckel abstracts,

disputing whether they were sufficiently disseminated to the public. Pet. App. 3a-4a, 7a; see Fed. Cir. App. 372-379.

Liquidia's IPR reply reiterated that challenged patent claims were invalid as obvious in light of the Voswinckel abstracts. Pet. App. 7a; see Fed. Cir. App. 456-492. Rebutting UTC's new public dissemination arguments, Liquidia's IPR reply explained that the abstracts were disseminated and available to skilled artisans before the critical date. noting that the versions of the abstracts that were attached to Liquidia's petition indicated on their face that both were published by established publishers, and further providing library-stamped copies of both abstracts and evidence regarding their indexing. Fed. Cir. App. 470-474. Liquidia also emphasized that (as evidenced by deposition testimony of both parties' experts) both abstracts were presented at conferences in front of thousands of attendees, including skilled artisans, who would have received abstract books containing the Voswinckel abstracts. Fed. Cir. App. 470-471, 475. Finally, Liquidia noted that artisans could clearly find the abstracts because two skilled artisans had in fact cited those abstracts in 2005 articles, and those articles were research aids that would have pointed others to the abstracts. *Id.*; see also Pet. App. 24a.

UTC then filed a sur-reply, which conceded that Liquidia's "Petition * * * asserted that [the Voswinckel abstracts] are prior art because they were 'presented' at conferences in 2004," Fed. Cir. App. 561 (emphasis added); see Fed. Cir. App. 562-570; Pet. App. 23a-24a; see also Pet. App. 23a ("The argument that Voswinckel JESC was publicly presented is not a change in theory

from the Petition, because Petitioner presented this argument in the Petition."). UTC's sur-reply claimed, however, that Liquidia's reply arguments regarding the public accessibility of these abstracts were new and untimely. Pet. App. 23a; see Fed. Cir. App. 561-562.

C. The PTAB Determined that the Challenged Claims Are Unpatentable

After briefing and oral argument, the PTAB issued final written decision determining that claims of the '793 patent challenged unpatentable. Pet. App. 4a; see Pet. App. 15a-63a. The PTAB first determined that the two abstracts identified by Liquidia qualified as prior art in light of evidence that they were both presented at the specific conferences Liquidia identified in its petition and cited in articles pre-dating the relevant cutoff date. Pet. App. 22a-25a. Because the abstracts were "presented publicly" in these ways, the references qualified as prior art. Pet. App. 23a; see Pet. App. 4a. The PTAB also concluded that UTC's patent claims were obvious, as it was already well known that inhaling treprostinil could help treat pulmonary hypertension, and doing so using dosage levels suggested by available literature was a step a skilled artisan would take. Pet. App. 61a.

The PTAB also rejected UTC's contention that Liquidia had made "new" arguments in its IPR reply brief, noting that "both of the arguments that [UTC] alleges are new—the argument that Voswinckel abstracts were presented publicly and the argument that these references were cited in other publicly available references—respond to [UTC]'s argument in the Patent Owner Response that Voswinckel JESC and Voswinckel JAHA were not publicly accessible."

Pet. App. 23a. As the PTAB further recognized, UTC never argued that Liquidia's reply argument about the dissemination of the abstracts at conferences was a "new" theory for relief. Pet. App. 23a.

UTC sought rehearing of the PTAB's final written Pet. App. 4a. The PTO's Precedential Opinion Panel denied rehearing, while also directing the PTAB to clarify whether the Voswinckel abstracts qualify as prior art. Pet. App. 4a-5a; see Pet. App. 66a. Pursuant to this direction, the PTAB confirmed that Voswinckel abstracts were prior art, as they were publicly accessible by virtue of their presentation and distribution in materials, including abstract books, at the conferences identified in the petition. Pet. App. 5a, 75a-80a. As the PTAB explained, the "evidence of record" demonstrated that one of the two abstracts had been "distributed to more than twenty thousand people before or at the time of the ESC Congress 2004," while the other was similarly distributed to conference attendees. Pet. App. 77a-80a. Accordingly, the PTAB again held that UTC's patent claims were obvious. Pet. App. 5a; see Pet. App. 84a.

D. The Federal Circuit Unanimously Affirmed in a Non-Precedential Decision

UTC appealed to the Federal Circuit, arguing, among other things, that the PTAB had erred in determining that the Voswinckel abstracts were prior art, and that the PTAB had "improperly exceeded the prior art theories set forth in Liquidia's petition." Pet. App. 6a. The Federal Circuit unanimously affirmed in a non-precedential decision.

At the outset, in assessing UTC's arguments on appeal, the Federal Circuit stated that it "review[ed] the Board's legal determinations de novo," "its factual

findings for substantial evidence," and "the Board's determination whether, under the Board's own regulations, a party exceeded the scope of a proper reply for abuse of discretion." *Id.* (citations and italics omitted). The Federal Circuit further recognized that, under 35 U.S.C. § 312(a)(3) and *SAS*, 584 U.S. at 367, the PTAB was not permitted to "deviate from the grounds in the petition and raise its own theories of unpatentability." Pet. App. 6a-7a.

The Federal Circuit then explained that Liquidia had not raised any new theory of unpatentability before the PTAB that was not in its petition. See Pet. 7a. As the Federal Circuit explained, "Liquidia's IPR petition asserted that each of the Voswinckel abstracts was publicly presented or published at least one year before the priority date of the '793 patent," and its IPR reply provided additional evidence "that both Voswinckel abstracts were publicly presented and sufficiently disseminated at conferences prior to the critical date such that they qualified as printed publications." Id. (citing Fed. Cir. App. 133, 135 (Liquidia's IPR Petition) and Fed. Cir. App. 471, 474-475 (Liquidia's Reply in Support of '793 IPR Petition)).

Turning to the next question of "whether, under the [PTAB]'s own regulations, a party exceeded the scope of a proper reply," Pet. App. 6a (citation omitted), the Federal Circuit found no abuse of discretion in the PTAB's determination "that Liquidia's arguments and evidence raised in its Reply were not untimely as they were made in direct response to UTC's attack on the prior art status of the abstracts first raised in its post-institution Patent Owner Response," Pet. App. 7a-8a.

Finally, on the merits, the Federal Circuit concluded that substantial evidence supported the PTAB's conclusion that the Voswinckel abstracts were sufficiently disseminated to constitute a printed publication and thus prior art. Pet. App. 9a. As the Federal Circuit explained, the evidence before the PTAB showed "that the two 2004 conferences at which the abstracts were presented were attended by over 20,000 attendees," and that "every attendee of either conference would have received a copy of the abstract book in which each of the Voswinckel abstracts appeared." Id. The Federal Circuit further concluded that the PTAB's obviousness determinations were supported by substantial evidence, Pet App. 9a-13a, and that UTC's "remaining arguments" "unpersuasive," and thus affirmed the Board's unpatentability determination, Pet. App. 14a.

UTC unsuccessfully sought rehearing en banc, and thereafter petitioned this Court for review.

REASONS FOR DENYING THE PETITION

The Petition should be denied for multiple reasons. At the threshold, this case does not implicate the issue raised by the Petition: that the Federal Circuit erroneously applies abuse-of-discretion review to the PTAB's reliance on new "grounds" or "publications" not present in an IPR petition. The Federal Circuit here did not review that question for abuse of discretion, but instead determined—without deferring to the PTAB—that the grounds and publications relied on by the PTAB in its final written decision were the same ones asserted in Liquidia's IPR petition. What the Federal Circuit reviewed for abuse of discretion was a distinct question involving the PTAB's application of its procedural rules: whether

Liquidia's IPR reply was appropriately responsive to UTC's IPR opposition. Because this case does not involve the issue claimed by UTC, certiorari should be denied.

In any event, there is no intra-Circuit split, and UTC's attempt to create one is based on a distortion of the cases it invokes and the conflation of two separate lines of precedent. In particular, the cases UTC cites as applying a de novo standard of review concern the procedural requirements of the Administrative Procedure Act, including as informed by Section 312. The Petition fails to acknowledge the nature of these cases, and notably, there is no APA claim at issue here. Meanwhile, these same cases recognize that the Federal Circuit appropriately reviews for abuse of discretion the parties' compliance with the PTAB's procedural rules, such as the question of whether a reply brief is appropriately responsive to In short, there is harmony, not disharmony, in the Federal Circuit caselaw invoked by UTC, and certainly not any disharmony implicating the decision in this case.

Finally, *Chevron* and *Loper Bright* are irrelevant to this case. No party or tribunal in this litigation has relied on, or even raised, the *Chevron* doctrine until UTC's Petition. UTC has thus waived *Chevron*'s overruling as a basis for review. And in any event, this case presents no issue of statutory ambiguity or an agency's attempt to resolve it, and thus no reason for further review under *Loper Bright*.

I. Certiorari Should Be Denied Because This Case Does Not Present the Question Claimed as a Basis for Review

As explained below, the intra-Circuit split proffered by UTC does not exist. See infra Section II. But as a threshold matter, certiorari should be denied because this case is an improper vehicle for resolving the claimed split, as it does not present the question claimed by UTC: whether the Federal Circuit erred by reviewing for abuse of discretion the PTAB's "new grounds and new reliance on publications" not raised in an IPR petition. See Pet. i, To the contrary, any deference 2-3, 13, 18-23. exercised by the Federal Circuit here concerned an entirely distinct question: whether Liquidia's IPR reply, in support of its already petitioned grounds and publications, were appropriately responsive to UTC's opposition. Because this case does not involve the Federal Circuit's deference to the PTAB regarding new "grounds" or "publications" beyond those in an IPR petition, certiorari should be denied.

The Federal Circuit itself recognized the existence of the two separate issues that UTC now seeks to conflate into one. First, the panel explained that it "review[s] the [PTAB]'s legal determinations de novo," and "[b]y statute, the scope of an IPR is limited to the grounds set forth in the initial petition." Pet. App. 6a (citing 35 U.S.C. § 312(a)(3) and SAS, 584 U.S. at 367). Accordingly, "[i]t is improper for the Board to deviate from the grounds in the petition and raise its own theories of unpatentability." Pet. App. 7a. And, paying no deference to the PTAB, the Federal Circuit correctly found no violation of this principle: Liquidia had, throughout the IPR proceeding, asserted the

same "grounds" (obviousness) and "printed publications" (the Voswinckel abstracts) in asserting unpatentability. *Id.*; *see* Fed. Cir. App. 133, 135 (asserting in petition that both abstracts were prior art). The Federal Circuit thus held that the PTAB had correctly limited its decision to the same grounds, printed publications, and theory of unpatentability in the petition. Pet. App. 7a.

Second, the Federal Circuit applied an abuse-ofdiscretion standard to a different issue: under the PTAB's rules, Liquidia's IPR reply submission regarding the public accessibility of the two abstracts was appropriately responsive to the arguments UTC had made in its brief. Pet. App. 7a-8a. As the Federal Circuit recognized, this was not a question of any new "grounds" or new "printed publications." Rather, it was simply the application of the PTAB's rules to a question about the proper course of briefing and argument on a subsidiary factual issue—namely, UTC's argument, raised for the first time in its IPR response, that the two publications identified in the petition (the Voswinckel abstracts) did not qualify as prior art because they had not been adequately disseminated. Pet. App. 7a. And as to that issue, the Federal Circuit appropriately asked whether the PTAB had abused its discretion in finding that Liquidia's reply submissions—none of which asserted any new grounds or printed publications were "made in direct response" to "UTC's attack" that was "first raised" in its response. Pet. App. 7a-8a.

Under applicable regulations and precedent, the Federal Circuit correctly found none.²

The Federal Circuit also did not, as UTC contends, hold that it "will let the Board consider anything not ruled out by the petition." Pet. 3. UTC advances this fiction by distorting the Federal Circuit's conclusion that Liquidia's reply arguments were "not inconsistent with, and therefore not new over, the grounds raised in its IPR petition." Pet. App. 8a. But read fairly and in context, what the Federal Circuit held—after ensuring for itself that Liquidia's reply relied on the same grounds and publications as its petition—was simply that the PTAB also did not abuse its discretion by concluding that Liquidia's reply arguments had not "cross[ed] the line from the responsive to the new" under PTAB rules. Pet. App. 7a-8a (quoting *Ericsson Inc. v. Intell.* Ventures I LLC, 901 F.3d 1374, 1380 (Fed. Cir. 2018)). This is not, as UTC misalleges, "maximum deference," Pet. i, but instead is a straightforward application of Federal Circuit precedent regarding review of complaints about application of the PTAB's rules. Indeed, there is nothing in the Federal Circuit's opinion that suggests the outcome would have been any different had the panel reviewed this question de novo—making this case an even weaker vehicle to address the question UTC presents.

² The Federal Circuit's holding was particularly sensible because, in opposing the institution of IPR, UTC had not disputed that the abstracts were prior art. Pet. App. 7a. For that reason, Liquidia's first opportunity to respond to this argument came in its reply brief during the IPR proceeding, where it provided evidence demonstrating that the abstracts had indeed been publicly disseminated before the relevant date.

In short, this case does not present the Court with any opportunity to consider whether the Federal Circuit errs, as part of a supposed intra-Circuit split, by deferring to the PTAB's reliance on new grounds or printed publications in an IPR, because the Federal Circuit granted no such deference here. Instead, UTC is simply dissatisfied with the PTAB's fact-bound and case-specific determination—affirmed by the Federal Circuit as supported by substantial evidence—that the same two abstracts identified in Liquidia's IPR petition were, in fact, disseminated at the same two conferences identified in Liquidia's IPR petition. UTC seeks to transform this factual disagreement into an issue implicating broader legal questions because it knows—and the cases it cites confirm (Pet. 21)—that factual determinations like this one are reviewed by appellate courts only for substantial evidence. See, e.g., Nobel Biocare Servs. AG v. Instradent USA, Inc., 903 F.3d 1365, 1375 (Fed. Cir. 2018) (reviewing question of "public accessibility" for "substantial evidence"); Medtronic, Inc. v. Barry, 891 F.3d 1368, 1380 (Fed. Cir. 2018) ("[w]hether a reference qualifies as a 'printed publication' is a legal question based on underlying factual determinations," including as to "the issue of a reference's public accessibility" (citation omitted)).

UTC cannot meet this standard for disturbing the PTAB's factual findings, and the fact-bound challenge it actually presents is entirely inappropriate for review by this Court. See Sup. Ct. R. 10 ("A petition for a writ of certiorari is rarely granted when the asserted error consists of erroneous factual findings or the misapplication of a properly stated rule of law."); United States v. Johnston, 268 U.S. 220, 227 (1925)

("We do not grant a certiorari to review evidence and discuss specific facts.").3

II. UTC Identifies No Intra-Circuit Split Warranting this Court's Review

UTC seeks this Court's attention by claiming an "unmistakable intra-circuit split" regarding "whether the PTO is entitled deference when making patentability determinations based on new grounds or publications not raised in the initial IPR petition." Pet. 13; *id.* at 13-18. There is no such split, and UTC's effort to create one misrepresents the cases it cites and conflates two entirely distinct issues.

On the one hand, several Federal Circuit cases, including virtually all of those UTC approvingly cites (at Pet. 15-16), apply a de novo standard of review in considering APA due process challenges, informed in some instances by Section 312 considerations, where

³ UTC's suggestion that the Voswinckel abstracts are "different prior art" because they appeared in abstract books, rather than in journal supplements, is baseless. Pet. 11; see id. at 22, 25. In assessing prior art, the operative references are the abstracts not the broader compilations in which they appeared—as it is well settled that "there are many ways in which a reference may be disseminated to the interested public." Jazz Pharms., Inc. v. Amneal Pharms., LLC, 895 F.3d 1347, 1355 (Fed. Cir. 2018) (citation omitted). Likewise, UTC's claim (Pet. 22) that the distribution of abstract books containing the Voswinckel abstracts is "hypothetical"—a factual finding reviewed only for substantial evidence on appeal—is entirely unfounded. Not only did the abstracts attached to the petition include specific dates and locations of the conferences at which they were presented, but copies of the same abstracts refer to "[t]his abstract book" and even include advertisements for booths at the conference. Fed. Cir. App. 2684, 7597-7613, and both parties' experts confirmed dissemination of the abstract books, Pet. App. 77a-80a.

an IPR respondent claims that it has been denied notice and an opportunity to be heard on an issue raised in the course of an IPR. 5 U.S.C. §§ 554(b)-(c). But the APA's procedural requirements are not at issue here; indeed, the Petition makes no APA argument at all. And on the other hand, several other cases—like this one—apply an abuse-of-discretion standard in considering compliance with the PTAB's rules, which govern everything from discovery to the responsiveness of reply and sur-reply briefs.

These are separate legal issues with distinct standards of review, which the Federal Circuit—unlike UTC here—takes care not to conflate. In reality, the cases on both sides of UTC's purported "split" agree with each other, and there is simply no conflict warranting this Court's review.

A. As UTC's Cases Show, the Federal Circuit Reviews De Novo the PTAB's Compliance with the APA's Procedural Requirements, as Informed by Section 312

The Petition invokes (at Pet. 15-16) several cases involving de novo review but fails to acknowledge what these cases were actually reviewing: alleged violations of the APA. UTC's cited cases thus concern an issue not presented by this case: the due process protections, including the right to be heard and to respond to arguments and evidence in adjudications, that the APA provides. *See*, *e.g.*, 5 U.S.C. §§ 554(b)-(c). The Petition makes no argument regarding the APA, and the APA cases it identifies do not create any intra-Circuit split. And in any event, the standard of review applied in these cases—in a couple of instances, also by reference to Section 312—conforms

to the one the panel applied here, as the panel reviewed "legal determinations de novo," including whether "the scope of [the] IPR [was] limited to the grounds set forth in the initial petition." Pet. App. 6a (citing 35 U.S.C. § 312(a)(3) and SAS, 584 U.S. at 367).

The APA's procedural requirements for IPR proceedings—the true subject of UTC's cited cases and the standard of review for claims that those requirements have been violated, are settled. "IPR proceedings are formal adjudications that must satisfy procedural requirements relevant Administrative Procedure Act (APA)." Parkervision, Inc. v. Vidal, 88 F.4th 969, 978 (Fed. Cir. 2023) (citation omitted). Under the APA, the PTAB must "timely inform' the patent owner of 'the matters of fact and law asserted,' must provide 'all interested parties opportunity for the submission and consideration of facts and arguments and hearing and decision on notice,' and must allow 'a party to submit rebuttal evidence as may be required for a full and true disclosure of the facts." Id. (quoting 5 U.S.C. §§ 554(b)(3), 554(c), 556(d)) (alterations omitted). As relevant here, the APA directs that "[t]he reviewing court shall * * * hold unlawful and set aside agency findings, and conclusions found be * * * without observance of procedure required by law." 5 U.S.C. § 706(2)(D). In light of this APA mandate, the Federal Circuit "review[s] the Board's compliance with the procedural requirements of the Administrative Procedure Act * * * de novo." Axonics, Inc. v. Medtronic, Inc., 75 F.4th 1374, 1380 (Fed. Cir. 2023) (citing 5 U.S.C. § 706(2)(D)).

While unmentioned by UTC in its Petition, the APA is, in fact, the subject of nearly all of the de novo

cases UTC approvingly cites (at Pet. 15-16). example, in In re NuVasive, Inc., 841 F.3d 966 (Fed. Cir. 2016), the Federal Circuit asked whether the PTAB's reliance on certain materials submitted by a petitioner "violated [the patent owner's] rights under the Administrative Procedure Act." Id. at 968. The Federal Circuit concluded that the PTAB's reliance on those materials did violate the APA, explaining that the PTAB had found a patent invalid on the basis of certain factual assertions that it deemed "essential" but had not been cited in the petition. *Id.* at 971-972. "[U]nder the APA's standards," the panel explained, the patent owner was "entitled to an adequate opportunity to respond," id. at 972, but did not receive that opportunity, as the PTAB had denied the patent owner's requests to file a sur-reply or address the new materials at oral argument, id. at 971-973.

Similarly, relying on NuVasive, the panel in TRUSTID, Inc. v. Next Caller, Inc., 2021 WL 4427918 Sept. 27, 2021) (non-precedential) considered an argument that "the Board violated the APA when it relied" on certain allegedly new material. Id. at *4. After explaining that the Federal Circuit "review[s] the Board's decision for compliance with the Administrative Procedure Act ('APA') de novo," id. at *2, the TRUSTID panel found "no APA violation here because [the patent owner] received adequate notice and an opportunity to be heard," id. at *4. Accordingly, the TRUSTID panel found that the PTAB did not "violate[] [the patent owner's] procedural rights" under the APA. *Id.* at *5.

The remaining cases invoked by UTC in a string cite (Pet. 16) addressed the same APA issue. See, e.g., AIP Acquisition LLC v. Cisco Sys., Inc., 714 F. App'x

1010, 1016 (Fed. Cir. 2017) (non-precedential) (finding "no APA violation" in PTAB's final decision because its prior decision instituting IPR "contained the exact same language," which "put [the patent owner] on notice and allowed it to respond both in its Patent Owner Response and during the oral hearing"); *In re Stepan Co.*, 660 F.3d 1341, 1343-1345 (Fed. Cir. 2011) (pre-AIA) (agreeing that Board of Patent Appeals and Interferences in reexamination proceeding had "violate[d] [the respondent's] administrative due process rights" to "a full and fair opportunity to litigate the Board's actual basis of rejection" by relying on new ground that patent examiner had not raised (citing APA)).

UTC highlights (at Pet. 15-16) Corephotonics Ltd. v. Apple Inc., 84 F.4th 990 (Fed. Cir. 2023), a case referencing both the APA and Section 312, but Corephotonics only confirms that the Federal Circuit in the instant case applied the standard of review that UTC claims should apply. According to Corephotonics, "[a]ny marked departure from the grounds identified with particularity in the petition would impose 'unfair surprise' on the patent owner and, consequently, violate both the APA and the IPR statute." *Id.* at 1002 (quoting Arthrex Inc. v. Smith & Nephew, Inc., 935) F.3d 1319, 1328 (Fed. Cir. 2019), which considered an APA challenge). And, though obscured in UTC's petition, the Federal Circuit in Corephotonics expressly contrasted the de novo standard of review for that issue with the abuse-of-discretion standard it applies to the distinct question of whether "the petitioner's reply [is limited] to addressing issues presented in the patent owner responses or the Board's institution decision"—a standard that is

"grounded in the Board's regulations." *Id.* at 1008; see also Wildcat Licensing WI LLC v. Atlas Copco Tools & Assembly Sys. LLC, 2024 WL 89395, at *2 (Fed. Cir. Jan. 9, 2024) (non-precedential) (cited at Pet. 16) (recognizing same distinction).⁴

In short, the Federal Circuit here did exactly what UTC claims it should have done, consistent with the cases cited by UTC: the Federal Circuit compared Liquidia's petition to the PTAB's final written decision and determined that the decision relied on precisely the *same* grounds, the *same* two abstracts, and the *same* theory of unpatentability as Liquidia's IPR petition itself. Pet. App. 7a. And it did so without deferring to any determination by the PTAB on that topic. There was thus no violation of the APA or Section 312, and no deviation from the cases cited by UTC.

B. As UTC's Cases Also Show, the Federal Circuit Reviews Compliance with the PTAB's IPR Rules, Including Regarding Reply Briefs, for Abuse of Discretion

Separate from the question whether any new grounds or publications have been inserted into an IPR proceeding in violation of the APA or Section 312, the Federal Circuit considers questions of compliance with the PTAB's regulations—including whether a petitioner's reply is responsive to a patent owner's opposition—for abuse of discretion. See Corephotonics, 84 F.4th at 1008 (recognizing the

⁴ This case—unlike nearly all of the de novo review cases cited by UTC—does not involve a claim that the PTAB violated the APA's procedural protections. Indeed, the Petition presents no argument regarding the APA at all. Nor does the Federal Circuit's ruling mention or rely upon the APA.

distinction between these two questions). The Federal Circuit's abuse-of-discretion caselaw, including the cases cited by UTC, recognize this distinction and agree with each other (and the decision below), confirming that there is no split warranting review.

By statute, the USPTO Director is required to set rules governing PTAB proceedings, including IPRs. 35 U.S.C. § 316. Those rules, though mostly unaddressed in the Petition, address precisely the issue presented here: the proper scope of a petitioner's reply. In particular, these rules provide that a "reply may only respond to arguments raised in the corresponding opposition, patent owner preliminary response, patent owner response, or decision on institution." 37 C.F.R. § 42.23(b). A patent owner may then submit a sur-reply, as UTC did here, and a "sur-reply may only respond to arguments raised in the corresponding reply and may not be accompanied by new evidence other than deposition transcripts of the cross-examination of any reply witness." Id. The PTAB's rules also govern a host of other procedural issues that arise in the course of an IPR proceeding for example, they set forth the procedures for discovery, id. § 42.51, the submission of evidence, id. §§ 42.61-65, and oral argument, id. § 42.70.

Absent any APA challenge, the Federal Circuit "review[s] for an abuse of discretion the [PTAB's] determination that a party violated these rules." *Parkervision*, 88 F.4th at 978-979. And as relevant here, "[t]he [PTAB's] determinations that a party exceeded the scope of a proper reply are reviewed for abuse of discretion." *Apple Inc. v. Andrea Elecs. Corp.*, 949 F.3d 697, 705 (Fed. Cir. 2020).

All of the cases UTC cites (Pet. 14-15) apply this settled standard of review in the context of claimed violations of the PTAB's procedural rules. In *Ericsson* Inc. v. Intellectual Ventures ILLC, 901 F.3d 1374 (Fed. Cir. 2018), for instance, the Federal Circuit considered whether the PTAB abused its discretion in rejecting certain arguments in a reply brief, after the patent owner had offered a new interpretation of its own patent "for the first time" in its IPR response. Id. at 1378, 1380. Noting that "under PTO regulations, the Board is entitled to strike arguments improperly raised for the first time in a reply," the Federal Circuit concluded that petitioner was "entitled to argue on reply" why the patent owner's newfound interpretation of its patent was not correct—a basic question of a reply's responsiveness. *Id.* at 1379-1380 (citing 37 C.F.R. § 42.23(b)).

Similarly, in Rembrandt Diagnostics, LP v. Alere, Inc., 76 F.4th 1376 (Fed. Cir. 2023), the Federal Circuit explained that "[d]ecisions related compliance with the [PTAB's] procedures are reviewed for an abuse of discretion." Id. at 1382 (quoting Ericsson, 901 F.3d at 1379). And after outlining the PTAB's procedures for submitting briefs and evidence, the Rembrandt panel determined that the PTAB was within its discretion to consider arguments raised in a reply because those arguments were "responsive to [the patent owner's] arguments and the Board's observations." Id. at 1385; see also Corephotonics, 84 F.4th at 1009 (approvingly citing Rembrandt as to responsiveness requirement).

The remaining abuse-of-discretion cases UTC invokes (at Pet. 14-15)—nearly all non-precedential—are also all in accord in applying this standard of

review. See, e.g., MModal LLC v. Nuance Comme'ns, Inc., 846 F. App'x 900, 906 (Fed. Cir. 2021) (nonprecedential) (reviewing whether reply provided a "permissible explanation and defense (in responding, e.g., to a Patent Owner's Response) of a point already sufficiently made" and finding no abuse of discretion in determination that argument exceeded permissible scope of reply); Kom Software, Inc. v. NetApp, Inc., 2021 WL 5985360, at *2 (Fed. Cir. Dec. 17, 2021) (nonprecedential) (finding no abuse of discretion in PTAB's determination that a petition had not raised an argument later asserted, where "[t]he statement [the petitioner] identifie[d] in its petition [regarding that argument] is not clearly a distinct argument"); *Netflix*, Inc. v. DivX, LLC, 84 F.4th 1371, 1378-1380 (Fed. Cir. 2023) (finding no abuse of discretion in PTAB's determination that petitioner exceeded proper scope of reply); Microsoft Corp. v. IPA Techs. Inc., 2022 WL 989403, at *6 (Fed. Cir. Apr. 1, 2022) (nonprecedential) (same); Uniloc 2017 LLC v. Facebook, Inc., 2021 WL 5370480, at *7-8 (Fed. Cir. Nov. 18, 2021) (non-precedential) (finding that PTAB abused discretion in "overlooking" statements made in petition and reply).

Tellingly, even the cases UTC cites as supposedly supporting its plea for de novo review (at Pet. 15-17), expressly agree that abuse-of-discretion review applies to questions about responsiveness or compliance with the PTAB's rules. See, e.g., Wildcat Licensing, 2024 WL 89395, at *2 ("We review decisions related to compliance with Board procedures for an abuse of discretion." (citing Ericsson, 901 F.3d at 1379)); Corephotonics, 84 F.4th at 1002-1003 ("[T]the Board has discretion to determine whether a petition

identified the specific evidence relied on in a reply and when a reply contention crosses the line from the responsive to the new. We review the Board's assessments of what has been argued to and put before it in an IPR for abuse of discretion." (quotations, citation, and alterations omitted)); Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd., 821 F.3d 1359, 1367 (Fed. Cir. 2016) ("[T]he Board's determinations that [petitioner] exceeded the scope of a proper reply in violation of 37 C.F.R. § 42.23(b) * * * are reviewed for an abuse of discretion."). Thus, UTC's own favorably cited cases confirm that there is in fact no split or disharmony in need of review.

Not only is there no split regarding the standard of review, but the Federal Circuit's settled application of abuse-of-discretion review to evaluate the PTAB's compliance with its procedural rules is not "illconceived." Pet. 15. In the course of IPR proceedings, the PTAB confronts all manner of procedural issues addressed by its rules—whether regarding reply briefs, discovery, evidence, or other issues. And in assessing the responsiveness of reply briefs in particular, the PTAB must take account of everything that has happened in the IPR to date—how the IPR was instituted and how the patent owner has attempted to defend its patent throughout the proceeding. 37 C.F.R. § 42.23(b). The PTAB is in the best position to make that assessment, and to subject its determination as to the rules for reply briefs and all other issues to de novo judicial review—absent any congressional directive requiring such review—would bog down the IPR process, contrary to Congress's directive of speed and efficiency and its statutory mandate that the PTO establish rules governing IPR. See 35 U.S.C. § 316(a)(11) (requiring PTAB to issue final written decision within 12 months of instituting IPR); id. § 316. It would also flood the Federal Circuit with appeals of the PTAB's procedural rulings, as parties would hope that de novo review would yield better results than the current abuse-of-discretion standard. Congress enacted the AIA to ease the burdens on federal courts, and the form of micromanagement a de novo standard would create simply cannot be squared with that objective.⁵

And contrary to UTC's assertions (Pet. 18-19), none of this implicates this Court's decision in *SAS Institute, Inc. v. Iancu*, 584 U.S. 357 (2018). *SAS* simply held that the PTAB must, pursuant to 35 U.S. § 318(a), resolve all claims for which it has instituted IPR. 584 U.S. at 359-360. Neither that principle nor Section 318 is at issue here, and the broader observation in *SAS* that "the petitioner's contentions, not the Director's discretion, define the scope of the litigation all the way from institution through to

⁵ Abuse of discretion is the default standard for assessing an agency's procedural rulings during adjudications. *See, e.g.*, *Napleton 1050, Inc. v. NLRB*, 976 F.3d 30, 39 (D.C. Cir. 2020) ("We review the Board's procedural rulings for abuse of discretion."). It is also the default standard of review for district courts' determinations regarding "whether to consider" arguments in a reply brief. *Flathead-Lolo-Bitterroot Citizen Task Force v. Mont.*, 98 F.4th 1180, 1188 (9th Cir. 2024); *see also, e.g.*, *Green v. U.S. Anesthesia Partners of Colo., Inc.*, 2023 WL 7015660, at *7 (10th Cir. Oct. 25, 2023) ("A court's consideration of a reply on * * * and denial of a surreply is reviewed for abuse of discretion." (citation omitted)); *Echevarria v. Astrazeneca Pharm. LP*, 856 F.3d 119, 133 n.18 (1st Cir. 2017) (abuse of discretion standard applies to district court's consideration of argument raised on reply).

conclusion" holds true here. *Id.* at 367. All of the cases UTC identifies—whether those considering the APA's due process requirements or the responsiveness of replies under the PTAB rules—recognize that the PTAB's decisions must rest on "the petitioner's contentions," and UTC identifies no conflict warranting review.

* * *

The purported intra-Circuit split UTC identifies is illusory. Informed by Section 312, the Federal Circuit appropriately reviews APA challenges de novo, and it appropriately reviews questions regarding compliance with the PTAB's rules for abuse of discretion. The cases cited by UTC reflect this distinction and provide no basis for this Court's review.

III. Chevron and Loper Bright Are Irrelevant to This Case

In a final ploy for this Court's attention, UTC seeks a grant, vacatur, and remand in light of *Loper Bright*. Pet. 23-25. But this case has nothing to do with *Chevron* or *Loper Bright*. Indeed, until the Petition, no one—least of all the Federal Circuit—claimed that this case involves any question of statutory ambiguity or an agency's attempt to resolve such ambiguity, which is the circumstance in which *Chevron* applied before it was overruled. Nor do any of the cases identified by UTC purport to rely on *Chevron*. Denial, not a GVR, is the proper resolution of the Petition.

A. This Case Does Not Involve Statutory Ambiguity or *Chevron* Deference

UTC identifies nothing in the Federal Circuit's decision—nor could it—indicating that the decision

relied on deference to the PTAB's interpretation of any federal statute under *Chevron*, *U.S.A.*, *Inc. v. Natural Resources Defense Council*, *Inc.*, 467 U.S. 837 (1984). And, as UTC concedes, *Chevron* deference is triggered only if, after "employing traditional tools of statutory construction, we find ourselves unable to discern Congress's meaning." Pet. 23 (citing *SAS*, 138 S. Ct. at 1358). "*Chevron* deference does not apply where the statute is clear." *Johnson v. Guzman Chavez*, 594 U.S. 523, 547 n.9 (2021). And nowhere in its decision did the Federal Circuit state, or even suggest, that any statute governing IPR proceedings was ambiguous—let alone that it was relying on *Chevron* in any way.

Rather than identify any actual connection between this case and *Chevron* (there is none), UTC seeks to concoct a connection by pointing to a claimed "split" and then arguing that "the only conceivable way the Federal Circuit" could have reached its decision on the purportedly wrong side of the split below was "some form of *Chevron* deference." Pet. 24. But there is no such split. See supra Section II. Nor is there any allegedly ambiguous statute that warranted any invocation of *Chevron* deference. Indeed, UTC never says what the Federal Circuit purportedly (and *sub silentio*) found ambiguous, nor how the Federal Circuit resolved that statutory ambiguity. And indeed, even if the intra-Circuit split alleged by UTC existed (it does not), it would not implicate *Chevron*, as *none* of the cases cited by UTC rely on *Chevron* or point to any form of statutory ambiguity. Put simply, this is not a *Chevron* case in any way, shape, or form, and thus *Chevron* framework provides no basis for this Court's review.

B. Loper Bright Has No Bearing On This Case

Likely recognizing there is no *Chevron* issue for this Court's review, UTC grasps for a potential GVR under this Court's recent decision in *Loper Bright Enterprises v. Raimondo*, 603 U.S. ---, 144 S. Ct. 2244 (2024). But there is no basis whatsoever for a GVR, as *Loper Bright* is irrelevant to this case. As explained, *Chevron* is irrelevant to this case, which has nothing to do with an agency's attempt to resolve statutory ambiguity or a federal court's review thereof. *See supra* Section III.A. Accordingly, this Court's overruling of *Chevron* in *Loper Bright* also has absolutely no connection to this case.

And, although *Chevron* and *Loper Bright* are both irrelevant here, it is also worth noting that Loper Bright itself made clear that it did "not call into question prior cases that relied on the Chevron framework." Id. at 2273. As the Court explained, "[t]he holdings of those cases that specific agency actions are lawful * * * are still subject to statutory stare decisis despite our change in interpretive methodology," and "[m]ere reliance on *Chevron* cannot constitute a 'special justification' for overruling such a holding, because to say a precedent relied on *Chevron* is, at best, 'just an argument that the precedent was wrongly decided." Id. (citations omitted) (quoting Halliburton v. Erica P. Johnson Fund., Inc., 573 U.S. 258, 266 (2014)). "That is not enough to justify overruling a statutory precedent." Loper Bright, 144 S. Ct. at 2273. Thus, even if the decision below had anything to do with *Chevron* (it did not), that alone would not be enough to require a GVR. And where, as here, the decision below had nothing at all to do with *Chevron*, denial—not GVR—is the proper disposition.

C. Any Argument Regarding *Chevron* Has Been Waived

Finally, even assuming *Chevron* deference were at issue here, UTC did not present this issue below and has therefore waived it. This Court "do[es] not normally decide issues not presented below" absent exceptional circumstances. Carlson v. Green, 446 U.S. 14, 17 n.2 (1980); see also Youakim v. Miller, 425 U.S. 231, 234 (1976) ("It is only in exceptional cases coming here from the federal courts that questions not pressed or passed upon below are reviewed." (citation omitted)). That is because it is "essential in order that parties may have the opportunity to offer all the evidence they believe relevant to the issues," and "in order that litigants may not be surprised on appeal by final decision there of issues upon which they have had no opportunity to introduce evidence." *Hormel v.* Helvering, 312 U.S. 552, 556 (1941). Accordingly, because UTC did not raise a *Chevron* argument below or at any step of this litigation, UTC cannot now invoke *Chevron* and *Loper Bright* as a basis for review.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted,

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