# APPENDICES

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**APPENDIX A**

NOTE: This disposition is nonprecedential.

# United States Court of Appeals for the Federal Circuit

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**UNITED THERAPEUTICS CORPORATION,**
*Appellant*

**v.**

**LIQUIDIA TECHNOLOGIES, INC.,**
*Appellee*

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2023-1805

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

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Decided: December 20, 2023

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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 BRITTNANY CAZAKOFF, JONATHAN DAVIES.

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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**

**APPENDIX B**

Trials@uspto.gov Paper 78
Tel: 571-272-7822 Entered: July 19, 2022

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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LIQUIDIA TECHNOLOGIES, INC.,
Petitioner,

v.

UNITED THERAPEUTICS CORPORATION,
Patent Owner.

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IPR2021-00406
Patent 10,716,793 B2

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Before ERICA A. FRANKLIN, CHRISTOPHER M. KAISER, and DAVID COTTA, *Administrative Patent Judges.*

KAISER, *Administrative Patent Judge*.

JUDGMENT
Final Written Decision
Determining All Challenged Claims Unpatentable
*35 U.S.C. § 318(a)*

## INTRODUCTION

*A. Background*

Liquidia Technologies, Inc. ("Petitioner") filed a Petition (Paper 2, "Pet.") requesting an *inter partes* review of claims 1–8 of U.S. Patent No. 10,716,793 B2 (Ex. 1001, "the '793 patent"). United Therapeutics Corporation ("Patent Owner") filed a Preliminary Response. Paper 13 ("Prelim. Resp.").

On August 11, 2021, we instituted *inter partes* review of claims 1–8 of the '793 patent on all grounds set forth in the Petition. Paper 18 ("Inst. Dec."). After institution of trial, Patent Owner filed a Response (Paper 29, "PO Resp."), Petitioner filed a Reply (Paper 44), and Patent Owner filed a Sur-Reply (Paper 55). In addition, both parties filed Motions to Exclude Evidence (Papers 65 and 66), Oppositions to their respective opponents' Motions to Exclude (Papers 68 and 69), and Replies in support of their own Motions to Exclude (Papers 71 and 72). At the request of both parties, we held an oral hearing, the transcript of which has been entered into the record. Paper 77 ("Tr.").

We have jurisdiction under 35 U.S.C. § 6. This is a Final Written Decision under 35 U.S.C. § 318(a) as to the patentability of the challenged claims of the '793 patent. For the reasons discussed below, we determine Petitioner has established by a preponderance of the evidence that each of claims 1–8 of the '793 patent is unpatentable.

*B. Related Matters*

The parties identify *United Therapeutics Corporation v. Liquidia Technologies, Inc.*, 1:20-cv-00755-RGA (D. Del.) ("the District Court proceeding"), as a related matter. Pet. 1; Paper 3, 1.

*C. The Asserted Grounds of Unpatentability*

Petitioner contends that claims 1–8 of the '793 patent are unpatentable based on the following grounds (Pet. 30–68):[1]

| Claim(s) Challenged | 35 U.S.C. §[2] | Reference(s)/Basis |
|---|---|---|
| 1–8 | 103(a) | '212 patent,[3] Voswinckel JESC,[4] Voswinckel JAHA[5] |
| 1–8 | 103(a) | '212 patent, Voswinckel JESC |
| 1 | 102(a) | Ghofrani[6] |
| 1, 3, 8 | 103(a) | Voswinckel JAHA, Ghofrani |

[1] Petitioner also relies on declarations from Nicholas Hill, M.D., and Igor Gonda, Ph.D. Exs. 1002, 1004, 1106, 1107.

[2] The '793 patent claims a priority date of May 15, 2006, and Petitioner "assumes the relevant priority date . . . is May 15, 2006." Pet. 12; Ex. 1001, code (60). Accordingly, patentability is governed by the versions of 35 U.S.C. §§ 102 and 103 preceding the amendments in the Leahy-Smith America Invents Act ("AIA"), Pub. L. No. 112–29, 125 Stat. 284 (2011).

[3] US 6,521,212 B1, issued Feb. 18, 2003 (Ex. 1006) (alleged to be prior art under 35 U.S.C. §§ 102(a), (b), (e)).

[4] Voswinckel, R., et al., *Inhaled treprostinil is a potent pulmonary vasodilator in severe pulmonary hypertension*, 25 EUROPEAN HEART J. 22 (2004) (Ex. 1007) (alleged to be prior art under 35 U.S.C. § 102(b)).

[5] 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) (Ex. 1008) (alleged to be prior art under 35 U.S.C. § 102(b)).

[6] Hossein Ardeschir Ghofrani, et al., *Neue Therapieoptionen in der Behandlung der pulmonalarteriellen Hypertonie*, 30 HERZ 296–302 (June 2005) (Ex. 1010) (alleged to be prior art under 35 U.S.C. § 102(a)). We rely on the English translation that follows the German original article as part of Ex. 1010.

| | | |
|---|---|---|
| 1, 3 | 102(a) | Voswinckel 2006[7] |
| 2, 4–8 | 103(a) | Voswinckel 2006, '212 patent |

*D. The '793 Patent*

The '793 patent, titled "Treprostinil Administration by Inhalation," issued on July 21, 2020. Ex. 1001, codes (45), (54). The patent "relates to methods and kits for therapeutic treatment and, more particularly, to therapeutic methods involving administering treprostinil using a metered dose inhaler and related kits." *Id*. at 1:20–23.

Treprostinil "is a prostacyclin analogue" that may be used to treat pulmonary hypertension. *Id*. at 5:37–41. According to the '793 patent, it was previously known to administer treprostinil by intravenous, subcutaneous, or inhalation routes to treat any of several conditions, including pulmonary hypertension. *Id*. at 5:42–58.

The '793 patent relates to the administration of treprostinil in high concentrations over a short inhalation time. *Id.* at 16:61–63, 17:44–46. This method of administration is described as reducing pulmonary vascular resistance and pulmonary artery pressure, as well as increasing cardiac output. *Id.* at 16:32–42, Fig. 10.

*E. Illustrative Claim*

Claims 1–8 of the '793 patent are challenged. Claim 1 is independent and illustrative; it recites:

> 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

[7] Robert Voswinckel, et al., *Inhaled Treprostinil for Treatment of Chronic Pulmonary Arterial Hypertension*, 144 ANNALS OF INTERNAL MEDICINE 149–50 (January 2006) (Ex. 1009) (alleged to be prior art under 35 U.S.C. § 102(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.

Ex. 1001, 18:23–31.

ANALYSIS

*A. Claim Construction*

In an *inter partes* review, we construe a claim in an unexpired patent "in accordance with the ordinary and customary meaning of such claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent." 37 C.F.R. § 42.100(b) (2020). "[T]he ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005) (en banc). "Importantly, the person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification." *Id.*

Neither party presents any terms for construction. Pet. 12–13 ("Petitioner does not believe construction of any claim term is required"); PO Resp. 7 (not proposing construction of any terms). Accordingly, we determine that no express construction of any claim term is necessary in order to decide whether to institute trial. *Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (citing *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999) ("[O]nly those terms need be construed that are in controversy, and only to the extent necessary to resolve the controversy.")).

*B. Asserted Obviousness over '212 Patent, Voswinckel JESC, and Voswinckel JAHA*

Petitioner argues that claims 1–8 would have been obvious over the combination of the '212 patent, Voswinckel JESC, and Voswinckel JAHA. Pet. 30–46. Patent Owner argues that Petitioner fails to show that Voswinckel JESC and Voswinckel JAHA are prior art to the '793 patent. PO Resp. 11–18. Patent Owner also argues that Petitioner fails to show that this combination of references teaches or suggest all the limitations of any of the challenged claims. PO Resp. 18–22, 38–40. In addition, Patent Owner also argues that Petitioner fails to show that a person of ordinary skill in the art would have had a reason to combine the teachings of these references. *Id.* at 23–38.

*1. '212 Patent*

The '212 patent teaches "[a] method of delivering benzindene prostaglandins to a patient by inhalation." Ex. 1006, code (57). In particular, the '212 patent teaches the use of "[a] benzindene prostaglandin known as UT-15," which "has unexpectedly superior results when administered by inhalation compared to parenterally administered UT-15 in sheep with induced pulmonary hypertension." *Id.* There is evidence in the present record that "UT-15" was also known as "Remodulin" or "treprostinil sodium." Ex. 1035, 582. According to the '212 patent, the UT-15 may be delivered either as droplets formed "from a solution or liquid containing the active ingredient(s)" via a nebulizer, or as a solid-phase powder via an inhaler. Ex. 1006, 5:30–41.

According to the '212 patent, this method may be used to "treat[] pulmonary hypertension in a mammal." *Id.* at 14:9–12. Moreover, the '212 patent teaches "medical use" of its method in a "human." *Id.* at 7:4–5. The necessary dose to achieve "a particular therapeutic purpose will, of course, depend upon the specific circumstances of the patient being treated and the magnitude of the effect desired by the patient's doctor. Titration to effect may be used to

determine proper dosage." *Id.* at 6:66–7:3. "[A]erosolized UT-15 has a greater potency as compared to intravascularly administered UT-15," so the '212 patent teaches delivering "only a fraction (10–50%) of the dosage delivered intravascularly" when using its inhalation delivery method. *Id.* at 8:8–12. Even at "high doses," however, the '212 patent teaches a lack of "significant non-lung effects, i.e., heart rate, cardiac output." *Id.* at 10:51–54.

*2. Voswinckel JESC*

Voswinckel JESC discusses a study to investigate "the acute hemodynamic response to inhaled treprostinil." Ex. 1007, 7. Of the 29 patients in the study, eight were administered a placebo, groups of six patients each were administered 16, 32, and 48 g/mL solutions of treprostinil, and three patients were administered a solution containing 64 µg/mL of treprostinil. *Id.* Each administration used an "OptiNeb ultrasound nebulizer, [made by] Nebu-Tec, Germany" for six minutes. *Id.* For each patient, various measurements were taken before administration of the treprostinil and at 0, 15, 30, 60, 90, 120, 150, and 180 minutes after administration. *Id.* According to Voswinckel JESC, "[t]reprostinil inhalation results in a significant long-lasting pulmonary vasodilatation," and, "at a concentration of 16 µg/mL, near maximal pulmonary vasodilatation is achieved without adverse effects." *Id.*

*3. Voswinckel JAHA*

Voswinckel JAHA discusses a study of 17 patients with "severe pulmonary hypertension" who received treprostinil inhalations. Ex. 1008, 3. These inhalations each involved "3 single breaths" using a "pulsed OptiNeb® ultrasound nebulizer" and a "600 µg/mL" treprostinil solution. *Id.* In addition, "[t]wo patients with idiopathic PAH received compassionate treatment with 4 inhalations of TRE per day after the acute test" and were "treated for more than 3 months." *Id.* According to Voswinckel JAHA, "inhalation resulted in a sustained, highly pulmonary selective

vasodilatation over 120 minutes," showing "strong pulmonary selective vasodilatory efficacy with a long duration of effect following single acute dosing," and "[t]olerability is excellent even at high drug concentrations and short inhalation times (3 breaths)." *Id.*

*4. Prior-Art Status of Voswinckel JESC and Voswinckel JAHA*

In arguing that claims 1–8 would have been obvious, Petitioner relies on Voswinckel JESC and Voswinckel JAHA, but Patent Owner argues that Petitioner fails to show sufficiently that either of these references qualifies as a "printed publication." PO Resp. 11–18.

Only "prior art consisting of patents or printed publications" may form "the basis of" an *inter partes* review. 35 U.S.C. § 311(b). Neither Voswinckel JESC nor Voswinckel JAHA is a patent, so Petitioner may not rely on these references unless they are "printed publications." *Id.* Public accessibility is the "touchstone in determining whether a reference constitutes a printed publication," and a reference is considered publicly accessible only if it was "disseminated or otherwise made available to the extent that persons interested and ordinarily skilled in the subject matter or art exercising reasonable diligence, can locate it." *Kyocera Wireless Corp. v. Int'l Trade Comm'n*, 545 F.3d 1340, 1350 (Fed. Cir. 2008) (quoting *SRI Int'l, Inc. v. Internet Sec. Sys. Inc.*, 511 F.3d 1186, 1194 (Fed. Cir. 2008); *In re Hall*, 781 F.2d 897, 898–99 (Fed. Cir. 1986)).

Patent Owner argues that, because Petitioner relies on Voswinckel JESC and Voswinckel JAHA having been "stored in libraries, public accessibility requires that the reference be both available at the library and sufficiently indexed or catalogued by the priority date." PO Resp. 12 (citing *Blue Calypso, LLC v. Groupon, Inc.*, 815 F.3d 1331, 1348 (Fed. Cir. 2016); *In re Klopfenstein*, 380 F.3d 1345, 1349 (Fed. Cir. 2004)). According to Patent Owner,

Petitioner fails to show sufficiently either of these requirements. *Id.* at 12–18.

But Petitioner does not rely solely on availability in libraries to show the prior-art status of Voswinckel JESC and Voswinckel JAHA. Instead, Petitioner also argues that "Voswinckel JESC is an abstract presented at the European Society of Cardiology (JESC) Congress," that Voswinckel JAHA "was publicly presented at the 2004 Scientific Sessions of the American Heart Association," and that both references were cited in other documents dating from before the priority date of the '793 patent whose public accessibility is not at issue. Pet. 22; Reply 3–4, 6–8.

Patent Owner objects that Petitioner's public-presentation and citation-in-other-references arguments are untimely because they should have been, but were not, presented in the Petition. Sur-Reply 2–3. We disagree. First, the argument that Voswinckel JESC was presented publicly appears in the Petition. Pet. 22. Second, although other of Petitioner's arguments appear for the first time in the Reply, they are not untimely. Reply 3–4, 6–8.

Petitioner is permitted a "limited opportunit[y]" to present new evidence in or with its Reply, as long as that new evidence is "responsive to the prior briefing" and does not constitute "changing theories after filing [the] petition." *Hulu, LLC v. Sound View Innovations, LLC*, IPR2018-01039, Paper 29, at 14–15 (PTAB Dec. 20, 2019) (precedential). Here, both of the arguments that Patent Owner alleges are new—the argument that Voswinckel JESC and Voswinckel JAHA were presented publicly and the argument that these references were cited in other publicly available references—respond to Patent Owner's argument in the Patent Owner Response that Voswinckel JESC and Voswinckel JAHA were not publicly accessible. PO Resp. 11–18. 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.

Pet. 22. As to both Voswinckel JESC and Voswinckel JAHA, Petitioner's Reply evidence showing citation to the references in other publicly accessible documents is merely additional evidence supporting Petitioner's original theory that a person of ordinary skill in the art could have located the references. Accordingly, we find that the following arguments made by Petitioner are not untimely: (1) that Voswinckel JESC was presented publicly, (2) that Voswinckel JESC was referenced in a publicly accessible document, and (3) that Voswinckel JAHA was referenced in a publicly accessible document.

Given the evidence supporting Petitioner's timely arguments, we are persuaded that Petitioner has shown by a preponderance of the evidence that Voswinckel JESC and Voswinckel JAHA were publicly accessible. "[T]he presence of a 'research aid' can…establish public accessibility" of a reference if that research aid "provide[s] a skilled artisan with a sufficiently definite roadmap leading to" the reference by "provid[ing] enough details [to] determine that an interested party is reasonably certain to arrive at the destination: the potentially invalidating reference." *Blue Calypso, LLC v. Groupon, Inc.*, 815 F.3d 1331, 1350 (Fed. Cir. 2016).

Here, Petitioner directs us to research aids for finding both Voswinckel JESC and Voswinckel JAHA: a "June 2005 Ghofrani article in the journal *Herz*" for the former, and "a March 2005 article authored by Roxana Sulica et al. in the *Expert Review of Cardiovascular Therapy*" for the latter. Reply 3, 7 (citing Ex. 1010, 298, 301; Ex. 1104, 359). The Ghofrani article cites Voswinckel JESC as providing a solution to patients experiencing "pain at the injection site" by replacing injected treprostinil for "pulmonary arterial hypertension" with "*inhaled* treprostinil." Ex. 1010, 298 (citing reference 6), 301 (defining reference 6 as Voswinckel JESC). The Ghofrani article also discusses the study reported in Voswinckel JESC, summarizing both the "major

reduction in pulmonary selective pressure and resistance" and the lack of "adverse effects" described in Voswinckel JESC. *Id.* The Sulica article cites to Voswinckel JAHA, explaining that the reference reports that "inhaled treprostinil demonstrated substantial pulmonary vasodilatory efficacy in acute administration, as well as symptomatic and functional benefit in chronic use in a small number of PAH patients." Ex. 1104, 351, 359. Thus, both the Ghofrani article and the Sulica article provide roadmaps directing a person of ordinary skill in the art looking for successful studies discussing the use of inhaled treprostinil in pulmonary arterial hypertension straight to Voswinckel JESC or Voswinckel JAHA. Because these articles provide these roadmaps, they are "research aid[s]" that "establish [the] public accessibility" of Voswinckel JESC and Voswinckel JAHA. *Blue Calypso*, 815 F.3d at 1350.

*5. Analysis*

Petitioner argues that the combination of the '212 patent, Voswinckel JESC, and Voswinckel JAHA teaches or suggests the subject matter of claims 1–8 and that a person of ordinary skill in the art would have had a reason to combine the teachings of these references with a reasonable expectation of success. Pet. 30–46. Patent Owner argues that this combination of references fails to teach or suggest delivering a dose of treprostinil within the dose range of the challenged claims in a single dosing event of one to three breaths. Prelim. Resp. 42–55.

a. Claim 1

*(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"*

Claim 1 recites "[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." Ex. 1001, 18:23–27. Petitioner argues that the '212 patent, Voswinckel JESC, and Voswinckel JAHA each teach or suggest this limitation. Pet. 35–37. Patent Owner does not dispute this argument. PO Resp. 10–40.

The '212 patent teaches treating pulmonary hypertension via inhalation of a benzindene prostaglandin called UT-15, which was also known as "treprostinil sodium." Ex. 1006, code (57) (identifying "benzindene prostaglandin" as "UT-15"), 2:66–3:5 ("This invention relates to…a method of treating pulmonary hypertension by administering an effective amount of a benzindene prostaglandin to a mammal in need thereof by inhalation."); Ex. 1035, 582 ("UT-15" also known as "treprostinil sodium"). Voswinckel JAHA teaches treating "patients with severe pulmonary hypertension" with "Inhaled Treprostinil Sodium (TRE)" with "3 single breaths" of "TRE solution 600 µg/ml," resulting in "strong pulmonary selective vasodilatory efficacy with a long duration of effect following single acute dosing." Ex. 1008, 3. Voswinckel JESC describes "the acute hemodynamic response to inhaled treprostinil" following the administration to patients of nebulized treprostinil solution in concentrations of 16, 32, 48, and 64 µg/ml for six minutes, resulting in "significant long-lasting pulmonary vasodilatation" without "adverse effects." Ex. 1007, 7.

Accordingly, Petitioner has shown by a preponderance of the evidence that the '212 patent, Voswinckel JESC, and Voswinckel JAHA each teach or suggest this portion of claim 1.

*(2) "With an inhalation device"*

Next, claim 1 recites "with an inhalation device." Ex. 1001, 18:27–28. Petitioner argues that the '212 patent, Voswinckel JESC, and Voswinckel JAHA each teach or suggest this limitation. Pet. 37. Patent Owner does not dispute this argument. PO Resp. 10–40. The '212 patent teaches the use in its inhalation method of "a nebulizer, inhaler, atomizer or aerosolizer" to "form[] droplets from a solution or liquid containing the active ingredient(s)." Ex. 1006, 5:30–32. Both Voswinckel JESC and Voswinckel JAHA teach the use of a "nebulizer" in their inhalation methods. Ex. 1007, 7 ("OptiNeb ultrasound nebulizer");

Ex. 1008, 3 ("the pulsed OptiNeb® ultrasound nebulizer"). Dr. Hill testifies that a person of ordinary skill in the art would have understood "that nebulizers and inhalers are inhalation devices." Ex. 1002 ¶ 94. Accordingly, Petitioner has shown by a preponderance of the evidence that the '212 patent, Voswinckel JESC, and Voswinckel JAHA each teach or suggest this limitation of claim 1.

*(3) "Wherein the therapeutically effective single event dose comprises from 15 micrograms to 90 micrograms of treprostinil or a pharmaceutically acceptable salt thereof"*

Claim 1 recites "wherein the therapeutically effective single event dose comprises from 15 micrograms to 90 micrograms of treprostinil or a pharmaceutically acceptable salt thereof." Ex. 1001, 18:28–30. Petitioner argues that the combination of the '212 patent and Voswinckel JESC teaches or suggests this limitation. Pet. 37–40. Patent Owner disagrees. PO Resp. 18–38.

Petitioner calculates the dose that the prior art teaches delivering by inhalation in three separate ways: (1) relying on Voswinckel JESC's solution concentrations and solution volumes taught by Ex. 1037, (2) relying on Voswinckel JESC's solution concentrations and solution volumes normally delivered according to the testimony of Petitioner's declarants, and (3) relying on the '212 patent's conversion from an intravascular treprostinil dose to an equivalent inhaled dose. Pet. 22–24, 38–39. According to Petitioner, each of these three calculation methods results in a teaching of a therapeutically effective single event dose comprising from 15 micrograms to 90 micrograms of treprostinil. *Id.*

We agree with Patent Owner that Petitioner's first and third calculation methods do not demonstrate that the prior art taught or suggested a therapeutically effective single event dose comprising from 15 micrograms to 90 micrograms of treprostinil, and we do not discuss these calculations any further. The preponderance of the evidence, however, supports Petitioner's argument that its second calculation demonstrates that the prior art taught or suggested a therapeutically effective single event dose comprising from 15 micrograms to 90 micrograms of treprostinil.

Voswinckel JESC teaches that "patients inhaled solvent solution (placebo) (n=8) or treprostinil for 6 min (OptiNeb ultrasound nebulizer, Nebu-tec, Germany) in concentrations of 16, 32, 48, and 64 µg/ml (n=6, 6, 6, and 3 patients)." Ex. 1007, 7. Although this teaching shows administration to patients of inhaled solutions with particular concentrations of treprostinil, it does not disclose the amount of solution administered, which is necessary in order to calculate the amount of treprostinil administered. *Id.* Petitioner directs us to the testimony of its declarants, Dr. Nicholas Hill and Dr. Igor Gonda, to understand how a person of ordinary skill in the art would have interpreted Voswinckel JESC's disclosure. Pet. 23 (citing Ex. 1002 ¶ 65; Ex. 1004 ¶ 56). Dr. Gonda testifies that "in May 2006…nebulizers conventionally deliver[ed] between 1 and 5 mL" of solution. Ex. 1004 ¶ 56. Relying on Dr. Gonda's testimony as well as his own experience, Dr. Hill testifies that a person of ordinary skill in the art in 2006 would have understood that "nebulizers…nebulize (i.e. aerosolize liquid) at least" 1 mL of solution. Ex. 1002 ¶ 65. Multiplying Voswinckel JESC's 16, 32, 48, or 64 micrograms of treprostinil per milliliter of solution by the 1 to 5 milliliters of solution in the testimony of Drs. Hill and Gonda, a person of ordinary skill in the art would have interpreted Voswinckel JESC as teaching the delivery of 16–80, 32–160, 48–240, or

64–320 micrograms of treprostinil. Each of those four dose ranges has at least one endpoint that falls within the 15–90 microgram claimed range.

Patent Owner argues that this evidence is insufficient to show that the combination of the '212 patent, Voswinckel JESC, and Voswinckel JAHA teaches or suggests a therapeutically effective single event dose comprising from 15 micrograms to 90 micrograms of treprostinil. Specifically, Patent Owner argues that the volume of solution that Drs. Hill and Gonda testify was typically used in nebulizers is "the fill volume," or the amount of solution loaded into a nebulizer to be nebulized, which cannot be used with the concentrations in Voswinckel JESC to arrive at the amount of treprostinil actually delivered to a patient. PO Resp. 30–31. This is because "there is no guarantee that the entire fill volume would be completely nebulized in" the time period over which Voswinckel JESC teaches delivering its dose of treprostinil. *Id.* at 30. In addition, Patent Owner argues that there were other factors that might have caused less than all the solution nebulized by a nebulizer to be actually delivered to the patient, none of which Petitioner accounts for. *Id.* at 31–32.

Petitioner "presented evidence that nebulizers at the time typically involved fill volumes of 1-5mL." Reply 10–11. To the extent that something less than the entire fill volume was delivered to the patient, either because it was not nebulized or because other factors resulted in the nebulized solution not reaching the mouthpiece, the preponderance of the evidence still supports the actual delivered solution volume being at least one milliliter. Dr. Hill testifies that the "at least 1 mL" of solution he discusses is the volume that "nebulizers at the time were known to nebulize," not the amount of liquid loaded into the nebulizer. Ex. 1002 ¶ 65. Patent Owner's declarant, Dr. Aaron Waxman, testifies that standard nebulizers had fill volumes of "3 to 5 [milliliters]" and that he had never administered a

dose as low as one milliliter to a patient. Ex. 1108, 153:1–22; 156:12–16.

Thus, Voswinckel JESC teaches delivering solution with a treprostinil concentration of 16, 32, 48, or 64 micrograms per milliliter, and the preponderance of the evidence supports a finding that a person of ordinary skill in the art would have understood the volume of solution delivered in Voswinckel JESC to be at least one milliliter. Accordingly, Petitioner has shown by a preponderance of the evidence that Voswinckel JESC teaches or suggests a therapeutically effective single event dose comprising from 15 micrograms to 90 micrograms of treprostinil.

*(4) "Delivered in 1 to 3 breaths"*

Claim 1 recites "delivered in 1 to 3 breaths." Ex. 1001, 18:31. Petitioner argues that Voswinckel JAHA teaches or suggests this limitation. Pet. 40–41. Patent Owner does not dispute this teaching of Voswinckel JAHA. PO Resp. 10–40.

Voswinckel JAHA teaches delivering to patients "a TRE inhalation by use of the pulsed OptiNeb® ultrasound nebulizer (3 single breaths, TRE solution 600 µg/ml)." Ex. 1008, 3. It also reports that "[t]olerability is excellent even at high drug concentrations and short inhalation times (3 breaths)." *Id.* Accordingly, Petitioner has shown by a preponderance of the evidence that Voswinckel JAHA teaches or suggests this limitation of claim 1.

b. Reason to Combine with a Reasonable Expectation of Success

As discussed above, Petitioner has shown sufficiently on the present record that the combination of the '212 patent, Voswinckel JESC, and Voswinckel JAHA teaches or suggests every limitation of claim 1. This alone is not sufficient to show that the challenged claims would have been obvious; Petitioner also must show that a person of ordinary skill would have had a reason to combine the teachings of the references and would have had a reasonable expectation of success in doing so.

Petitioner argues that a person of ordinary skill in the art would have had a reason to combine the teachings of the '212 patent, Voswinckel JESC, and Voswinckel JAHA. Pet. 30–34. Patent Owner argues that a person of ordinary skill in the art would have had "serious concerns about side effects" that would have persuaded them not to combine the teachings of the '212 patent, Voswinckel JESC, and Voswinckel JAHA. PO Resp. 37–38.

The '212 patent teaches the use of inhaled treprostinil sodium for the treatment of pulmonary hypertension at doses between 10 and 50 percent of the doses needed for intravascular delivery. Ex. 1006, code (57), 6:1–2, 8:8–12. According to the '212 patent, the inhaled treprostinil sodium is used in sheep, which are a model for pulmonary hypertension in humans. *Id*. at 9:14–27. Dr. Hill testifies that, based on these teachings, a person of ordinary skill in the art would have looked for further information regarding "experimentation [with] inhaled treprostinil in humans." Ex. 1002 ¶ 78. On the present record, such information can be found in Voswinckel JESC, which reports on a study in which humans with pulmonary hypertension inhaled treprostinil and experienced "significant long-lasting pulmonary vasodilatation . . . without adverse effects." Ex. 1007, 7.

Dr. Hill testifies that, based on the teachings of these references a person of ordinary skill would reasonably have expected that treprostinil could safely and effectively treat pulmonary hypertension in humans. Ex. 1002 ¶ 79. Dr. Hill also testifies that a person of ordinary skill in the art "would have been motivated to further decrease the 6 minute administration time in Voswinckel JESC." Ex. 1002 ¶ 80. Specifically, Dr. Hill testifies that patients often did not adhere to "inhalation therapy for respiratory diseases," that "[p]oor adherence to medication was known to correlate with worse outcomes," and that "reducing administration time or the number of breaths required for therapy [was known to] improve adherence rates." *Id*. (citing Ex. 1002 ¶¶ 36–37; Ex. 1030, 63; Ex. 1032, 179–80; Ex. 1077, 4). Voswinckel JAHA teaches administering treprostinil in three breaths using a high concentration of treprostinil in the aerosolized solution. Ex. 1008, 3. Accordingly, Dr. Hill testifies that a person of ordinary skill in the art would have looked to Voswinckel JAHA to improve patient adherence to the treatment suggested by the combination of the '212 patent and Voswinckel JESC, providing a reason to combine its teachings with those of the other two references. Ex. 1002 ¶¶ 80–82.

Against this evidence, Patent Owner directs us to the report in Voswinckel JESC that "there were no significant adverse effects" at the lowest treprostinil concentration but that "mild and transient" "[h]eadache, cough or bronchoconstriction were observed" in some patients at higher doses, and that one patient at Voswinckel JESC's highest treprostinil dose "complained of major headache for 1 hour." Ex. 1007, 7; *see* PO Resp. 37–38. As Patent Owner puts it, "Voswinckel JESC warns in its Conclusion that 'at a concentration of 16 µg/ml, near maximal pulmonary vasodilation is achieved without adverse effects' but '[a]t higher doses, local and systemic side effects may occur.'" PO Resp. 37–38 (quoting Ex. 1007, 7). Because Petitioner's

proffered reason to combine the teachings of the '212 patent, Voswinckel JESC, and Voswinckel JAHA requires an increase in treprostinil concentration in order to administer the full dose in three breaths, Patent Owner argues that Voswinckel JESC's warning about side effects at higher doses would have persuaded a person of ordinary skill in the art not to pursue such a course. *Id.*

The preponderance of the evidence supports Petitioner's position. Patent Owner is correct that Voswinckel JESC notes that side effects could occur more frequently at higher doses than at lower doses. Ex. 1007, 7. But there is considerable evidence of record that a person of ordinary skill in the art would not have avoided increasing Voswinckel JESC's dose due to the side effects reported in Voswinckel JESC. First, Dr. Hill testifies that "[p]otential side effects are always weighed against potential clinical benefit, and pulmonary arterial hypertension is a serious, life-threatening disease where physicians and patients are more willing to tolerate side effects… to obtain clinical benefit." Ex. 1106 ¶ 74. Second, Dr. Waxman testifies that "[u]sually the headache goes away" and "there are things that can be done to help ameliorate the cough so in general we are able to get over that issue." Ex. 1108, 101:19–102:10. Together with Voswinckel JESC's description of potential side effects as "mild and transient," this evidence supports a finding that a person of ordinary skill in the art would not have been deterred from pursuing the course that is supported by the evidence to which Petitioner directs us.

With respect to reasonable expectation of success, Petitioner argues that a person of ordinary skill in the art would have had a reasonable expectation of success in combining the teachings of the '212 patent, Voswinckel JESC, and Voswinckel JAHA because Voswinckel JAHA teaches that "[t]olerability is excellent" for its short-duration, high-concentration treprostinil inhalation therapy. Pet. 33

(citing Ex. 1008, 3). Other than the argument discussed above about side effects reported in Voswinckel JESC, Patent Owner does not raise any timely counter to this argument.[8] PO Resp. 10–40. The record supports Petitioner's argument. Ex. 1008, 3.

Accordingly, Petitioner has shown by a preponderance of the evidence that a person of ordinary skill in the art would have had a reason to combine the teachings of the '212 patent, Voswinckel JESC, and Voswinckel JAHA and that they reasonably would have expected to succeed in doing so.

[8] In the Sur-Reply, Patent Owner raises for the first time three arguments against a reasonable expectation of success. Sur-Reply 21–22 (arguing that a person of ordinary skill in the art would not expect success in delivering Voswinckel JESC's dose over Voswinckel JAHA's three breaths because (1) it would require "increas[ing] the number [of] doses per day," (2) Voswinckel JAHA "lacked any placebo arm," and (3) Voswinckel JESC and Voswinckel JAHA used patients with differing pulmonary vascular resistances). "A sur-reply may only respond to arguments raised in the corresponding reply." 37 C.F.R. § 42.23(b). Petitioner's Reply did not raise any argument regarding a reasonable expectation of success. Reply 1–27. Therefore, we do not consider these newly raised arguments as they exceed the proper scope of the Sur-Reply.

c. Objective Indicia of Nonobviousness

Patent Owner directs us to evidence of three objective indicia that Patent Owner argues show the nonobviousness of the challenged claims. PO Resp. 55–62. Petitioner argues that the claims would have been obvious despite the evidence to which Patent Owner directs us. Reply 23–27.

*(1) Unexpected Results*

First, Patent Owner directs us to evidence that allegedly demonstrates that the challenged claims would have been nonobvious because they "unexpectedly achieved a therapeutically effective dose that was well tolerated" despite the fact that such "high doses of treprostinil were known in the art to produce dose-limiting side effects." PO Resp. 55. According to Patent Owner, the challenged claims "produce[d] a new and unexpected result which is different in kind and not merely in degree from the results of the prior art," which is evidence of those claims' nonobviousness. *Id.* at 55– 57 (quoting *In re Aller*, 220 F.2d 454, 456 (CCPA 1955)). Specifically, Patent Owner argues that the inhaled treprostinil dose recited in the challenged claims represented an increase of "an order of magnitude" over "the maximal tolerated dose" of "intravenous epoprostenol" or "intravenous treprostinil." *Id.* at 56. Similarly, Patent Owner argues that the challenged claims cover doses of inhaled treprostinil higher than a dose of inhaled iloprost that many patients were unable to tolerate. *Id.* at 56–57.

"[U]nexpected results must establish . . . a difference between the results obtained and those of the closest prior art." *Bristol-Myers Squibb v. Teva Pharms. USA*, 752 F.3d 967, 977 (Fed. Cir. 2014). Petitioner argues that the prior art over which Patent Owner argues the challenged claims showed unexpected results is not the closest prior art. Reply 24. We agree. As noted above, Patent Owner argues that the challenged claims show unexpected results over inhaled iloprost, intravenous epoprostenol, and

intravenous treprostinil. PO Resp. 55–57. But the challenged claims recite inhaled treprostinil, and, as discussed above, inhaled treprostinil is taught by each of the '212 patent, Voswinckel JESC, and Voswinckel JAHA. Ex. 1001, 18:22–44; Ex. 1006, code (57); Ex. 1007, 7; Ex. 1008, 3; Ex. 1035, 582. Patent Owner does not even allege that the results of the challenged claims are unexpected over these references.[9] Accordingly, we find that the evidence of record does not establish that the challenged claims produced a result that was unexpected over the closest prior art.

*(2) Copying*

Second, Patent Owner directs us to evidence that allegedly demonstrates that the challenged claims would have been nonobvious because Petitioner copied Patent Owner's product, Tyvaso, which is an embodiment of the challenged claims, when Petitioner developed its product, LIQ861. PO Resp. 57–61.

"[F]or objective indicia of nonobviousness to be accorded substantial weight, its proponent must establish a nexus between the evidence and the merits of the claimed invention." *Lectrosonics, Inc. v. Zaxcom, Inc.*, IPR2018-01129, Paper 33, 32 (PTAB Jan. 24, 2020) (precedential) (citing *ClassCo, Inc. v. Apple, Inc.*, 838 F.3d 1214, 1220 (Fed. Cir. 2016)). A patentee is entitled to a presumption of nexus "when the patentee shows that the asserted objective evidence is tied to a specific product and that product 'embodies the claimed features, and is coextensive with them.'" *Fox Factory, Inc. v. SRAM, LLC*, 944 F.3d 1366, 1373 (Fed. Cir. 2019) (quoting *Polaris Indus., Inc. v. Arctic Cat, Inc.*, 882 F.3d 1056, 1072 (Fed. Cir. 2018) (quoting

[9] Patent Owner argues that Voswinckel JESC and Voswinckel JAHA are not prior art to the '793 patent. PO Response 44–55; Sur-Reply 2–11, 25. As discussed above, however, Petitioner has shown by a preponderance of the evidence that these references qualify as prior art.

*Brown & Williamson Tobacco Corp. v. Philip Morris Inc.*, 229 F.3d 1120, 1130 (Fed. Cir. 2000))).

Here, Patent Owner does not allege, let alone "show[]" as required by *Fox Factory*, that Petitioner's LIQ861 product "is coextensive with" the features claimed in the '793 patent. 944 F.3d at 1373; *see* PO Resp. 57–61; Sur-Reply 26. Patent Owner does allege that the LIQ861 product embodies the challenged claims, PO Resp. 58–61, and we presume for purposes of our analysis that Patent Owner's allegation on this issue is correct. But *Fox Factory* requires both a showing that the product in question embodies the claims and a showing that the product in question is coextensive with the claims, and Patent Owner satisfies at most one of those two requirements. Accordingly, we find that a presumption of nexus is inappropriate.

"A finding that a presumption of nexus is inappropriate does not end the inquiry into secondary considerations." *Fox Factory*, 944 F.3d at 1373. "To the contrary, the patent owner is still afforded an opportunity to prove nexus by showing that the evidence of secondary considerations is the 'direct result of the unique characteristics of the claimed invention.'" *Id.* at 1373–74 (quoting In *re Huang*, 100 F.3d 135, 140 (Fed. Cir. 1996)). "Where the offered secondary consideration actually results from something other than what is both claimed and *novel* in the claim, there is no nexus to the merits of the claimed invention," meaning that "there must be a nexus to some aspect of the claim not already in the prior art." *In re Kao*, 639 F.3d 1057, 1068–69 (Fed. Cir. 2011) (emphasis in original).

On the other hand, there is no requirement that "objective evidence must be tied exclusively to claim elements that are not disclosed in a particular prior art reference in order for that evidence to carry substantial weight." *WBIP, LLC v. Kohler Co*., 829 F.3d 1317, 1331 (Fed. Cir. 2016). A patent owner may show, for example, "that it is the claimed combination as a whole that serves as a nexus for the objective evidence; proof of nexus is not limited to only when objective evidence is tied to the supposedly 'new' feature(s)." *Id*. Ultimately, the fact finder must weigh the secondary considerations evidence presented in the context of whether the claimed invention as a whole would have been obvious to a skilled artisan. *Id*. at 1331–32.

Here, Patent Owner directs us to several pieces of evidence that it contends show the LIQ861 product has a nexus to the challenged claims. First, as noted above, Patent Owner argues that LIQ861 embodies those claims. PO Resp. 58–61. Second, Patent Owner notes that "[t]he pharmacokinetics and bioavailability of a 79.5 microgram capsule dose [of LIQ861] was directly compared [by Petitioner] with Patent Owner's commercial product," demonstrating that "Petitioner's commercial product had comparable treprostinil bioavailability with Tyvaso® when delivered in a similar dosage range." *Id.* at 57–58 (citing Ex. 2085). Third, Patent Owner directs us to the new drug application Petitioner filed with the FDA, "relying in part on FDA's previous findings of efficacy and safety of Tyvaso® for the treatment of PAH." *Id.* at 58 (citing Ex. 2089, 3).

Taking these pieces of evidence in reverse order, we note first that the new drug application for LIQ861 was filed "under the 505(b)(2) regulatory pathway." *Id.*; *see also* Reply 25; Ex. 2089, 3. As Petitioner notes, Reply 25, and as Patent Owner does not dispute, Sur-Reply 26, applications for drugs under this pathway do not necessarily copy all aspects of the original drug, but they may rely on the investigations that showed the safety and efficacy of the original drug that uses the same active ingredient. 21 U.S.C. § 355(b)(2). In this respect, they differ from applications under the § 505(j) regulatory pathway, under which the new drug must generally have the same "active ingredient," "route of administration," "dosage form," "strength," and "labeling" as the original drug. 21 U.S.C. § 355(j)(2). Because the challenged claims here recite limitations requiring administration by inhalation of a particular amount of treprostinil in a particular number of breaths (and in some cases using a particular type of device and with the drug in a particular form), evidence that Petitioner merely relied on previous studies of the safety and efficacy of the recited active ingredient is not particularly strong evidence of copying.

Next, we consider the evidence that Petitioner compared the pharmacokinetics and bioavailability of its LIQ861 product with those of Patent Owner's Tyvaso product. Ex. 2085. Patent Owner argues that this evidence shows that "Petitioner's commercial product had comparable treprostinil bioavailability with Tyvaso® when delivered in a similar dosage range." PO Resp. 57–58. Regardless of whether an objective indicium of nonobviousness has its nexus to a single "aspect of the claim not already in the prior art," *Kao*, 639 F.3d at 1068–69, or to "the claimed combination as a whole," *WBIP*, 829 F.3d at 1331, it still must have some nexus to the claim in question. The challenged claims, however, do not recite any limitations for treprostinil bioavailability or pharmacokinetics. Ex. 1001,

18:22–44. Accordingly, evidence that Petitioner formulated its product to have similar bioavailability and pharmacokinetics to Patent Owner's product is, at most, very weak evidence of copying as to the claims at issue here.

Finally, we consider the evidence that LIQ861 embodies the challenged claims. PO Resp. 58–61. "Not every competing product that arguably falls within the scope of a patent is evidence of copying; otherwise, 'every infringement suit would automatically confirm the nonobviousness of the patent.'" *Wyers v. Master Lock Co.*, 616 F.3d 1231, 1246 (quoting *Iron Grip Barbell Co., Inc. v. USA Sports, Inc.*, 392 F.3d 1317, 1325 (Fed. Cir. 2004)). Proof of copying requires "actual evidence of copying efforts as opposed to mere allegations regarding similarities between the accused product and a patent." *Liqwd, Inc. v. L'Oreal USA, Inc.*, 941 F.3d 1133, 1137–38 (Fed. Cir. 2019). Thus, evidence that LIQ861 embodies the challenged claims is not evidence that could, without more, support a finding that Petitioner copied Patent Owner's patented method. As discussed above, to the extent there is any evidence of what *Liqwd* refers to as "copying efforts" beyond mere similarity between LIQ861 and the challenged claims, that evidence shows that Petitioner copied only features that appear in the prior art, are not recited in the challenged claims, or both. Accordingly, we do not find that Patent Owner has shown that Petitioner copied the method of the challenged claims.

*(3) Long-Felt and Unmet Need*

Patent Owner directs us to evidence that allegedly demonstrates that the challenged claims would have been nonobvious because "[t]he claimed invention of the '793 patent satisfies a long-felt unmet need in the treatment of pulmonary hypertension." PO Resp. 61–62; *see* Sur-Reply 26. Patent Owner relies on three separate theories to demonstrate this long-felt need. First, in the Response, Patent Owner argues that the approval of inhaled treprostinil

as the first treatment for "pulmonary hypertension associated with interstitial lung disease" satisfied "a completely unmet medical need." PO Resp. 61–62 (quoting Ex. 2056, 105:6–8). Second, also in the Response, Patent Owner argues that Petitioner admitted that its LIQ861 product "fulfill[ed] a significant unmet need for PAH patients by maximizing the therapeutic benefits of treprostinil by safely delivering doses to the lungs in 1 to 2 breaths using a discreet, convenient, easy-to-use inhaler." *Id.* at 62 (quoting Ex. 2085). Third, in the Sur-Reply, Patent Owner argues that its Tyvaso product satisfied a need for an "inhaled treatment for pulmonary hypertension" that avoided the "inconvenient dosing and side effects of Ventavis," the only previously approved treatment. Sur-Reply 26 (citing Ex. 1002 ¶ 42; Ex. 1108, 44:19–21, 49:17–50:10; Ex. 2055, 28:22–29:20). Each of these arguments fails for a different reason.

We begin with Patent Owner's third argument, that Tyvaso satisfied a need for an inhaled treatment that avoided the dosing problems and side effects of Ventavis. Patent Owner offers this argument for the first time in the Sur-Reply. *Id.* "A sur-reply may only respond to arguments raised in the corresponding reply." 37 C.F.R. § 42.23(b). "'Respond,' in the context of 37 C.F.R. § 42.23(b), does not mean proceed in a new direction with a new approach as compared to the positions taken in a prior filing." Patent Trial and Appeal Board Consolidated Trial Practice Guide 74 (Nov. 2019), available at https://www.uspto.gov/sites/default/files/documents/tpgnov.pdf. As discussed in more detail below, in its prior filings, Patent Owner's only positions with respect to long-felt need were (1) that the patented method satisfied a need for a treatment for pulmonary hypertension associated with interstitial lung disease and (2) that Petitioner admitted that its product satisfied a need. PO Resp. 61–62. Neither of those positions related to a need for a

treatment that avoided the problems associated with Ventavis. *Id.* Accordingly, Patent Owner's argument in the Sur-Reply is a new argument that we do not consider further.

Next, we consider Patent Owner's argument that the method of the '793 patent provided the first treatment for pulmonary hypertension associated with interstitial lung disease. *Id.* Even if this is true, it is extremely weak evidence of the nonobviousness of the claims at issue because those claims do not cover treatment of pulmonary hypertension associated with interstitial lung disease. There are multiple groups of pulmonary hypertension conditions. Ex. 1088, 1. In addition to other groups not relevant here, these groups include "WHO Group 1," or "[p]ulmonary arterial hypertension," and "WHO Group 3," or "[p]ulmonary hypertension associated with interstitial lung disease." *Id.* Patent Owner's declarant, Dr. Waxman, testifies that all pulmonary hypertension groups other than Group 1 fall outside the scope of the claims of the '793 patent. Ex. 1132, 116:9–119:12. Dr. Hill agrees. Ex. 1106 ¶ 100. Thus, to the extent the challenged claims satisfied a long-felt and unmet need for a treatment for pulmonary hypertension associated with interstitial lung disease, Patent Owner has not shown that that need is tied to any limitation of the challenged claims or to any challenged claim as a whole.

Finally, we consider Patent Owner's argument that Petitioner admitted that its LIQ861 product "fulfill[ed] a significant unmet need for PAH patients by maximizing the therapeutic benefits of treprostinil by safely delivering doses to the lungs in 1 to 2 breaths using a discreet, convenient, easy-to-use inhaler." PO Resp. 62 (quoting Ex. 2085). "Evidence of a long-felt but unresolved need can weigh in favor of the non-obviousness of an invention because it is reasonable to infer that the need would not have persisted had the solution been obvious." *Apple Inc. v. Samsung Elecs. Co.*, 839 F.3d 1034, 1056 (Fed. Cir. 2016).

Patent Owner directs us to two pieces of evidence. First, Patent Owner directs us to Exhibit 2085, which states that LIQ861 "fulfill[ed] a significant unmet need for PAH patients by maximizing the therapeutic benefits of treprostinil by safely delivering doses to the lungs in 1 to 2 breaths using a discreet, convenient, easy-to-use inhaler." Ex. 2085, 1. This demonstrates that Petitioner believed its product satisfied a particular "significant unmet need," but it does not demonstrate how long that need persisted. *Id.* Second, Patent Owner directs us to page F-7 of Exhibit 2089, but this page does not address the filling of any need by LIQ861. Ex. 2089, F-7. Thus, Patent Owner does not show that any previously unmet need satisfied by LIQ861 was a need that had persisted, as required by *Apple v. Samsung*. Accordingly, we do not find that Patent Owner has shown that the patented method satisfied any previously unmet and long-felt need.

d. Dependent Claims

Claims 2–8 of the '793 patent depend directly or indirectly from claim 1. Ex. 1001, 18:32–45. Petitioner argues that the combination of the '212 patent, Voswinckel JESC, and Voswinckel JAHA teaches or suggests the additional limitations of these claims. Pet. 41–46. Patent Owner does not dispute these arguments, except with respect to claims 4, 6, and 7. PO Resp. 38–40.

We have reviewed the evidence cited by Petitioner with respect to dependent claims 2, 3, 5, and 8, and we are persuaded that Petitioner has shown by a preponderance of the evidence that the combination of the '212 patent, Voswinckel JESC, and Voswinckel JAHA teaches or suggests the subject matter of these claims. For example, claim 2 depends from claim 1 and recites a further limitation that requires that "the inhalation device [be] a soft mist inhaler," and Petitioner directs us to evidence that soft mist inhalers were known in the prior art, as well as evidence that soft mist inhalers were known to be suitable for inhaled delivery of drugs in a small number of breaths. Ex. 1001, 7:33–39, 18:32–33; Ex. 1002 ¶¶ 106–110; Ex. 1004 ¶¶ 66–71; Ex. 1006, 5:30–32; Ex. 1034, 175.

The parties dispute the obviousness of claims 4, 6, and 7. Claim 4 depends from claim 1 and recites a limitation requiring that "the inhalation device [be] a dry powder inhaler." Ex. 1001, 18:36–37. Claim 6 depends from claim 4 and adds a limitation requiring that "the formulation [be] a powder." *Id.* at 18:40–41. Claim 7 depends from claim 6 and adds a limitation requiring that "the powder comprise[] particles less than 5 micrometers in diameter." *Id.* at 18:42–43. Petitioner argues that each of these limitations is taught or suggested by the '212 patent. Pet. 43–45 (citing Ex. 1006, 5:30–32, 5:37–41, 14:19–21; Ex. 1002 ¶¶ 116–117; Ex. 1004 ¶¶ 77–80; Ex. 1038, 311). Patent Owner argues that Petitioner's obviousness argument with respect to these claims is inconsistent with Petitioner's argument in the parallel District Court proceeding that these claims are not enabled. PO Resp. 38–40. Specifically, Patent Owner argues that Dr. Gonda's testimony here that a person of ordinary skill in the art "would have had a reasonable expectation of success that the 'powder' disclosed and claimed in the '212 Patent could be 'inhaled' by a patient using a dry powder inhaler" contradicts Dr. Gonda's testimony in District Court that a person of ordinary skill

in the art "would be unable to formulate a treprostinil powder suitable for administration via a dry powder inhaler for [pulmonary hypertension] patients without excessive experimentation." PO Resp. 38–39 (quoting Ex. 1004 ¶ 80; Ex. 2091, 40–61). Because Dr. Gonda's District Court testimony is more "lengthy" than his testimony here, Patent Owner argues that the District Court testimony is more reliable and that, accordingly, we should not rely on Dr. Gonda's testimony here. *Id.* at 40.

Dr. Gonda's testimony here provides support for Petitioner's argument that a person of ordinary skill in the art would have had a reasonable expectation of success in combining the teachings of the '212 patent, Voswinckel JESC, and Voswinckel JAHA in order to arrive at the invention of claims 4, 6, and 7. Ex. 1004 ¶ 80. Reasonable expectation of success is a separate inquiry from enablement. *UCB, Inc. v. Accord Healthcare, Inc.*, 890 F.3d 1313, 1327 (Fed. Cir. 2018) (finding no "authority for the proposition that the presumption of" enablement of prior art "precludes . . . finding that there was no reasonable expectation of success"). Accordingly, the mere fact that Dr. Gonda testifies to a lack of enablement in one forum and to the presence of a reasonable expectation of success in a second forum does not render unreliable the testimony in either forum. Therefore, we credit the unrebutted testimony of Dr. Gonda that a person of ordinary skill in the art "would have had a reasonable expectation of success that the 'powder' disclosed and claimed in the '212 Patent could be 'inhaled' by a patient using a dry powder inhaler." Ex. 1004 ¶ 80. In addition, Dr. Gonda's testimony in this proceeding is supported by a citation to Ex. 1038, an October 2005 article that states that dry powder inhalers "are a widely accepted inhaled delivery dosage form," as well as to Ex. 1019, an article stating that 14 separate dry powder inhalers were approved in the United States by 2006. Ex. 1019, 33; Ex. 1038, 1311. This evidence provides us with an additional

reason to credit Dr. Gonda's testimony as to reasonable expectation of success.

Moreover, even if there were some connection between enablement and reasonable expectation of success, Patent Owner concedes that the '212 patent enables its own claims. Tr. 43:6–50:9. In other words, the '212 patent provides enough information for a person of ordinary skill in the art to have made and used the invention defined by the claims of the '212 patent. *See* 35 U.S.C. § 112. That invention includes "[a] method for treating pulmonary hypertension in a mammal comprising delivering to said mammal an effective amount of [treprostinil] or its pharmaceutically acceptable salt or ester by inhalation," wherein the treprostinil "is inhaled in powder form comprising particles less than 10 micrometers in diameter." Ex. 1006, 14:9–12, 14:19–21. To the extent that, despite *UCB*, 890 F.3d at 1327, there remains any connection at all between a reasonable expectation of success and enablement, the fact that a person of ordinary skill in the art was enabled to make and use this invention presumably would have rendered that person more likely to expect success in achieving the similar invention of claims 4, 6, and 7 of the '793 patent.

Further, as discussed above with respect to the reason to combine the teachings of the '212 patent, Voswinckel JESC, and Voswinckel JAHA, Petitioner directs us to other evidence that a person of ordinary skill in the art would have had a reasonable expectation of success.

For all these reasons, we determine that Petitioner has shown by a preponderance of the evidence that a person of ordinary skill in the art would have had a reason to combine the teachings of the '212 patent, Voswinckel JESC, and Voswinckel JAHA and would have had a reasonable expectation of success in doing so in order to arrive at the invention of the challenged claims, including claims 4, 6, and 7.

Thus, we move on to whether the prior art teaches or suggests the additional limitations of claims 4, 6, and 7. Petitioner argues that the '212 patent teaches or suggests each of these limitations, and Patent Owner does not dispute that argument. Pet. 43–45; PO Resp. 38–40. Claim 4 recites a limitation requiring that "the inhalation device [be] a dry powder inhaler." Ex. 1001, 18:36–37. The '212 patent teaches using an "inhaler" to deliver treprostinil, that "solid formulations, usually in the form of a powder, may be inhaled in accordance with the present invention," and that treprostinil "is inhaled in powder form." Ex. 1006, 5:30–32, 5:37–39, 14:19–21. Dr. Hill testifies that a person of ordinary skill in the art would have known that the "inhaler" used to deliver the "powder" of the '212 patent was a dry powder inhaler. Ex. 1002 ¶ 116. Claim 6 depends from claim 4 and adds a limitation requiring that "the formulation [be] a powder." Ex. 1001, 18:40– 41. The '212 patent teaches that "solid formulations, usually in the form of a powder, may be inhaled in accordance with the present invention," as well as that treprostinil "is inhaled in powder form." Ex. 1006, 5:37–39, 14:19–21. Claim 7 depends from claim 6 and adds a limitation requiring that "the powder comprise[] particles less than 5 micrometers in

diameter." Ex. 1001, 18:42–43. The '212 patent teaches that "the particles are preferably less than 10 micrometers in diameter, and more preferably, less than 5 micrometers in diameter." Ex. 1006, 5:39–41. Accordingly, Petitioner has shown by a preponderance of the evidence that the '212 patent teaches or suggests the additional limitations of claims 4, 6, and 7 of the '793 patent.

e. Conclusion

As discussed above, Petitioner has shown by a preponderance of the evidence that the combination of the '212 patent, Voswinckel JESC, and Voswinckel JAHA teaches or suggests the subject matter of claims 1–8. Petitioner also has shown by a preponderance of the evidence that a person of ordinary skill in the art would have had a reason to combine the teachings of the '212 patent, Voswinckel JESC, and Voswinckel JAHA and would have had a reasonable expectation of success in doing so to arrive at the invention of the challenged claims. In addition, the preponderance of the evidence shows that there is at most very weak evidence of objective indicia of nonobviousness, including unexpected results, copying, and long-felt but unmet need. Weighing together the evidence of the prior art teaching or suggesting the subject matter of the claims, of a reason to combine the teachings of the prior art with a reasonable expectation of success, and of objective indicia of nonobviousness, we conclude that Petitioner has demonstrated that claims 1–8 of the '793 patent would have been obvious over the combination of the '212 patent, Voswinckel JESC, and Voswinckel JAHA and, accordingly, that those claims are unpatentable.

*C. Asserted Obviousness over '212 Patent and Voswinckel JESC*

Petitioner argues that claims 1–8 would have been obvious over the combination of the '212 patent and Voswinckel JESC. Pet. 46–50. Because Petitioner has shown by a preponderance of the evidence that all of the challenged claims would have been obvious over the similar combination of the '212 patent, Voswinckel JESC, and Voswinckel JAHA, we need not reach this asserted ground.

*D. Grounds Relying on Ghofrani or Voswinckel 2006*

Petitioner argues that claim 1 was anticipated by Ghofrani; that claims 1, 3, and 8 would have been obvious over the combination of Voswinckel JAHA and Ghofrani; that claims 1 and 3 were anticipated by Voswinckel 2006; and that claims 2 and 4–8 would have been obvious over the combination of Voswinckel 2006 and the '212 patent. Pet. 50–64. Patent Owner argues that each of these grounds fails because Petitioner fails to show sufficiently that Ghofrani and Voswinckel 2006 qualify as prior art. PO Resp. 44–54. Petitioner disagrees, arguing that these references qualify as prior art under 35 U.S.C. § 102(a). Pet. 25–30.

In the institution decision, we determined that, on the preliminary record available at the time, Petitioner had not shown that either Ghofrani or Voswinckel 2006 qualified as prior art. Inst. Dec. 37–43. Since that decision, Petitioner has neither supplemented the record nor made any additional arguments on this issue. Reply 1–27. During the hearing, Petitioner did not agree that it had abandoned its argument on the grounds asserting Ghofrani or Voswinckel 2006. Tr. 35:13–36:10. Nevertheless, in the absence of any new evidence or argument, we have been directed to nothing that persuades us to reach any decision other than we reached initially. Accordingly, our analysis below mirrors the analysis we conducted in the institution decision.

*1. Prior-Art Status of Ghofrani*

Ghofrani is an article published in the German journal Herz in June 2005, less than one year before the priority date of the '793 patent. Pet. 25; Ex. 1010, 9; Ex. 1036 ¶¶ 47–55. Petitioner argues that Ghofrani is prior art to the '793 patent under 35 U.S.C. § 102(a). Pet. 25–27. Patent Owner disagrees, arguing that Petitioner has not shown sufficiently that Ghofrani is "by others" under § 102(a). PO Resp. 44–51.

As both parties acknowledge, establishing prior-art status under § 102(a) requires showing that the reference is "by others," meaning that it was authored by an entity different from the entity that invented the challenged patent. Pet. 26–27; PO Resp. 44–46; *see Lacks Industries, Inc. v. McKechnie Vehicle Components USA, Inc.*, 322 F.3d 1335, 1346 (Fed. Cir. 2003) ("it is well-settled law that an inventor's own disclosure will not anticipate his later invention" unless published more than one year prior to the priority date (internal quotation marks omitted)).

The authors of Ghofrani are "Hossein Ardeschir Ghofrani, Robert Voswinckel, Frank Reichenberger, Friedrich Grimminger, [and] Werner Seeger." Ex. 1010, 9. The inventors of the '793 patent are Horst Olschewski, Robert Roscigno, Lewis J. Rubin, Thomas Schmehl, Werner Seeger, Carl Sterritt, and Robert Voswinckel. Ex. 1001, code (72). Thus, there are, as Petitioner argues, "inventors listed on the '793 Patent that are not listed as authors on Ghofrani, and vice versa." Pet. 26. Specifically, Ghofrani, Reichenberger, and Grimminger authored the Ghofrani reference but were not inventors of the '793 patent; and Olschewski, Roscigno, Rubin, Schmehl, and Sterritt were inventors of the '793 patent but not authors of the Ghofrani reference.

Petitioner argues that these differences alone are sufficient to show that Ghofrani is "by others." *Id.* at 26–27. We agree that it is possible, depending on the state of the

rest of the evidence of record, for any difference between the authors of an alleged prior-art reference and the inventors of a challenged patent to render the reference "by others" for purposes of § 102(a). *See, e.g.*, *In re Katz*, 687 F.2d 450, 455 (CCPA 1982) ("ambiguity [was] created by the printed publication" where authors included people not named as inventors); *cf. In re Land*, 368 F.2d 866, 877 (CCPA 1966) (for purposes of § 102(e), reference authored by one co-inventor was "by another").

That said, it is not always sufficient for Petitioner merely to show a difference between a list of authors and a list of inventors. Where the record contains evidence that the reference was derived entirely from the work of the inventors or at least one joint inventor, this evidence may be sufficient to show that the reference is not "by others" for purposes of § 102(a). *Katz*, 687 F.2d at 455–56 (finding inventor's declaration of sole inventorship sufficient to render reference authored by inventor and others not "by others"). Although the testimony of an inventor that the reference in question was derived from the inventors' work may be sufficient on its own, at least where it is not "a mere pro forma restatement of the oath in [the inventor's] application," affidavits from the other authors disclaiming the invention are particularly strong evidence that the reference is not "by others." *Id.* ("Submission of such affidavits or declarations would have ended the inquiry . . . ."). Here, for the reasons discussed below, the preponderance of the evidence persuades us that, despite the differences between its list of authors and the list of the inventors of the '793 patent, Ghofrani is not "by others" for purposes of § 102(a).

Petitioner's first argument that Ghofrani is "by others" is that there are people who are authors of Ghofrani who are not inventors of the '793 patent. Pet. 26. But Dr. Seeger, one of the inventors of the '793 patent, as well as an author of Ghofrani, describes the roles of the other authors

of Ghofrani, explaining that Dr. Ghofrani drafted the portion of the article "relating to phosphodiesterase inhibitors," that Drs. Reichenberger and Grimminger drafted the portion of the article relating to "the use of selective endothelin A receptor agonists for treating pulmonary hypertension," and that he and Dr. Voswinckel—another co-inventor—drafted the portion of the article relating to "the use of inhaled iloprost and inhaled treprostinil for treatment of pulmonary hypertension," the only portion on which Petitioner's unpatentability case rests. Ex. 2003 ¶¶ 4–8. Dr. Seeger's testimony is corroborated by the testimony of Drs. Ghofrani, Reichenberger, and Grimminger, each of whom testifies that they "did not make material contributions to" the portion of the Ghofrani reference relating to inhaled treprostinil. Ex. 2004 ¶¶ 4–5; Ex. 2005 ¶¶ 4–5; Ex. 2006 ¶¶ 4–5. This is precisely the type of testimony that the *Katz* court held should "end[] the inquiry" into whether Ghofrani was "by others." 687 F.2d at 455–56. Accordingly, this evidence overcomes Petitioner's argument that the difference between the Ghofrani authors and the inventors of the '793 patent is sufficient to show that Ghofrani is "by others."

Petitioner also argues that the failure to include some of the inventors of the '793 patent—Olschewski, Roscigno, Rubin, Schmehl, and Sterritt—as authors of Ghofrani renders Ghofrani "by others." Pet. 26–27. But "the fact that a reference does not list any co-inventors as authors . . . is certainly not dispositive in itself." *Allergan, Inc. v. Apotex Inc.*, 754 F.3d 952, 969 (Fed. Cir. 2014); *see* MPEP § 2132.01(I) ("An inventor's or at least one joint inventor's disclosure of his or her own work within the year before the application filing date cannot be used against the application as prior art under pre-AIA 35 U.S.C. 102(a)."). Moreover, Dr. Seeger explains the roles of the other named inventors in designing trials and clinical studies leading to the patent application. Ex. 2003 ¶¶ 22–27. In particular,

Dr. Seeger testifies that the Ghofrani reference did not report on the details of the studies and trials that were in part designed by these other authors, explaining why they did not contribute to writing Ghofrani, even though they were involved in the related work that gave rise to the '793 patent. *Id.* ¶¶ 11–12. Dr. Seegar further explains that, "any study that formed the basis of our discussion of inhaled trepostinil in [Ghofrani and two other references] was performed by me in conjunction with my ongoing collaboration with Drs. Voswinckel, Olschewski, Rubin, Schmehl, Sterrit, and Roscigno." *Id.* ¶ 12. Again, then, the preponderance of the evidence supports a determination that Ghofrani is not "by others" for purposes of § 102(a).

*2. Prior-Art Status of Voswinckel 2006*

The issues and arguments regarding Voswinckel 2006 are quite similar to those discussed above regarding Ghofrani. Petitioner argues that Voswinckel 2006 qualifies as prior art under § 102(a) and that it is "by others" both because some of its authors—specifically, Ghofrani and Grimminger—are not inventors of the '793 patent and because some inventors of the '793 patent—specifically, Olschewski, Roscigno, Rubin, Schmehl, and Sterritt—are not authors of Voswinckel 2006. Pet. 27–30. Patent Owner disagrees, pointing to the testimony of Drs. Seeger, Ghofrani, and Grimminger explaining the role that the other inventors of the '793 patent played, as well as making clear that neither Ghofrani nor Grimminger authored the portion of Voswinckel 2006 that is relevant as prior art. PO Resp. 44–46, 51–54; Ex. 2003 ¶¶ 20–21 (describing the roles of Drs. Ghofrani and Grimminger, explaining that they "did not participate in the design of any of the studies, did not select the dosing regimen, and did not conduct analysis of patient results discussed in . . . Voswinckel 2006"); 19 ("any study that formed the basis of our discussion of inhaled treprostinil in this reference was performed by me in

connection with my ongoing collaboration with [the other inventors]").

For the same reasons discussed above with respect to Ghofrani, we determine that the preponderance of the evidence shows that Petitioner has not shown sufficiently that Voswinckel 2006 is "by others."

*3. Conclusion*

For the reasons discussed above, Petitioner has not shown that either Ghofrani or Voswinckel 2006 qualifies as prior art. Accordingly, Petitioner has not shown the unpatentability of any challenged claim on any ground that relies on either Ghofrani or Voswinckel 2006.

*E. Motions to Exclude Evidence*

Each party filed a motion to exclude evidence. Paper 65; Paper 66. We consider each motion separately below.

*1. Petitioner's Motion to Exclude*

Petitioner moves to exclude Exhibits 2092, 2100, 2101, 2102, and 2103 as not authenticated and, for Ex. 2092, as incomplete. Paper 65, 1. Petitioner also moves to exclude the portions of Patent Owner's Sur-Reply that rely on these exhibits. *Id.*

We do not rely on any of the exhibits Petitioner challenges in reaching our decision in this case. Accordingly, we dismiss Petitioner's motion to exclude as moot.

*2. Patent Owner's Motion to Exclude*

Patent Owner moves to exclude Exhibits 1037, 1114, 1117, and 1120 as hearsay and, for Ex. 1037, as not authenticated, irrelevant, and lacking the original writing. Paper 66, 2. Patent Owner also moves to exclude Exhibits 1029, 1050, 1066, 1074, and 1078 as not authenticated. *Id.* Patent Owner moves to exclude Exhibit 1087 as lacking personal knowledge and as irrelevant. *Id.* Patent Owner also moves to exclude portions of Exhibit 1112 as not based on sufficient facts and analysis. *Id.* Further, Patent Owner moves to exclude the portions of Petitioner's Petition and Reply, as well as the portions of Exhibits 1002 and 1004, that cite these exhibits. *Id.* at 2–3.

We do not rely on any of the exhibits or portions of exhibits Patent Owner moves to exclude in reaching our decision in this case, with two exceptions: paragraphs 36 and 42 of Ex. 1002, which cite Ex. 1029, and paragraph 56 of Ex. 1004, which Patent Owner argues cites Ex. 1029, Ex. 1050, and Ex. 1066. We dismiss as moot Patent Owner's motion to exclude, except as to these paragraphs of Exhibits 1002 and 1004. We discuss the remaining portions of Patent Owner's motion to exclude below.

a. Paragraphs 36 and 42 of Exhibit 1002

Patent Owner moves to exclude paragraphs 36 and 42 of Exhibit 1002 because they rely on Exhibit 1029, which Patent Owner argues lacks authentication. Paper 66, 2–3.

Certain items are self-authenticating under Federal Rule of Evidence ("FRE") 902, and, for items that are not self-authenticating, FRE 901 provides that "the proponent [of the evidence in question] must produce evidence sufficient to support a finding that the item is what the proponent claims it is." Fed. R. Evid. 901(a). The evidence showing "that the items is what the proponent claims it is" may include "[t]estimony that an item is what it is claimed to be," or "[t]he appearance, contents, substance, internal patterns, or other distinctive characteristics of the item, taken together with all the circumstances," among other things. Fed. R. Evid. 901(b).

Here, Dr. Hill, Petitioner's declarant, testifies three times that Exhibit 1029 is the "Ventavis Label 2004." Ex. 1002 ¶¶ 36, 41, 42. Dr. Gonda, another declarant for Petitioner, testifies that Exhibit 1029 is the "Ventavis (iloprost) Label." Ex. 1004 ¶ 56 n.4. Dr. Waxman, Patent Owner's declarant, cites to Exhibit 1029 twice as support for the approved dose for, and side effects experienced by, patients taking Ventavis. Ex. 2052 ¶ 100. The "appearance, contents, substance, internal patterns, [and] other distinctive characteristics," Fed. R. Evid. 901(b), of Ex. 1029 confirm the testimony of Drs. Hill, Gonda, and Waxman. The document contains sections titled "description," "clinical pharmacology," "indications and usage," "contraindications," "warnings," "precautions," "adverse reactions," "overdosage," "dosage and administration," "how supplied," "storage," and "patient information," with each section providing information related to "Ventavis." Ex. 1029, 1–17. This information is consistent with a drug label for Ventavis, which is what Dr. Hill and Dr. Gonda testify, what Dr. Waxman assumes, and what Petitioner argues, Ex. 1029 is. Accordingly, we find that Petitioner has "produce[d] evidence sufficient to support a finding that [Ex. 1029] is what [Petitioner] claims it is." Fed. R. Evid. 901(a). Because Ex. 1029 does not lack authentication, we deny

Patent Owner's motion to exclude paragraphs 36 and 42 of Ex. 1002, which cite to Ex. 1029.

b. Paragraph 56 of Exhibit 1004

Patent Owner moves to exclude paragraph 56 of Exhibit 1004 because it relies on Exhibits 1029, 1050, and 1066, all of which Patent Owner argues lack authentication. Paper 66, 2–3. We discuss Exhibit 1029 above, finding that it is sufficiently authenticated. The situation with respect to Exhibits 1050 and 1066 is similar. Dr. Gonda testifies that Ex. 1050 is the "Pulmozyme® Label" and that Ex. 1066 is the "AccuNeb® Label." Ex. 1004 ¶ 56 n.4. Moreover, Dr. Gonda's testimony about what Exhibits 1050 and 1066 are is confirmed by the contents of those exhibits. Exhibit 1050 contains sections titled "description," "clinical pharmacology," "indications and usage," "contraindications," "warnings," "precautions," "adverse reactions," "overdosage," "dosage and administration," and "how supplied," with each section providing information related to "Pulmozyme." Ex. 1050, 1–2. Exhibit 1066 contains sections titled "description," "clinical pharmacology," "indications and usage," "contraindications," "warnings," "precautions," "adverse reactions," "overdosage," "dosage and administration," "how supplied," "storage," and "patient's instructions for use," with each section providing information related to "AccuNeb." Ex. 1066, 1–2. This information is consistent with drug labels for Pulmozyme and AccuNeb, which is what Dr. Gonda testifies, and what Petitioner argues, Exhibits 1050 and 1066 are. Accordingly, we find that Petitioner has "produce[d] evidence sufficient to support a finding that [Ex. 1050 and Ex. 1066 are] what [Petitioner] claims [they are]." Fed. R. Evid. 901(a). Because Exhibits 1050 and 1066 do not lack authentication, we deny Patent Owner's motion to exclude paragraph 56 of Ex. 1004, which cites to those exhibits.

## CONCLUSION[10]

For the reasons discussed above, Petitioner has shown by a preponderance of the evidence that claims 1–8 of the '793 patent are unpatentable.

| Claims | 35 U.S.C. § | Reference(s)/Basis | Claims Shown Unpatentable | Claims Not Shown Unpatentable |
|---|---|---|---|---|
| 1–8 | 103(a) | '212 patent, Voswinckel JESC, Voswinckel JAHA | 1–8 | |
| 1–8 | 103(a) | '212 patent, Voswinckel JESC[11] | | |
| 1 | 102(a) | Ghofrani | | 1 |

[10] Should Patent Owner wish to pursue amendment of the challenged claims in a reissue or reexamination proceeding subsequent to the issuance of this Decision, we draw Patent Owner's attention to the April 2019 Notice Regarding Options for Amendments by Patent Owner Through Reissue or Reexamination During a Pending AIA Trial Proceeding. *See* 84 Fed. Reg. 16,654 (Apr. 22, 2019). If Patent Owner chooses to file a reissue application or a request for reexamination of the challenged patent, we remind Patent Owner of its continuing obligation to notify the Board of any such related matters in updated mandatory notices. *See* 37 C.F.R. §§ 42.8(a)(3), (b)(2).

[11] This Final Written Decision does not reach these grounds because Petitioner has proven all challenged claims are unpatentable based on obviousness over the combination of the '212 patent, Voswinckel JESC, and Voswinckel JAHA

| | | | | |
|---|---|---|---|---|
| 1, 3, 8 | 103(a) | Voswinckel JAHA, Ghofrani | | 1, 3, 8 |
| 1, 3 | 102(a) | Voswinckel 2006 | | 1, 3 |
| 2, 4–8 | 103(a) | Voswinckel 2006, '212 patent | | 2, 4–8 |
| **Overall Outcome** | | | 1–8 | |

ORDER

It is hereby

ORDERED that, based on the preponderance of the evidence, claims 1–8 of the '793 patent have been shown to be unpatentable;

FURTHER ORDERED that Petitioner's Motion to Exclude is dismissed as moot;

FURTHER ORDERED that Patent Owner's Motion to Exclude is denied as to paragraphs 36 and 42 of Exhibit 1002 and as to paragraph 56 of Exhibit 1004;

FURTHER ORDERED that Patent Owner's Motion to Exclude is dismissed as moot in all other respects; and

FURTHER ORDERED that, because this is a Final Written Decision, parties to this proceeding seeking judicial review of this Decision must comply with the notice and service requirements of 37 C.F.R. § 90.2

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**APPENDIX C**

Trials@uspto.gov Paper 81
571-272-7822 Date: October 26, 2022

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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LIQUIDIA TECHNOLOGIES, INC.,
Petitioner,
v.
UNITED THERAPEUTICS CORPORATION,
Patent Owner.

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IPR2021-00406
Patent 10,716,793 B2

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Before KATHERINE K. VIDAL, *Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office*, SCOTT R. BOALICK, *Chief Administrative Patent Judge*, and JACQUELINE WRIGHT BONILLA, *Deputy Chief Administrative Patent Judge.*

PER CURIAM.

ORDER

The Office received a request for Precedential Opinion Panel (POP) review of issues raised in the Board's Final Written Decision. Ex. 3003; *see* Paper 78. In the request, Patent Owner argues that the Board improperly determined that the Voswinckel JESC (Ex. 1007) and Voswinckel JAHA (Ex. 1008) references were publicly accessible and therefore qualify as prior art under pre-AIA 35 U.S.C. § 102(b) because a person of ordinary skill in the art would have been able to find them with the benefit of certain research aids. Paper 79, 1–3; *see* Paper 78, 8–12. The request was referred to the POP panel referenced above.

We have reviewed the request, the Board's Final Written Decision, the Papers, and the Exhibits in the above-listed proceeding. We determine that the Board's Final Written Decision did not address adequately whether the Voswinckel JESC and Voswinckel JAHA references qualify as prior art. *See* Paper 78, 8–12. Specifically, the Board's analysis did not consider whether the research aids themselves were available prior to the critical date, such that a person of ordinary skill in the art would have used them to find Voswinckel JESC and Voswinckel JAHA. *Id.* at 12. Further, the Board's analysis did not address whether the Voswinckel JESC and Voswinckel JAHA references were publicly accessible by way of their presentation and/or inclusion in distributed materials, such as at a conference or library. Paper 78, 8–12; *see In re Klopfenstein*, 380 F.3d 1345, 1350–52 (Fed. Cir. 2004) ("The determination of whether a reference is a 'printed publication' under 35 U.S.C. § 102(b) involves a case-by-case inquiry into the facts and circumstances surrounding the reference's disclosure to members of the public.").

However, because the record has been fully developed on these issues, the Board panel is best suited to make the appropriate factual findings for this analysis in its decision on rehearing. Accordingly, we deny Patent Owner's request for POP review of the Final Written Decision. With this denial of POP review, authority over all issues in this case — including consideration of Patent Owner's pending rehearing request — is returned to the original panel. We direct the Board, in its consideration on rehearing, to clearly identify whether the Voswinckel JESC and Voswinckel JAHA references qualify as prior art. Such analysis shall clarify whether the relied upon research aids were available prior to the critical date and whether the Voswinckel JESC and Voswinckel JAHA references were publicly accessible by way of their presentation and/or inclusion in distributed materials, such as at a conference or library.

Accordingly, based on the foregoing, it is:

ORDERED that the request for POP review is denied;

FURTHER ORDERED that the original panel maintains authority over all matters, including considering the submitted rehearing request in view of the complete record; and

FURTHER ORDERED that the Board, on rehearing, shall clearly identify whether the Voswinckel JESC and Voswinckel JAHA references qualify as prior art.

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**APPENDIX D**

Trials@uspto.gov Paper 82
Tel: 571-272-7822 Entered: February 2, 2023

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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LIQUIDIA TECHNOLOGIES, INC.,
Petitioner,

v.

UNITED THERAPEUTICS CORPORATION,
Patent Owner.

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IPR2021-00406
Patent 10,716,793 B2

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Before ERICA A. FRANKLIN, CHRISTOPHER M. KAISER, and DAVID COTTA, *Administrative Patent Judges.*

KAISER, *Administrative Patent Judge*.

DECISION

Denying Patent Owner's Request on Rehearing of Final Written Decision

*37 C.F.R. § 42.71(d)*

## INTRODUCTION

Liquidia Technologies, Inc. ("Petitioner") filed a Petition (Paper 2, "Pet.") requesting an *inter partes* review of claims 1–8 of U.S. Patent No. 10,716,793 B2 (Ex. 1001, "the '793 patent"). United Therapeutics Corporation ("Patent Owner") filed a Preliminary Response. Paper 13 ("Prelim. Resp.").

On August 11, 2021, we instituted *inter partes* review of claims 1–8 of the '793 patent on all grounds set forth in the Petition. Paper 18 ("Inst. Dec."). After institution of trial, Patent Owner filed a Response (Paper 29, "PO Resp."), Petitioner filed a Reply (Paper 44), and Patent Owner filed a Sur-Reply (Paper 55). In addition, both parties filed Motions to Exclude Evidence (Papers 65 and 66), Oppositions to their respective opponents' Motions to Exclude (Papers 68 and 69), and Replies in support of their own Motions to Exclude (Papers 71 and 72). At the request of both parties, we held an oral hearing, the transcript of which was entered into the record. Paper 77 ("Tr.").

On July 19, 2022, we issued a Final Written Decision determining that Petitioner had proven by a preponderance of evidence that all the challenged claims were unpatentable. Paper 78 ("Final Dec."). On August 18, 2022, Patent Owner requested rehearing and filed a request that rehearing be conducted by the Precedential Opinion Panel. Paper 79 ("Req. Reh'g"); Paper 80. The request for rehearing by the Precedential Opinion Panel was denied, returning jurisdiction to us to consider the rehearing request itself. Paper 81.

For the reasons discussed below, we deny Patent Owner's Request for Rehearing. Where the present decision differs from the Final Written Decision, the present decision controls. Otherwise, the Final Written Decision remains in force.

ANALYSIS

*A. The Final Written Decision*

Petitioner asserted the unpatentability of the challenged claims on six separate grounds. Final Dec. 3–4. Four of those grounds relied on references referred to as Voswinckel 2006 and Ghofrani, both of which we determined did not qualify as prior art. *Id.* at 3–4, 36–41. The remaining two grounds both relied on a reference referred to as Voswinckel JESC, and one of the grounds also relied on a reference referred to as Voswinckel JAHA. *Id.* at 3.

Patent Owner argued during the trial that Petitioner had not proven that either Voswinckel JESC or Voswinckel JAHA had been made publicly accessible early enough to qualify as prior art in the way that Petitioner argued they did. PO Resp. 11–18; Sur-Reply 2–11. Petitioner countered these arguments with several arguments for the public accessibility of Voswinckel JESC and Voswinckel JAHA. Reply 2–9. In particular, Petitioner argued that each of these references was cited in a publicly available journal article that could have served as a research aid to help a person of ordinary skill in the art locate the references. *Id.* at 3–4 (arguing that Voswinckel JESC was cited in Ghofrani), 7–8 (arguing that Voswinckel JAHA was cited in Sulica).

In the Final Written Decision, we were persuaded by Petitioner's argument regarding these research aids. Final Dec. 10–12. Based in part on our determination that these research aids established the public accessibility of Voswinckel JESC and Voswinckel JAHA, we determined that Petitioner had proven by a preponderance of the evidence that each of the challenged claims would have been obvious over the combination of the '212 patent, Voswinckel JESC, and Voswinckel JAHA. *Id.* at 12–35.

*B. The Rehearing Request*

Patent Owner seeks rehearing of our Final Written Decision on the ground that we overlooked Patent Owner's argument that the Ghofrani and Sulica research aids had been "published *after* the critical §102(b) date of May 15, 2005." Req. Reh'g 1 (emphasis in original). Patent Owner notes that this argument appeared in the Sur-Reply. *Id.* at 5 (citing Sur-Reply 9). According to Patent Owner, had we not overlooked this argument, we would have determined that Petitioner had not shown that Voswinckel JESC and Voswinckel JAHA were publicly accessible in the way necessary to treat them as prior art to the '793 patent. *Id.* at 5–14.

When it requested rehearing, Patent Owner also requested that the rehearing be conducted by the Precedential Opinion Panel. Ex. 3003. The Precedential Opinion Panel denied that request and directed us to consider Patent Owner's rehearing request. Paper 81, 3. The Precedential Opinion Panel directed us, "in [our] consideration on rehearing, to clearly identify whether the Voswinckel JESC and Voswinckel JAHA references qualify as prior art" and specified that "[s]uch analysis shall clarify whether the relied upon research aids were available prior to the critical date and whether the Voswinckel JESC and Voswinckel JAHA references were publicly accessible by way of their presentation and/or inclusion in distributed materials, such as at a conference or library." *Id.*

*C. Standard of Review*

A request for rehearing of an institution decision is reviewed under the abuse of discretion standard. 37 C.F.R. § 42.71(c). "The burden of showing a decision should be modified lies with the party challenging the decision." 37 C.F.R. § 42.71(d). "The request must specifically identify all matters the party believes the Board misapprehended or overlooked, and the place where each matter was previously addressed in a motion, an opposition, reply, or a sur-reply." *Id.* An abuse of discretion may be found where a decision "(1) is clearly unreasonable, arbitrary, or fanciful; (2) is based on an erroneous conclusion of law; (3) rests on clearly erroneous fact findings; or (4) involves a record that contains no evidence on which the Board could rationally base its decision." *Redline Detection, LLC v. Star Envirotech, Inc.*, 811 F.3d 435, 442 (Fed. Cir. 2015) (quoting *Abrutyn v. Giovanniello*, 15 F.3d 1048, 1050–51 (Fed. Cir. 1994) (citation omitted)).

*D. We Overlooked Patent Owner's Argument*

Patent Owner is correct that its argument that the Ghofrani and Sulica research aids were dated after May 15, 2005, appeared in the Sur-Reply. Sur-Reply 9–11. Patent Owner also is correct that we overlooked this argument in relying on these research aids as supporting that Petitioner had established that Voswinckel JESC and Voswinckel JAHA were prior art to the '793 patent. Final Dec. 11–12; Paper 81, 2 ("the Board's analysis did not consider whether the research aids themselves were available prior to the critical date").

*E. Reconsideration of the Record Shows that the Research Aids Did Not Establish the Prior-Art Status of Voswinckel JESC and Voswinckel JAHA*

Petitioner argued that Voswinckel JESC and Voswinckel JAHA were "prior art to the '793 Patent under at least 35 U.S.C. § 102(b)." Pet. 22, 24. In the Final Written Decision, we determined that Petitioner had shown that these references were prior art based on the existence of research aids. Final Dec. 10–12. As noted above, that determination overlooked Patent Owner's argument that the research aids themselves were published too late for their mention of Voswinckel JESC and Voswinckel JAHA to render those references prior art under § 102(b). We now consider that argument.

To qualify as prior art under § 102(b), a reference must have been publicly accessible "more than one year prior to the date of application for patent in the United States." 35 U.S.C. § 102(b) (2006). Here, the parties agree that the application that ultimately led to the issuance of the '793 patent was filed May 15, 2006. Pet. 12; PO Resp. 5. Thus, to qualify as § 102(b) prior art, Voswinckel JESC and Voswinckel JAHA must have been publicly accessible before May 15, 2005.

Petitioner argues that Voswinckel JESC "was cited in the June 2005 Ghofrani article in the journal *Herz* . . . , an article that was publicly accessible." Reply 3 (citing Ex. 1010, 298, 301). Patent Owner argues that "Ghofrani bears a July 2005 date-stamp." Sur-Reply 9 (citing Ex. 1121, 1). Petitioner does not explain its characterization of Ghofrani as a "June 2005" article. The pages of Ghofrani cited by Petitioner do not indicate a June 2005 publication date. Ex. 1010, 298, 301. The same article appears, however, as Exhibit 1121, which bears a date of July 7, 2005. *Compare* Ex. 1010, *with* Ex. 1121. Accordingly, Patent Owner's characterization of Ghofrani as having been published in July 2005 is better supported by the evidence of record than is

Petitioner's characterization of Ghofrani as having been published in June 2005. Even if the evidence of record supported Petitioner's June 2005 publication date, that date is still later than May 15, 2005, so the citation of Voswinckel JESC in Ghofrani does not show that Voswinckel JESC was prior art under § 102(b).

Petitioner argues that Voswinckel JAHA "was cited by a March 2005 article authored by Roxana Sulica et al. in the *Expert Review of Cardiovascular Therapy*." Reply 7 (citing Ex. 1104, 359). Patent Owner argues that the Sulica article "shows only the year 2005." Sur-Reply 9 (citing Ex. 1104, 347). We agree with Patent Owner. The Sulica article bears a 2005 copyright date but otherwise does not indicate when it was published. Ex. 1104, 347. The 2005 copyright date does not support a finding that the Sulica article was published before May 15, 2005, so the citation of Voswinckel JAHA in the Sulica article does not show that Voswinckel JAHA was prior art under § 102(b).

*F. Reexamination of the Record Shows that Voswinckel JESC and Voswinckel JAHA Were Prior Art to the '793 Patent Due to Distribution at Conferences*

The Precedential Opinion Panel directed us, "in [our] consideration on rehearing, to clearly identify whether the Voswinckel JESC and Voswinckel JAHA references qualify as prior art" and specified that "[s]uch analysis shall clarify . . . whether the Voswinckel JESC and Voswinckel JAHA references were publicly accessible by way of their presentation and/or inclusion in distributed materials, such as at a conference or library." Paper 81, 3. Accordingly, we consider below whether the evidence of record establishes the prior-art status of Voswinckel JESC and Voswinckel JAHA due to presentation and/or inclusion in distributed materials. We answer this question in the affirmative.

"Because there are many ways in which a reference may be disseminated to the interested public, 'public accessibility' has been called the touch-stone in determining whether a reference constitutes a 'printed publication.'" *Jazz Pharm., Inc. v. Amneal Pharm., LLC*, 895 F.3d 1347, 1356 (Fed. Cir. 2018) (quoting *In re Hall*, 781 F.2d 897, 898–99 (Fed. Cir. 1986)). A reference is considered publicly accessible if it was "disseminated or otherwise made available to the extent that persons interested and ordinarily skilled in the subject matter or art, exercising reasonable diligence, can locate it." *Id.* at 1355–56 (citing *In re Wyer*, 655 F.2d 221, 226 (CCPA 1981)). Under at least some circumstances, a reference may be a printed publication under § 102(b) if it was "displayed to the public," even if it "was not later indexed in any database, catalog, or library." *In re Klopfenstein*, 380 F.3d 1345, 1350 (Fed. Cir. 2004). There are several factors relating to whether such a display is sufficient to constitute a printed publication, including "the length of time the display was exhibited, the expertise of the target audience, the existence (or lack thereof) of reasonable expectations that the material displayed would not be copied, and the simplicity or ease with which the material displayed could have been copied." *Id.* In addition, distribution of a reference at a professional conference may, under at least some circumstances, constitute sufficient dissemination to show public accessibility. *Nobel Biocare Services AG v. Instradent USA, Inc.*, 903 F.3d 1365, 1375–80 (Fed. Cir. 2018); *Medtronic, Inc. v. Barry*, 891 F.3d 1368, 1380–83 (Fed. Cir. 2018).

*1. Voswinckel JESC Was Sufficiently Distributed at a Conference to be Publicly Accessible as of the Conference Date*

A reference may be "[a] printed publication ' . . . if it was sufficiently disseminated at the time of its publication.'" *Medtronic*, 891 F.3d at 1381 (quoting *Suffolk Techs., LLC v. AOL Inc.*, 752 F.3d 1358, 1365 (Fed. Cir. 2014)). Several factors are relevant to the determination of whether distribution of a reference at a conference constitutes such sufficient dissemination. *Id.* at 1381–82. These include "the size and nature of the meetings and whether they are open to people interested in the subject matter of the material disclosed," as well as "whether there is an expectation of confidentiality between the distributor and the recipients of the materials." *Id.* at 1382. "The expertise of the target audience can [also] be a factor in determining public accessibility." *Id.* To the extent that these factors are addressed via testimonial evidence, corroboration of that evidence may be necessary. *Nobel Biocare*, 903 F.3d at 1377–78. "Corroborating evidence may include documentary or testimonial evidence," and "[c]ircumstantial evidence can be sufficient corroboration." *Id.* (citing *TransWeb, LLC v. 3M Innovative Props. Co.*, 812 F.3d 1295, 1301 (Fed. Cir. 2016)).

Voswinckel JESC is an abstract contained in "Volume 25 Abstract Supplement August/September 2004" of "European Heart Journal," with a subtitle indicating that the journal is the "Journal of the European Society of Cardiology" and that the supplement relates to "ESC Congress 2004," held "28 August – 1 September" in "Munich, Germany." Ex. 1007, 1; *see also* Ex. 1089, 1. The Table of Contents organizes abstracts into categories, including "Epidemiology and treatment of pulmonary arterial hypertension," with each category associated with an entry corresponding to a day of the conference, such as "Day 2—Sunday 29 August 2004." *Id.* at 2. Each of these categories points to a page or pages in the supplement, with those pages containing

abstracts that report the "Background," "Methods," "Results," and "Conclusion" of studies. *Id.* at 7.

The conference with which Voswinckel JESC is associated "is the largest medical congress in Europe and among the top three cardiology meetings in the world," and "it has become an established forum for the exchange of science as much as education." Ex. 1105, 19. Attendees of the conference include "basic scientists, nurses and allied professionals working in the field of cardiovascular care of patients." *Id.* At the 2004 conference, there were "24,527 attendees," including "18,413 professionals, 4,715 exhibitors, 636 journalists and 763 accompanying persons." *Id.* Both Petitioner's declarant, Dr. Nicholas Hill, and Patent Owner's declarant, Dr. Aaron Waxman, testify that anyone who paid to attend the ESC Congress 2004 would have received a copy of the abstract book from which Voswinckel JESC is excerpted, either at the meeting itself or as a distribution before the meeting. Ex. 1106 ¶ 28; Ex. 1108, 105:16–108:1.

Thus, the evidence of record shows that Voswinckel JESC was distributed to more than twenty thousand people before or at the time of the ESC Congress 2004 in late August and early September of 2004. Those twenty thousand recipients included both highly skilled professionals, including scientists, nurses, and other clinicians, as well as journalists and those who accompanied the professionals and the journalists. That the recipients included journalists and "accompanying persons" suggests very strongly that there was no expectation that the contents of Voswinckel JESC would be kept confidential. Moreover, Drs. Hill and Waxman corroborate

one another's testimony, and their testimony is further corroborated by the contents of both Voswinckel JESC itself and Exhibit 1105. The distribution of Voswinckel JESC to over twenty thousand recipients, including thousands of experts in the field of cardiology, with no expectation of confidentiality, establishes that Voswinckel JESC was a printed publication as of the date of the conference at which that distribution occurred. Because that conference occurred in August and September 2004, more than one year before the May 15, 2006 application date of the '793 patent, Voswinckel JESC was a printed publication early enough to qualify as prior art under 35 U.S.C. § 102(b).

*2. Voswinckel JAHA Was Sufficiently Distributed at a Conference to be Publicly Accessible as of the Conference Date*

Like Voswinckel JESC, Voswinckel JAHA is associated with a professional conference. Ex. 1008. It is an abstract that has been extracted from a document headed "Supplement to Circulation," subtitled "Journal of the American Heart Association" and "Abstracts from Scientific Sessions 2004," indicating that those sessions occurred "November 7–10." *Id.* at 1. The abstract in question appears in a section titled "Pulmonary Arterial Hypertension: New Therapies," subtitled "Subspecialty: Integrative Biology" and indicating that the session occurred on "Wednesday" in "Hall I2" of the "Ernest N Morial Convention Center." *Id.* at 3. We take official notice that the range of dates from November 7, 2004, to November 10, 2004, includes Wednesday, November 10, 2004.

Both Dr. Hill and Dr. Waxman agree that attendance at the Scientific Sessions 2004 conference was large. Ex. 1106 ¶ 22 ("a [person of ordinary skill in the art] would have attended the Scientific Sessions 2004 Conference, as it is one of the principal conferences on the circulatory system and diseases and conditions affecting circulation"); Ex. 1108, 116:4–21 (testifying that attendance at Scientific Sessions

2004 was likely larger than the 18,000 professionals who attended ESC Congress 2004). Dr. Hill testifies that the conference was "attended by physicians and researchers working on and studying the cardiovascular system, including pulmonary circulation." *Id.* Both Dr. Hill and Dr. Waxman also agree that a copy of the abstract book from which Voswinckel JAHA is excerpted would have been provided to all attendees at Scientific Sessions 2004. Ex. 1106 ¶ 23; Ex. 1108, 108:3–20. We have not been directed to any evidence of record indicating there was any expectation of confidentiality. The distribution of thousands of copies of Voswinckel JAHA at the conference is strong evidence that Voswinckel JAHA was a printed publication as of the date of the conference. Because that conference occurred in November 2004, more than one year before the May 15, 2006 application date of the '793 patent, Voswinckel JAHA was a printed publication early enough to qualify as prior art under 35 U.S.C. § 102(b).

*3. Conclusion*

As instructed by the Precedential Opinion Panel, we have considered "whether the Voswinckel JESC and Voswinckel JAHA references qualify as prior art" and in particular "whether the Voswinckel JESC and Voswinckel JAHA references were publicly accessible by way of their presentation and/or inclusion in distributed materials, such as at a conference." Paper 81, 3. As discussed above, we find that both references were distributed sufficiently at professional conferences to be publicly accessible at the time of those conferences. By virtue of this public accessibility, both Voswinckel JESC and Voswinckel JAHA were printed publications early enough to qualify as prior art under 35 U.S.C. § 102(b).

*G. Asserted Obviousness over '212 Patent, Voswinckel JESC, and Voswinckel JAHA*

Petitioner argues that claims 1–8 would have been obvious over the combination of the '212 patent, Voswinckel JESC, and Voswinckel JAHA. Pet. 30–46. As discussed above, Petitioner has shown by a preponderance of the evidence that both Voswinckel JESC or Voswinckel JAHA qualify as prior art. Accordingly, we do not disturb the obviousness analysis in the Final Written Decision, which relies on the prior-art status of Voswinckel JESC and Voswinckel JAHA. Final Dec. 12–35.

*H. Remaining Grounds*

Petitioner argues that claims 1–8 would have been obvious over the combination of the '212 patent and Voswinckel JESC. Pet. 46–50. We do not disturb the determination in the Final Written Decision that we need not reach this ground "[b]ecause Petitioner has shown by a preponderance of the evidence that all of the challenged claims would have been obvious over the similar combination of the '212 patent, Voswinckel JESC, and Voswinckel JAHA." Final Dec. 36.

Petitioner argues that claim 1 was anticipated by Ghofrani; that claims 1, 3, and 8 would have been obvious over the combination of Voswinckel JAHA and Ghofrani; that claims 1 and 3 were anticipated by Voswinckel 2006; and that claims 2 and 4–8 would have been obvious over the combination of Voswinckel 2006 and the '212 patent. Pet. 50–64. These grounds fail for the reasons discussed in the Final Written Decision. Final Dec. 36–41.

CONCLUSION[1]

For the reasons discussed above, Patent Owner has shown that we overlooked its argument regarding the date of availability of the research aids that Petitioner argued showed that Voswinckel JESC and Voswinckel JAHA qualified as prior art. A proper consideration of that argument shows that the research aids do not establish the prior-art status of Voswinckel JESC and Voswinckel JAHA, but there is no change to the outcome with respect to Petitioner's asserted grounds of unpatentability, because the distribution of Voswinckel JESC and Voswinckel JAHA at professional conferences proves the prior-art status of those references. Accordingly, we deny Patent Owner's request for rehearing.

When all arguments are properly considered, Petitioner has shown by a preponderance of the evidence that claims 1–8 of the '793 patent are unpatentable.

Outcome of Decision on Rehearing:

| Claims | 35 U.S.C § | Reference(s)/Basis | Denied | Granted |
|---|---|---|---|---|
| 1–8 | 103(a) | '212 patent, Voswinckel JESC, Voswinckel JAHA | 1–8 | |
| **Overall Outcome** | | | 1–8 | |

[1] Should Patent Owner wish to pursue amendment of the challenged claims in a reissue or reexamination proceeding subsequent to the issuance of this Decision, we draw Patent Owner's attention to the April 2019 Notice Regarding Options for Amendments by Patent Owner Through Reissue or Reexamination During a Pending AIA Trial Proceeding. *See* 84 Fed. Reg. 16,654 (Apr. 22, 2019). If Patent Owner chooses to file a reissue application or a request for reexamination of the

Final Outcome of Final Written Decision after Rehearing:

| Claims | 35 U.S.C. § | Reference(s)/Basis | Claims Shown Unpatentable | Claims Not Shown Unpatentable |
|---|---|---|---|---|
| 1–8 | 103(a) | '212 patent, Voswinckel JESC, Voswinckel JAHA | 1–8 | |
| 1–8 | 103(a) | '212 patent, Voswinckel JESC[2] | | |
| 1 | 102(a) | Ghofrani | | 1 |
| 1, 3, 8 | 103(a) | Voswinckel JAHA, Ghofrani | | 1, 3, 8 |
| 1, 3 | 102(a) | Voswinckel 2006 | | 1, 3 |
| 2, 4–8 | 103(a) | Voswinckel 2006, '212 patent | | 2, 4–8 |
| **Overall Outcome** | | | 1–8 | |

challenged patent, we remind Patent Owner of its continuing obligation to notify the Board of any such related matters in updated mandatory notices. *See* 37 C.F.R. §§ 42.8(a)(3), (b)(2).

[2] Neither the Final Written Decision nor this Rehearing Decision reaches this ground because Petitioner has proven all challenged claims are unpatentable based on obviousness over the combination of the '212 patent, Voswinckel JESC, and Voswinckel JAHA.

ORDER

It is hereby

ORDERED that Patent Owner's Request for Rehearing is denied;

FURTHER ORDERED that the determination in the Final Written Decision that the research aids relied on by Petitioner show the prior-art status of Voswinckel JESC and Voswinckel JAHA is overturned and replaced with the determination in the present decision that the distribution of Voswinckel JESC and Voswinckel JAHA at professional conferences establishes the prior-art status of those references;

FURTHER ORDERED that, based on the preponderance of the evidence, claims 1–8 of the '793 patent have been shown to be unpatentable;

FURTHER ORDERED that all other rulings in the Final Written Decision remain undisturbed; and

FURTHER ORDERED that parties to this proceeding seeking judicial review of this Decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

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**APPENDIX E**

NOTE: This disposition is nonprecedential.

# United States Court of Appeals for the Federal Circuit

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**UNITED THERAPEUTICS CORPORATION,**
*Appellant*

**v.**

**LIQUIDIA TECHNOLOGIES, INC.,**
*Appellee*

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2023-1805

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

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**ON PETITION FOR PANEL REHEARING AND REHEARING EN BANC**

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Before MOORE, *Chief Judge*, LOURIE, DYK, PROST, REYNA, TARANTO, CHEN, HUGHES, STOLL, CUNNINGHAM, and STARK, *Circuit Judges*.[1]

PER CURIAM.

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[1] Circuit Judge Newman did not participate.

**O R D E R**

United Therapeutics Corporation filed a combined petition for panel rehearing and rehearing en banc. A response was invited by the court and filed by Liquidia Technologies, Inc. The petition was referred to the panel that heard the appeal, and thereafter the petition was referred to the circuit judges who are in regular active service.

Upon consideration thereof,

IT IS ORDERED THAT:

The petition for panel rehearing is denied.

The petition for rehearing en banc is denied.

The mandate of the court will issue March 19, 2024.

FOR THE COURT

[SEAL]
/s/ Jarrett B. Perlow
Jarrett B. Perlow
Clerk of Court

March 12, 2024
Date

## APPENDIX F

35 U.S.C. § 311

### § 311. Inter partes review

Effective: January 14, 2013

**(a) In General.**--Subject to the provisions of this chapter, a person who is not the owner of a patent may file with the Office a petition to institute an inter partes review of the patent. The Director shall establish, by regulation, fees to be paid by the person requesting the review, in such amounts as the Director determines to be reasonable, considering the aggregate costs of the review.

**(b) Scope.**--A petitioner in an inter partes review may request to cancel as unpatentable 1 or more claims of a patent only on a ground that could be raised under section 102 or 103 and only on the basis of prior art consisting of patents or printed publications.

**(c) Filing Deadline.**--A petition for inter partes review shall be filed after the later of either--

**(1)** the date that is 9 months after the grant of a patent; or

**(2)** if a post-grant review is instituted under chapter 32, the date of the termination of such post-grant review.

## APPENDIX G

35 U.S.C. § 312

### § 312. Petitions

Effective: September 16, 2012

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

**(1)** the petition is accompanied by payment of the fee established by the Director under section 311;

**(2)** the petition identifies all real parties in interest;

**(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; and

**(B)** affidavits or declarations of supporting evidence and opinions, if the petitioner relies on expert opinions;

**(4)** the petition provides such other information as the Director may require by regulation; and

**(5)** the petitioner provides copies of any of the documents required under paragraphs (2), (3), and (4) to the patent owner or, if applicable, the designated representative of the patent owner.

**(b) Public Availability.**--As soon as practicable after the receipt of a petition under section 311, the Director shall make the petition available to the public.