No. 2023-1805

United States Court of Appeals for the Federal Circuit

UNITED THERAPEUTICS CORPORATION,

Appellant,

– v. –

LIQUIDIA TECHNOLOGIES, INC.,

Appellee.

APPEAL FROM THE PATENT TRIAL & APPEAL BOARD
IPR2021-00406

APPELLANT'S PETITION FOR PANEL REHEARING AND REHEARING EN BANC

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CERTIFICATE OF INTEREST

Counsel for Appellant certifies the following:

1. The full name of every party represented by me is:

United Therapeutics Corporation.

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is:

None.

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party represented by me are:

BlackRock Inc., collectively through different BlackRock entities, may own 10% or more of its stock.

4. The names of all law firms and the partners or associates that appeared for the party now represented by me in the trial court or are expected to appear in this court (and who have not or will not enter an appearance in this case) are:

Foley & Lardner: Stephen B. Maebius, Michael Houston, George Quillin, Jason N. Mock; McDermott Will & Emery: Judy Mohr, Ph.D., April E. Weisbruch, Mandy Kim

5. The title and number of any case known to me to be pending in this or any other court or agency that will directly affect or be directly affected by this Court's decision in the pending appeal are:

United Therapeutics Corporation v. Liquidia Technologies, Inc., Nos. 2022-2217, 2023-1021 (Fed. Cir.); originating from *United Therapeutics Corporation v. Liquidia Technologies, Inc.*, 1-20-cv-755 (D. Del.)

6. Any information required under Fed. R. App. P. 26.1(b) (organizational victims in criminal cases) and 26.1(c) (bankruptcy case debtors and trustees):

None.

Dated: January 19, 2023

/s/ *Douglas H. Carsten*
Douglas H. Carsten

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GLOSSARY

'793 Patent	U.S. Patent No. 10,716,793 (Appx1001-Appx1025)
Board	Patent Trial and Appeal Board
JAHA	IPR Exhibit 1008: Circulation: Journal of the American Heart Association (Appx1241-Appx1243)
JESC	IPR Exhibit 1007: European Heart Journal: Journal of the European Society of Cardiology (Appx1234-Appx1240)
Liquidia	Appellee Liquidia Technologies, Inc.
Op.	Opinion (Dkt. 52)
POP	Precedential Opinion Panel
POR	Patent Owner Response
UTC	Appellant United Therapeutics Corporation

RULE 35(b) STATEMENT

Based on my professional judgment, I believe the panel decision is contrary to the following decisions of the Supreme Court of the United States or the precedents of this Court:

- *SAS Inst. Inc., v. Iancu*, 138 S. Ct. 1348 (2018);
- *In re NuVasive, Inc.*, 841 F.3d 966 (Fed. Cir. 2016);
- *Corephotonics, Ltd. v. Apple Inc.*, 84 F.4th 990 (Fed. Cir. 2023);
- *Norian Corp. v. Stryker Corp.*, 363 F.3d 1321 (Fed. Cir. 2004).

RULE 40(a)(2) STATEMENT

The Panel overlooked the following facts:

- Liquidia's Petition never argued that JAHA was publicly "presented" or "disseminated" at a conference;
- For JAHA, the Board determined that Liquidia's "presentation" theory was untimely, because—unlike for JESC—it was "a change in theory from the petition" Appx0010 (citing only Pet. at 22 for JESC, and finding "not untimely" only that "JESC was presented publicly"); and
- UTC never had an adequate opportunity to respond to Liquidia's new Reply arguments concerning the public accessibility of newly alleged prior art references.

The Panel also overlooked the Court's "newness restriction" and that the Board's errors—pertaining to new grounds of unpatentability not advanced in the Petition—are subject to *de novo* review.

INTRODUCTION

The Panel's decision begs for scrutiny. An IPR petition must describe the printed publications relied upon and the specific theories of invalidity to be addressed. 35 U.S.C. § 312(a)(3). Yet the Panel affirmed an obviousness finding based on (1) a theory undeniably absent from Liquidia's Petition and (2) references omitted from the Petition that no one has seen and are not in the record. And the Board denied UTC the opportunity to fully respond to the untimely arguments. The Panel's reasoning departs from the statutory limits on IPR proceedings and precedent. Without correction, the Panel's decision will create unnecessary confusion and encourages sandbagging.

First, the Panel decision announced an unprecedented and unsupported legal standard for adjudicating the scope of IPRs. Rather than cabin the Board's review to the petition—as the statute requires—the Panel deferred to the "discretion" of the Board to rely on distinct public accessibility theories never advanced in the petition so long as they are "not inconsistent with" theories advanced in the petition. Op. 8. But this new and practically limitless "inconsistency" standard—unchecked by *de novo* review—is foreclosed by § 312(a)(3) and Supreme Court precedent. The petition governs the scope of proceedings, not the Board's

"discretion"; thus, the Board may not entertain theories advanced after institution. *SAS*, 138 S. Ct. at 1356.

Applying the Panel's inconsistency test, a general contention that one reference was "publicly accessible prior to the critical date" gives the petitioner carte blanche to advance *any* new theory of public accessibility—even based on a different, never-seen, unasserted reference—after institution. *Id*. This is no standard at all. The Board is authorized to decide theories only on the grounds raised "in writing and with particularity" in the initial petition. § 312(a)(3). *En banc* review is warranted where this Court is repeatedly asked to review the "fine line" the Board walks "when interpreting the scope of a petition and determining what arguments have been fairly presented." *Netflix, Inc. v. DivX, LLC*, 84 F.4th 1371, 1377 (Fed. Cir. 2023) (collecting cases). Left uncorrected, the Panel's decision will stoke uncertainty and confusion about the Board's newly-granted authority to consider any theory not "inconsistent with" the petition.

Second, the Panel's holding that IPR petitioners need not provide any "evidence of actual existence" of references asserted to be § 102(b) prior art conflicts with precedent. Op. 8. It is, and always remains, the patent challenger's burden to prove that the invention was "described in a printed publication . . . more than one year prior to the date of the

application." 35 U.S.C. § 102(b); *Medtronic, Inc. v. Barry*, 891 F.3d 1368, 1381 (Fed. Cir. 2018). "[G]eneral practice" of dissemination at academic conferences is not "substantial evidence of actual availability" of a specific publication. *Norian*, 363 F.3d at 1330. But general industry practice was all that Liquidia offered. Incredibly, Liquidia presented only speculation that the not-in-evidence "abstract books" on which the Board based its public accessibility determination existed. Liquidia presented no evidence that those abstract books had the same content as JESC and JAHA or described the claimed invention to the public as § 102(b) requires. Here, too, the Panel's decision conflicts with binding law and must be corrected.

BACKGROUND

Liquidia's Petition asserted that the '793 patent claims were obvious over a combination involving two journal supplements, JESC and JAHA. The Petition asserted that JESC and JAHA were "published" in journal supplements and available at libraries. Appx0133-Appx0135. As background, the Petition also stated that JESC—but not JAHA—was "presented" at a conference. *Id.* The Petition focused on publication and alleged availability in libraries, with no evidence regarding what was allegedly made available in any conference "presentation"—*e.g.*, no testimony from an attendee that knew what information was available

in print or by oral presentation. Appx0133-Appx0135 (citing Appx1164-Appx1167, Appx1886-Appx1897). Consequently, UTC's POR disputed public accessibility of those journal supplements. Appx0373-Appx0379.

Faced with evidence that the JESC and JAHA journal supplements were unindexed and not available in libraries, Liquidia's Reply advanced new arguments asserting (i) that different, not-in-evidence references—"abstract books"—were available prior to the critical date and (ii) that JAHA was "presented." Appx0471-Appx0472, Appx0474-Appx0476. The Board denied UTC's request to submit responsive evidence in sur-reply. Appx0540.

Addressing timeliness, the Board's FWD stated that new evidence in reply is permitted if it "does not constitute 'changing theories' after filing [the] petition." Appx0010 (quoting *Hulu, LLC v. Sound View Innovations, LLC*, IPR2018-01039, Paper 29, at 14-15 (PTAB Dec. 20, 2019)) (precedential). Under that standard, the Board found that Liquidia's "research aid" theory was "merely additional evidence supporting Petitioner's *original theory* that a person of ordinary skill in the art could have located the [published] references," *i.e.*, JESC/JAHA. *Id.* (emphasis added). The Board also found that Liquidia's Petition properly raised the "presentation" theory for JESC. Appx0010.

Liquidia's Petition never contended that JAHA was "publicly presented." The words just aren't there. The FWD therefore could not—and did not—find that Liquidia had presented this argument "in the Petition," nor did it find the theory "not untimely." *Id.* Thus, the Board tacitly—yet clearly—found it untimely. The Board never revisited that correct finding.

The FWD relied on a "research aid" theory and nothing else for public accessibility of JESC and JAHA. But at UTC's request, the POP rejected that rationale, noting that the research aids themselves did not qualify as prior art.

On rehearing, the Board pivoted to Liquidia's new theory: that the asserted JESC and JAHA journal supplements were prior art based on conference "dissemination" of "abstract books." Appx0058-Appx0061. UTC had no opportunity to present responsive evidence.

ARGUMENT

I. Whether a theory of unpatentability was properly raised in the Petition is a question of law entitled to *de novo* review—the Court's deference to the Board's "discretion" contravenes § 312(a)(3), *SAS*, *In re NuVasive*, and *Corephotonics*.

1. The Panel's decision—which permits agency "discretion" to adjudicate theories never raised in the petition—contradicts the Patent Act and binding precedent. As the Panel acknowledged, the controlling

law is clear: "[b]y statute, the scope of an IPR is limited to the grounds set forth in the initial petition." Op. 6 (citing 35 U.S.C. § 312(a)(3)). "[T]he statute tells us that the petitioner's contentions, *not the Director's discretion*, define the scope of the litigation all the way *from institution* through *to conclusion*." *Id.* at 6-7 (emphasis added) (quoting *SAS,* 138 S. Ct. at 1357). Accordingly, "it is therefore improper for the Board to deviate from the grounds in the petition[.]" *Id.* at 7. This should be the end of the story.

Despite this controlling precedent, the Panel decision explicitly deferred to the Board's "discretion" to adopt theories never raised in the Petition. Op. 8. Yet that is not the law: a petitioner may reply to patent owner's responsive arguments and evidence but may not change theories and expand the scope of the petition through new arguments and rationales offered after institution. This "newness restriction stems from the statutory mandate that the petition govern the IPR proceeding, so 'whether a ground the Board relied on is new is a question of law' we review de novo." *Corephotonics*, 84 F.4th at 1008 (cleaned up) (emphasis added) (quoting *In re NuVasive*, 841 F.3d at 970). It is this Court's duty to police that statutory requirement *de novo*; it may not simply defer to the "discretion" of the Board as the Panel decision did here.

2. There is no argument in the Petition supporting the Board's reliance on "abstract books." These books, which allegedly "would have" been available at a conference, are different than journal supplements, and the Petition did not assert any theory of public availability concerning conference "distribution" of not-in-evidence "abstract books." *Corephotonics*, 84 F.4th at 1009. In fact, the Petition makes no reference at all to "abstract books." Liquidia raised the abstract books argument for the first time in its Reply. Nonetheless, it is the only public accessibility argument relied on by the Board. Appx0060-Appx0061.

The legal error is particularly stark for JAHA. Liquidia limited its Petition to a single theory of public accessibility for JAHA: that it was "published in the Journal of the American Heart Association on October 26, 2004[.]" Appx0135. Yet the Panel concluded that "Liquidia's IPR petition asserted that each of the Voswinckel abstracts was *publicly presented*[.]" Op. 7. That is flatly incorrect and alone justifies rehearing: the Petition made no assertions concerning JAHA being presented publicly, or any JAHA-related conference. *Compare* Appx00135 *with* Appx00133. Full stop.

3. To elide these uncontroverted facts, the Panel decision sets forth a novel and erroneous legal standard that must be corrected. In no uncertain terms, the Panel explained that "Liquidia's arguments were

not inconsistent with, and therefore not new over, the grounds raised in its IPR petition." Op. 8. (emphasis added). This new rule equating newness with inconsistency is strictly forbidden by law—it is only the "petitioner's contentions, not the Director's discretion" that defines the scope of litigation. *SAS*, 138 S. Ct. at 1357.

4. This Court's precedent also precludes a "not inconsistent with" standard. The Panel decision conflates cases permitting reply *evidence* with prohibited new unpatentability *theories*. Until now, no opinion from this Court has permitted the Board to change theories midstream such that, as a matter of discretion, it can decide any new argument "not inconsistent with" arguments made in the petition.

First, the Panel relies on *Anacor* for the proposition that a petitioner "may introduce new evidence after the petition stage if the evidence is a legitimate reply to evidence introduced by the patent owner." *Anacor Pharms. v. Iancu*, 889 F.3d 1372, 1380-82 (Fed. Cir. 2018) (emphasis added). But the Board's "discretion" to permit responsive *evidence* in support of a theory initially asserted in the petition has no bearing on the key statutory question at issue here—whether the Board has the authority to decide new public accessibility *theories* beyond the scope of the petition. Both the statute and *SAS* conclusively answer that question: the Board has no such authority, and

the Panel erred by ignoring this "newness restriction." *Corephotonics*, 84 F.4th at 1008; Op. 7.

Second, the Panel relies on *Axonics* to explain that consistent with *SAS* a petitioner is "entitle[d] to respond to new arguments made in a patent owner response." Op. 7-8 (citing *Axonics, Inc. v. Medtronic, Inc.*, 75 F.4th 1374, 1380 (Fed. Cir. 2023)). But UTC made no such "new arguments" and neither the Board nor the Panel identified any. Moreover, *Axonics* concerned a petitioner's right to respond to a claim construction first offered in the patent owner response—not about Petitioner's new arguments, evidence, and theories that expand the scope of the petition. *Id*. This Court explicitly distinguished *Axonics* from *Intelligent Bio-Systems*, where the "reply brief and declaration exceeded the proper scope for a reply because they cited . . . references which were not relied upon to support unpatentability in the Petition." *Id*. at 1383; *Intelligent Bio-Systems v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1369 (Fed. Cir. 2016). That is, Axonics' reply was proper because it "relied on the same embodiments as it relied on in the petition," and its theory of unpatentability never changed from the petition. *Axonics*, 75 F.4th at 1383-84. *Axonics* does not sanction the Board to decide extra-petition theories raised first in reply—even if deemed responsive.

Third, the Panel's reliance on *Ericsson* is misplaced. In *Ericsson*, this Court made clear that Ericsson cited no new evidence and did not "make a meaningfully distinct contention, but instead expand[ed] *the same argument made in its Petition*[.]" *Ericsson Inc. v. Intellectual Ventures I LLC*, 901 F.3d 1374, 1381 (Fed. Cir. 2018) (emphasis added). The same cannot be said for Liquidia. For example, the Petition's theory of JAHA public accessibility was only "publication" by journal supplement; Liquidia then pivoted to an entirely new rationale of "conference" "distribution" of a different unasserted reference (*i.e.*, an "abstract book") that is not in evidence.

Unlike UTC's challenge, none of these cases adjudicated the statutory limits of the Board's authority. Moreover, just last week, the same three-judge panel held that a petitioner's failure to "identify a distinct alternative argument" concerning a "*subset*" of the argument made in the petition was "untimely and improper" "new argument." *Apple Inc. v. Masimo Corp.*, No. 2022-1890, 2024 WL 137336, at *3 (Fed. Cir. Jan. 12, 2024) (citing *Intelligent Bio-Sys.*, 821 F.3d at 1369). Applying that standard here, the Panel should have reversed the Board's reliance on Liquidia's "new" abstract book dissemination argument.

5. The Panel's decision will open the floodgates for belated arguments that—by statute—were required to be raised in the petition.

The Panel's decision not only invites sandbagging by PTAB litigants but adopts a lopsided IPR framework where the petitioner "must be afforded a reasonable opportunity in reply to present argument and evidence," while denying those same procedural safeguards for the patent owner. *Axonics*, 75 F.4th at 1383. For example, under the Panel's ruling, the Board properly exercised its "discretion" to adopt brand new theories *and* to prohibit patent owner from offering evidence in response. *See* Appx0894-Appx0895; Appx6415-Appx6420; Appx0540. This violated UTC's due process rights under the APA and requires remand. This Court has expressed its "confiden[ce] that in circumstances such as these, the Board will allow an appropriate opportunity for a patent owner to submit evidence with a sur-reply." *Axonics*, 75 F.4th at 1384. Yet, no such due process was afforded to UTC. *See In re NuVasive*, 841 F.3d at 971.

Statute and Supreme Court authority foreclose the Panel's new "not inconsistent with" standard and its deference to the Board, *see* U.S.C. § 312(a)(3); *SAS,* and due process requires, at a minimum, that UTC be permitted to fully address new theories offered in Reply. Accordingly, the Panel and/or *en banc* Court should correct the Panel decision and reverse the Board's decision.

II. The Panel's *presumption* of public accessibility based on industry custom of what "would have" occurred is contrary to § 102(b) and *Norian*.

Section 102(b) requires the patent challenger to prove that "the invention *was* . . . *described* in a printed publication . . . more than one year prior to the date of the application." 35 U.S.C. § 102(b) (pre-AIA) (emphasis added). Proving that an asserted reference is a "printed publication" requires an evidence-based "case-by-case inquiry into the facts and circumstances surrounding the reference's disclosure to members of the public." *Jazz Pharms., Inc. v. Amneal Pharms., LLC*, 895 F.3d 1347, 1355-56 (Fed. Cir. 2018) (quoting *In re Klopfenstein*, 380 F.3d 1345, 1350 (Fed. Cir. 2004)). This Court forbids presuming public accessibility based on a conference's "general practice"; rather, the patent challenger must prove that the asserted references "were actually available." *Norian Corp. v. Stryker Corp.*, 363 F.3d 1321, 1330 (Fed. Cir. 2004); *see also Jazz*, 895 F.3d at 1360 (rejecting "a [*per se*] rule that would supplant the case-by-case inquiry consistently applied throughout our case law.").

The Panel's decision violated this precedent by relying on speculation about what "would have" typically occurred at conferences in the absence of case-specific evidence concerning what was "actually available to the public." *Norian*, 363 F.3d at 1330. The decision also

relied on an erroneous standard that permits a finding of public availability absent *any* evidence that "the invention was described" in the reference found to be available more than a year before the critical date. § 102(b).

Section 102(b) states that a person "shall" be entitled to a patent "unless" the invention "was described" in a printed publication. The Supreme Court has explained "that courts must presume that a legislature says in a statute what it means and means in a statute what it says there." *Conn. Nat'l Bank v. Germain*, 503 U.S. 249, 253-54 (1992) (collecting authorities); *accord Frederick v. Shinseki*, 684 F.3d 1263, 1269 (Fed. Cir. 2012). Congress thus made two things clear: (1) the patent challenger bears the burden of proving what "was" made available to the public and (2) what "was" made available to the public, must "describe" "the invention." Neither requirement was met here.

1. Consistent with the statutory mandate that the patent challenger must prove what "was" made available, this Court has specifically held that "testimony" concerning "the general practice . . . for presenters to hand out abstracts to interested attendees" is not "substantial evidence of actual availability." *Norian*, 363 F.3d at 1330. The Court reasoned that substantial evidence of public accessibility did not exist where a co-author gave a copy of an abstract to a meeting

organizer but "could not recall whether copies of the Abstract were *actually available* to hand out." *Id.* (emphasis added).

Norian is consistent with this Court's unfaltering requirement that courts assess the case-specific "facts and circumstances surrounding the reference's disclosure to members of the public." *In re Klopfenstein*, 380 F.3d at 1350. Inherent in proving disclosure to the public is that the references "were actually available." *Norian* Corp., 363 F.3d at 1330. Yet, the Panel's decision failed to require the patent challenger to prove what "was" made available to the public. § 102(b).

The Panel decision permits precisely what *Norian* prohibited—replacing case-specific evidence with a presumption of public availability based solely on "general" industry practice. Beyond speculation that conference abstract books "typically" "would have" been disseminated (Appx3137-Appx3138), at some unknown time and place to unspecified attendees, the Board credited no evidence establishing existence of the hypothetical "abstract books." Appx0059-Appx0061.

Next, the Panel decision concluded that requiring Liquidia to provide "evidence of *actual* existence" of the claimed invention "is not the proper standard." Op. 8. This flips the § 102(b) burden on its head. It is axiomatic that a reference must first exist before it can "describe[]" the invention, be made available to the public, and result in "loss of right to

[the] patent." § 102(b). And the patent owner is entitled to the patent "unless" the challenger makes this statutory showing. *Id.*; *Medtronic*, 891 F.3d at 1381. Yet, the Panel decision holds that Liquidia had no obligation to produce a "declarant" or "the abstract books themselves." Op. 9. Even if true, § 102(b) obligates Liquidia to *somehow* prove that the claimed invention "was" "described" to the public before the critical date. That burden was not met here.

The Panel decision seems to rely on the permissive nature of the word "could" to relieve petitioners of its burdens. Op. 8 (emphasizing that "the standard for public accessibility is whether a person of skill in the art *could*, after exercising reasonable diligence, access a reference") (quoting *Samsung Elecs. Co. v. Infobridge Pte. Ltd.*, 929 F.3d 1363, 1374 (Fed. Cir. 2019)). But that assumes that the reference (1) existed and (2) was made available to the public. Here, there is no evidence of existence beyond speculation and zero evidence as to the content, if any, made available to the public.

In fact, *Samsung* made clear that for a reference to be considered publicly accessible, the patent challenger must make "a satisfactory *showing* that such document *has been disseminated* or otherwise *made available*" to the relevant public. *Samsung,* 929 F.3d at 1374 (emphasis added) (quoting *Jazz*, 895 F.3d at 1355-56). Now the Court says the

patent challenger need not provide any "evidence of *actual* existence or dissemination" to establish public accessibility. Op. 8. The conflict in law could not be clearer.

2. The Panel decision relies on this Court's rule that "there is no requirement to show that particular members of the public *actually received* the information." *Id.* (quoting *Jazz Pharms.*, 895 F.3d at 1356). But, by its own terms, that rule only applies "[o]nce accessibility is proved." *Id.* It does not relieve the petitioner of its initial burden to prove the reference existed and was publicly available under § 102(b). *Norian Corp.*, 363 F.3d at 1330; *In re Wyer*, 655 F.2d 221, 226 (CCPA 1981). Further, having no requirement to produce the allegedly available reference only makes sense when it is *undisputed* that it is the *same* as the asserted prior art reference. That is not the case here.

3. Never before has this Court permitted a document not-in-evidence to stand in the place of the asserted "printed publication" when the parties dispute the identicality of the disclosure alleged to have been made available to the public. For example, in *Nobel*, "the actual copy of the ABT Catalog" "obtained" at the conference was in evidence (Appx7972-Appx8034), corroborated by "specific details" that the catalog had "identical pages" to those asserted as prior art (Appx7914-Appx7971). *Nobel Biocare Services AG v. Instradent USA, Inc.*, 903 F.3d

1365, 1376-78 (Fed. Cir. 2018). In *Medtronic* a copy of the asserted "Video and Slides" was in evidence, mooting any concern of disparate disclosures (Appx7881-Appx7913); the only question was "whether such materials were sufficiently disseminated at the time of their distribution at the conferences." *Medtronic*, 891 F.3d at 1381. In *MIT*, "the document itself was actually disseminated." *Massachusetts Inst. of Tech. v. AB Fortia*, 774 F.2d 1104, 1109 (Fed. Cir. 1985). Similarly, in *In re Klopfenstein*, "there [we]re no factual disputes between the parties" that the asserted "reference was displayed to the public." 380 F.3d at 1348, 1350. The lack of any evidence corroborating the disclosure of the hypothetical abstract books with the asserted JAHA and JESC references precludes a finding that the claimed invention "was" "described" before the critical date as required by § 102(b).

4. Here, the content of the hypothetical abstract books is hotly contested. To the extent they exist, nobody has ever viewed the not-in-evidence abstract books or corroborated that they contain the same information as the JAHA and JESC journal supplements. Moreover, the Board could not have made such a finding as the Board relied only on deponents' speculation about what "would have" occurred—and the deponents have never seen the hypothetical abstract books. This alone is fatal in an IPR proceeding that is statutorily limited to the substance

of publicly available "printed publications" that "describe" the claimed invention. 35 U.S.C. §§ 311(b); 102(b).

The Panel's acceptance of speculation based solely on industry custom, instead of case-specific evidence of how "the invention was described" to the public, creates substantial uncertainty concerning the proper standard by which public availability must be proved.

CONCLUSION

The Court should grant panel rehearing or rehearing *en banc*.

Respectfully submitted,

/s/ *Douglas H. Carsten*
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Dated: January 19, 2024

CERTIFICATE OF COMPLIANCE

Pursuant to Federal Rule of Appellate Procedure 32(g), the undersigned counsel for United Therapeutics Corporation certifies that this brief:

(i) complies with the type-volume limitation of Federal Rules of Appellate Procedure 35(b) and 40(b) because it contains 3,892 words, including footnotes and excluding the parts of the brief exempted by Rule 32(f) and Circuit Rule 32(b)(2); and

(ii) complies with the typeface requirements of Rule 32(a)(5) and the type style requirements of Rule 32(a)(6) because it has been prepared using Microsoft Office Word and is set in Century Schoolbook font in a size equivalent to 14 points or larger.

Dated: January 19, 2024

/s/ *Douglas H. Carsten*
Douglas H. Carsten

ADDENDUM

NOTE: This disposition is nonprecedential.

United States Court of Appeals for the Federal Circuit

UNITED THERAPEUTICS CORPORATION,
Appellant

v.

LIQUIDIA TECHNOLOGIES, INC.,
Appellee

2023-1805

Appeal from the United States Patent and Trademark Office, Patent Trial and Appeal Board in No. IPR2021-00406.

Decided: December 20, 2023

DOUGLAS H. CARSTEN, McDermott Will & Emery, LLP, Irvine, CA, argued for appellant. Also represented by ARTHUR PAUL DYKHUIS; ADAM WILLIAM BURROWBRIDGE, Washington, DC; WILLIAM COVINGTON JACKSON, Goodwin Procter LLP, Washington, DC; SHAUN R. SNADER, United Therapeutics Corporation, Washington, DC.

SANYA SUKDUANG, Cooley LLP, Washington, DC, argued for appellee. Also represented by BRITTANY CAZAKOFF, JONATHAN DAVIES.

Before LOURIE, PROST, and REYNA, *Circuit Judges*.

LOURIE, *Circuit Judge*.

United Therapeutics Corporation ("UTC") appeals from the final written decision of the U.S. Patent and Trademark Office Patent Trial and Appeal Board ("the Board") in an *inter partes* review ("IPR") concluding that claims 1–8 of U.S. Patent 10,716,793 ("the '793 patent") are unpatentable. *Liquidia Techs., Inc. v. United Therapeutics Corp.*, No. IPR2021-00406, 2022 WL 2820717 (P.T.A.B. July 19, 2022) ("*Decision*"). For the following reasons, we *affirm*.

BACKGROUND

UTC owns the '793 patent, which is directed to methods of treating pulmonary hypertension comprising inhalation of treprostinil. Claim 1 is the only independent claim. It reads as follows:

> 1. A method of treating pulmonary hypertension comprising administering by inhalation to a human suffering from pulmonary hypertension a therapeutically effective single event dose of a formulation comprising treprostinil or a pharmaceutically acceptable salt thereof with an inhalation device, wherein the therapeutically effective single event dose comprises from 15 micrograms to 90 micrograms of treprostinil or a pharmaceutically acceptable salt thereof delivered in 1 to 3 breaths.

'793 patent at col. 18, ll. 23–31. As relevant here, dependent claims 4, 6, and 7 include additional limitations directed to dry powders. Those claims read as follows:

> 4. The method of claim 1, wherein the inhalation device is a dry powder inhaler.

> 6. The method of claim 4, wherein the formulation is a powder.
>
> 7. The method of claim 6, wherein the powder comprises particles less than 5 micrometers in diameter.

Id. at col. 18, ll. 36–37, 40–43.

Liquidia Technologies, Inc. ("Liquidia") petitioned for IPR of all claims of the '793 patent, asserting that they would have been obvious over, *inter alia*, U.S. Patent 6,521,212 ("the '212 patent"), in view of Voswinckel JESC ("JESC")[1] and Voswinckel JAHA ("JAHA")[2] (collectively, "the Voswinckel abstracts"). The '212 patent, an unrelated patent owned by UTC, is directed to methods of delivering benzindene prostaglandins, such as treprostinil sodium, to patients via inhalation to treat pulmonary hypertension. *See* '212 patent at Abstract, J.A. 1207. JESC is an abstract that describes a study in which patients inhaled solutions of treprostinil in concentrations of 16, 32, 48, and 64 µg/mL via a nebulizer. *See* J.A. 1240. JAHA is an abstract that describes a study in which patients inhaled solutions of treprostinil sodium via a nebulizer in 3 single breaths. *See id.* at 1243.

Before the Board, UTC challenged the prior art status of the Voswinckel abstracts, arguing that Liquidia had failed to adequately show that those references qualified as "printed publications" under pre-AIA 35 U.S.C. § 102(b).

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[1] R. Voswinckel et al., *Inhaled treprostinil is a potent pulmonary vasodilator in severe pulmonary hypertension*, 25 EUROPEAN HEART J. 22 (2004), J.A. 1234–1240.

[2] Robert Voswinckel et al., *Inhaled Treprostinil Sodium (TRE) For the Treatment of Pulmonary Hypertension*, in Abstracts from the 2004 Scientific Sessions of the American Heart Association, 110 CIRCULATION III-295 (Oct. 26, 2004), J.A. 1241–43.

Decision at *3. Specifically, UTC argued that, because in its petition Liquidia relied on those abstracts having been stored in libraries, it was required to establish that the abstracts would have both been available at the library and sufficiently indexed or categorized by priority date. *Id.* at *4. The Board observed, however, that Liquidia had not relied solely on the availability of those references in libraries to establish their prior art status. *Id.* Rather, Liquidia had also asserted that each abstract had been presented at a public conference and that they were both cited in other documents dating from before the priority date of the '793 patent. *Id.* On the second of these two theories, the Board concluded that Liquidia had shown by a preponderance of the evidence that each of the Voswinckel abstracts was prior art because it had been cited in a "research aid," *i.e.*, a publicly accessible article that provided a "sufficiently definite roadmap leading to" the abstract. *Id.* at *5 (quoting *Blue Calypso, LLC v. Groupon, Inc.*, 815 F.3d 1331, 1350 (Fed. Cir. 2016)).

Having found the Voswinckel abstracts to be prior art, the Board concluded that a person of ordinary skill in the art would have been motivated to combine those abstracts with the '212 patent to arrive at the claimed invention. *See id.* at *5–9. This, the Board found, was true despite UTC's evidence of objective indicia of nonobviousness, such as unexpected results, copying, and long-felt and unmet need. *Id.* at *9–13. Accordingly, the Board found all claims of the '793 patent unpatentable as obvious. *See id.* at *15.

UTC requested rehearing of the Board's decision, and included a request for rehearing by the U.S. Patent and Trademark Office's Precedential Opinion Panel ("the Panel") on the issue of whether or not the Voswinckel abstracts were prior art. *See Liquidia Tech., Inc. v. United Therapeutics Corp.*, IPR2021-00406, Paper 81 (Oct. 26, 2022) at 2, J.A. 885. The Panel denied UTC's request but determined that the Board had failed to consider whether the "research aids" in which the abstracts were cited were

themselves available prior to the critical date of the '793 patent, *i.e.*, May 15, 2005. *Id.* It also determined that the Board had not adequately addressed whether the Voswinckel abstracts "were publicly accessible by way of their presentation and/or inclusion in distributed materials, such as at a conference or library." *Id.* Accordingly, the Panel directed the Board to, in its consideration on rehearing, "clearly identify whether the [Voswinckel abstracts] qualify as prior art." *Id.* at 3, J.A. 886.

In its decision on rehearing, the Board maintained that the Voswinckel abstracts were prior art. *See Liquidia Tech., Inc. v. United Therapeutics Corp.*, IPR2021-00406, Paper 82 (Feb. 2, 2023) ("*Rehearing Decision*"), J.A. 50–67. Conceding that it had overlooked the fact that the research aids did not pre-date May 15, 2005, *see id.* at 5–7, J.A. 54–56, the Board nevertheless found that Liquidia had adequately shown that the abstracts had been publicly distributed at conferences prior to that date, *id.* at 7–12, J.A. 56–61. Specifically, the Board concluded that JESC was distributed at the European Society of Cardiology Congress that was held from August 28, 2004, to September 1, 2004, in Munich, Germany, and that JAHA was distributed at the American Heart Association's Scientific Sessions that occurred from November 7, 2004, to November 10, 2004, in New Orleans, Louisiana. *Id.*; *see* J.A. 1241. Both parties' experts agreed that a person of ordinary skill in the art would have been one of over 20,000 attendees at each of those conferences and that an "abstract book" from which each of the abstracts was excerpted would have been provided to all attendees. *Rehearing Decision* at 10, 12, J.A. 59, 61. Accordingly, the Board maintained that the abstracts were prior art and denied UTC's rehearing request.

UTC timely appealed. We have jurisdiction under 28 U.S.C. § 1295(a)(4)(A) and 35 U.S.C. § 141(c).

DISCUSSION

We review the Board's legal determinations *de novo*, *In re Elsner*, 381 F.3d 1125, 1127 (Fed. Cir. 2004), and its factual findings for substantial evidence, *In re Gartside*, 203 F.3d 1305, 1316 (Fed. Cir. 2000). A finding is supported by substantial evidence if a reasonable mind might accept the evidence as adequate to support the finding. *Consol. Edison Co. v. NLRB*, 305 U.S. 197, 229 (1938). Moreover, we review the Board's determination whether, under the Board's own regulations, a party exceeded the scope of a proper reply for abuse of discretion. *Axonics, Inc. v. Medtronic, Inc.*, 75 F.4th 1374, 1380 (Fed. Cir. 2023).

UTC raises three challenges on appeal. First, it argues that the Board erred in determining that the Voswinckel abstracts are prior art. Second, it argues that, even if those abstracts are prior art, the Board erred in finding that the claimed dose would have been obvious over the '212 patent in combination with the Voswinckel abstracts. And finally, it argues that the Board legally erred in its treatment of dependent claims 4, 6, and 7, and that its obviousness determination as to those claims was not supported by substantial evidence. We address each argument in turn.

I

UTC contends that the Board's prior art analysis as to the Voswinckel abstracts suffered from two errors. First, it argues that the Board's analysis improperly exceeded the prior art theories set forth in Liquidia's petition. Second, it argues that the Board's determination that the abstracts were publicly accessible as of the critical date was not supported by substantial evidence.

A

By statute, the scope of an IPR is limited to the grounds set forth in the initial petition. 35 U.S.C. § 312(a)(3); *see SAS Inst. Inc., v. Iancu*, 138 S. Ct. 1348, 1357 ("[T]he statute tells us that the petitioner's contentions, not the

Director's discretion, define the scope of the litigation all the way from institution through to conclusion."). It is therefore improper for the Board to deviate from the grounds in the petition and raise its own theories of unpatentability. *Sirona Dental Sys. GmbH v. Institut Straumann AG*, 892 F.3d 1349, 1356 (Fed. Cir. 2018). UTC argues that the Board violated this principle when it concluded that the Voswinckel abstracts were prior art based on an "abstract book" theory. In UTC's view, this theory was not advanced by Liquidia until its Reply before the Board, and that it was therefore untimely. *See* Appellant's Br. at 33. We disagree.

As the Board recognized, 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, making each of them printed publications within the meaning of § 102(b). *See Decision* at *4; *see also* Petition at 22, 24, J.A. 133, 135. UTC first challenged the sufficiency of those grounds in its post-institution Patent Owner Response. *See* Patent Owner Response at 11–18, J.A. 372–79. Thereafter, in its Reply, Liquidia asserted, with 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. *See* J.A. 471, 474–75.

The Board found 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. *Decision* at *4, J.A. 10. This conclusion was not an abuse of the Board's discretion. *See Anacor Pharms., Inc. v. Iancu*, 889 F.3d 1372, 1380–82 (Fed. Cir. 2018) (explaining that the petitioner "may introduce new evidence after the petition stage if the evidence is a legitimate reply to evidence introduced by the patent owner"); *see also Axonics*, 75 F.4th at 1380 (explaining that a

petitioner's entitlement to respond to new arguments made in a patent owner response is consistent with *SAS*). As the Board observed, Liquidia's arguments were not inconsistent with, and therefore not new over, the grounds raised in its IPR petition—that the Voswinckel abstracts were publicly accessible prior to the critical date. *Ericsson Inc. v. Intell. Ventures I LLC*, 901 F.3d 1374, 1380 (Fed. Cir. 2018) ("[T]he Board has discretion to determine whether a petition for *inter partes* review identified the specific evidence relied on in a reply and when a reply contention crosses the line from the responsive to the new."). Accordingly, we conclude that the Board did not abuse its discretion in considering the arguments and evidence raised in Liquidia's Reply.

B

UTC next argues that, even if timely, the Board erred in finding that the Voswinckel abstracts were publicly accessible because its "abstract book" theory was entirely "hypothetical" and supported only by "conclusory expert testimony." Appellant's Br. at 37. In its view, the Board's theory would have been adequately supported only if Liquidia had provided "evidence of *actual* existence or dissemination" of the books. *Id.* (emphasis added). But that is not the proper standard.

Public accessibility is the "touchstone in determining whether a reference constitutes a 'printed publication.'" *Blue Calypso*, 815 F.3d at 1348 (quoting *In re Hall*, 781 F.3d 897, 898–99 (Fed. Cir. 1986)). "Our cases have consistently held that the standard for public accessibility is whether a person of ordinary skill in the art *could*, after exercising reasonable diligence, access a reference." *Samsung Elecs. Co. v. Infobridge Pte. Ltd.*, 929 F.3d 1363, 1374 (Fed. Cir. 2019). Once accessibility is proved, "there is no requirement to show that particular members of the public *actually received* the information." *Jazz Pharms., Inc. v. Amneal Pharms., LLC*, 895 F.3d 1347, 1356 (Fed. Cir.

2018) (quoting *Constant v. Adv. Micro-Devices, Inc.*, 848 F.2d 1560, 1569 (Fed. Cir. 1988)) (emphasis added). Contrary to UTC's position then, Liquidia had no obligation to produce, for example, a declarant testifying to having received the abstract books in which the Voswinckel abstracts appeared, let alone the abstract books themselves.

We find that the Board's conclusion that the Voswinckel abstracts were sufficiently disseminated such that each constituted a printed publication was supported by substantial evidence. Specifically, the Board determined that the two 2004 conferences at which the abstracts were presented were attended by over 20,000 attendees. *Rehearing Decision* at 7–12, J.A. 58–61. And both Liquidia's and UTC's experts testified that every attendee of either conference would have received a copy of the abstract book in which each of the Voswinckel abstracts appeared. *See id.* Further still, the Board found that neither abstract book would have been disseminated with any expectation of privacy, given that the conference attendees included scientists, physicians, and nurses, *as well as* journalists. *See id.* at 59. Substantial evidence therefore supports the Board's conclusion that the Voswinckel abstracts qualify as prior art.

II

UTC's next challenges pertain to the Board's obviousness analysis as to independent claim 1.

A

Claim 1 requires the inhalation of a therapeutically effective single event dose of 15 micrograms to 90 micrograms of treprostinil or a therapeutically acceptable salt thereof. '793 patent at col. 18, ll. 28–30. The Board concluded that, although no reference explicitly taught this dose, the person of ordinary skill in the art would have understood the solutions in JESC to have delivered an

amount of treprostinil within the claimed range. *Decision* at *6–7. That finding was supported by substantial evidence.

JESC discloses the administration of treprostinil solution via a nebulizer to patients in concentrations of 16, 32, 48, and 64 µg/mL. J.A. 1240. As the Board recognized, JESC does not disclose the volume of solution administered, which is necessary to calculate the amount (in µg) of treprostinil administered. *Decision* at *6. Accordingly, the Board looked to the declarations of Liquidia's two experts, each of which testified that, at the time of the invention, nebulizers delivered at least 1 mL and up to 5 mL of solution. *Id.* (citing J.A. 1054, 1166). Based on those delivery volumes, the Board concluded that the amounts of treprostinil delivered in JESC would have been from 16–80, 32–160, 48–240, or 64–320 µg, each of which has at least one endpoint that falls within the claimed range of 15–90 µg. *Id.*

UTC argues that the Board's conclusion was error because the experts' testimony related only to *fill* volume, not volume actually delivered. Appellant's Br. at 43. Because no nebulizer can be 100% efficient, UTC argues it was error to rely on the experts' testimony without accounting for other factors, such as patients' breathing volume and patterns, and individual nebulizer characteristics (*e.g.*, residual volume, nebulization rate, etc.). *Id.* But the Board considered, and rejected, those same arguments. Specifically, it concluded that, "[t]o the extent that something less than the entire fill volume was delivered to the patient, . . . the preponderance of the evidence still supports actual delivered solution volume being at least one milliliter." *Decision* at *7. And, to be sure, UTC's own expert testified that, in 2006, he had not administered treprostinil via a nebulizer that utilized less than one milliliter of drug solution. *Id.* (citing J.A. 3185).

Accordingly, the Board's finding that the combination of the '212 patent, JESC, and JAHA would have rendered obvious claim 1 was supported by substantial evidence.

B

UTC further challenges the Board's consideration of its evidence of objective indicia of nonobviousness, arguing that the Board "clearly erred" by concluding that UTC had failed to even allege that the invention demonstrated unexpected results over the '212 patent, JESC, and JAHA. Appellant's Br. at 49–50 (citing *Decision* at *10). This argument, only a single paragraph in UTC's opening brief, borders on waiver. *See SmithKline Beecham Corp. v. Apotex Corp.*, 439 F.3d 1312, 1320 (Fed. Cir. 2006). But even if given due consideration, we conclude that the Board's determination was supported by substantial evidence.

Before the Board, UTC only provided evidence that the claimed compositions exhibited unexpected results over inhaled iloprost, intravenous epoprostenol, and intravenous treprostinil. *See Decision* at *10. But, as the Board recognized, the claims require inhaled treprostinil, which is taught by each of the '212 patent, JESC, and JAHA, making those references the closest prior art. And the only argument made by UTC that the claimed invention was unexpected over those references was a conclusory statement that "the ability to administer treprostinil at high doses in only 1–3 breaths and with fewer side effects was unexpected." J.A. 585. With no other evidence to consider, we see no error in the Board's conclusion that UTC failed to satisfy its burden in establishing unexpected results.

III

Finally, we turn to UTC's challenge to the Board's treatment of dependent claims 4, 6, and 7, which are directed to the inhalation of dry powder formulations of treprostinil. UTC argues that the Board failed to consider each claim as a separate invention and that none of the '212

patent, JESC, or JAHA discloses any dry powder dosages. Specifically, it argues that the Board failed to explain why a person of ordinary skill in the art would "reasonably expect to succeed in preparing a therapeutically effective *dry powder* formulation" using concentrations prepared only for solutions. Appellant's Br. at 55.

But, as Liquidia explains, UTC never raised this particular argument before the Board. Instead, it argued that claims 4, 6, and 7 were not obvious "because the prior art lacks disclosure of a single event dose of 15–90 µg delivered in 1–3 breaths, *regardless of the form of administration* (liquid *or powder*)." Patent Owner Response at 41, J.A. 401 (emphases added). We therefore find UTC's argument forfeited. *Fresenius USA, Inc. v. Baxter Int'l, Inc.*, 582 F.3d 1288, 1296 (Fed. Cir. 2009) (explaining that this court may decline to consider an argument "[i]f a party fail[ed] to raise [that] argument before the trial court, or present[ed] only a skeletal or undeveloped argument to the trial court.").

In any event, the Board's conclusion that dependent claims 4, 6, and 7 were obvious was supported by substantial evidence. Namely, as the Board observed, the '212 patent, which is also owned by UTC, discloses the use of an "inhaler," and that "solid formulations, usually in the form of a powder, may be inhaled in accordance with the present invention." '212 patent at col. 5, ll. 30, 37–39, J.A. 1228. It also teaches that such formulations have particle sizes of preferably "less than 5 micrometers in diameter." *Id.* at col. 5, ll. 39–41, J.A. 1228. The Board relied not only on these disclosures, but also on the unrebutted testimony of Liquidia's expert that a person of ordinary skill in the art would have had a reasonable expectation of success in arriving at the claimed dry powder formulation based on the combined teachings of the '212 patent, JESC, and JAHA. *Decision* at *14.

CONCLUSION

We have considered UTC's remaining arguments and find them unpersuasive. For the reasons provided above, we *affirm* the Board's unpatentability determination.

AFFIRMED

35 U.S.C. § 102(b) (pre-AIA)

A person shall be entitled to a patent unless--

. . .

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States[.]

35 U.S.C. § 312(a)(3)

(a) Requirements of Petition.--A petition filed under section 311 may be considered only if--

. . .

(3) the petition identifies, 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, including—

(A) copies of patents and printed publications that the petitioner relies upon in support of the petition[.]

CERTIFICATE OF SERVICE

The undersigned counsel hereby certifies that on January 19, 2024, the foregoing document was filed using the Court's CM/ECF system, which will send notice of such filing to all registered CM/ECF users.

Dated: January 19, 2024

/s/ *Douglas H. Carsten*
Douglas H. Carsten