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Paper 78
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

LIQUIDIA TECHNOLOGIES, INC.,
Petitioner,

v.

UNITED THERAPEUTICS CORPORATION,
Patent Owner.

IPR2021-00406
Patent 10,716,793 B2

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, 3	102(a)	Voswinckel 2006[7]

[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.

[7] Robert Voswinckel, et al., *Inhaled Treprostinil for Treatment of Chronic Pulmonary Arterial Hypertension*, 144 ANNALS OF INTERNAL MEDICINE

Claim(s) Challenged	35 U.S.C. §[2]	Reference(s)/Basis
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

149–50 (January 2006) (Ex. 1009) (alleged to be prior art under 35 U.S.C. § 102(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.

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 μg/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

[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.

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 *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
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	

[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.

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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