PUBLIC VERSION

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Paper 112
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MOM ENTERPRISES, LLC,
Petitioner,

v.

ELAINE AND REINHOLD W. VIETH,
Patent Owner.

IPR2023-00726
Patent 9,066,958 B2

Before JOHN G. NEW, SHERIDAN K. SNEDDEN, and CYNTHIA M. HARDMAN, *Administrative Patent Judges.*

HARDMAN, *Administrative Patent Judge*.

JUDGMENT
Final Written Decision
Determining All Challenged Claims Unpatentable
Denying-in-Part and Dismissing-in-Part Patent Owner's and Petitioner's Motions to Exclude (Papers 94, 95)
Granting-in-Part Patent Owner's Motion to Seal (Paper 93)
Granting Joint Renewed Motion to Seal (Paper 107) and Petitioner's Renewed Motion to Seal (Paper 109)
35 U.S.C. § 318(a)

I. INTRODUCTION

This is a Final Written Decision in an *inter partes* review challenging the patentability of claims 1 and 3–5 of U.S. Patent No. 9,066,958 B2 ("the '958 patent," Ex. 1001). We have jurisdiction under 35 U.S.C. § 6.

Petitioner has the burden of proving the unpatentability of the challenged claims by a preponderance of the evidence. 35 U.S.C. § 316(e). Having analyzed the parties' arguments and cited evidence, for the reasons discussed below, we determine that Petitioner has demonstrated by a preponderance of the evidence that claims 1 and 3–5 are unpatentable.

A. Procedural History

Petitioner MOM Enterprises, LLC filed a Petition requesting *inter partes* review of claims 1 and 3–5 of the '958 patent. Paper 2 ("Pet."). Elaine and Reinhold W. Vieth (collectively, "Patent Owner") filed a Preliminary Response. Paper 6 ("Prelim. Resp."). Petitioner and Patent Owner respectively filed an authorized pre-institution Reply and Sur-reply. Papers 8, 9. In view of the then-available preliminary record, we instituted an *inter partes* review. Paper 10 ("Inst. Dec.").

After institution, Patent Owner filed a Response to the Petition. Paper 61[1] ("PO Resp."). Petitioner filed a Reply. Paper 74[2] ("Reply"). Patent Owner filed a Sur-reply. Paper 91[3] ("Sur-reply").

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[1] Paper 61 is sealed (i.e., available to the parties and Board only); a redacted version appears as Paper 108.

[2] Paper 74 is sealed; a redacted version appears as Paper 75, but as discussed below (*see supra* Section IV.A.1), we direct Patent Owner to revisit its redactions in Paper 75.

[3] Paper 91 is sealed; a redacted version appears as Paper 106.

Among other orders entered in this proceeding, we denied Petitioner's Motion to Compel Routine Discovery, or in the Alternative, for Additional Discovery. *See* Paper 44. We granted Patent Owner's Motion for Additional Discovery (documents). *See* Paper 45. We granted-in-part Patent Owner's Motion for Additional Discovery (depositions). *See* Paper 53.

We granted-in-part Patent Owner's Motion to Strike portions of Petitioner's Reply. *See* Paper 89. Our Order identifies specific material that we struck from the Reply (largely related to Petitioner's attempt to argue, for the first time in Reply, that Harder anticipates the challenged claims). *See id.*

The parties each filed a motion to exclude. We address those motions below. *See supra* Section III.

The parties filed various motions to seal. We previously resolved a number of these motions, and address the three remaining motions to seal below. *See supra* Section IV.

On June 17, 2024, we held an oral hearing, the transcript of which is of record. Paper 111 ("Tr.").

B. Real Parties in Interest

Petitioner identifies itself as the real party in interest. Pet. 47.

Patent Owner identifies Elaine and Reinhold W. Vieth, Ddrops Company, The Fifth Child, Ltd., and CSS Pharmaceutica, Inc. as the real parties in interest. Paper 20, 2.

C. Related Matters

The '958 patent is asserted in *Ddrops Company, Reinhold Vieth, Elaine Vieth v. MOM Enterprises, LLC d/b/a Mommy's Bliss*, 1:22-cv-00332-GBW (D. Del. March 16, 2022). Pet. 47; Paper 20, 2.

D. The '958 Patent

The '958 patent is titled "Vitamin D Compositions and Method of Administration to a Human Being." Ex. 1001, code (54). The '958 patent was filed on February 13, 2007, and claims priority to CA 2558202, filed on September 14, 2006.[4] Ex. 1001, codes (22), (30).

The Specification explains that, in 2005, the American Academy of Pediatrics recommended that "all breast-fed infants should receive 200 IU (5 mcg) of oral vitamin D drops daily, beginning during the first 2 months of life." *Id.* at 2:16–23. The Specification asserts that "[t]he need to provide vitamin D at an earlier age makes the problem of providing vitamin D nutrition more complicated" because "[s]maller infants are more difficult to handle" and "breast-feeding mothers may not want to give their infants foreign liquids." *Id.* at 2:27–32. Per the Specification, "the recommendations from pediatric societies and government bodies provide no detail or any method for exactly how to give vitamin D to the breast-feeding infant." *Id.* at 2:32–35.

The Specification describes several known liquid vitamin D preparations. *See id.* at 2:53–3:17. "One prescription product contains vitamin D in an unspecified oil, (20,000 IU (500 mcg) per mL of oil). The

[4] "Petitioner assumes a September 14, 2006 priority date" "[s]olely for this IPR." Pet. 8. Patent Owner does not dispute this date. *See generally* Patent Owner Response. For purposes of this Decision, we apply a September 14, 2006, priority date.

method for use involves mixing two drops into . . . milk or mash." *Id.* at 3:7–16. According to the Specification, "[t]his is not a practical way to provide vitamin D for breast-fed infants younger than two months of age, because it presumes that nutrition is provided by some means other than the breast." *Id.* The Specification describes "a need for a safe, convenient and efficacious method of administering nutritional or therapeutic amounts of vitamin D to a human being, particularly, a suckling infant." *Id.* at 3:43–49.

According to the '958 patent inventors:

> We have found that the difficulties with the aforesaid previous ways of providing vitamin D to an infant can be overcome by the process of application of vitamin D in a one-drop (about 33 microliter) volume of medium-chain triglyceride oil onto a pacifier or nipple and into the mouth of a suckling infant. . . . [T]he process of nipple or pacifier application eliminates the need to administer vitamin D directly into the mouth with a dropper, or in a larger volume that infants commonly spit out or gag on, or have to take with food.

Id. at 4:15–26.

The Specification describes an experiment testing a "number of liquids to determine their efficiency in the practice of the invention." *Id.* at 6:47–48. "One drop of each liquid was applied onto a nipple to determine whether it would adhere well enough so that no portion of it would drip off in a timeframe of 10 seconds." *Id.* at 6:49–51. "Water based preparations and alcohol did not adhere to the nipple." *Id.* at 7:21–22. The Specification reports that various oil vehicles (canola, olive, sesame, vitamin E acetate, and medium chain triglyceride) adhered to the nipple. *See id.* at Table 1. Medium-chain triglycerides oil ("MCT")[5] "was particularly desirable"

[5] The patent explains that "[t]he medium chain triglycerides of use in the practice of the invention have carbon-chain lengths of 6–12 and, preferably,

because it had less "residual oily feel on the pacifier" as compared to the other tested oils. *Id.* at 7:22–27. "[R]esidual oily feel on the pacifier was interpreted as a sign of incomplete uptake of the drop with its dose from the pacifier." *Id.*

E. The Challenged Claims

Petitioner challenges claims 1 and 3–5 of the '958 patent. We reproduce below claim 1, the only independent challenged claim.

> 1. A method of delivering a nutritional or therapeutic amount of vitamin D to a human being, said method comprising:
>
> (i) applying one drop of a composition consisting of a nutritional or therapeutic effective amount of 9 to 9000 mcg/ml vitamin D in a liquid triglyceride of 6 to 12 carbon chain length, to an exterior surface of an object, wherein said drop adheres to the surface of said object; and
>
> (ii) having said human being suck or lick said composition directly from said object.

Ex. 1001, 9:34–47.

Claim 3 limits the human being to an infant, and the object to "a woman's nipple or the external surface of a pacifier." *Id.* at 9:48–50. Claim 4 limits the concentration of vitamin D to 150–450 mcg/ml. *Id.* at 10:1–3. Claim 5 recites that the "triglyceride comprises at least 95% triglycerides having a carbon-chain length selected from 8 to 10." *Id.* at 10:4–6.

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the composition medium comprises at least 95% triglycerides having a carbon-chain length selected from 8–10." Ex. 1001, 5:17–28. MCT is obtained from the oil of *Cocos nucifera* L. and *Elaeis guineensis* Jacq. (i.e., coconut and palm oil). *Id.* at 5:21–24; Ex. 1003 (Williams Decl.) ¶ 54.

F. The Asserted Grounds of Unpatentability

We instituted trial based on the following asserted grounds of unpatentability:

Claim(s) Challenged	35 U.S.C. §[6]	References[7]
1, 5	103(a)	Harder,[8] Wolf,[9] European Pharmacopoeia[10]
3	103(a)	Harder, Wolf, European Pharmacopoeia, Blass[11]
4	103(a)	Harder, Wolf, European Pharmacopoeia, Gartner[12]

[6] The Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) ("AIA"), amended 35 U.S.C. § 103. Because the September 14, 2006, priority date we apply herein (*see supra* n.4) is before the effective date of the amendment, we refer to the pre-AIA version of § 103.

[7] Each of the asserted references contains multiple sets of page numbers. We use the page numbers in the footer of the document. Where the parties used a different set of page numbers, we have converted the parties' citations to the corresponding page number in the footer.

[8] Ulrike Harder, *Wochenbettbetreuung in der Klinik und zu Hause*, 18–23 (Hippokrates 2003) ("Harder"). Petitioner relies on an English translation of an excerpt of the original German language document. The translation is Exhibit 1007; the German language document is Exhibit 1006.

[9] H. Wolf, *Rachitisprophylaxe beim Säugling*, in 27(3) Deutsche Medizinische Wochenschrift 1530–1531 (1970) ("Wolf"). Petitioner relies on an English translation of an excerpt of the original German language document. The translation is Exhibit 1009; the German language document is Exhibit 1008.

[10] Council of Europe, European Pharmacopeia 4th ed. Supp. 4.3, 3148–3150 (2002) ("European Pharmacopeia," Ex. 1010).

[11] E. M. Blass and L. B. Watt, *Suckling- and sucrose-induced analgesia in human newborns*, 83 Pain 611–623 (1999) ("Blass," Ex. 1011).

[12] L. M. Gartner et al., *Prevention of Rickets and Vitamin D Deficiency: New Guidelines for Vitamin D Intake*, 111(4) Pediatrics 908–910 (2003) ("Gartner," Ex. 1012).

Pet. 2–3; Inst. Dec. 6, 48. Petitioner relies on supporting evidence including the declarations of Robert O. Williams III, Ph.D. (Ex. 1004) and Dr. J. Usha Raj (Ex. 1040).[13] Patent Owner relies on supporting evidence including the declarations of inventor Reinhold Vieth, Ph.D. (Ex. 2068),[14] Paul Horowitz, M.D. (Ex. 2069), Chris Temovsky (Ex. 2071),[15] and Steven M. Reid, Ph.D. (Ex. 2072).[16]

II. ANALYSIS

A. Principles of Law

"In an [*inter partes* review], the petitioner has the burden from the onset to show with particularity why the patent it challenges is unpatentable." *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016); 37 C.F.R. § 42.104(b). This burden of persuasion never shifts to the patent owner. *See Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015) (discussing the burden of proof in *inter partes* review). To prevail, Petitioner must demonstrate unpatentability by a preponderance of the evidence. 35 U.S.C. § 316(e).

A claim is unpatentable as obvious under 35 U.S.C. § 103(a) if the differences between the claimed subject matter and the prior art are such that the subject matter, as a whole, would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said

[13] Patent Owner moves to exclude the entire declarations of Drs. Williams and Raj. As we discuss below (*see infra* Section III.B), we deny Patent Owner's request to exclude these declarations.

[14] Exhibit 2068 is sealed; a redacted version appears as Exhibit 2078.

[15] Exhibit 2071 is sealed; a redacted version appears as Exhibit 2079.

[16] Exhibit 2072 is sealed; a redacted version appears as Exhibit 2080.

subject matter pertains. *See* 35 U.S.C. § 103(a) (2006); *see also KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved based on underlying factual findings including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of ordinary skill in the art; and (4) any objective indicia of nonobviousness. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966). An obviousness determination requires finding a reason to combine the asserted prior art teachings, accompanied by a reasonable expectation of achieving what is claimed in the challenged patent. *See Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1367 (Fed. Cir. 2016). "[A]ny need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed." *KSR*, 550 U.S. at 419–20.

B. Level of Ordinary Skill in the Art

We consider the grounds of unpatentability in view of the understanding of a person of ordinary skill in the art (sometimes abbreviated herein as "POSITA") as of September 14, 2006. *See supra* n.4. Petitioner contends that a person of ordinary skill in the art

> would have a doctorate degree in Pharmaceutics or a related field with several years of experience in formulating compositions of and delivering medicines and nutritional supplements along with a bachelor's of science degree in biology, chemistry, biochemistry or a related field. In the alternative, a POSITA who does not have this formal education would have additional years of related work experience in formulating compositions of and delivering medications and/or nutritional supplements to humans, such as a nurse.

Pet. 6 (quoting Ex. 1004 (Williams Decl.) ¶ 20) (citations omitted).

Prior to institution, Patent Owner indicated that it "agree[s] with the first sentence" of Petitioner's proposal, but not with the alternative option recited in the second sentence, because Patent Owner disagrees that a nurse would have the skills required of a person of ordinary skill in the art. Prelim. Resp. 18 (citing, *e.g.*, Ex. 1001, 7:31–34, 8:27–31; Ex. 2008 (Vieth Decl.) ¶ 32).

For purposes of our Institution Decision, we adopted part of the agreed portion of Petitioner's proposal, namely, a person of ordinary skill in the art "would have a doctorate degree in Pharmaceutics or a related field with several years of experience in formulating compositions of and delivering medicines and nutritional supplements." Inst. Dec. 12. We found it unnecessary to specify a particular bachelor's degree, because it did not appear to add any relevant subject matter beyond that possessed by someone having a doctorate degree in pharmaceutics or a related field with several years of experience in formulating compositions of and delivering medicines and nutritional supplements. *Id.* at 12–13.

We also found that the alternative option recited in the second sentence of Petitioner's proposal is not supported, because Petitioner does not adequately explain for how many years and in what settings a person (or a nurse) might obtain "related work experience in formulating compositions of . . . medications and/or nutritional supplements to humans" that would be equivalent to that of a person having a doctorate degree in Pharmaceutics or a related field with several years of experience. *Id.* at 13.

Thus, in the Institution Decision, we found that a person of ordinary skill in the art as of September 14, 2006, would have had a doctorate in Pharmaceutics or a related field with several years of experience in

formulating compositions of and delivering medicines and nutritional supplements. *Id.*

Following institution, Patent Owner agreed with the Board's finding on a level of skill in the art. *See* PO Resp. 7. Petitioner does not directly address the Board's finding, other than to state: "[n]otably, co-inventor Elaine Vieth ***was a practicing nurse*** at the time of the invention, suggesting a nurse could be a POSITA." Reply 8 n.5 (citing Ex. 1039 (Vieth Depo. Tr.) 45:13–47:12; *Daiichi Sankyo Co. v. Apotex, Inc.*, 501 F.3d 1254, 1257 (Fed. Cir. 2007)). This fact is not sufficient, on its own, to persuade us to add a nurse to our statement of the level of skill in the art. *Daiichi Sankyo* states, "[f]actors that ***may be*** considered in determining level of ordinary skill in the art include . . . the educational level of the inventor." 501 F.3d at 1256 (emphasis added; citations omitted). Thus, although the educational level of the inventor may be considered, the level of skill need not necessarily include the educational level of every inventor. Here, Petitioner merely notes that Ms. Vieth was a practicing nurse at the time of the invention, but does not otherwise argue why defining the level of skill to include a nurse is necessary or appropriate in this case.

Accordingly, we maintain the level of skill we defined at institution, i.e., a person of ordinary skill in the art would have had a doctorate in Pharmaceutics or a related field with several years of experience in formulating compositions of and delivering medicines and nutritional supplements. Nevertheless, our analysis herein would not change even if the level of skill in the art expressly included a nurse.

C. Claim Construction

In AIA proceedings we interpret a claim "using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. 282(b)." 37 C.F.R. § 42.100(b). Under this standard, we construe the claim "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." *Id.*

1. *Overview*

Petitioner asserts that "[n]o terms need to be construed to resolve the issues presented by this Petition, and the claims should be afforded their plain and ordinary meaning in view of the intrinsic evidence as would have been understood by a person of ordinary skill in the art." Pet. 5. In its Preliminary Response, Patent Owner similarly did not request any particular claim constructions, but apprised us that in the parallel district court litigation, the court entered a Claim Construction Order, which adopted the parties' agreed constructions of several terms, and construed the term "vitamin D." *See* Prelim. Resp. 8–10; Ex. 2005 (district court claim construction order).

In our Institution Decision, we preliminarily construed the term "wherein said drop adheres to the surface of said object" by likewise adopting the parties' agreed construction, and the term "vitamin D" by adopting the district court's construction. *See* Inst. Dec. 15–16.

Following institution, the parties raise no issues that necessitate a construction of "vitamin D." Accordingly, we find on the complete record now before us, we need not construe "vitamin D." *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017)

("[W]e need only construe terms 'that are in controversy, and only to the extent necessary to resolve the controversy.'" (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999))).

Additionally, although Patent Owner indicates that it agrees with the construction of "wherein said drop adheres to the surface of said object" we adopted in our Institution Decision, it also states that part of that construction "deserves explication." PO Resp. 9. Accordingly, we address this term below.

2. *"wherein said drop adheres to the surface of said object"*

In our Institution Decision, we adopted the parties' agreed construction of "wherein said drop adheres to the surface of said object," which reads:

> the drop is sufficiently viscous so that one drop does not immediately drip or roll away from the object that enters the mouth, so that no portion would drip off the object and surface. The drop does not coat or adhere to the object so as to prevent efficient removal of the drop from the object.

Inst. Dec. 14–15.

Following institution, Patent Owner states that it agrees with this construction, but also states that the last sentence of the construction (i.e., "The drop does not coat or adhere to the object so as to prevent efficient removal of the drop from the object."), "deserves explication." PO Resp. 9. Patent Owner then quotes a lengthy paragraph from its declarant, Dr. Reid, which states, among other things, that "the drop adheres ***so as to remain localized*** to facilitate its removal from the surface so that a nutritional or therapeutic effective dose of vitamin D is delivered to a human," and "the drop does not spread out, coat, or form a film on the surface because any of these actions would compromise removal of the

drop." *Id.* at 10 (quoting Ex. 2072 (Reid Decl.) ¶ 26) (emphasis added); *see also* Sur-reply 8 (arguing that the construction "makes clear that . . . the drop must remain localized to facilitate its removal from the surface"). Patent Owner also quotes Dr. Reid as asserting that "[t]he surface is one to which the drop adheres . . . this does not include, for example, a spoon . . . ." PO Resp. 10.

To the extent Patent Owner is arguing that the additional requirements recited by Dr. Reid should be read into the agreed construction, we reject such an argument. Patent Owner provides no persuasive reasoning as to why or on what basis the agreed construction should be modified to add these additional limitations. Patent Owner, for example, does not demonstrate, and we cannot otherwise discern, how the '958 patent supports the additional limitations. As Petitioner correctly observes, the '958 patent says nothing about a drop "adher[ing] so as to remain localized," and instead only tests whether a "drop 'drips off' versus '[a]dheres.'" Reply 12 (quoting Ex. 2072 (Reid Decl.) ¶ 26; Ex. 1001, 7:22–24). Additionally, Patent Owner points to nothing in the '958 patent that persuasively demonstrates that the term "object" recited in claim 1 excludes a spoon.

In view of the above, we maintain the agreed-upon construction of "wherein said drop adheres to the surface of said object" as meaning:

> the drop is sufficiently viscous so that one drop does not immediately drip or roll away from the object that enters the mouth, so that no portion would drip off the object and surface. The drop does not coat or adhere to the object so as to prevent efficient removal of the drop from the object.

D. Overview of the Asserted Prior Art

1. *Harder (Ex. 1007)*

Harder is an excerpt of a German-language book titled "Wochenbett-betreuung in der Klinik und zu Hause" ("Childbed care in clinics and at home"). Ex. 1006 (German-language Harder); Ex. 1007 (Harder (Sherman translation)) 1 at ¶ 1. It is undisputed that Harder was published on January 10, 2003. Pet. 2, 11; *see generally* PO Resp.

Section 15.9 of Harder is titled "Prophylaxis of bleeding, rickets and tooth decay," and contains subsections regarding vitamin K, vitamin D, and fluoride supplementation in babies. *See* Ex. 1007, 3.

Harder teaches "[f]our options for the prophylaxis of rickets." *Id.* at 5. Petitioner focuses on Harder's "Option 3," which includes daily supplementation using "Vigantol® oil," "a prescription-only medicine." *Id.* at 6. Harder explains that Vigantol oil supplementation is useful in children who are susceptible to allergies, given that it "contains only one excipient as a vehicle for the fat-soluble vitamin D, namely medium-chain triglycerides (vegetable oil)." *Id.* Harder states: "Use of the oil is simple: 1 drop of Vigantol® oil is given to the baby to be licked off from the tip of a spoon once a day before a breastfeed or a meal. Under no circumstances should it be put directly in the baby's mouth!" *Id.*

Harder was not before the Examiner during prosecution of the application that led to the '958 patent. Pet. 11.

2. *Wolf (Ex. 1009)*

Wolf is an article titled "Rachitisprophylaxe beim Säugling" ("Prophylaxis of rickets in babies"). Ex. 1008 (German-language Wolf) 4;

Ex. 1009 (Wolf) 6. It is undisputed that Wolf was published on July 3, 1970. Pet. 2, 13; *see generally* PO Resp.

Wolf teaches that "prophylaxis of rickets . . . is essential for young babies," and requires daily vitamin D_3 supplementation. Ex. 1009, 6. Wolf states that "[i]t has been found that 400 I.U. of vitamin D_3 (0.01 mg of cholecalciferol) are generally sufficient for preventing rickets when this dose is given daily," but based on the author's own investigations, higher daily doses of 500 I.U. of vitamin D_3 should be administered "during the first year of life and during the following winter (October to April)." *Id.* at 6–7.

Wolf lists several commercially-available vitamin D_3 preparations and their daily doses. *Id.* at 8 (Table 8). The preparations include "Vigantol®," manufactured by "Bayer/Merck." *Id.* Wolf describes the daily dose of Vigantol as "1 drop," and describes the product as having a vitamin D_3 content of "1 ml = 0.5 mg = 30 drops = 20 000 I.U. of D_3." *Id.* Wolf teaches that "[d]rops or tablets should not be added to the bottle, but administered to the baby on a spoon with some liquid." *Id.* at 7.

Wolf was not before the Examiner during prosecution of the application that led to the '958 patent. Pet. 13.

3. *European Pharmacopoeia (Ex. 1010)*

European Pharmacopoeia is published by the Council of Europe in accordance with the Convention on the Elaboration of a European Pharmacopoeia. Ex. 1010, 2. It is undisputed that European Pharmacopoeia was published in January 2003. Pet. 2; *see generally* PO Resp.

According to Petitioner's declarant Dr. Williams, European Pharmacopoeia is a "reference work for the quality control of medicines," and includes official standards for substances for pharmaceutical use,

including MCT. Ex. 1004 (Williams Decl.) ¶¶ 71–72; Ex. 1010, 5. European Pharmacopoeia defines MCT as a "[m]ixture of triglycerides of saturated fatty acids, mainly of caprylic acid (octanoic acid, $C_8H_{16}O_2$) and of capric acid (decanoic acid, $C_{10}H_{20}O_2$)," and specifies that MCT contains a "minimum [of] 95.0 per cent of saturated fatty acids with 8 and 10 carbon atoms." Ex. 1010, 5. It states that MCTs are obtained from coconut and palm oil. *Id.*

4. *Blass (Ex. 1011)*

Blass is an article titled "Suckling- and sucrose-induced analgesia in human newborns." Ex. 1011, 6. It is undisputed that Blass was published in December 1999. Pet. 2–3, 18; *see generally* PO Resp.

Blass reports an experiment wherein different interventions were offered to infants undergoing blood collection via a heel lance, to determine whether the interventions reduced pain reactivity. *See* Ex. 1011, 7. One intervention was a pacifier dipped in sucrose. *Id.* at 7, 8.

Blass reports that "relative to the water-control and water-pacifier groups, sucrose in combination with a pacifier, drastically reduced crying and grimacing during the painful procedure of heel lance." *Id.* at 9. Blass concludes that "[s]weet solutions can be readily given to infants on a pacifier in advance of and during necessary treatments or evaluations that may be moderately painful." *Id.* at 16.

Blass was before the Examiner during prosecution of the application that led to the '958 patent. *See* Ex. 1002 (prosecution history) 75.

5. *Gartner (Ex. 1012)*

Gartner is an article titled "Prevention of Rickets and Vitamin D Deficiency: New Guideline for Vitamin D Intake." Ex. 1012, 3. It is

undisputed that Gartner was published on April 11, 2003. Pet. 3, 19; *see generally* PO Resp.

Gartner teaches that "[r]ickets in infants attributable to inadequate vitamin D intake and decreased exposure to sunlight continues to be reported in the United States." Ex. 1012, 3. Gartner accordingly teaches that "based on the recommendations of the National Academy of Sciences," "[i]t is recommended that all infants, including those who are exclusively breastfed, have a minimum intake of 200 IU of vitamin D per day." *Id.* Gartner teaches that this recommendation "differ[s] from the 400 IU per day that has been recommended in previous editions of the *Pediatric Nutrition Handbook* of the American Academy of Pediatrics (AAP)." *Id.*

Gartner was not before the Examiner during prosecution of the application that led to the '958 patent. Pet. 19.

E. Asserted Grounds of Unpatentability

1. *Patent Owner's "Preliminary" Arguments Regarding Harder*

Patent Owner argues that "[b]efore the Board can even consider the merits of Petitioner's argument, it must first clear multiple preliminary hurdles," namely (1) which translation of Harder to consider; and (2) "whether a POSITA would even consider Harder." PO Resp. 29. We address these arguments in turn.

a) Harder Translation

Because Harder is written in German, Petitioner relies on an English-language translation of Harder. *See* Pet. 2; *see also* 37 C.F.R. § 42.63(b) (requiring English translation). There are multiple translations of Harder in

the record (together with translator declarations).[17] We begin with a chronology of the different translations.

In 2017, in connection with a district court litigation concerning the '958 patent,[18] Petitioner's counsel obtained (on behalf of a client different than Petitioner) a translation of Harder, performed by Rebecca Amy Tinworth. *See, e.g.*, PO Resp. 12. Ms. Tinworth's declaration and translation appear in this record as Exhibit 1021.

The Petition relies on Ms. Tinworth's translation of Harder, as later amended by David Joshua Sherman. *See* Pet. 11; Ex. 1007. Mr. Sherman testifies that "Rebecca Amy TINWORTH performed the attached translation," and that he added the term "'to be licked off' (for the German 'zum Ablecken') on page 4 of the translation," to "make[] the translation a more accurate reflection of the German text." Ex. 1007, 1.

Prior to institution of this *inter partes* review, Patent Owner characterized Mr. Sherman's translation as "inaccurate and manipulated," and argued that the addition of "the critical 'to be licked off' phrase" to Ms. Tinworth's translation "is a blatant attempt by Petitioner to change the Harder translation to fit its litigation strategy." *See* Prelim. Resp. 21.

In response to Patent Owner's criticism, after issuance of our Institution Decision but before filing of the Patent Owner Response,

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[17] The relevant documents are: Exhibit 1007 (Sherman Declaration and translation); Exhibit 1021 (Tinworth Declaration and translation); Exhibit 1022 (Sherman Supplemental Declaration and translation); Exhibit 1023 (Benyunes Declaration and translation).

[18] The litigation was captioned *Ddrops Company et al. v. iHerb Inc. et al.*, 0:16-cv-04278-JNE-TNL (D. Minn). *See* Ex. 1021, 1. Petitioner was not a party to this now-terminated litigation. *See* Pet. 47.

Petitioner filed additional translation materials, including a supplemental declaration from Mr. Sherman (Exhibit 1022) and an additional translation of Harder performed by Stephen Benyunes (Exhibit 1023). *See* Paper 26, 4–5 (Petitioner's motion requesting authorization); Paper 35 (order granting authorization).

In its Patent Owner Response, Patent Owner continues to attack Petitioner's Harder translations. *See, e.g.*, PO Resp. 11–15. According to Patent Owner, because the original translation from the prior litigation (Exhibit 1021, performed by Ms. Tinworth) did not include the "critical" word "licked," "Petitioner's counsel obtained several additional translations of Harder after demanding they include the word 'licked.'" *Id.* at 1, 32. Patent Owner characterizes the later Sherman and Benyunes translations as "manipulated" and "doctored" and the result of "a coordinated effort between Petitioner, its counsel, and its experts to twist the evidence to fit their legal arguments." *Id.* at 1, 12; *see also id.* at 12–15. Patent Owner urges that "[a]ny analysis of Harder . . . should be based on Tinworth's untainted translation," which it contends is the only translation of record that "is untainted by the manipulations of Petitioner's counsel." *Id.* at 15.

We disagree with Patent Owner that we should base our analysis on the Tinworth translation. The preponderance of the evidence indicates that the Tinworth translation is missing words, namely, the phrase "to be licked off," which appears in the later Sherman and Benyunes translations.[19] Patent

[19] As Patent Owner correctly notes (PO Resp. 15), the added phrase is slightly different in the Sherman and Benyunes translations. *Compare* Ex. 1007 (Harder (Sherman translation)) 6 ("1 drop of Vigantol® oil is given to the baby ***to be licked off*** from the tip of a spoon once a day before a breastfeed or a meal.") (emphasis added), *with* Ex. 1023 (Harder (Benyunes

Owner does not persuade us of any nefarious intent in Petitioner obtaining modified translations that include this phrase. Instead, as we discuss below, the evidence of record indicates that the phrase "zum Ablecken," which appears in the German-language version of Harder, means "to be licked off." A translation of this phrase was missing from the Tinworth translation and was included in the later Sherman and Benyunes translations, making these later translations more correct than the Tinworth translation.

To begin, the German-language version of Harder states: "Einmal täglich vor dem Stillen bzw. der Mahlzeit wird 1 Tropfen Vigantol® Öl vorne auf einem Löffel dem Baby **zum Ablecken** gegeben." Ex. 1006 (Harder (German)) 21 (emphasis added). Ms. Tinworth translated this sentence as stating: "l drop of Vigantol® oil is given to the baby from the tip of a spoon once a day before a breastfeed or a meal." Ex. 1021 (Tinworth Decl.) 5.

After obtaining the Tinworth translation, Petitioner's counsel asked Mr. Sherman (who was Ms. Tinworth's supervisor) to review this particular sentence in Ms. Tinworth's translation to ensure the accuracy of the translation.[20] *See* Ex. 2024 (Sherman Depo. Tr.) 27:20–28:12, 29:8–14. Mr. Sherman performed the review and signed a declaration stating, "I have reviewed the [Tinworth] translation and confirm that the addition of 'to be

translation)) 8 ("Once a day before breastfeeding or a meal, the baby is given 1 drop of Vigantol® oil on the tip of a spoon ***to lick off***.") (emphasis added). We find that the slightly different language and sentence structure between the two translations is not meaningful.

[20] The record indicates that Ms. Tinworth was unavailable to perform the requested review, hence the involvement of her supervisor, Mr. Sherman. *See* Ex. 2024 (Sherman Depo. Tr.) 29:15–30:1; Ex. 2033, 1.

licked off' (for the German 'zum Ablecken') on page 4 of the translation in the fifth line of the second paragraph under Option 3 makes the translation a more accurate reflection of the German text." Ex. 1007 (Sherman Decl.) ¶ 3. He reaffirmed this in a supplemental declaration, stating in relevant part, "I have reviewed one sentence of the translation prepared by Rebecca Amy TINWORTH . . . . I confirm that the addition of 'to be licked off' as a translation for the German phrase 'zum Ablecken' . . . provides a fuller and more accurate reflection of the German text (MOM-1006)." Ex. 1022 (Sherman Supp. Decl.) ¶ 3.

When Patent Owner deposed Mr. Sherman, he again reaffirmed that addition of the phrase "to be licked off" "reflects the German source more accurately" and is "a better reflection of my interpreted meaning of the German source text." Ex. 2024 (Sherman Depo. Tr.) 76:4–14; *see also* Reply 10. Thus, the record reflects that even though Mr. Sherman revisited the disputed sentence of the Tinworth translation at the request of Petitioner's counsel, he amended it to more accurately reflect the German source text.

The preponderance of the record evidence demonstrates the accuracy of adding the phrase "to be licked off" to the Harder translation. First, Mr. Sherman testifies that "zum Ablecken" means "to lick off." Ex. 1022 (Sherman Supp. Decl.) ¶ 3. Second, Mr. Sherman's translation is corroborated by a German-to-English dictionary, which indicates the German word "ablecken" means "to lick off." *See id.* at n.1 (citing Cambridge Dictionary, attached to Sherman Supp. Decl. as Ex. C).

Third, Mr. Sherman's translation is consistent with Mr. Benyunes's translation of Harder, which includes "to lick off" in his Harder translation.

See Ex. 1023 (Benyunes Decl. and translation) 8. Patent Owner criticizes the process by which Mr. Benyunes performed his translation (because he began with Ms. Tinworth's translation), but does not persuade us that Mr. Benyunes's translation is inaccurate in any way. *See* PO Resp. 15, 32. Mr. Benyunes prepared his translation independent of Mr. Sherman's, and when Patent Owner deposed Mr. Benyunes he reaffirmed the accuracy of his translation. *See* Ex. 2023 (Benyunes Depo. Tr.) 69:2–7, 97:13–22; *see also* Reply 10.

Despite offering its own translation of Harder's table of contents, Patent Owner does not offer a translation of the sentence it disputes. *See* Reply 11 (citing Ex. 2070 (MacKenzie Decl.)). There is also no indication that Ms. Tinworth disagreed with Mr. Sherman's addition. *See id.* at 1–2, 10 (noting that Patent Owner did not depose Ms. Tinworth). Although Patent Owner is correct that it is "not obligated to depose Tinworth or obtain another translation" (Sur-reply 3), the absence of any translation demonstrating that Mr. Sherman and Mr. Benyunes's understanding of "zum Ablecken" is incorrect leaves a one-sided record, with all of the information consistent with Mr. Sherman's translation.[21] We see no evidence of record

[21] During the oral hearing, Patent Owner suggested that the Tinworth translation is correct because she is a woman and was reading Harder in the context of "the fact that you don't put a spoon in . . . a baby's mouth." *See* Tr. 26:16–18. Dr. Vieth similarly asserted that Tinworth's translation "is the correct one because she's a mother or probably a mother." Ex. 1039 (Vieth Depo. Tr.) 108:21–109:1 (cited at Reply 10). We reject these arguments as unfounded speculation, and because Patent Owner forfeited them by not timely raising them in a brief of record. *See, e.g.*, Inst. Dec. 47 ("The Board will deem forfeited any issue not raised in a timely response to the Petition, or as permitted in another manner during trial, even if asserted in the Preliminary Response or discussed in this Decision."); Paper 11, 9 ("Patent

that contradicts Petitioner's argument that "zum Ablecken" means "to be licked off" or the correctness of Mr. Sherman's Harder translation submitted with the Petition (Exhibit 1007).

For the above reasons, we find unavailing Patent Owner's arguments that we should use only Ms. Tinworth's translation of Harder and reject the later Sherman and Benyunes translations for alleged "gamesmanship." PO Resp. 15, 32. Instead, we find that the translation of Harder that Petitioner relied on in the Petition (Exhibit 1007, Sherman translation) is reliable and appropriate to use in this proceeding.

b) Whether a Person of Ordinary Skill in the Art Would Have Considered Harder

Patent Owner makes several arguments that implicate whether Harder is analogous art and whether a person of ordinary skill in the art would have consulted Harder, based on Harder's credentials compared to those of a person of ordinary skill in the art. We begin with the latter issue, then turn to analyzing whether Harder is analogous art.

Patent Owner argues that Harder is "neither written by nor for a person of ordinary skill in the art," but is rather a book "written by midwives for midwives" that "offers practical solutions for midwives to typical problems that might be faced in the first months of an infant's life." PO Resp. 1, 16 (citing Ex. 2070 (MacKenzie Decl. and translation) ¶¶ 1–5; Ex. B); *see also id.* at 30–31. Patent Owner contends that a person of ordinary skill in the art "would not have consulted" Harder, and instead would have consulted references such as "textbooks and peer-reviewed

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Owner is cautioned that any arguments not raised in the response may be deemed waived.").

articles" written by "similarly-situated" and "similarly educated individuals." *Id.* at 30–31 (citing Ex. 2072 (Reid Decl.) ¶¶ 52–57; Ex. 2068 (Vieth Decl.) ¶¶ 58–59; Ex. 2069 (Horowitz Decl.) ¶ 6(f)).

Patent Owner does not adequately support its argument that a person of ordinary skill in the art would have eschewed Harder given the author's credentials. Dr. Reid asserts that "the person of ordinary skill . . . would have consulted the collective wisdom and experience of like-minded and like-educated authorities," while Dr. Vieth asserts that he "do[es] not believe that a researcher seeking to solve the problem and 5 inter-related variables identified above would consult or use the Harder reference in connection with their research." Ex. 2072 (Reid Decl.) ¶ 55; Ex. 2068 (Vieth Decl.) ¶ 59. We accord these opinions little weight, because they are self-serving and unsupported by reference to objective, corroborating evidence of record. *See, e.g.*, *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 281, 294 (Fed. Cir. 1985) ("Lack of factual support for expert opinion going to factual determinations . . . may render the testimony of little probative value in a validity determination."); *Xerox Corp. v. Bytemark*, IPR2022-00624, Paper 9, 15 (PTAB 2023) (precedential) (explaining that declaration testimony that "is conclusory and unsupported" and which "adds little to the conclusory assertion for which it is offered to support . . . is entitled to little weight").

Dr. Horowitz offers a similar opinion, drawing on his experience as a pediatrician:

> As a pediatrician, skilled in the art, I have conferred directly with midwives but I have never relied upon information from a book by a midwife as if it were an academic medical reference because midwife education and training is generally not as

> rigorous or comprehensive as that of physicians or PhD's whom I consider experts.

Ex. 2069 (Horowitz Decl.) ¶ 6(f)). This opinion is unavailing. The level of skill we adopt herein is not limited to pediatricians, and thus the scope of relevant prior art is not coextensive with sources pediatricians would have consulted. *See supra* Section II.B. Dr. Horowitz and Dr. Reid also purport to compare the rigor of a PhD's education and training to that of a midwife, but the record is devoid of any information comparing the curricula. *See* Ex. 2069 (Horowitz Decl.) ¶ 6(f)); Ex. 2072 (Reid Decl.) ¶ 53. Accordingly, we accord little weight to these opinions.

Additionally, these opinions are inconsistent with Patent Owner's admission that "[t]he relevant prior art concerns formulations of medicaments or nutritive supplements to humans and particularly infants." PO Resp. 7. Harder concerns exactly this subject matter, i.e., delivering various formulations of nutritional supplements to infants. *See* Ex. 1007 (Harder), 3 (addressing administration of various formulations of vitamin K and D and fluoride to babies).

Moreover, "[i]n resolving questions of obviousness, 'we presume full knowledge by the inventor of all the prior art in the field of his endeavor.'" *Airbus S.A.S. v. Firepass Corp.*, 941 F.3d 1374, 1380 (Fed. Cir. 2019) (quoting *In re Wood*, 599 F.2d 1032, 1036 (CCPA 1979)). "Prior art is analogous and can be applied in an obviousness combination if it either (1) 'is from the same field of endeavor [as the claimed invention], regardless of the problem addressed' or (2) 'is reasonably pertinent to the particular problem with which the inventor is involved.'" *Unwired Planet, LLC v. Google Inc.*, 841 F.3d 995, 1000–01 (Fed. Cir. 2016) (quoting *In re Clay*, 996 F.2d 656, 658–59 (Fed. Cir. 1992)). We analyze each test below, and

under both, find that Harder is analogous art that a person of ordinary skill in the art is presumed to have known.

(1) Whether Harder is from the Same Field of Endeavor as the Claimed Invention

To determine the applicable field of endeavor, we consider "explanations of the invention's subject matter in the patent application." *In re Bigio*, 381 F.3d 1320, 1325 (Fed. Cir. 2004). The '958 patent identifies the field of the invention as "relat[ing] to compositions comprising vitamin D in a medium-chain triglyceride medium and use thereof for human beings, particularly, breast-feeding infants." Ex. 1001, 1:10–12. We find that Harder addresses exactly the same subject matter. *See, e.g.*, Ex. 1007 (Harder) 6 ("**Vigantol® oil** . . . contains only one excipient as a vehicle for the fat-soluble vitamin D, namely medium-chain triglycerides (vegetable oil). . . . 1 drop of Vigantol® oil is given to the baby to be licked off from the tip of a spoon once a day before a breastfeed or a meal."); Reply 8–9.

Petitioner articulates the field of endeavor somewhat differently, namely, "ensuring proper infant nutrition." Reply 8. Even using this view, we find that Harder is in the same field of endeavor, because it was identifiable in a library catalog under the topic "Postnatal Care," and includes information on "[n]utrition of the newborn and infant," including regarding "[p]rophylaxis of bleeding, rickets and tooth decay." *See* Ex. 1025 (Munford Supp. Decl.) ¶ 15; Ex. 2070 (MacKenzie Decl. and translation) 23; Ex. 1007 (Harder) 3.

Patent Owner argues that "Harder is from a different field than the '958 Patent," but does not clearly explain why. Sur-reply 14. Patent Owner also does not clearly identify the relevant field of endeavor, but does assert

that a person of ordinary skill in the art would have consulted "authorities in the fields of pharmaceutics and the delivery of medicants." PO Resp. 30. To the extent Patent Owner contends that the relevant field of endeavor is "pharmaceutics and the delivery of medicants," we still find that Harder is in the same field of endeavor, because it addresses the delivery of medicants including vitamin K, vitamin D, and fluoride to babies. *See* Ex. 1007 (Harder) 3; Reply 7–8.

Accordingly, we find that Harder is analogous art because it is from the same field of endeavor as the claimed invention.

(2) Whether Harder is Reasonably Pertinent to the Same Problem with Which the Inventor is Involved

We also find that Harder is reasonably pertinent to the same problem with which the inventor is involved. "A reference is reasonably pertinent if, even though it may be in a different field from that of the inventor's endeavor, it is one which, because of the matter with which it deals, logically would have commended itself to an inventor's attention in considering his problem." *In re Clay*, 966 F.2d 656, 659 (Fed. Cir. 1992).

Patent Owner articulates the problem addressed by the inventors as: "How do you reliably deliver vitamin D to a human being or an infant, in a form and method that is reliably safe and nutritionally effective, amenable and acceptable to the recipient?" PO Resp. 4 (emphasis omitted); *see also* Ex. 2068 (Vieth Decl.) ¶ 29. Patent Owner argues that nothing in Harder "addresses or considers a solution to the problem of efficiently and effectively delivering a nutritionally therapeutic dose of vitamin D to an infant, much less a human being." PO Resp. 31 (citing Ex. 2072 (Reid Decl.) ¶¶ 58–60).

We disagree with Patent Owner that Harder does not address or consider the problem of "efficiently and effectively delivering a nutritionally therapeutic dose of vitamin D to an infant." We find that Harder expressly addresses exactly this subject matter, e.g., by providing several options for delivering vitamin D to infants and children. *See* Ex. 1007 (Harder) 5–6 (presenting "[f]our options for the prophylaxis of rickets"); *see also* Reply 9 ("A POSITA seeking to improve vitamin D delivery to an infant would surely have sought to understand current known delivery methods, and Harder details four options that were in use before the priority date.").

Petitioner articulates the problem faced by the inventors somewhat differently than Patent Owner does, namely, how do you "administer[] vitamin D to infants to prevent rickets," and "how to deliver the correct dose of vitamin D to an infant, recognizing the challenges inherent in giving babies medicine and ensuring they are not exposed to toxic levels of vitamin D?" Reply 5, 9. Harder is clearly pertinent to this problem, because it provides several options for delivering vitamin D to infants and children to prevent rickets, and addresses how to prevent administering too much vitamin D (e.g., "Should 2 drops fall onto the spoon, the spoon should be washed and the process started again."). *See* Ex. 1007 (Harder) 5–6.

Accordingly, we find that Harder is analogous art because it is reasonably pertinent to the same problem with which the inventor is involved.

(3) Conclusion

For the above reasons, we find that Harder is both in the same field of endeavor as the '958 patent, and is reasonably pertinent to the same problem with which the inventors were involved, and that a person of ordinary skill

in the art would not have eschewed Harder based on Harder's credentials. In sum, we find that Harder is analogous art and that a person of ordinary skill in the art would have considered Harder.

2. *Alleged Obviousness of Claims 1 and 5 Over Harder, Wolf, and European Pharmacopoeia*

Petitioner asserts that claims 1 and 5 are unpatentable as obvious over Harder, Wolf, and European Pharmacopoeia. *See* Pet. 22–33. Patent Owner opposes. *See* PO Resp. 27–38, 44–64. After considering all of Petitioner's and Patent Owner's arguments and cited evidence (including Patent Owner's arguments regarding objective indicia of nonobviousness, discussed below), we find that Petitioner shows by a preponderance of the evidence that claims 1 and 5 are unpatentable as obvious over Harder, Wolf, and European Pharmacopoeia.

a) Findings Regarding Petitioner's Arguments

We begin by summarizing our findings regarding Petitioner's demonstration of how the cited prior art references teach or suggest each claim limitation, and why a person of ordinary skill in the art would have been motivated to combine the references with a reasonable expectation of success. We arrived at these findings after taking into account all of the arguments and cited evidence of record, including Patent Owner's arguments addressed below.

(1) Claim 1

The preamble of claim 1 recites: "A method of delivering a nutritional or therapeutic amount of vitamin D to a human being, said method comprising . . . ." Generally, a preamble does not limit a claim. *See Allen Eng'g Corp. v. Bartell Indus., Inc.*, 299 F.3d 1336, 1346 (Fed. Cir. 2002). Here, neither party argues that the preamble is limiting. *See, e.g.*, Reply 15

("The preamble is not limiting . . . ."); Sur-reply 5 ("Patent Owners have *not* made any arguments based on the preamble."). Nevertheless, to the extent the preamble is limiting, the record demonstrates by a preponderance of the evidence that Harder and Wolf both teach the importance of, and methods for, delivering a nutritional or therapeutic amount of vitamin D to infants for the prophylaxis of rickets, e.g., via the daily administration of one drop of Vigantol oil. Pet. 25–27, 28; Ex. 1007 (Harder) 5–6; Ex. 1009 (Wolf) 6–7, Table 1. Harder indicates that "[u]se of the [Vigantol] oil is simple," and that it "has proved to be successful over many years." Ex. 1007 (Harder) 5–6. Accordingly, both Harder and Wolf teach "[a] method of delivering a nutritional or therapeutic amount of vitamin D to a human being."

Regarding claim 1's recitation of "(i) applying one drop of a composition . . . to an exterior surface of an object . . . ; and having said human being suck or lick said composition directly from said object," Petitioner persuasively demonstrates that Harder teaches administering one drop of Vigantol oil to an infant from an exterior surface of an object (a spoon), and having the infant lick the drop directly from the tip of the spoon. *See* Pet. 28, 29; Ex. 1007 (Harder) 6 ("1 drop of Vigantol® oil is given to the baby to be licked off from the tip of a spoon once a day before a breastfeed or a meal."); Ex. 1004 (Williams Decl.) ¶¶ 80, 101.

Regarding the portion of claim 1(i) that recites a composition consisting of "a nutritional or therapeutic effective amount of 9 to 9000 mcg/ml vitamin D," Petitioner persuasively demonstrates that Wolf teaches that a drop of Vigantol oil contains 505.04 mcg/ml vitamin D, which falls within the 9–9000 mcg/ml vitamin D range recited in claim 1. Pet. 27–28; Ex. 1009 (Wolf) 7–8, Table 1; Ex. 1004 (Williams Decl.) ¶¶ 96–98.

Regarding the portion of claim 1(i) that recites a composition "consisting of . . . vitamin D in a liquid triglyceride of 6 to 12 carbon chain length," Harder teaches that Vigantol oil is a liquid product that "contains only one excipient as a vehicle for the fat-soluble vitamin D, namely medium-chain triglycerides (vegetable oil)."). Ex. 1007 (Harder) 6; Pet. 28; Ex. 1004 (Williams Decl.) ¶ 99. Petitioner demonstrates that "medium-chain triglycerides are a 'minimum 95.0 percent of saturated fatty acids with 8 to 10 carbon atoms.'" Pet. 28; Ex. 1010 (European Pharmacopoeia) 5; Ex. 1004 (Williams Decl.) ¶ 104. The 8–10 carbon chain length of the MCT taught in Harder falls within the claimed range of triglycerides having 6 to 12 carbon chain length.

Finally, regarding the limitation in claim 1(i) that recites "wherein said drop adheres to the surface of said object" as we have construed it above (*see supra* Section II.C.2), Petitioner persuasively demonstrates that the composition disclosed in Harder (i.e., vitamin D in MCT) "will inherently 'adhere'" to the surface of the spoon. *See* Pet. 29 n.5, 30–31. "When the prior art does not expressly disclose a claim limitation, inherency may supply a missing claim limitation in an obviousness analysis." *Hospira, Inc. v. Fresenius Kabi*, 946 F.3d 1322, 1329 (Fed. Cir. 2020) (citation omitted). "Inherency is established in the context of obviousness when the limitation at issue necessarily must be present, or the natural result of the combination of elements explicitly disclosed by the prior art." *Id.* (citation omitted). "[T]he work of the inventor or the patentee can be used as the evidence of inherency." *Id.* at 1329–30; *see also Par Pharm. Inc. v. TWI Pharms. Inc.*, 773 F.3d 1186, 1195 (Fed. Cir. 2014) (noting that "the

patent itself" may "define[] the limitation at issue as a property that is necessarily present") (citation omitted).

We agree with Petitioner that the Specification identifies only viscosity and triglyceride chain length as impacting adherence, such that "the adhering property claimed is merely a property of the particular oil for delivery of vitamin D." Pet. 30–31; Ex. 1001, 6:34–7:27; Ex. 1004 (Williams Decl.) ¶¶ 50–52. In particular, the Specification discloses test results showing that a composition consisting of vitamin D and MCT "adhered" to a nipple in the sense that no portion of it dripped off the nipple in 10 seconds, and it "adhered to the nipple well enough to make [it] suitable for handling during breastfeeding or for use of a pacifier." *See* Ex. 1001, 6:49–55, Table 1, 7:21–27. The Specification contrasts MCT with water-based preparations and alcohol, all of which dripped off and thus "did not adhere to the nipple." *See id.* at Table 1, 7:21–22. Based on these test results, the Specification concludes that MCT "adheres," stating: "The medium-chain triglycerides of use in this invention are liquids that are sufficiently viscous so that one drop does not immediately drip or roll away from the part of the nipple or pacifier that enters the mouth of an infant." *Id.* at 6:34–37.

Harder teaches that a composition that consists only of vitamin D in MCT (Ex. 1007 (Harder) 6), and the Specification teaches that MCT necessarily adheres to the surface of objects, in the manner claimed. Thus, on the full trial record, we agree with Petitioner that the statements and results in the Specification demonstrate that Harder inherently teaches the "adheres" limitation of the claim, because it teaches that Vigantol oil has the same composition as the oil tested in the Specification (i.e., MCT), which is

taught to "adhere." Pet. 29–31. We therefore find that Petitioner establishes by a preponderance of the evidence that Harder inherently teaches or suggests the "adheres" claim limitation.

To the extent the "adheres" limitation is not inherent in Harder, we find that Harder nevertheless suggests this limitation. We agree with Petitioner that "[f]rom Harder's teachings, it would have already been apparent to a person of ordinary skill in the art that medium chain triglycerides possessed the properties needed to adhere to the surface of an object." Ex. 1004 (Williams Decl.) ¶ 53. This is because Harder teaches a "method of delivering Vitamin D in a composition of medium chain triglycerides by placing one drop on the tip of a spoon for the infant to 'lick' off." *Id.* ¶ 52; Ex. 1007 (Harder) 6. "[A] POSITA would understand that any substance that does not adhere to the surface would naturally drip off," yet Harder teaches that the "[u]se of the [Vigantol] oil is simple" and "has proved to be successful over many years." Pet. 30–31; Ex. 1004 (Williams Decl.) ¶ 103; Ex. 1007 (Harder) 5–6. For the above reasons, we find that Petitioner demonstrates by a preponderance of the evidence that Harder teaches or suggests the "adheres" limitation.

Turning to motivation to combine, we find that Petitioner demonstrates by a preponderance of the evidence that a person of ordinary skill in the art would have had a reason to combine Harder, Wolf, and European Pharmacopoeia with a reasonable expectation of success, namely, "to provide a complete composition and dosage of Vigantol oil." Pet. 22–23; Ex. 1004 (Williams Decl.) ¶ 77; Ex. 1007 (Harder) 5–6. First, Petitioner demonstrates that Wolf teaches the daily dosage of Vigantol oil and the size of a single drop, while Harder teaches a method for its delivery (placing one

drop on the tip of a spoon). Pet. 22–23; Ex. 1009 (Wolf) 7–8; Ex. 1007 (Harder) 5–6. Petitioner sufficiently shows that "[g]iven the subject matter overlap between Wolf and Harder," a person of ordinary skill in the art would have been motivated "to combine Wolf and Harder to administer a composition of vitamin D oil to an infant." Pet. 23; Ex. 1004 (Williams Decl.) ¶ 83; Ex. 1009 (Wolf) 7; Ex. 1007 (Harder) 6. Second, Petitioner demonstrates that a person of ordinary skill in the art would have consulted European Pharmacopoeia, which governs the quality standards of Vigantol, to understand the use of MCT in the composition of Vigantol oil disclosed in Harder. Pet. 22, 24; Ex. 1007 (Harder) 5–6; Ex. 1010 (European Pharmacopeia) 5; Ex. 1004 (Williams Decl.) ¶ 84.

(2) Claim 5

Claim 5 depends from claim 1 and further recites that the "triglyceride comprises at least 95% triglycerides having a carbon-chain length selected from 8 to 10." Ex. 1001, 10:4–6. As Petitioner demonstrates, Harder expressly teaches vitamin D in "medium-chain triglycerides," and a "person of ordinary skill in the art would [have] recognize[d] in view of European Pharmacopoeia that medium-chain triglycerides are composed of at least 95% triglycerides with a[n] 8 to 10 carbon chain length." Pet. 32–33; Ex. 1001, 5:21–28; Ex. 1004 (Williams Decl.) ¶¶ 58, 99; Ex. 1007 (Harder) 6; Ex. 1010 (European Pharmacopeia) 5.

(3) Conclusion

We find that Petitioner has demonstrated by a preponderance of the evidence that the combination of Harder, Wolf, and European Pharmacopeia teaches or suggests each limitation of claims 1 and 5, and that a person of ordinary skill in the art would have been motivated to combine the

references, with a reasonable expectation of success. Before making a conclusion as to whether claims 1 and 5 would have been obvious, we first consider Patent Owner's arguments, beginning with objective indicia of nonobviousness.

b) Analysis of Patent Owner's Arguments

(1) Whether the Prior Art Teaches Certain Claim Limitations

(a) "a composition consisting of . . . vitamin D in a liquid triglyceride of 6 to 12 carbon chain length"

Claim 1 recites in relevant part, "a composition consisting of . . . vitamin D in a liquid triglyceride of 6 to 12 carbon chain length." On Sur-reply, Patent Owner for the first time argues that "Petitioner has not produced admissible evidence of the composition of Vigantol." Sur-reply 4 (capitalization modified). According to Patent Owner, "[e]stablishing that Vigantol consists of MCT and vitamin D is critical to Petitioner's invalidity argument," but "Harder's statement regarding Vigantol is hearsay" and is "inaccurate and ambiguous." *Id.* at 4–5.

Patent Owner's arguments are unavailing. First, its assertion that "Harder's statement is inaccurate and ambiguous" because "vegetable oils are typically long-chain triacylglycerols" comes too late. *Id.* at 4. Patent Owner did not raise this argument in its Patent Owner Response.[22] Instead,

[22] Patent Owner did raise a similar argument in its Preliminary Response. *See* Prelim. Resp. 33–34 ("One of ordinary skill in the art . . . would know that vegetable oil as referred to in [Harder] does not exclude the presence of long-chain triglycerides."). Patent Owner, however, forfeited this argument because it did not repeat it in its Patent Owner Response. *See* Inst. Dec. 47; *see also In re Nuvasive, Inc.*, 842 F.3d 1376, 1381 (Fed. Cir. 2016) (explaining that a patent owner waives an issue presented in its preliminary

in that filing, Patent Owner argued only that "Harder provides no information regarding the composition of the oil she used – Vigantol® oil – a product that is not available in the U.S. or Canada and is only available by prescription in a few European countries." PO Resp. 17 (citing Ex. 2069 (Horowitz Decl.) ¶ 6(h)). That contention is plainly incorrect, given that Harder expressly teaches that Vigantol "contains only one excipient as a vehicle for the fat-soluble vitamin D, namely medium-chain triglycerides (vegetable oil)." Ex. 1007 (Harder) 6. As discussed above (*see supra* Section II.E.2.a.1), Petitioner shows by a preponderance of the evidence that a person of ordinary skill in the art would have understood "the 'medium-chain triglycerides' of Harder to have 8 to 10 carbon chain length," which falls within the claimed range of triglycerides having 6 to 12 carbon chain length. Pet. 28.

Second, Patent Owner's argument that "Harder's statement regarding Vigantol is hearsay" because "Petitioner is relying on Harder to prove the actual chemical composition of Vigantol" is improper, because it appears only in Patent Owner's Sur-reply, not in a motion to exclude, and thus unfairly deprives Petitioner of an opportunity to respond to it. Sur-reply 4; *see also generally* Paper 95 (Patent Owner's Motion to Exclude).

In any event, even if we were to consider Patent Owner's hearsay argument, it would fail. Hearsay "is a statement, other than one made by the declarant while testifying at the trial or hearing, offered in evidence to prove the truth of the matter asserted." Fed. R. Evid. 801(c). In the present

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response if it fails to renew the issue in its response after trial is instituted); Patent Trial and Appeal Board Consolidated Trial Practice Guide (November 2019) ("TPG"), *available at* https://www.uspto.gov/TrialPracticeGuideConsolidated, 52.

context, the "actual chemical composition of Vigantol" is irrelevant. Sur-reply 4. The Petition alleges obviousness based on Harder's teachings about Vigantol's composition, not on the actual chemical composition of the actual Vigantol product. In other words, Petitioner cites Harder not to prove the actual chemical composition of Vigantol, but for the effect that Harder's statement would have had on the person of ordinary skill in the art. *See* Pet. 28 ("A POSITA would therefore understand the 'medium-chain triglycerides' of Harder to have 8 to 10 carbon chain length, or it at least would have been obvious to use the recommended composition in the European Pharmacopoeia Supplement.").

For the above reasons, we find that Patent Owner's arguments do not undermine Petitioner's showing by a preponderance of the evidence that Harder teaches the claim limitation "a composition consisting of . . . vitamin D in a liquid triglyceride of 6 to 12 carbon chain length."

(b) "nutritional or therapeutic effective amount"

Patent Owner makes several arguments suggesting that Petitioner has not established that by following Harder's method, the human or infant would actually receive a "nutritional or therapeutic effective amount" of vitamin D. For example, Patent Owner argues that Petitioner has not established (i) that the infant could remove all of the drop from the spoon, given that "some amount of the oil will adhere and remain in the spoon;" (ii) "the number of licks an infant would have to make to obtain a therapeutically effective dose of vitamin D;" or (iii) that "delivery of a nutritional or therapeutic amount[] of vitamin D is the 'natural result' of [Harder's] method." *See* PO Resp. 18 (citing Ex. 2025 (Williams Depo. Tr.) 137:4–18; 138:1–24; 139:1–6; 139:23–140:10); Sur-reply 6.

Patent Owner's arguments are not commensurate with the scope of the challenged claims. To establish unpatentability, Petitioner need not show that a human or infant could remove a drop of vitamin D oil from a spoon (via a certain number of licks or otherwise) such that the human or infant would "***receive*** a nutritionally therapeutic or effective dose of vitamin D." PO Resp. 35. In other words, claim 1 "does not require ensuring that the entire dose is delivered." Reply 7; *see also id.* at 2, 5–6, 15–16. Claim 1 instead recites a method with two active steps: (i) applying one drop of a certain vitamin D composition to the surface of an object; and (ii) having a human being suck or lick the composition directly from the object.[23] Ex. 1001, 9:34–44. It does not recite any limitation specifying how much of the drop the human actually receives or ingests upon sucking or licking the composition, and thus Patent Owner's arguments on this issue are unavailing. *See, e.g.*, *In re Self*, 671 F.2d 1344, 1348 (CCPA 1982) (rejecting arguments "not based on limitations appearing in the claims").

On Sur-reply, Patent Owner argues that "[t]he specification discloses that the 'nutritional or therapeutic amount' limitation relates to efficiency of the transfer of the Vitamin D from the surface to the human." Sur-reply 6 (citing Ex. 1001, 4:50–57). To the extent Patent Owner seeks to read into the claim term "nutritional or therapeutic effective amount" a requirement related to "efficiency of the transfer of the Vitamin D from the surface to the human," we decline to do so. Patent Owner did not timely request construction of the claim term "nutritional or therapeutic effective amount," and thus has waived this argument. However, even if we were to consider

[23] As noted above, neither party argues that the preamble is limiting. *See supra* Section II.E.2.a.1.

this argument, it is unavailing. The cited passage in the Specification does not address the meaning of the claim term "nutritional or therapeutic effective amount," let alone purport to define it. *See, e.g.*, *Thorner v. Sony Comput. Entm't Am. LLC*, 669 F.3d 1362, 1365 (Fed. Cir. 2012) (internal quotations omitted) ("To act as its own lexicographer, a patentee must clearly set forth a definition of the disputed claim term other than its plain and ordinary meaning.").

That said, even if the challenged claims require that the human or infant ***receive*** a nutritionally therapeutic or effective dose of vitamin D or that the method actually deliver a nutritional or therapeutic amount of vitamin D into the human or infant's body, we find that Harder teaches or suggests this subject matter. Harder teaches administering a vitamin D dosage squarely within the claimed ranges, and teaches that the vitamin D oil she discusses "has proved to be successful over many years" in treating children. Ex. 1007 (Harder) 6; Reply 6. We credit the testimony of Petitioner's declarant Dr. Raj stating that Harder's method is "very feasible and easy to perform," and that a baby could lick and/or suck a vitamin D drop from a spoon, even if the drop rolled away from the tip of the spoon. Ex. 1040 (Raj Decl.) ¶¶ 15–23.

For the above reasons, we find that Patent Owner's arguments do not undermine Petitioner's showing by a preponderance of the evidence that Harder teaches or suggests the "nutritional or therapeutic effective amount" limitation recited in claim 1.

(c) "wherein said drop adheres to the surface of said object"

Patent Owner argues several reasons why Petitioner has not established that Harder teaches or suggests the claim limitation, "wherein

said drop adheres to the surface of said object." First, Patent Owner argues that Harder does not mention adherence. PO Resp. 18 (citing Ex. 2025 (Williams Depo. Tr.) 130:10–15). This argument is unavailing. Express disclosure of "adherence" is unnecessary because as discussed above, Petitioner demonstrates that Harder inherently discloses the "adheres" limitation. *See supra* Section II.E.2.a.1. We additionally agree with Petitioner that Harder would have suggested to a person of ordinary skill in the art that the Vigantol oil she discusses had sufficient viscosity in one drop to be administered using a spoon, thus satisfying the "adherence" limitation as construed herein. *See* Pet. 30–31 ("[A] POSITA would understand that any substance that does not adhere to the surface would naturally drip off or away from the tip, rendering the disclosed method of delivery ineffective."); Ex. 1004 (Williams Decl.) ¶ 103.

Second, Patent Owner disputes that a drop of vitamin D in MCT inherently meets the "adheres" limitation. This is because, Patent Owner argues, the drop "when placed on the tip of a spoon, in fact coats or adheres to the spoon, thereby preventing the efficient removal of the drop either through licking (assuming an infant could lick) or through sucking." PO Resp. 33. In support of this assertion, Patent Owner relies on a test performed by its declarant Dr. Reid.

Dr. Reid explains that he "performed a test to determine whether a drop of a 400 IU solution of MCT oil, when applied to the tip of a spoon, would remain on the tip or spread out and coat the bowl, i.e., concave surface, of the spoon." PO Resp. 33–34. In his test, Dr. Reid used Baby Ddrops as a stand-in for Vigantol (which was not "readily available") and a steel spoon. *See* Ex. 2072 (Reid Decl.) ¶¶ 65–66. He performed the test

holding the spoon in two different positions, i.e., (1) "the spoon was positioned to enforce parallelism between the spoon bowl rim and the countertop," and (2) "the angle of the spoon was set to 14.8"—an angle "chosen to approximate the position in which a spoon is held and brought to a mouth, such as by an adult to an infant." *Id.* ¶¶ 67–68; *see also id.* at pages 68–69 (photos of spoon at two different angles).

Dr. Reid found that at "spoon angle = 0.0," "the drop immediately rolled downward to rest at the bottommost area of the spoon bowl, leaving a film or coating of oil extending from the tip of the spoon to the drop's resting point." *Id.* ¶ 70. At "spoon angle = 14.8," "the drop immediately rolled, though more slowly, downward to rest at the bottommost area of the angled spoon bowl, also leaving a film or coating of oil extending from the tip of the spoon to the drop's resting point." *Id.* ¶ 71.

Patent Owner contends that Dr. Reid's test "showed that the drop, under two different angles, immediately rolled toward the bottom of the spoon and left a film or coating on the spoon," and "never remained on the tip of the spoon." PO Resp. 34 (citing, e.g., Ex. 2072 (Reid Decl.) ¶¶ 65–77, Ex. B; Ex. 2068 (Vieth Decl.) ¶¶ 60–64; Ex. 2069 (Horowitz Decl.) ¶ 67(a)). According to Patent Owner, "[t]hese results contradict Williams['s] assertion that an oil has 'sufficient viscosity to adhere to and not immediately drip or roll away from an object each and every time.'"[24] PO Resp. 34 (citing Ex. 1004 (Williams Decl.) ¶ 50).

[24] For clarity, the assertion of Dr. Williams that Patent Owner and Dr. Reid are responding to reads: "[A]ccording to the '958 Patent, if an oil composed of 9 to 9000 mcg/ml vitamin D includes liquid triglycerides that have a carbon chain length of 6–12, as described in Claim 1, it will have sufficient

Patent Owner's argument, and Dr. Reid's results, are unavailing. Even if the drop in Dr. Reid's test immediately rolled toward the bottom of the spoon, left a film or coating on the spoon, and never remained on the tip of the spoon, none of these actions is prohibited under the agreed construction of the "adheres" term that applies in this proceeding. *See supra* Section II.C.2. Indeed, we agree with Petitioner that "[t]he patent says nothing about a drop 'adher[ing] so as to remain localized.'" Reply 12 (quoting Ex. 2072 (Reid Decl.) ¶ 26); *see also* Ex. 1001, 6:50–52, 7:22–24, Table 1 (examining whether various liquid vehicles applied to a nipple "would adhere well enough so that no portion of it would drip off in a timeframe of 10 seconds," and finding that "[t]he oil vehicles all adhered to the nipple well enough to make them suitable for handling during breastfeeding or for use of a pacifier," whereas the ethanol-based solution "drips off" and thus "did not adhere to the nipple").

The agreed construction instead prohibits the drop from "immediately drip[ping] or roll[ing] away from the object that enters the mouth, *so that no portion would drip off the object and surface*." *See supra* Section II.C.2. Dr. Reid's test confirmed this does not happen; he acknowledged that the drop "did not physically separate in whole or in part from the spoon." Ex. 2072 (Reid Decl.) ¶ 74; *see also id.* at ¶ 72 ("[I]t was not a consideration, and in fact it was impossible, for the drop to ever drip off the spoon."); Reply 6.

Patent Owner contends that Dr. Reid's remarks about the drop not separating from the spoon represent an "innocuous explanation about the test

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viscosity to adhere to and not immediately drip or roll away from an object each and every time." Ex. 1004 (Williams Decl.) ¶ 50.

design." Sur-reply 9. Patent Owner argues that Dr. Reid "never tested whether MCT can drip off a metal spoon at angles steeper than 14.8 degrees," and thus did not test whether the drop would roll off the spoon. *Id.*

These arguments are unavailing. A person following Harder's instructions to administer the drop to a baby "from the tip of the spoon" could easily prevent the drop from rolling away from the tip of the spoon, simply by holding the spoon at an appropriate angle. *See, e.g.*, *KSR Int'l Co.*, 550 U.S. at 421 (noting that a person of ordinary skill in the art is "a person of ordinary creativity, not an automaton"). Petitioner's declarant Dr. Raj confirmed that one drop of Baby Ddrops "stays at the tip" of a small plastic spoon and "does not fall off" if the spoon is held with "a slight tilt downwards." Ex. 1040 (Raj Decl.) ¶ 20.

Even if the drop rolls into the bowl of the spoon (as observed by Dr. Reid), we disagree with Patent Owner that this "makes 'efficient removal' of the drop difficult if not impossible." Sur-reply 10. Instead, we agree with Dr. Raj that one could simply tilt the spoon "downwards when presenting it to a baby so that the drop with [sic, will] roll forward to the tip of the spoon," or use a small spoon, which "can be given to a baby into its mouth so that the drop can be either licked or sucked off the bowl of the spoon." Ex. 1040 (Raj Decl.) ¶¶ 21, 22; *see also* Ex. 2081 (Raj Depo. Tr.) 111:10–112:6 (explaining that if the drop "rolls down or slides down, it doesn't matter because the whole spoon can be put into the baby's mouth").

Patent Owner asks us to disregard Dr. Raj's testimony because the spoons she used in her tests were not available until 2012, which is years after the 2006 priority date. *See* Sur-reply 19. We decline Patent Owner's request. First, Dr. Raj explained that her opinions were not limited to the

Munchkin brand spoons, but were based on use of small plastic spoons with smooth edges, which are suitable for use with a baby. *See* Ex. 2081 (Raj Depo. Tr.) 95:11–96:12.

Second, even if the exact brand of spoon Dr. Raj used in her testing was not available as of the priority date, the record evidences the common-sense understanding that spoons appropriate for use with babies were available as of 2006. Harder and Wolf both teach administering a drop of vitamin D oil to a baby via a spoon, with Harder indicating that the method is "simple" and the "oil has proved to be successful over many years." Ex. 1007 (Harder) 6; Ex. 1009 (Wolf) 7. This suggests that spoons appropriate for use in the method existed. Dr. Raj testifies that in her experience as a practicing pediatrician working with "hundreds of mothers," she was aware that "it's a logical thing" to use a spoon to administer substances to a baby. Ex. 2081 (Raj Depo. Tr.) 130:8–18. She also testified to using small metal spoons with babies throughout her career and with her own babies, and confirmed that such spoons are used by parents "all over the world, [in] many, many, situations." Ex. 2081 (Raj Depo. Tr.) 90:9–91:11. Dr. Vieth acknowledges that spoons vary in size. Ex. 2068 (Vieth Decl.) ¶ 24. Thus, the record demonstrates by a preponderance of the evidence that spoons suitable for use with babies existed before the priority date.

Patent Owner appears to suggest that the nature of the surface onto which you drip the claimed composition impacts adherence. *See, e.g.*, Tr. 68:10–18 (Patent Owner's counsel arguing that challenged claim 1 is "not talking about any object . . . [i]t says you've got to have an object that will work where adhere requires that A adheres to B"); PO Resp. 10 (quoting Ex. 2072 (Reid Decl.) ¶ 26, which states that "not just any liquid

triglyceride and not just any surface will suffice: the combination of the two establishes a relationship of adherence," and that spoons are excluded from the "adheres" term); Ex. 2068 (Vieth Decl.) ¶ 24 ("Some of the liquid will adhere and remain on the spoon in wide variation depending on whether the spoon is made from wood, paper, plastic, silver, stainless steel, or some other substance.").

We reject Patent Owner's argument. First, it is not sufficiently developed in any brief such that we can ascertain the basis of the argument. Second, there is no persuasive evidence of record indicating that the material of the spoon impacts whether a drop will adhere, and we are not directed to any portion of the Specification that indicates that the surface onto which one applies the drop impacts adherence. Rather, as discussed above (*see supra* Section II.E.2.a.1), the Specification indicates only that the properties of the vitamin D vehicle impact adherence. *See, e.g.*, Ex. 1001, 6:34–37, 6:49–55, Table 1, 7:21–27. Moreover, to the extent Patent Owner is suggesting that Dr. Raj's test on a small plastic spoon is not indicative of what would happen with Dr. Reid's larger metal spoon, we disagree. Dr. Raj testified that when she held a big metal spoon at a suitable angle, a drop of Baby Ddrops stayed at the tip of the spoon.[25] Ex. 2081 (Raj Depo. Tr.) 128:16–129:14.

[25] Patent Owner asserts that Dr. Raj "agreed" that metal spoons "would never be used with an infant," which Patent Owner argues is "contrary to Harder's suggestion." Sur-reply 19. Patent Owner mischaracterizes Dr. Raj's testimony. She did not take issue with using a metal spoon with a baby. Rather, she testified that she would not use a "large" spoon with a baby. *See* Ex. 2081 (Raj Depo. Tr.) 85:19–86:15 ("[C]learly, I was not going to use a large tablespoon to feed a baby."). She testified that she has used small metal spoons with a baby: "I have throughout my career,

For the above reasons, we find that Patent Owner's arguments do not undermine Petitioner's showing by a preponderance of the evidence that Harder teaches or suggests the "wherein said drop adheres to the surface of said object" limitation recited in claim 1.

> *(d) "having said human being suck or lick said composition directly from said object"*

As discussed above (*see supra* Section II.E.1.a), Patent Owner argues that we should limit our analysis of Harder to the Tinworth translation, which does not include the phrase "to be licked off." *See, e.g.*, PO Resp. 12. Patent Owner argues that "[Dr.] Williams admitted at his deposition that he cannot give his obviousness opinion without that phrase in the Harder translation." *See id.* (citing Ex. 2025 (Williams Depo. Tr.) 99:5–100:21, 120:10–19).

As discussed above (*see supra* Section II.E.1.a), we do not agree to limit our analysis to the Tinworth translation. But even if we were limited to that translation, Patent Owner's argument would fail. A person of ordinary skill in the art is "a person of ordinary creativity, not an automaton." *KSR Int'l Co.*, 550 U.S. at 421. We find that even if Harder did not include the phrase "to be licked off," it would have been apparent to a person of ordinary skill in the art that after placing a drop on a spoon as directed in Harder, one then gives the spoon to the baby so the baby can lick or suck the

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including with my own babies, used small metal spoons. Metal spoons are available in a small size. And metal spoons are used all over the world, many, many, situations." *Id.* at 90:9–91:11; *see also id.* at 111:24–112:6 ("I've seen spoons being used [in] all shapes, sizes. And even the large plastic – metal spoon has been used. It's just not a spoon that you can put the whole spoon into a baby's mouth, but it has been used.").

drop off the spoon. Although we do not need expert testimony to make this finding (*see, e.g.*, *Intercontinental Great Brands LLC v. Kellogg N. Am. Co.*, 869 F.3d 1336, 1348 (Fed. Cir. 2017) ("some cases involve technologies and prior art that are simple enough that no expert testimony is needed")), Petitioner's declarant Dr. Raj confirmed as much. *See* Ex. 1040 (Raj Decl.) ¶ 14 (noting that regardless of the translation used, a person following Harder's instruction would understand that the spoon is given to the baby so the baby can lick the drop from the spoon). This is also confirmed by the instructions for Petitioner's product. Although the instructions do not expressly state that the baby should lick or suck the drop from the nipple or pacifier, Patent Owner nevertheless contends that Petitioner's product embodies the challenged claims. *See* PO Resp. 48–49; Ex. 2061, 4 (Mommy's Bliss product instructions); Ex. 2071 (Temovsky Decl.) ¶ 108, Ex. X at page 254.

For the above reasons, we find that Patent Owner's arguments do not undermine Petitioner's showing by a preponderance of the evidence that Harder teaches or suggests the "having said human being suck or lick said composition directly from said object" limitation recited in claim 1.

(2) Whether Petitioner Establishes an Adequate Motivation to Combine

Patent Owner asserts that "a POSITA would not consider Wolf as combinable with Harder and *European Pharmacopeia*," but fails to explain why. PO Resp. 33. In support, Patent Owner cites paragraph 63 of Dr. Reid's Declaration (*see id.*), but that paragraph does not address this issue. Accordingly, Patent Owner's argument fails as we are unable to ascertain any evidentiary basis for the argument.

In its Sur-reply, Patent Owner argues that "Petitioner has not identified why a POSITA would be motivated to combine the three or four references" identified in the Petition's asserted grounds of unpatentability, and that "a POSITA would have to pick and choose parts of voluminous prior art references from disparate fields." Sur-reply 12. We disagree with Patent Owner and find that the Petition adequately and persuasively explains why a person of ordinary skill in the art would have been motivated to combine the cited teachings of the asserted prior art references. *See* Pet. 22–24, 33–34, 35–37; *see also supra* Section II.E.2.a.1 (discussing Petitioner's rationale as to why a person of ordinary skill in the art would have combined Harder, Wolf, and European Pharmacopeia), and *infra* Section II.E.3 (discussing Petitioner's rationale as to a person of ordinary skill in the art would have added Blass).

Patent Owner also argues that it was "blocked from determining whether Petitioner is claiming that a motivation to combine existed." Sur-reply 12. This argument is unavailing: the Petition itself sets forth Petitioner's positions on motivation to combine. *See* Pet. 22–24, 33–34, 35–37. To the extent Patent Owner's argument relates to allegedly improper instructions not to answer during Dr. Williams's deposition, we address that argument below. *See infra* Section II.E.2.d.1.

We find that Patent Owner's arguments do not undermine Petitioner's demonstration of an adequate motivation to combine the references identified in the Petition's asserted grounds of unpatentability.

(3) Whether a Person of Ordinary Skill in the Art Would Have Had a Reasonable Expectation of Success that a Baby Could Lick or Suck a Drop of Vitamin D from a Spoon

Patent Owner argues that "Harder's suggestion is incompetent" because "[a]n infant does not possess the ability to lick anything from surfaces, including spoons." PO Resp. 16–18, 35; *see also id.* at 35 ("an infant could not lick anything from a spoon because the tongue would be depressed below the spoon"), 38 (arguing that Harder "is contrary to scientific fact regarding the inability of infants to lick much less suck on an object such as a spoon"). Patent Owner also argues that "[p]ediatricians advise against inserting any object, such as a spoon, into an infant's mouth." *Id.* at 17–18 (citing Ex. 2068 (Vieth Decl.) ¶¶ 46–52, 60–71, 93, 100, Exs. D, E, F; Ex. 2069 (Horowitz Decl.) ¶¶ 6(h), 7(a); Ex. 2072 (Reid Decl.) ¶¶ 76–81).

According to Patent Owner, "[i]nfants do not and cannot lick a substance off any surface for purposes of feeding," and instead use their "tongue as part of rooting method to find a mother's nipple for suckling." PO Resp. 17. Patent Owner and Dr. Reid further contend that a person of ordinary skill in the art "would have no expectation of success that a baby could lick or suck a spoon, essentially ensuring that the baby could not obtain the full dose of vitamin D because the drop rolls away from the spoon tip and subsequently forms a film." Ex. 2072 (Reid Decl.) ¶ 80; PO Resp. 36.

Patent Owner's arguments are unavailing. First, they are inconsistent with Harder, which indicates that "[u]se of the [Vigantol] oil is simple" and "has proved to be successful over many years." Ex. 1007 (Harder) 5–6.

Second, Patent Owner's argument that an infant cannot lick anything for purposes of ingestion is unavailing. *See* PO Resp. 17; Ex. 2068 (Vieth Decl.) ¶ 50. The record demonstrates that "[a] baby is able to 'lick' in the sense that its tongue sticks out and a caregiver can cause it to make contact with the drop on the spoon to retrieve some of the composition." *See, e.g.*, Reply 15; Ex. 1036 (Horowitz Depo. Tr.) 79:3–10, 81:3–22; Ex. 1028 (Shelov), 11; Ex. 2068 (Vieth Decl.) page 104 (discussing baby breastfeeding sequence, including licking and suckling phases). As Petitioner correctly notes, "[t]he claims do not require removal of any particular amount of the drop." Reply 15; *see also supra* Section II.E.2.b.1.b.

But even assuming *arguendo* an infant cannot lick a substance off a spoon, neither Harder's method nor the claims are limited to infants. *See, e.g.*, Reply 14. Harder's Option 3 is proposed for "the case of ***children*** who are susceptible to allergies," and specifies administering the oil to ***babies***; it is not limited to infants for whom the rooting reflex is still active. *See* Ex. 1007 (Harder) 6 (emphasis added). Additionally, claim 1 is broadly directed to "human being[s]," not just infants. *See* Ex. 1001, 9:43. Although claim 3 narrows the human being to an "infant," the '958 Specification defines "infant" to include "babies and small children," which is much broader than just infants who have an active rooting reflex. *See id.* at 4:1–3. Patent Owner does not argue, and the record does not otherwise indicate, that "small children" would be unable to lick or suck a vitamin D drop off an object such as a spoon, even if the drop rolled away from the tip of the spoon.

In fact, the record demonstrates that babies and small children are able to remove substances from spoons, consistent with Harder's teachings. *See* Reply 14. For example, Patent Owner's pediatrician, Dr. Horowitz, agrees that babies six months of age and older can eat food off a spoon. Ex. 1036 (Horowitz Depo. Tr.) 81:14–22, 83:6–12. Petitioner's pediatrician, Dr. Raj, confirms that "a baby can take the whole spoon into its mouth and suck and/or lick the drop off from" a small plastic spoon. Ex. 1040 (Raj Decl.) ¶ 17. Additionally, "[c]ommon sense" and Ddrops' own ads and product instructions "tell[] us that spoons can be used with infants." *See* Reply 16–18; Ex. 1030, 1 (Baby Ddrops Amazon listing, which markets the product for "Infants" and depicts placement of one drop "[o]nto a clean surface," which is shown as a spoon); Ex. 1032, 1 (Ddrops Baby Tummy Relief Liquid Drops Amazon listing, which markets the product for "Newborns" and states, "[j]ust one drop can be licked off a clean surface, such as a clean spoon"); Ex. 1038 (Temovsky Depo. Tr.) 42:2–43:18, 84:4–85:7, 86:7–87:6 (acknowledging the foregoing product advertisements); Ex. 1041 (Munchkin spoon ad) 1 (depicting feeding baby with spoon).

For these reasons, we reject Patent Owner's arguments that an infant is unable to suck or lick the drop of vitamin D oil from a spoon, such that Harder's method is unfeasible or inoperable or there is a lack of reasonable expectation of success in achieving the claimed subject matter.

(4) Whether Harder and/or Wolf Teach Away

Patent Owner argues that both Harder and Wolf teach away from the claimed invention. *See* PO Resp. 18, 19, 33, 37–38.

As to Harder, Patent Owner points to its "Option 1," which Harder describes as crushing vitamin D tablets in spoonful of water. PO Resp. 18,

37–38; Ex. 1007 (Harder) 5–6. Patent Owner argues that Harder calls Option 1 the "most reliable method for preventing rickets," while Option 3 (the option on which Petitioner relies) is specifically presented only for children susceptible to allergies, and "possesses a higher risk of toxic overdose." PO Resp. 18. According to Patent Owner, "[g]iven the limited alternative-use options and the strict warning concerning Option 3, Harder teaches away from using a single drop." *Id.* at 37.

This argument is unavailing. We agree with Petitioner that "[i]t is of no moment that Harder teaches three additional options, so long as the fourth option is a '*suitable* option from which the prior art did not teach away.'" Reply 9 (quoting *PAR Pharm., Inc. v. TWI Pharms., Inc.*, 773 F.3d 1186, 1197–98 (Fed. Cir. 2014)). Harder does not "criticize, discredit, or otherwise discourage" Option 3, and thus does not teach away. *See id.* (quoting *In re Fulton*, 391 F.3d 1195, 1201 (Fed. Cir. 2004)).

Turning to Wolf, Patent Owner argues that it teaches away because it teaches administering the vitamin D drop with some liquid, such that "there is no single-drop and the composition does not consist of vitamin D and MCT," as recited in claim 1. PO Resp. 19–20, 37–38; Ex. 1009 (Wolf) 7; Ex. 2072 (Reid Decl.) ¶¶ 84–85; Ex. 2068 (Vieth Decl.) ¶¶ 79–83. We agree with Petitioner that Wolf does not teach away, because it does not discredit or discourage administering one drop without liquid; instead, it merely provides an alternative means of administering the dose (i.e., with some liquid). *See* Reply 19. Additionally, Wolf does not undermine Harder's teaching to administer one drop, because "Wolf's teaching is not specific to Vigantol oil but also applies other vitamin D_3 preparations" such as tablets, and because Wolf "pre-dates Harder by several decades." Pet. 14; Reply 19.

In sum, we disagree with Patent Owner that Wolf and Harder teach away from the claimed subject matter.

c) Objective Indicia of Nonobviousness

Notwithstanding what the teachings of the prior art would have suggested to one skilled in the art, objective evidence of nonobviousness (also called "secondary considerations") may demonstrate that the challenged claims would not have been obvious. *See In re Piasecki*, 745 F.2d 1468, 1471–72 (Fed. Cir. 1984). Nevertheless, evidence of secondary considerations does not necessarily control the obviousness conclusion. *See, e.g.*, *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1372 (Fed. Cir. 2007) ("the record establish[ed] such a strong case of obviousness" that allegedly unexpected results were insufficient to overcome obviousness conclusion); *Leapfrog Enters. Inc. v. Fisher-Price Inc.*, 485 F.3d 1157, 1162 (Fed. Cir. 2007) ("given the strength of the prima facie obviousness showing, the evidence on secondary considerations was inadequate to overcome a final conclusion" of obviousness).

Patent Owner argues that there is evidence of copying, long-felt need, industry praise, and commercial success, and that the evidence has a nexus to two commercial products. *See, e.g.*, PO Resp. 46. We address each of these issues below.

(1) Nexus

"For objective evidence of secondary considerations to be accorded substantial weight, its proponent must establish a nexus between the evidence and the merits of the *claimed invention*." *In re Kao*, 639 F.3d 1057, 1068 (Fed. Cir. 2011). We apply a rebuttable presumption of nexus "if the patentee shows that the asserted evidence is tied to a specific product

and that the product *is* the invention disclosed and claimed." *Fox Factory, Inc. v. SRAM, LLC*, 944 F.3d 1366, 1373 (Fed. Cir. 2019). "Conversely, when the thing that is commercially successful is not coextensive with the patented invention—for example, if the patented invention is only a component of a commercially successful machine or process, the patentee is not entitled to a presumption of nexus." *Id.* (citation omitted). Even in the absence of a presumed nexus, a patentee "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.* (citation omitted).

Patent Owner argues that both the Baby Ddrops product (sold by Ddrops Company, Patent Owner's exclusive licensee, *see* Paper 20, 2) and Petitioner's product (Mommy's Bliss Baby Organic Vitamin D Drops, hereinafter "Mommy's Bliss product") embody the challenged claims. PO Resp. 47–49. Petitioner does not dispute that these products embody the claims. *See generally* Reply. We credit Patent Owner's arguments and evidence that these two products embody the claims (i.e., meet the composition and method limitations of the claims). *See* PO Resp. 47–49; Ex. 2071 (Temovsky Decl.) ¶¶ 19, 26–28, 31–34, pages 36–57 (Baby Ddrops product specifications and packaging); Ex. 2022, 190–94 (Mommy's Bliss product certificates of analysis), 229–37 (Mommy's Bliss product specifications); Ex. 2072 (Reid Decl.) ¶ 103; Ex. 2061 (Mommy's Bliss product instructions) 4.

Nevertheless, we find that Patent Owner is not entitled to a presumption of nexus, or alternatively, that Petitioner has rebutted any presumption, because Patent Owner has not demonstrated that the

instructions for these two products are coextensive with the claimed method. *See Volvo Penta of the Americas, LLC v. Brunswick Corp.*, 81 F.4th 1202, 1211 (Fed. Cir. 2023) (noting that a presumption of nexus "requires both that the product embodies the invention and is coextensive with it," and clarifying that these are two separate requirements). The user instructions for both products recite use according to the claimed method (i.e., by placing one drop on a nipple or other surface for a baby to suck off), but also according to unclaimed, prior art methods (i.e., by mixing one drop with milk, juice, or food). *See* Reply 25; Ex. 2071 (Temovsky Decl.) page 52 (Baby Ddrops product instructions); Ex. 2061, 4 (Mommy's Bliss product instructions); *see also* Ex. 1001, 3:8–11 (discussing prior art method of mixing two drops of vitamin D oil into milk or mash); Ex. 2071 (Temovsky Decl.) ¶¶ 43, 45, 47, 49 (explaining that the prior art vitamin D products D-Vi-Sol and Zarbee's were administered by mixing 1 mL or 0.25 mL, respectively, with milk, formula, or food).

In its Sur-reply, Patent Owner acknowledges that "the last line of the product instructions on the [Baby Ddrops and the Mommy's Bliss] products includes a non-infringing use," but argues that this "merely states *an alternative* use, not the primary or preferred use," which "hardly destroy[s] the nexus between the product and the patent claims." Sur-reply 21. We disagree. Patent Owner does not adequately explain why the instruction to mix the products with milk, juice, or food is "not the primary or preferred use." Indeed, the product instructions for both products simply present alternative ways of using the product, without indicating a "primary" or "preferred" use. *See* Ex. 2071 (Temovsky Decl.) page 52 (Baby Ddrops product instructions); Ex. 2061, 4 (Mommy's Bliss product instructions).

We find that the presence of unclaimed, prior art methods on the Baby Ddrops and Mommy's Bliss product labels means that neither "product *is* the invention disclosed and claimed." *Fox Factory*, 944 F.3d at 1373. Thus, we do not accord a presumption of nexus between the claimed method and Baby Ddrops and Mommy's Bliss product instructions.

Nevertheless, even in the absence of a presumed nexus, a patentee "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.* (internal quotations omitted). We turn to an analysis of Patent Owner's evidence, including as applicable whether Patent Owner has established that the evidence of secondary considerations is the direct result of the unique characteristics of the claimed invention.

(2) Copying

Patent Owner argues that Petitioner and others in the industry copied the claimed invention. *See* PO Resp. 49–54. We first address the alleged copying by Petitioner, then by others in the industry (third parties).

(a) Petitioner's Alleged Copying

Patent Owner argues that Petitioner copied the patented elements of the '958 patent and Baby Ddrops in "a two-step process," i.e., by first copying "all aspects of the patented invention in 2016–17 except for the chemical composition," and then by later changing the composition of its product from sunflower oil to MCT, thus arriving at a product "essentially identical to" Baby Ddrops. PO Resp. 50. Patent Owner argues that Petitioner did not address or rebut the copying allegations. Sur-reply 24.

It is undisputed that Petitioner was aware of Baby Ddrops when it began developing the Mommy's Bliss product. *See, e.g.*, PO Resp. 50;

Ex. 2043 (email listing Baby Ddrops among other competitive products); Ex. 2026 (Kaderali Depo. Tr.) 33:15–19; Ex. 2046 (new product development presentation, listing Baby Ddrops among other competitive products) 8–9. It is also undisputed that upon its launch in 2016, the Mommy's Bliss product had user instructions similar to those of Baby Ddrops, but a different composition, in that Baby Ddrops used MCT whereas the Mommy's Bliss product used sunflower oil and contained vitamin E. *See, e.g.*, PO Resp. 50; Ex. 2027 (Medina Depo. Tr.) 51:9–52:23; *compare* Ex. 2060 (Mommy's Bliss ingredients and instructions), *with* Ex. 2071 (Temovsky Decl.) page 52 (Baby Ddrops ingredients and instructions).

It is also undisputed that sometime after the initial product launch, Petitioner changed the glass bottle of the Mommy's Bliss product to a plastic squeeze bottle, but soon discovered that the new bottle caused the product to have stability issues. *See, e.g.*, Ex. 2026 (Kaderali Depo. Tr.) 92:11–23, 140:21–141:23. To rectify the stability problem, in late 2020, Petitioner reformulated its product by changing the sunflower oil vehicle to MCT and excluding vitamin E, which had been used as a preservative for the sunflower oil. *See id.* at 93:3–8; Ex. 2027 (Medina Depo. Tr.) 62:5–63:4; Ex. 2050 (email) 3; Ex. 2071 (Temovsky Decl.) ¶¶ 105–07; Ex. 2060 (Mommy's Bliss packaging showing sunflower oil and vitamin E "to maintain freshness"). The record demonstrates that Petitioner knew at the time it reformulated the Mommy's Bliss product that the Baby Ddrops product was made with MCT. Ex. 2027 (Medina Depo. Tr.) 65:6–66:9; PO Resp. 52.

Patent Owner argues that following this two-step evolution, the Mommy's Bliss product is now the same as Baby Ddrops, and asks us to conclude that Petitioner copied Baby Ddrops. *See, e.g.*, PO Resp. 50–53.

Although it is undisputed that Petitioner had access to Baby Ddrops when it first created and later reformulated the Mommy's Bliss product, neither party timely indicates how Petitioner devised the instructions for the Mommy's Bliss product.[26] Nevertheless, it is undisputed that the instructions are substantially similar to those for Baby Ddrops. Given the Federal Circuit's directive that "[e]vidence of access and substantial similarity *is* evidence of copying," we conclude that Patent Owner has established at least some circumstantial evidence that Petitioner copied the product instructions from the Baby Ddrops product. *Medtronic, Inc. v. Teleflex Innovations SARL*, 70 F.4th 1331, 1340 (Fed. Cir. 2023).

As to the product composition, Patent Owner urges an inference of copying because when Petitioner reformulated its product it was aware that Baby Ddrops was made with MCT. *See* PO Resp. 52 (citing Ex. 2027 (Medina Depo. Tr.) 65:6–66:9). But the same testimony Patent Owner relies on indicates that Petitioner was aware that other competitors used MCT too. *See* Ex. 2027 (Medina Depo. Tr.) 66:10–67:3, 68:15–69:3. As such, we cannot clearly infer that in selecting MCT, Petitioner was attempting to

[26] During the oral hearing, Petitioner's counsel suggested that Petitioner copied the instructions not from Baby Ddrops, but from a manufacturer of its Italian probiotic product. *See* Tr. 56:24–57:12 (citing Paper 96). This argument appears only in Petitioner's Opposition to Patent Owner's Motion to Exclude, not in Petitioner's Reply (Paper 96). Accordingly, this argument is untimely and forfeited. *See* Inst. Dec. 47; Paper 11, 9.

replicate Baby Ddrops, as opposed to one of the other competitive products that contained MCT.

Considering the totality of the evidence, including Petitioner's access to Baby Ddrops, the similarity of the Mommy's Bliss product and Baby Ddrops and their respective instructions, and the fact that other commercially-available vitamin D products using MCT were in the marketplace at the time Petitioner elected to use MCT, we conclude that Patent Owner has established at least some circumstantial evidence that Petitioner copied Baby Ddrops.

(b) Alleged Copying by Third Parties

Patent Owner alleges that Canadian "competitors copied Ddrops' product," and after Ddrops Company commenced patent infringement litigation in Canada, it "obtained judgments and settlements stipulating to the validity, enforceability and infringement of the Canadian patent corresponding to the '958 Patent." PO Resp. 53.

Patent Owner does not persuade us that the Canadian competitors copied the patented subject matter. Patent Owner does not point us to any evidence regarding the details of the Canadian products, let alone any objective evidence that the Canadian companies had access to Ddrops and/or undertook efforts to replicate Baby Ddrops or the claimed subject matter. *See Wyers v. Master Lock Co.*, 616 F.3d 1231, 1246 (Fed. Cir. 2010) ("[C]opying requires evidence of efforts to replicate a specific product, which may be demonstrated through internal company documents, direct evidence such as disassembling a patented prototype, photographing its features, and using the photograph as a blueprint to build a replica, or access

to the patented product combined with substantial similarity to the patented product.").

Patent Owner instead asserts only that the Canadian entities stipulated to infringement. *See* PO Resp. 53; Ex. 2071 (Temovsky Decl.) ¶¶ 86–93. The infringement and copying inquiries, however, are not one and the same. *See Medtronic, Inc.*, 70 F.4th at 1340. As the Federal Circuit has explained, "[n]ot 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*, 616 F.3d at 1246 (quoting *Iron Grip Barbell Co. v. USA Sports, Inc.*, 392 F.3d 1317, 1325 (Fed. Cir. 2004)). Thus, on this record, we find that Patent Owner does not establish copying by the Canadian competitors.

Patent Owner also alleges that its U.S. distributors "had access to the [Baby Ddrops] product and . . . copied it to sell under their own brands." PO Resp. 53. Patent Owner asserts that it commenced patent infringement suits against these distributors, which were quickly settled, with the distributors agreeing to cease sales of the accused products. *Id.*; Ex. 2071 (Temovsky Decl.) ¶¶ 94–101. Patent Owner does not allege that the U.S. distributors stipulated to infringement.

Here too, Patent Owner's arguments and evidence fall short of establishing that the U.S. distributors copied. Patent Owner does not point us to any evidence regarding the details of the U.S. distributors' products, let alone any objective evidence that the companies undertook efforts to replicate Baby Ddrops or the claimed subject matter. *See Wyers*, 616 F.3d at 1246. Thus on this record, we find that Patent Owner has not established by

a preponderance of the evidence that its U.S. distributors copied Baby Ddrops or the claimed subject matter.

In view of the above, we give no weight to Patent Owner's assertions that third parties copied the claimed method.

(3) Long-Felt, Unmet Need

Patent Owner argues that there was "a long-felt but unmet need that had existed for centuries" for a method of "deliver[ing] vitamin D to a human being or an infant, in a form and method that is reliably safe and nutritionally effective, amenable and acceptable to the recipient." PO Resp. 54–55, 57; *see also* Sur-reply 25–26 (citing "the need for a product and method comprising the elements claimed in the '958 Patent to easily and effectively administer vitamin D to humans, particularly infants"). Patent Owner acknowledges that vitamin D supplements existed as of the priority date, but argues that they had "different oils as carriers for vitamin D, different methods of administration," and none "instructed that one drop could be effectively given by placing one drop on an object or a mother's nipple or pacifier." PO Resp. 56 (emphasis omitted) (citing Ex. 2071 (Temovsky Decl.) ¶¶ 35–53); *see also* Ex. 2068 (Vieth Decl.) ¶¶ 19–28; Ex. 2069 (Horowitz Decl.) ¶ 6.

Patent Owner does not persuade us of a long-felt, unmet need that was solved by the claimed invention. *See, e.g.*, *Sjolund v. Musland*, 847 F.2d 1573, 1582 (Fed. Cir. 1988) (holding that a proponent of objective evidence of long-felt need must show that "the *claimed invention* satisfied a long felt need"). To the extent a need existed for a product and method to easily and effectively administer vitamin D to humans, particularly infants, that need was already met prior to the patented invention. *See, e.g.*, Reply 27; *Newell*

Cos. Inc., v. Kenney Mfg. Co., 864 F.2d 757, 768 (Fed. Cir. 1988) ("[O]nce another supplied the key element, there was no long-felt need or, indeed, a problem to be solved . . . ."). Specifically, Harder and Wolf both disclose a method of administering to an infant a precise amount of vitamin D in a small, controlled volume (one drop alone (Harder) or with some liquid (Wolf)) on an object (a spoon).[27] *See* Ex. 1007 (Harder) 6; Ex. 1009 (Wolf) 8; *see also* Ex. 1007 (Harder) 6 (stating that "[Vigantol] oil has proved to be successful over many years"); Ex. 2068 (Vieth Decl.) ¶¶ 75, 77 (confirming that Vigantol is a "particular brand of vitamin D in MCT" available in Europe). Harder even discloses the same oil (MCT) recited in the '958 claims. *See* Ex. 1007 (Harder) 6.

"Where the differences between the prior art and the claimed invention are as minimal as they are here, . . . it cannot be said that any long-felt need was unsolved." *Geo. M. Martin Co. v. All. Mach. Sys. Int'l LLC*, 618 F.3d 1294, 1304 (Fed. Cir. 2018). When addressing long-felt need, Patent Owner does not address Harder or Vigantol at all. *See generally* PO Resp. 54–59; Sur-reply 25–26; *see also* Reply 4 ("Patent Owners' analysis depends on an alternate reality in which Vigantol and Harder were not known.").

For the above reasons, we find that Patent Owner has not established the existence of a long-felt, unmet need that was solved by the claimed invention.

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[27] To the extent Patent Owner argues that Harder and/or Vigantol could not have met the long-felt need because the method is "ineffective" due to infants being unable to lick or use a spoon (*see, e.g.*, Ex. 2069 (Horowitz Decl.) ¶ 6(h); PO Resp. 16–17), we disagree, as further discussed below (*see infra* Sections II.E.2.b.1.c, d and II.E.2.b.3).

(4) Industry Praise

"Industry praise must . . . be linked to the patented invention." *Geo. M. Martin Co.*, 618 F.3d at 1305. Patent Owner relies on praise and awards directed to "the complete Ddrops' product – the undisputed embodiment of the '958 Patent." Sur-reply 27.

The problem with Patent Owner's arguments is that the claims and Baby Ddrops product are not coextensive. As discussed above (*see supra* Section II.E.2.c.1), Baby Ddrops's instructions include unclaimed methods. Thus, below we review the cited praise and awards to ascertain whether Patent Owner demonstrates that they have a nexus to the claimed subject matter.

First, Patent Owner cites two alleged statements from competitors, namely a statement that "You have a nice new technology here. It's really good," and another statement that the competitor "wanted to figure out how to do a product like Ddrops."[28] PO Resp. 60; Ex. 2068 (Vieth Decl.) ¶¶ 54–55. We give no weight to these statements, because they are directed to the product as a whole (which includes instructions for non-infringing uses), and Patent Owner has not demonstrated that these statements were specifically directed to the claimed subject matter.

Additionally, industry praise linked to "element[s] already known in the prior art" or "[un]connect[ed] . . . to the novel elements of the claims"

[28] In its Reply, Petitioner argues that these statements, as well as the statements in paragraph 55 of Mr. Temovsky's Declaration (addressed in the next paragraph), are inadmissible hearsay. *See* Reply 27–28. Petitioner, however, did not move to exclude these statements. Accordingly we do not engage with this argument. *See* 37 C.F.R. § 42.64(c) ("A motion to exclude evidence must be filed to preserve any objection."); TPG 79.

carries little weight in an obviousness analysis. *See, e.g.*, *S. Ala. Med. Sci. Found. v. Gnosis S.P.A.*, 808 F.3d 823, 827 (Fed. Cir. 2015). Here, we agree with Petitioner that Harder teaches that Vigantol oil "provides the claimed dosage of vitamin D in just one drop of an MCT oil," and teaches placing one drop on an object (a spoon), for administration to the baby, as claimed. *See* Reply 25–26. Given the minimal differences between the claimed method and Harder, it is unclear whether the competitors were allegedly praising anything about the claimed subject matter that was not already present in Harder.

Patent Owner next argues that "[c]ustomers and physicians have lauded the patented features of Ddrops' product," as allegedly demonstrated in paragraph 55 and exhibits G and T of Mr. Temovsky's Declaration (Ex. 2071). PO Resp. 60. Paragraph 55 of Mr. Temovsky's Declaration states in relevant part: "Individuals often approach me with success stories regarding the efficacy and ease of use of the Ddrops patented method and product." *Id.* ¶ 55. We accord this statement little weight because it is self-serving, unsupported by objective evidence, and does not elucidate any aspect of the claimed subject matter that these individuals allegedly praised that is not already taught in Harder.

Mr. Temovsky also cites customer reviews presented in Exhibits G and T of his Declaration. *See id.* Exhibits G and T appear to be compilations of emails received by Ddrops, printouts of reviews from Amazon and other online marketplaces, and copies of social media posts. Despite Patent Owner bearing the burden of establishing that the praise is the "direct result of the unique characteristics of the claimed invention," Patent Owner does not point us to any specific alleged praise in these

voluminous exhibits. *Fox Factory*, 944 F.3d at 1373–74 (quoting *In re Huang*, 100 F.3d 135, 140 (Fed. Cir. 1996)). Patent Owner instead points us generally to tens of pages of emails, social media posts, and reviews that praise a variety of claimed, unclaimed, and prior art features. Patent Owner makes no effort to parse through the compilations to specifically direct us to relevant praise. Accordingly, on this record Patent Owner has failed to adequately carry its burden of establishing that customer praise has a nexus to any allegedly unique characteristic of the claimed invention (e.g., not already disclosed by Harder). *See, e.g.*, *DeSilva v. DiLeonardi*, 181 F.3d 865, 867 (7th Cir. 1999) ("A brief must make all arguments accessible to the judges, rather than ask them to play archeologist with the record."); *Ormco Corp. v. Align Tech., Inc.*, 463 F.3d 1299, 1311–12 (Fed. Cir. 2006) ("Evidence of commercial success, or other secondary considerations, is only significant if there is a nexus between the claimed invention and the commercial success."); *see also* Reply 28 ("Patent Owners fail to tie the industry praise to any novel limitation.").

Patent Owner also argues that Baby Ddrops was "used on *The Price is Right* television show" and "became the go-to product for research studies." PO Resp. 60; Ex. 2071 (Temovsky Decl.) ¶¶ 56–61, 68, Exs. H–K, Q. This evidence is not persuasive because, once again, the product itself is not coextensive with the claims, and Patent Owner does not point us to any evidence indicating why the product was selected for the gameshow or research studies, let alone any evidence that it was selected based on praise specific to any aspects of the claimed subject matter that were not already disclosed in the prior art.

Patent Owner also points to a research article where the authors speculated that Baby Ddrops was more popular than D-Vi-Sol[29] due to the ease of use of Baby Ddrops:

> Interestingly 80% of care-givers reported giving their infants D-Drops® versus only 16% who supplemented with D-Vi-Sol. The reason for the popularity of D-Drops® may be their ease of administration requiring only a single drop that can be placed on the mother's breast prior to nursing, versus the need to use a dropper to administer D-Vi-Sol®.

PO Resp. 60–61 (quoting Ex. 2071 (Temovsky Decl.) Ex. R and citing ¶ 69). Given the equivocal nature of the statement ("the popularity of D-Drops® ***may*** be their ease of administration") and lack of detail as to why the authors cite ease of administration versus other differences between D-Drops and D-Vi-Sol, we disagree with Patent Owner that "[t]his is high praise" for the claimed invention. PO Resp. 61. In any event, Harder already disclosed administration of a single drop that avoided the "need to use a dropper." Praise of "element[s] already known in the prior art" carries little weight in an obviousness analysis.[30] *Gnosis S.P.A.*, 808 F.3d at 827.

Finally, Patent Owner points to awards bestowed to Ddrops for the Baby Ddrops product. *See* PO Resp. 61; Ex. 2071 (Temovsky Decl.) ¶¶ 62–

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[29] According to Patent Owner, D-Vi-Sol was the "market-leading" vitamin D product at the time Baby Ddrops was introduced. *See* PO Resp. 56.

[30] Patent Owner does not argue that a novel feature of the claims versus Harder is the identification of a nipple (claim 3) versus a spoon (Harder), but even if Patent Owner were to make such an argument, it would be unavailing. Petitioner asserts, and Patent Owner does not dispute, that during prosecution Dr. Vieth "disclosed . . . a prior art teaching" indicating that "[a] solution in Germany is to put an oral vitamin D preparation on the mother's nipple once a day before the baby breastfeeds." Reply 20 (citing Ex. 2008 (Vieth Decl.) ¶ 14).

66, Exs. L–P. Mr. Temovsky asserts that these "awards occurred because of Ddrops' innovative features—specifically the use of the 1 drop method of administration of Vitamin D to deliver a therapeutic dose." Ex. 2071 (Temovsky Decl.) ¶ 67.

We accord no weight to Mr. Temovsky's assertion that the awards have a nexus to "the 1 drop method of administration of Vitamin D to deliver a therapeutic dose." As an initial matter, Harder discloses such a "1 drop method," and praise of "element[s] already known in the prior art" carries little weight in an obviousness analysis. Ex. 1007 (Harder) 6; *Gnosis S.P.A.*, 808 F.3d at 827. Additionally, Mr. Temovsky's statement is self-serving and not corroborated by citation to objective evidence of record. None of the awards themselves indicate that the "1 drop method" was a factor in bestowing the award. *See* Ex. 2071 (Temovsky Decl.) Exs. L–P.

In sum, we accord Patent Owner's evidence of industry praise no weight.

(5) Commercial Success

"Commercial success is relevant because the law presumes an idea would successfully have been brought to market sooner, in response to market forces, had the idea been obvious to persons skilled in the art." *Merck & Co., Inc. v. Teva Pharm. USA, Inc.*, 395 F.3d 1364, 1376 (Fed. Cir. 2005). "[I]f the feature that creates the commercial success was known in the prior art, the success is not pertinent." *Ormco Corp.*, 463 F.3d at 1312. However, commercial success can be "linked to the inventive combination of known elements." *WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1332 (Fed. Cir. 2016). A patent challenger may rebut evidence of commercial success by showing that the success was due to extraneous factors other than the

patented invention, such as "additional unclaimed features." *Id.* at 1329 (citations omitted).

Patent Owner relies on the alleged commercial success of both Baby Ddrops and the Mommy's Bliss product. We address each product in turn.

(a) Baby Ddrops

Patent Owner argues that since the introduction of Baby Ddrops, it "has grown its sales and market share" in Canada and the U.S., "without significant spending on advertising." PO Resp. 62 (citing, e.g., Ex. 2071 (Temovsky Decl.) ¶¶ 70–78, 83–85, Ex. S). Patent Owner asserts that "this success, based on customer reviews, was due to the patented features of the product and the instructions covering the patented method." *Id.* (citing, e.g., Ex. 2071 (Temovsky Decl.) ¶ 81, Ex. G); *see also* Sur-reply 22–23 (asserting that Patent Owner has presented "strong, undisputed evidence that the Ddrops product experienced huge commercial success due to the unique features claimed in the '958 Patent").

Patent Owner's arguments suffer from the same deficiencies we discussed above regarding praise, namely, that Patent Owner has not adequately demonstrated nexus, given that the claimed method and product instructions are not coextensive. Mr. Temovsky states:

> I attribute the financial successes to the innovation of formula and administration instructions contained in the Ddrops' Patented Product. Ddrops' Patented Product includes only vitamin D3 in MCT oil (fractionated coconut oil) and a hassle-free method of administration of the composition to an infant by applying one drop to an exterior surface of an object, such as a mother's nipple or a clean surface, to allow the drop to be sucked or licked from the object.

Ex. 2071 (Temovsky Decl.) ¶ 81. Here, Mr. Temovsky attempts to tie success to the patented method, but does not indicate a basis for attributing

the success to the claimed method, as opposed to the unclaimed methods recited on the Baby Ddrops label. Additionally, Patent Owner fails to tie the alleged success to something novel in the claims. Mr. Temovsky refers to Baby Ddrops including only vitamin D in MCT and method of applying one drop to an exterior surface of an object, to allow the drop to be sucked or licked from the object. *Id.* As discussed at length above, Harder teaches exactly this subject matter (where the object is a spoon).

Patent Owner and Mr. Temovsky also point to customer reviews, including those quoted in paragraph 83 of Mr. Temovsky's Declaration, and attached as Exhibits G and T to his Declaration. The reviews quoted in paragraph 83 of Mr. Temovsky's Declaration demonstrate the problem with Patent Owner's evidence. The reviews reference both the claimed method (e.g., "Easy for breastfeeding or just put a drop on a pacifier [*sic*]."; "quickly drop some vitamin D on your nip before baby latches on") and unclaimed methods (e.g., adding a drop to a bottle ("he sometimes accidentally does more than one drop and has to start a new bottle") or directly to the baby's mouth ("easy to . . . drop a drop in babies [sic] mouth directly")). Ex. 2071 (Temovsky Decl.) ¶ 83. The customer reviews in Exhibits G and T of Mr. Temovsky's declaration are similarly mixed, in that they reference both claimed methods and non-claimed methods. Again, Patent Owner makes no effort to specifically direct us to relevant praise, distinguish the praise directed to unclaimed and prior art features, or to tie any relevant praise to the alleged commercial success. *See, e.g.*, *DeSilva*, 181 F.3d at 867.

For the above reasons, on this record we find that Patent Owner has failed to adequately carry its burden of establishing that the alleged commercial success of Baby Ddrops is the direct result of any allegedly

unique characteristic of the claimed invention. Accordingly, we accord no weight to Patent Owner's evidence of commercial success of Baby Ddrops.

(b) Mommy's Bliss Product

Patent Owner argues that "[s]imply by copying what Ddrops was doing Petitioner was able to achieve 'significant growth in vitamin D' with its reformulated product," while Ddrops' market share fell. PO Resp. 63–64 (citing Ex. 2026 (Kaderali Depo. Tr.) 121:9–122:9, 123:22–126:16; Ex. 2086[31] (internal business review) 13; Ex. 2053 (internal business review); Ex. 2054 (sales and market share data) 8–9, 12; Ex. 2058 (internal business review) 31; Ex. 2071 (Temovsky Decl.) ¶¶ 79–80, Ex. S). Stated differently, Patent Owner posits that "Petitioner stole Ddrops' commercial success by introducing its knock-off product, experiencing, for the first time since introducing a vitamin D product five years earlier, commercial success attributable to the '958 Patent." Sur-reply 24.

Petitioner responds that "Patent Owners' argument is ***temporally impossible***," because "Ddrops' market share declined in *2020*, not 2021," before Petitioner introduced its alleged "complete" copy of Baby Ddrops (i.e., the Mommy's Bliss product reformulated with MCT). Reply 26 (citing Ex. 2071 (Temovsky Decl.) Ex. S); Ex. 2026 (Kaderali Depo. Tr.) 110:13–111:13 (testifying that Mommy's Bliss product reformulated with MCT launched in the first half of 2021); PO Resp. 52 (acknowledging that Petitioner's "reformulated product was introduced in 2021").

Petitioner also asserts that Patent Owner has not established a nexus between any commercial success of the Mommy's Bliss product and the claimed method. Petitioner points to unclaimed features and differences

[31] Exhibit 2086 is a corrected version of Exhibit 2051.

between the Mommy's Bliss product and Baby Ddrops that allegedly explain the success of the Mommy's Bliss product, including introduction in 2020 of a bottle format that made dispensing easier, positioning in the baby care segment (instead of the vitamin segment, like Baby Ddrops), and the product's organic formulation. Reply 26–27 (citing, e.g., Ex. 1038 (Temovsky Depo. Tr.) 78:20–80:2, 80:13–25, 81:1–5, 82:19–86:3; Ex. 2026 (Kaderali Depo. Tr.) 140:21–142:4). According to Petitioner, "Patent Owners' declarant on secondary considerations, Dr. Reid, failed to consider the impact of these unpatented properties in his analysis." *Id.* at 27 (citing Ex. 1037 (Reid Depo. Tr.) 71:6–73:9).

In its Sur-reply, Patent Owner maintains that "Ddrops' market share declined substantially in 2021 after Petitioner introduced its copy-cat product," while Petitioner's market share climbed. Sur-reply 23. Patent Owner discounts the bottle design, because "in its post-copying marketing and sales materials," Petitioner allegedly did not promote the bottle, and instead only promoted only the change from sunflower oil to MCT. *Id.* (citing, e.g., Ex. 2026 (Kaderali Depo. Tr.) 122:24–123:6, 144:23–145:12; Ex. 2027 (Medina Depo. Tr.) 81:9–12); *see also* Ex. 2062 (website printout) 1). Patent Owner also argues that "[d]espite selling an organic product for five years (since 2016), Petitioner's market share vis-à-vis Ddrops' product was lower – until it copied the MCT formula." Sur-reply 23.

The record shows that Ddrops' market share declined from 27% in 2019, to 17% in 2020, to 16% in 2021. *See* Ex. 2071 (Temovsky Decl.) Ex. S. Patent Owner asks us to attribute this decline to Petitioner "stealing" Ddrops' market share by introducing a "copy-cat product." *See* PO Resp.

63–64. This argument is unavailing, because the Mommy's Bliss product reformulated with MCT was launched in 2021, *after* Ddrops had already lost significant market share from 2019 to 2020. *See* Reply 26; Ex. 2026 (Kaderali Depo. Tr.) 110:13–111:13; PO Resp. 52. We agree with Petitioner that Patent Owner's theory that Petitioner "stole" Ddrops' market share is temporally impossible. Reply 26.

Separately, however, the record does demonstrate that market share for the Mommy's Bliss product increased after it launched the reformulated product. *See, e.g.*, Ex. 2054 (sales and market share data) 9 (showing market share increase for the Mommy's Bliss product over 2021); Ex. 2026 (Kaderali Depo. Tr.) 123:22–125:17 (discussing same). Patent Owner asks us to infer that this market share increase is tied to the claimed subject matter, because this success allegedly occurred only after Petitioner "completed" its copy of Baby Ddrops. *See, e.g.*, PO Resp. 63 ("Simply by copying what Ddrops was doing Petitioner was able to achieve 'significant growth in vitamin D' with its reformulated product.").

Such a conclusion, however, requires findings that the success of Baby Ddrops in the first place was due to the claimed method, and thus the success of the alleged "copycat" product was successful for the same reason. As discussed in the previous section, Patent Owner has not demonstrated a nexus between any success of Baby Ddrops and the claimed method. Nor has Patent Owner otherwise carried its burden of establishing that the commercial success of the reformulated Mommy's Bliss product is the direct result of any allegedly unique characteristic of the claimed invention.

For completeness, we note that Petitioner also has not persuaded us that the increased success of the reformulated product was due to the bottle

format or other unclaimed features. Petitioner merely speculates that these factors drove product sales. *See* Reply 26. On this record, the reasons for the increased market share for the Mommy's Bliss product following its reformulation remain unclear.

For the above reasons, we accord no weight to Patent Owner's evidence of commercial success of the Mommy's Bliss product.

(6) Summary of Objective Indicia Findings

As discussed above, we give no weight to Patent Owner's arguments that third parties copied Baby Drops, or that Baby Drops or the claimed subject matter satisfied a long-felt, unmet need. Additionally, we give no weight to Patent Owner's arguments regarding industry praise and commercial success, because Patent Owner has not demonstrated a nexus between any praise or commercial success and the claimed subject matter. We give some weight to Patent Owner's evidence that Petitioner copied Baby Ddrops, which we consider as part of the totality of the evidence further discussed below.

d) Parties' Arguments Regarding Declarants

Both parties argue reasons why we should accord testimony from the other side's declarants little weight.[32] Before making our conclusion on obviousness of the challenged claims, we analyze these arguments below.

(1) Patent Owner's Arguments Regarding Dr. Williams

Patent Owner asks that we "give little weight" to Dr. Williams's opinions, because "Petitioner's counsel provided him with the prior art

[32] The parties also each moved to exclude some declarant testimony. Below, we separately address the parties' motions to exclude. *See infra* Section III.

references and asserted combinations and even wrote the first draft" of his declaration. PO Resp. 1–2; *see also id.* at 23–27; Sur-reply 16–18. We decline to do so, in view of Dr. Williams's confirmations that the draft declaration he received from counsel was "based on his conversations, his opinions, and his thoughts on the prior art," "he made revisions" to the draft, and "the declaration accurately reflects his opinions, and that he would not have signed it otherwise." Reply 23; Ex. 2025 (Williams Depo. Tr.) 30:3–31:8 ("that first draft was provided by Fish based on my opinions and discussions"), 33:10–13 (explaining that he revised the draft), 167:20–168:25.

Patent Owner next takes issue with Dr. Williams's deposition, arguing that Petitioner's counsel instructed Dr. Williams "not to answer essential questions based on bogus claims of privilege." PO Resp. 24; *see also* Sur-reply 17–18. Petitioner responds that Patent Owner's questions "were framed to invade the work product privilege or unfairly smear Dr. Williams if that effort was blocked." Reply 23–24. We decline to discount Dr. Williams's testimony based on counsel's objections made during his deposition. Patent Owner did not approach the Board during or shortly after the deposition to address any concern about the deposition, depriving us of the opportunity to evaluate the propriety of the complained-about objections. *See* Reply 24 ("Patent Owner did not consult the Board or raise any other form of complaint prior to presenting it in the Response."). We decline to try and discern the propriety of the objections based on the parties' volley of accusations in the Response, Reply, and Sur-reply.

Patent Owner also argues that we should discount Dr. Williams's testimony because his "answers reveal significant fundamental deficiencies,"

including that he did not review the Petition or Institution Decision, did not know "the number of licks an infant would have to make to receive a nutritionally-sufficient dose of vitamin D from a spoon or surface," and "did not consider any secondary indicia of non-obviousness in reaching his opinions." PO Resp. 25–26, 45.

Patent Owner makes no persuasive argument as to why Dr. Williams should have reviewed the Petition or the Institution Decision (which post-dates his Declaration). Patent Owner also does not persuade us that it was important for Dr. Williams to know how many licks an infant would have to make to receive a nutritionally-sufficient dose of vitamin D from a spoon or surface, because as discussed above, the claimed method does not require receipt of a nutritionally-sufficient dose of vitamin D. Patent Owner also does not persuade us to discount Dr. Williams's testimony because he did not consider the secondary indicia of nonobviousness that Patent Owner developed in the record *after* Dr. Williams submitted his declaration. Although secondary indicia must be considered before the fact-finder makes a determination on obviousness, it is the panel, not Dr. Williams, who is making the ultimate determination on obviousness. *See, e.g.*, *In re Reuter*, 670 F.2d 1015, 1023 (CCPA 1981) (expert's opinion on ultimate legal issue entitled to no weight).

In sum, we are not persuaded to discount Dr. Williams's testimony. In any event, even if we were to wholesale discount it, our findings and conclusions would remain the same. As the Federal Circuit has recognized, "some cases involve technologies and prior art that are simple enough that no expert testimony is needed." *Intercontinental Great Brands LLC*, 869 F.3d at 1348. We find this to be such a case. Harder, for example, teaches a

clear, straightforward method, and the similarities between Harder and the claims are apparent, even without Dr. Williams's testimony.

We further address Patent Owner's complaints about Dr. Williams's testimony below. *See infra* Section III.B.2.

(2) Patent Owner's Arguments Regarding Dr. Raj

Patent Owner argues a litany of reasons why Dr. Raj is allegedly "unqualified to opine here," including because "[s]he is a neonatologist specializing in the circulation in the lung;" "[s]he has never testified as an expert witness in a patent action;" and is not a linguist or German-speaker. Sur-reply 18. Patent Owner also argues that Dr. Raj's opinion of "how a pediatrician at some time in the 2000s might read" Harder "is worthless" because a pediatrician is not a person of ordinary skill in the art, and that "her 'test' of some post-critical date random plastic spoons should be disregarded." *Id.* at 18, 19.

Patent Owner does not convince us to "ignore" or discount Dr. Raj's opinions based on her credentials and experience. Sur-reply 16. Her specialization in lung circulation, lack of experience in patent actions, and lack of German language or linguistic skills are not relevant to her opinions here. Rather, we find that Dr. Raj, a pediatrician and mother who has worked with "hundreds of mothers," is well-qualified to respond to Dr. Reid's spoon test and to Patent Owner's arguments that spoons cannot be used with infants and an infant cannot remove a drop of oil from a spoon. *See, e.g.*, Ex. 2081 (Raj Depo. Tr.) 15:21–25, 90:9–91:11, 130:8–18. We further address Patent Owner's complaints about Dr. Raj's testimony below. *See infra* Section III.B.1.

(3) Petitioner's Arguments Regarding Drs. Reid, Horowitz, and Vieth

Petitioner argues that Dr. Reid "is a patent attorney, not a POSITA," and thus "[h]is opinions on the claims should be given no weight." Reply 21. Petitioner's argument is moot, because we do not rely on Dr. Reid's opinions to construe any claim term or the scope of the challenged claims.

Petitioner also argues that Dr. Horowitz "is not a POSITA," and thus his opinions on claim construction and patentability should be given no weight. Reply 22. Petitioner does not explain why Dr. Horowitz is not qualified as a person of ordinary skill in the art (e.g., by comparing his experience and credentials to those recited in the level of skill in the art we use herein). In any event, Petitioner's argument regarding claim construction is moot, because we do not rely on Dr. Horowitz's opinions (if any) to construe any claim term or the scope of the challenged claims. To the extent we rely on Dr. Horowitz's opinions herein, we find that Dr. Horowitz, a pediatrician, is qualified to opine on those topics (such as whether babies can be fed with a spoon and whether there was a long-felt need for the claimed method of using a particular vitamin D supplement). *See, e.g.*, Ex. 2069 (Horowitz Decl.) ¶ 4(a)–(c). Thus, Petitioner does not convince us to discount Dr. Horowitz's opinions based on his credentials and experience.

Petitioner also suggests that Drs. Horowitz and Vieth are biased because they profit from the sale of Ddrops products. Reply 21–22; *see also* Sur-reply 16 (acknowledging that Drs. Horowitz and Vieth profit from such sales). Drs. Horowitz and Vieth presented testimony under oath and Petitioner cross-examined them, which are both mechanisms to guard

against deceptive testimony. Based on the totality of the record, we are not persuaded to discount their testimony because it is allegedly tainted by financial bias.

Petitioner also argues that we should discount Dr. Vieth's testimony as lacking creditability. Reply 22. In support, Petitioner argues that although Dr. Vieth testified that he "never used 'Vigantol' oil in connection with the research or preparation of the inventions claimed in the '958 Patent," his lab notebook shows that he effectively sought to recreate the properties of Vigantol oil. *Id.* (quoting Ex. 2008 (Vieth Decl.) ¶ 10). Petitioner does not persuade us of an inconsistency between Dr. Vieth's testimony and his research, because Petitioner has not demonstrated that using Vigantol and seeking to recreate an oil having its properties are one and the same.

e) Conclusion on Alleged Obviousness of Claims 1 and 5 Over Harder, Wolf, and European Pharmacopoeia

In making our determination on obviousness, we consider the totality of the arguments and evidence of record, including the teachings of the combined references in relation to secondary considerations. *See Volvo Penta of the Americas, LLC v. Brunswick Corp.*, 81 F.4th 1202, 1215–16 (Fed. Cir. 2023).

Petitioner's showing on obviousness is very strong. We ascertain no significant differences between the claimed subject matter and the cited prior art. *See Graham*, 383 U.S. at 17–18. As discussed above, Petitioner demonstrates by a preponderance of the evidence that Harder teaches or suggests most, if not all, of the limitations of claim 1, including application of one drop of vitamin D in MCT oil to the exterior surface of an object for an infant to suck or lick off, with Wolf and European Pharmacopeia

specifying details about the dosage in one drop and the carbon chain length of MCT oil. *See supra* Section II.E.2.a, b. Harder also suggests that the drop of vitamin D "adheres" to a spoon, and the Specification confirms that the MCT oil described in Harder will inherently adhere to the surface of an object. *See supra* Sections II.E.2.a.1, II.E.2.b.1.c.

For the reasons explained above, we assign the evidence of long-felt but unsolved need, industry praise, and commercial success no weight. *See supra* Section II.E.2.c. Although Patent Owner shows that Petitioner had access to Baby Ddrops and its own product is substantially similar to Baby Ddrops—which is some indication that Petitioner may have copied Baby Ddrops—in the absence of more compelling objective indicia of other secondary considerations (which we do not find on this record), a showing of copying is only equivocal evidence of nonobviousness. Specifically, to illuminate whether copying in a particular context actually indicates nonobviousness of the merits of the invention, the Federal Circuit has looked for other facts, typically the presence of significant other objective indicia already having such a nexus. *See Ecolochem Inc. v. S. Cal. Edison Co.*, 227 F.3d 1361, 1380 (Fed. Cir. 2000) ("[A] showing of copying is only equivocal evidence of non-obviousness in the absence of more compelling objective indicia of other secondary considerations."); *Cable Elec. Prods., Inc. v. Genmark, Inc.*, 770 F.2d 1015, 1028 (Fed. Cir. 1985) (overruled on other grounds) (explaining why copying does not necessarily demonstrate nonobviousness).

As discussed above, Patent Owner shows that Petitioner had access to the patented Baby Ddrops product, and shows that Petitioner's product is substantially similar to Baby Ddrops, but does not address how Petitioner

arrived at the product instructions, nor does it show by a preponderance of the evidence that Petitioner intentionally copied the oil used in Baby Drops (which was also used in other competitive products). Thus, Patent Owner's evidence of copying is weak.

Nevertheless, even if we assume that Petitioner copied Baby Ddrops, we find that the record as a whole does not demonstrate nonobviousness. Where (as here), the claimed subject matter represents "no more than 'the predictable use of prior art elements according to their established functions,' the secondary considerations are inadequate to establish nonobviousness as a matter of law." *Wyers v. Master Lock Co.*, 616 F.3d 1231, 1246 (Fed. Cir. 2010) (quoting *KSR*, 550 U.S. at 417); *see also Anderson's–Black Rock, Inc. v. Pavement Salvage Co.*, 396 U.S. 57, 61 (1969) (considering secondary considerations but holding that "those matters without invention will not make patentability"); *Agrizap, Inc. v. Woodstream Corp.*, 520 F.3d 1337, 1344 (Fed. Cir. 2008) ("In this case, the objective evidence of nonobviousness simply cannot overcome such a strong prima facie case of obviousness.").

On balance, considering the complete record before us, Petitioner's strong evidence of obviousness—which is based in part on Harder and Wolf, references the Examiner did not consider during prosecution—substantially outweighs Patent Owner's evidence of nonobviousness. Therefore, we determine that Petitioner has established, by a preponderance of the evidence, that claims 1 and 5 of the '958 patent would have been obvious to one of ordinary skill in the art at of the time of the invention based on the combination of Harder, Wolf, and European Pharmacopeia.

3. *Alleged Obviousness of Claim 3 Over Harder, Wolf, European Pharmacopoeia, and Blass*

Claim 3 depends from claim 1 and further recites: "wherein said human being is an infant and said object is a woman's nipple or the external surface of a pacifier." Ex. 1001, 9:48–50.

We find that Petitioner has demonstrated by a preponderance of the evidence that it was "known that an infant could suck medicine or a supplement off of a pacifier." Pet. 34. In particular, Petitioner has demonstrated that Blass describes delivering a substance to an infant's mouth by applying it to a pacifier. *Id.* at 34–35; Ex. 1004 (Williams Decl.) ¶¶ 66–70; Ex. 1011 (Blass) 7–8. Petitioner also demonstrates that a person of ordinary skill in the art would have looked to Blass to improve Harder's method:

> It would have been obvious to improve the method of Harder by applying the drop to a pacifier instead of to the tip of the spoon, because a POSITA would recognize, as a matter of common sense and human experience, that the spoon disclosed in Harder is not a natural surface for an infant, in contrast with a nipple or nipple-like shape, and may sometimes inhibit an effective delivery if the infant refuses to suck. . . . A POSITA would [have] be[en] motivated to use a surface, such as a pacifier, that would more likely trigger the sucking reflex to ensure delivery of the complete dose applied to the surface.

Ex. 1004 (Williams Decl.) ¶ 106; *see also id.* ¶¶ 85–87; Pet. 33–35; Ex. 2081 (Raj Depo. Tr.) 38:11–13 ("all babies have a very strong suck reflex"); Ex. 2069 (Horowitz Decl.) ¶ 6(h) (noting "natural suckle action" upon "latching onto the nipple"). Accordingly, we find that Petitioner has demonstrated by a preponderance of the evidence that a person of ordinary skill in the art would have been motivated to improve Harder's method by replacing the spoon with a pacifier, because they would have known that a

pacifier is more likely to trigger the sucking reflex than a spoon, thus better ensuring delivery of the complete vitamin D drop that Harder teaches to administer to the infant.

Patent Owner argues that Blass "has nothing to say about delivering medication" or liquids, let alone "delivery of a certain dose."[33] PO Resp. 40 (citing, e.g., Ex. 2072 (Reid Decl.) ¶¶ 88, 91; Ex. 2068 (Vieth Decl.) ¶¶ 84, 96). Patent Owner contrasts Harder's warning about the risk of overdose of Vigantol with "the comparatively haphazard pacifier-dipping methodology of Blass," and concludes that "a POSITA would not have looked to Blass for suggesting an alternative method of delivering a medicament, such as Vigantol®." *Id.* at 41 (citing Ex. 2072 (Reid Decl.) ¶ 91). Patent Owner also argues that a person of ordinary skill in the art would have had no reason to combine Harder and Wolf with Blass because Harder and Wolf are concerned with the prevention of rickets, whereas Blass "is unconcerned with rickets or any other medical indication, medicaments, or their delivery to infants." *Id.* at 41, 42; Ex. 2072 (Reid Decl.) ¶ 94.

These arguments are unavailing. Each of Harder, Wolf, and Blass are concerned with delivery of a substance into a baby's mouth via an object (vitamin D oil via spoon in Harder and Wolf; sucrose solution via pacifier in Blass). We see no reason why the identity of the substance (a medicament in Harder and Wolf; an analgesia-inducing agent in Blass) matters; what matters is the conveyance of a substance into a baby's mouth via a suitable

[33] For the first time in Sur-reply, Patent Owner argues that Blass "is in an entirely different field – pain management." Sur-reply 12–13. Patent Owner did not address Blass's field in its Patent Owner Response, and thus has forfeited any argument that Blass is non-analogous art because it allegedly is in a different field of endeavor. *See* Inst. Dec. 47; Paper 11, 9.

surface. We agree with Petitioner that Blass would have motivated a person of ordinary skill in the art to use a pacifier, because Blass teaches that a pacifier is an effective surface to trigger a sucking reflex. Pet. 34.

Patent Owner argues that Blass "does not satisfy the adhere limitation because the sugar water used in Blass would not adhere to a pacifier." PO Resp. 42. This argument is unavailing because Petitioner relies on Harder, not Blass, to meet the "adheres" limitation. *See* Pet. 34, 29–31 (addressing limitation 1[e] ("wherein said drop adheres to the surface of said object")).

Patent Owner and Dr. Reid also appear to suggest that because Harder describes the spoon method as "simple," a person of ordinary skill in the art would not have needed to improve Harder's method by using a pacifier. *See* PO Resp. 41–42; Ex. 2072 (Reid Decl.) ¶ 94. This argument is unavailing. Even though Harder's method is "simple," Petitioner adequately establishes that a person of ordinary skill in the art would have understood from Blass that a pacifier could improve it. Reply 19–20; Pet. 34. Indeed, Patent Owner's declarant Dr. Horowitz agreed that a person of ordinary skill in the art would have known "that a baby is more likely to suck on a pacifier than off of a spoon." Ex. 1036 (Horowitz Depo. Tr.) 113:1–9; *see also id.*, 14:12–23; Reply 19–20. As Petitioner establishes, "Dr. Horowitz even testified that a POSITA would have 'explore[d] other options to using a spoon,'" and pacifiers were known to be a "reasonable" alternative to a mother's nipple. *See* Reply 19–20; Ex. 1036 (Horowitz Depo. Tr.) 111:16–23; Ex. 1039 (Vieth Depo. Tr.) 83:14–23. For the above reasons, we find that Patent Owner's arguments do not undermine Petitioner's demonstration of an adequate motivation to combine Harder, Wolf, and Blass.

Finally, Patent Owner argues that "Blass was carefully considered by the examiner during prosecution," which is "strong evidence that Blass in combination with other references does not suggest the limitations of claim 3." PO Resp. 42–43 (citing Ex. 1002 (prosecution history) 28, 60–66); *see also id.* at 22. We disagree, because the Examiner did not consider at least Harder and Wolf, nor did the Examiner have the benefit of the record we have before us. *See, e.g.*, Pet. 11, 13, 40–41.

For the reasons discussed above, and taking into account all of the arguments and cited evidence of record (including Patent Owner's arguments regarding objective indicia of nonobviousness), we conclude that Petitioner has demonstrated by a preponderance of the evidence that claim 3 of the '958 patent is unpatentable as obvious over Harder, Wolf, European Pharmacopoeia, and Blass.

4. *Alleged Obviousness of Claim 4 Over Harder, Wolf, European Pharmacopoeia, and Gartner*

Claim 4 depends from claim 1 and narrows the dose of vitamin D in the claimed composition to "150 to 450 mcg/ml vitamin D." Ex. 1001, 10:1–3. Petitioner argues that Wolf, published in 1970, taught daily doses of vitamin D of 400 and 500 I.U., but Gartner, published in 2003, teaches "a lowered daily dosage of 200 I.U. of vitamin D." Pet. 35–37 (citing, *e.g.*, Ex. 1009 (Wolf) 6, 9; Ex. 1004 (Williams Decl.) ¶¶ 89–90; Ex. 1012 (Gartner) 3). Petitioner argues that "ongoing studies can result in changes in recommended dosages of vitamin D supplements," and Gartner would have motivated a person of ordinary skill in the art to administer a dosage of 200 I.U. of vitamin D, based on the updated dosage recommendations. Pet. 36, 37; Ex. 1004 (Williams Decl.) ¶¶ 88–93, 107–10. We are persuaded by Petitioner's arguments.

Patent Owner reiterates the arguments it made for claims 1 and 5. PO Resp. 43–44 (citing Ex. 2072 (Reid Decl.) ¶¶ 95–97; Ex. 2068 (Vieth Decl.) ¶ 97). We addressed those arguments above. *See supra* Section II.E.1, 2. Patent Owner also argues that Gartner does not disclose how a vitamin D supplement "should be delivered and does not disclose any mechanism for reliably delivering the proper dose of vitamin D to a human being." PO Resp. 44 (citing Ex. 2072 (Reid Decl.) ¶¶ 95–97; Ex. 2068 (Vieth Decl.) ¶ 97). These arguments are unavailing because Petitioner relies on Harder and Wolf, not Gartner, to meet the claim limitations directed to administering the dose. *See, e.g.*, Pet. 25–31.

For the reasons discussed above, and taking into account all of the arguments and cited evidence of record (including Patent Owner's arguments regarding objective indicia of nonobviousness), we conclude that Petitioner has demonstrated by a preponderance of the evidence that claim 4 of the '958 patent is unpatentable as obvious over Harder, Wolf, European Pharmacopoeia, and Gartner.

III. MOTIONS TO EXCLUDE

A. Petitioner's Motion to Exclude (Paper 94)

Petitioner filed a motion to exclude certain evidence submitted by Patent Owner. Paper 94 ("Pet. MTE"). Patent Owner opposes the motion. Paper 97 ("PO MTE Opp."). Petitioner filed a Reply in further support of its motion. Paper 98 ("Pet. MTE Reply").

Below we address each of the materials Petitioner seeks to exclude.

1. *Portions of the Temovsky Declaration (Ex. 2071)*

Petitioner seeks to exclude various portions of the Temovsky Declaration, as follows.

a) Paragraphs 67, 80–84

Petitioner requests that we exclude paragraphs 67 and 80–84 of the Temovsky Declaration (Ex. 2071) under Federal Rules of Evidence ("FRE") 602 (Need for Personal Knowledge) and 701 (Opinion Testimony by Lay Witnesses), because these paragraphs allegedly include "testimony for which the declarant lacks foundation to opine on the basis of Ddrops' praise or Mommy's Bliss' success." Pet. MTE 1–2. According to Petitioner, these paragraphs include Mr. Temovsky's opinions that Baby Ddrops won awards and achieved financial success due to its composition and "1 drop method of administration," and that Ddrops' market share decreased due to Mommy's Bliss changing its product composition. *Id.* at 2. Petitioner asserts that "[t]hese paragraphs contain opinion testimony from a lay person that is not rationally based upon first-hand knowledge or observation." *Id.* Petitioner also asserts that "Mr. Temovsky is not testifying about general matters within his knowledge, experience, and perception," but rather he provides "impermissible biased opinions" that are allegedly contradicted by other evidence of record. *Id.*; Pet. MTE Reply 2.

Patent Owner responds by pointing out, among other things, that Mr. Temovsky has been the co-president of Ddrops since 2008; he was personally involved with applying for the awards about which he testifies; and he has personal knowledge of Ddrops' market share information. *See* PO MTE Opp. 2, 3–4 (citing Ex. 1038 (Temovsky Depo. Tr.) 63:25–64:5, 64:14–66:15, 70:9–73:23; 132:19–135:13).

We agree with Patent Owner that Mr. Temovsky's declaration and testimony "establish that his evidence and opinions are based on his years of experience in the industry; his years as co-president of Ddrops primarily

responsible for sales and marketing; and his personal involvement with the process of applying for and receiving the industry awards." PO MTE Opp. 5. Regarding Petitioner's argument that Mr. Temovsky's opinions are allegedly contradicted by other evidence of record, that goes to the weight to be accorded his testimony, not its admissibility. Accordingly, we deny Petitioner's request to exclude paragraphs 67 and 80–84 of the Temovsky Declaration (Ex. 2071) under FRE 602 and 701.

b) Paragraph 69 and Exhibit R

Petitioner requests that we exclude paragraph 69 and Exhibit R of Mr. Temovsky's declaration under FRE 802 (Rule Against Hearsay) "because they contain a statement in an article made outside of this proceeding that is relied upon for the truth of the matter asserted." Pet. MTE 3. According to Petitioner, the statement is "speculation by the authors of a journal article made outside this proceeding as to a suspected 'reason for the popularity of Ddrops,'" and no hearsay exception applies. *Id.*

Patent Owner argues that "[u]nder Rule 803(18), a statement contained in a journal is admissible if it is established as a reliable authority." PO MTE Opp. 6. Patent Owner further argues that Dr. Vieth, "an expert in the field, established the reliability and authoritativeness of the article." *Id.* (citing Ex. 1039 (Vieth Depo. Tr.) 152:1–13, 153:4–19). Patent Owner also argues that "[t]he exception in Rule 803(3)" applies, because the statement "is being offered to show the state of mind of the authors, not for the truth of the matter asserted." PO MTE Opp. 8.

Petitioner responds that Rule 803(18) does not apply, because "Mr. Temovsky is not a qualified scientific expert that can explain the article under Rule 803(18)," and Patent Owner "cannot admit the statements

through Dr. Vieth," because he "did not rely on the article in his direct examination." Pet. MTE Reply 3. Petitioner does not respond to Patent Owner's argument based on the state of mind exception in Rule 803(3).

Contrary to Petitioner's suggestion, we do not find that the statement in the journal article is offered for the truth of the matter asserted therein (i.e., "[t]he reason for the popularity of D-Drops"). *See* Ex. 2071 (Temovsky Decl.) Ex. R at 6–7. Rather, we find that Patent Owner offers the statement in an effort to show that third parties have praised "the patented features of the '958 Patent." PO Resp. 61. For this reason, we deny Petitioner's request to exclude paragraph 69 and Exhibit R of Mr. Temovsky's declaration as impermissible hearsay.

c) Paragraphs 46, 83, and Exhibits G and T

Petitioner requests that we exclude paragraphs 46 and 83 and Exhibits G and T of Mr. Temovsky's declaration under FRE 802 (Rule Against Hearsay) because these items "contain customer reviews that are offered for the truth of the matter asserted," and for which no hearsay exception applies. Pet. MTE 4.

Patent Owner argues that "[u]nder Fed. R. Evid. 803(3), the state of mind exception to the hearsay rule, statements by consumers are admissible and are not hearsay." PO MTE Opp. 7 (citing *Lincare Holdings Inc. v. Doxo, Inc.*, 2024 WL 865881, at *2 (M.D. Fla. Feb. 29, 2024) ("[C]ustomers' statements to Plaintiffs' customer representatives are not hearsay or are subject to the state of mind exception to hearsay."); *You Fit, Inc. v. Pleasanton Fitness, LLC*, 2013 WL 521784, at *5 n.13 (M.D. Fla. Feb. 11, 2013) (consumer postings on Yelp.com are not hearsay, but rather "demonstrate the consumer's confusion, a then-existing mental state");

Discover Fin. Servs. v. Visa U.S.A. Inc., 2008 WL 4560707, at *4–5 (SDNY Oct. 9, 2008) ("[T]estimony concerning the motivation of customers for ceasing to deal with a business is admissible under the 'state of mind' exception to the hearsay rule . . . , rule 803(3), of the federal rules of evidence, provided that there is otherwise admissible proof that business was lost.")). Patent Owner argues that the statements are not being offered to prove the truth of the matter asserted, but rather "are being offered to prove the then-existing state of mind of the declarant." PO Resp. 26.

Petitioner responds that the "customer reviews do not fall under the then-existing state of mind exception of FRE 803(3)" because they do not reflect a motivation (i.e., a reason for purchase), but rather reflect hearsay from observations post-purchase. Pet. MTE Reply 3. Petitioner argues that Patent Owner has not laid the foundation that the reviewing customers purchased Baby Ddrops. *Id.* at 4.

We do not rely on paragraph 46 of Mr. Temovsky's declaration. Accordingly, we dismiss Petitioner's request to exclude this paragraph as moot. *See* TPG 79–80 ("[C]onsideration of the objected-to evidence is often unnecessary to resolve the patentability of the challenged claims, and the motion to exclude is moot.").

We do not find that the quotes from customer reviews cited in paragraph 83 and appearing in Exhibits G and T are offered for the truth of the statements expressed in the reviews. Rather, Patent Owner cites them in an attempt to show that customers have praised the patented method. *See, e.g.*, PO Resp. 60, 62. For this reason, we deny Petitioner's request to exclude paragraph 83 and Exhibits G and T of Mr. Temovsky's declaration as impermissible hearsay.

2. *Portions of the Reid Declaration (Ex. 2072)*

Petitioner argues that we should exclude paragraphs 106–116 of Dr. Reid's declaration "under FRE 702 because Dr. Reid does not meet the qualifications for this expert testimony." Pet. MTE 4. Specifically, Petitioner argues that in paragraphs 106–116, Dr. Reid presents a chronology of product development and market share positioning of Baby Ddrops and Petitioner's vitamin D product and opines on alleged copying, but Dr. Reid is "not an economist or industry expert," and as a chemist, he "is only qualified to opine on the characteristics of the product compositions, not their impact in the marketplace." *Id.* at 5.

Patent Owner responds that given Dr. Reid's years of experience in the pharmaceutical field "coupled with what he learned about the vitamin D market through his extensive work in this case, he clearly is qualified to opine beyond 'the characteristics of the product compositions.'" PO MTE Opp. 10 (quoting Pet. MTE 5); *see also id.* (noting that Dr. Reid spent over 230 hours working on this matter, citing Ex. 1037 (Reid Depo. Tr.) 12:8–15). Patent Owner also asserts that "the information at issue here is not so complex that one would need a degree in economics to understand it." *Id.* at 11.

We do not rely on paragraphs 106–116 of Dr. Reid's declaration (including because the opinions in these paragraphs are duplicative of Patent Owner's other arguments and cited evidence on copying and commercial success already discussed herein,[34] and because Patent Owner does not

[34] For example, in paragraphs 106–116, Dr. Reid sets forth a "chronology of product development at MOM" and alleges commercial success of Baby Ddrops, citing, *e.g.*, testimony from Ms. Kaderali, Ms. Medina, MOM

appear to cite paragraphs 112–116 in its briefs). Accordingly, we dismiss Petitioner's request to exclude these paragraphs as moot. *See* TPG 79–80.

B. Patent Owner's Motion to Exclude (Paper 95)

Patent Owner filed a motion to exclude certain evidence submitted by Petitioner. Paper 95 ("PO MTE"). Petitioner opposes the motion. Paper 96 ("Pet. MTE Opp."). Patent Owner filed a Reply in further support of its motion. Paper 99 ("PO MTE Reply").

Below we address each of the materials Patent Owner seeks to exclude.

1. *Raj Declaration (Ex. 1040)*

Patent Owner argues that we should exclude "[Dr.] Raj's declaration and testimony[35] . . . in its entirety" under *Daubert v. Merrill Dow Pharms., Inc.*, 509 U.S. 579 (1993), and because her opinions are allegedly irrelevant. PO MTE 5.

First, Patent Owner argues that Dr. Raj does not speak German and "never applied any technical methodology or relied on any skills or training when picking the Sherman translation" over the Tinworth translation. *Id.* at 2. Patent Owner thus argues that Dr. Raj is unqualified to opine on the Harder translations and "[t]herefore, the Board should exclude all opinions of Raj regarding which translation of Harder is more complete or more accurate or how it would be understood." *Id.*

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internal documents, and the Temovksy Declaration, all of which we separately considered, as discussed above. *See, e.g.*, *supra* Section II.E.2.c.

[35] It is unclear whether Patent Owner seeks to exclude only Dr. Raj's Declaration, or also the transcript of her deposition (Exhibit 2081). To the extent Patent Owner also seeks exclusion of Exhibit 2081 (filed by Patent Owner itself), we deny that request for the same reasons discussed herein.

Patent Owner's request to exclude Dr. Raj's declaration on this ground is moot, because we do not rely on her opinions regarding "which translation of Harder is more complete or more accurate." *Id.*; *see* TPG 79–80. In fact, Dr. Raj did not even opine on the accuracy of any translations. *See* Ex. 2081 (Raj Depo. Tr.) 27:17–28:5 ("I don't speak German so I was not asked to opine on the accuracy of the translation . . . ."). To the extent Patent Owner is contending that Dr. Raj's selection of the Sherman translation over the Tinworth translation somehow provides a basis to exclude her declaration, we disagree. *See* PO MTE 2. Dr. Raj's selection of one translation over another required comparing English-language documents (i.e., the translators' declarations). *See, e.g.*, Ex. 2081 (Raj Depo. Tr.) 44:7–45:15, 47:3–48:15 (discussing her comparison of the Sherman, Tinworth, and Benyunes declarations). We find that Dr. Raj, who testified at length in English, is qualified to compare English-language documents.

Second, Patent Owner argues that we should exclude Dr. Raj's opinions on "how [Harder] would be understood" because she "opines on Harder from the perspective of a non-POSITA, i.e., a pediatrician." PO MTE 2; PO MTE Reply 3. Patent Owner's argument is unavailing. As an initial matter, Patent Owner makes no argument as to why we should necessarily exclude pediatricians from the level of ordinary skill in the art. For example, although the level of skill in the art we use in this proceeding recites specific degrees, it also allows for a degree in "a related field." *See supra* Section II.B. Indeed, Patent Owner's pediatrician, Dr. Horowitz, states without any analysis that he is a person of ordinary skill in the art. *See* Ex. 2069 (Horowitz Decl.) ¶ 6(f); Ex. 1036 (Horowitz Depo. Tr.) 55:3–5.

We agree also with Petitioner that "Dr. Raj's opinions about how a pediatrician might understand the instructions in Harder responds to Patent Owners' pediatrician's [Dr. Horowitz's] testimony." Pet. MTE Opp. 2. We further agree with Petitioner that Dr. Raj need not be a person of ordinary skill in the art to respond to Dr. Horowitz's opinions that "Harder's method of using a spoon would not be 'efficacious' and would be 'suboptimal.'" Pet. MTE Opp. 3 (quoting Ex. 2069 (Horowitz Decl.) ¶ 7).

Patent Owner's assertion that "Dr. Horowitz addresses Harder from the prospective [sic] of a POSITA whereas Raj opines on Harder from the perspective of a non-POSITA, i.e., a pediatrician," is not persuasive. PO MTE Reply 3 (citing Ex. 2069 (Horowitz Decl.) ¶¶ 4(a)-(e), 6(f)-(q), Ex. A; Ex. 1036 (Horowitz Depo. Tr.) 8:2–12:5, 55:3–5). Dr. Horowitz testifies that his "opinions are based on [his] education, training, decades of experience, and review of referenced materials." Ex. 1036 (Horowitz Depo. Tr.) 55:3–5; Ex. 2069 (Horowitz Decl.) ¶ 4(e). He expressly draws on his experience "[a]s a pediatrician, skilled in the art," in opining on Harder. *Id.* ¶ 6(f). Thus, to the extent Dr. Horowitz's opinions are relevant and appropriate, so are Dr. Raj's opinions in response thereto.

Patent Owner also argues that Dr. Raj has training and experience substantially above that of a typical pediatrician, and "she provides no bridge of analysis between her opinion and that of a typical pediatrician." PO MTE 4. This argument is unavailing. We are not apprised of anything in Dr. Raj's opinions that suggest she is employing any training and experience that is substantially above that of a typical pediatrician.

Patent Owner also argues that Dr. Raj's opinions are "speculative" and "conclusory." PO MTE 4. Such arguments are not appropriate in a

motion to exclude. As stated in the Trial Practice Guide, "[a] motion to exclude is not a vehicle for addressing the weight to be given evidence—arguments regarding weight should appear only in the merits documents." TPG 79.

Finally, Patent Owner argues that Dr. Raj's experiment with the Munchkin spoon and her opinions based thereon are irrelevant, because there is no indication that the Munchkin spoons were commercially available as of the priority date of the challenged claims, and she "offers no analysis or data to show how her test results from the Munchkin spoon can be extrapolated to the entire universe of small generic spoons." PO MTE 4–5.

This argument is unavailing. As Petitioner notes, Dr. Raj's declaration indicates "the properties of the [Munchkin spoon] brand that made it suitable for infants: it was a 'smaller plastic spoon, which has smooth edges,'" "allow[ing] a baby to take the whole spoon into its mouth to suck or lick." Pet. MTE Opp. 3 (citing Ex. 1040 (Raj Decl.) ¶ 17). Additionally, Dr. Raj testified that her opinions apply to "a generic small spoon with smooth edges." Ex. 2081 (Raj Depo. Tr.) 110:10–17. Patent Owner does not persuade us that Dr. Raj's opinions are limited to spoons that post-date the priority date of the challenged claims. Accordingly, we decline to exclude Dr. Raj's declaration as irrelevant on this basis.

For the above reasons, we deny Patent Owner's request to exclude Dr. Raj's declaration.

2. *Williams Declaration (Ex. 1004)*

Patent Owner asserts that "[d]espite the established limited scope of Rule 26(b)(4)(C) [work product protection], Petitioner's counsel repeatedly instructed Williams not to answer essential and proper questions based on

disingenuous claims of privilege." PO MTE 7. Patent Owner appears to suggest that based on alleged gaps and deficiencies in Dr. Williams's Declaration, and the allegedly improper instructions not to answer questions at deposition, we should sanction Petitioner by excluding Dr. Williams's Declaration. *Id.* at 10; *see also id.* at 11 ("Due to the improper and numerous instructions not to answer, Williams effectively was not available for cross-examination, and so his direct testimony should not be considered."); *see also id.* (suggesting that the Board "draw an adverse inference").

Patent Owner's arguments are not directed to challenging the admissibility of Dr. Williams's testimony. Instead, Patent Owner seeks to strike the testimony and/or obtain sanctions for alleged deficiencies at deposition. *See* Pet. MTE Opp. 4. Motions to strike and motions for sanctions require separate authorization, and Patent Owner did not request such authorization. Accordingly, on this basis alone we deny Patent Owner's request to exclude Dr. Williams's Declaration.

Patent Owner also asserts that "[t]o the extent Petitioner's counsel permitted him to answer, Williams revealed he did little (if any) work himself regarding his opinions or declaration," and "revealed significant defects in his opinions." PO MTE 9; *see also id.* at 6. Patent Owner thus asks us to accord Dr. Williams's testimony little weight. *See id.* at 11. Arguments going to the weight according to evidence, instead of its admissibility, are not appropriate in a motion to exclude. *See* TPG 79.

3. *Various Petitioner Exhibits (Exhibits 1026, 1027, 1029, 1030–1032, 1034, 1035, 1042–1048)*

Patent Owner seeks to exclude the following exhibits: Exhibits 1042–1046 (dictionaries; machine translations); Exhibits 1026, 1027 (product

packaging); Exhibits 1030–1032, 1034, 1035 (webpages); Exhibit 1029 (database printout); Exhibit 1048 (article); Exhibit 1047 (email). PO MTE 12–15. Of the cited exhibits, we rely herein only on Exhibits 1030 and 1032. We dismiss Patent Owner's request to exclude the other exhibits as moot. *See* TPG 79–80.

As to Exhibit 1030 (Baby Ddrops Amazon listing), Patent Owner's sole argument is that it has been "'annotated' by Petitioner." PO MTE 14 (citing Reply 17). On page 17 of the Reply, Petitioner pastes an image from Exhibit 1030 and adds an arrow to call our attention to a portion of the image. Patent Owner fails to explain why this calls for exclusion of Exhibit 1030 under any Federal Rule of Evidence. Accordingly, we deny Patent Owner's request to exclude Exhibit 1030.

As to Exhibit 1032 (Ddrops Baby Tummy Relief Liquid Drops Amazon listing), Patent Owner contends that this is an "unrelated, different" Ddrop product, and so is not relevant. PO MTE 14 (citing FRE 402, 403). We agree with Petitioner that this exhibit is relevant to the credibility of Patent Owner's argument that an infant cannot use a spoon or remove a drop of vitamin D oil from a spoon. *See* Pet. MTE Opp. 14. Accordingly, we deny Patent Owner's request to exclude Exhibit 1032.

IV. MOTIONS TO SEAL

A. Patent Owner's Motion to Seal (Paper 93)

Patent Owner requests to seal portions of five items: (1) Petitioner's Reply (Paper 74); (2) Exhibit 1039 (Temovsky Deposition Transcript); (3) Exhibit 2083 (Temovsky Errata); (4) Exhibit 1038 (Vieth Deposition Transcript); and (5) Patent Owner's Sur-reply (Paper 91). Paper 93.

Petitioner filed a response to Patent Owner's motion, limited to addressing item (5), i.e., portions of Patent Owner's Sur-reply (Paper 91). Paper 105.

The parties represent that the information sought to be sealed has not been published or otherwise made public. *See* Paper 93, 7; Paper 105, 3. Unless otherwise noted, we accept the parties' representations as accurate and consider these representations in determining whether good cause has been established to seal the requested information.

We address each item in more detail below.

1. *Petitioner's Reply (Paper 74)*

Petitioner filed its Reply (Paper 74), together with a redacted version of the Reply (Paper 75).

Patent Owner contends that the material redacted in Paper 74 (which falls on pages 4 and 26 of Petitioner's Reply) relates to confidential research and development and market share information. Paper 93, 3–4.

Regarding the research and development information on Reply page 4, we find that this is the type of information that businesses typically keep confidential, and that Patent Owner has established good cause to seal this material.

However, regarding the market share information on Reply page 26, we are not persuaded that Patent Owner has sufficiently established the confidentiality of the particular statements sought to be redacted. For example, duplicative information appears to exist in Petitioner demonstrative number 83 (which was filed subsequent to Patent Owner's motion to seal). Accordingly, we deny without prejudice Patent Owner's request to seal the information on Reply page 26. Patent Owner shall reevaluate these proposed redactions in light of other information that is publicly available on

the docket. If Patent Owner renews its request to seal the information on page 26 of Petitioner's reply, within 10 business days of this order, it shall file an appropriate motion to seal. Alternatively, if Patent Owner no longer seeks redactions to the information on page 26 of Petitioner's reply, it shall inform the Board via email, within 10 business days of this order.

2. *Exhibit 1038 (Temovsky Deposition Transcript); Exhibit 2083 (Temovsky Errata)*

A redacted version of Exhibit 1038 is in the record as Exhibit 2089, and a redacted version of Exhibit 2083 is in the record as Exhibit 2091.

We find that the information Patent Owner requests to seal in these materials is Ddrops' confidential "market share data (Ex 1038, pages 70–75, 133, and 138) and trade secret information (Ex 1038, pages 24–25 and Ex 2091, page 1)," including royalty information, of the type that businesses typically keep confidential to avoid competitive harm. Paper 93, 4–5. Accordingly, for the above reasons, we find that Patent Owner has established good cause to seal the requested portions of the Temovsky Deposition Transcript and Errata, and thus grant Patent Owner's request to seal Exhibits 1038 and 2083.

3. *Exhibit 1039 (Vieth Deposition Transcript)*

A redacted version of Exhibit 1039 is in the record as Exhibit 2090.

We find that the information Patent Owner requests to seal in the Vieth Deposition Transcript is research and development information of the type that businesses typically keep confidential to avoid competitive harm. Accordingly, for the above reasons, we find that Patent Owner has established good cause to seal the requested portions of the Vieth Deposition Transcript, and grant Patent Owner's request to seal Exhibit 1039.

4. *Patent Owner's Sur-reply (Paper 91)*

A redacted version of Paper 91 is in the record as Paper 106.[36]

In Patent Owner's Sur-reply (Paper 91), Patent Owner requests to seal market share data (at Paper 91, pages 22–23) because its disclosure "would be detrimental to Ddrops' business and is prohibited by contractual provisions restricting disclosure and use of the market share information imposed by the vendor of the information." Paper 93, 6.

Petitioner requests to seal "a portion of one sentence on page 23" that discloses "confidential MOM information relating to sales and volume information relating to MOM's commercial product." Paper 105, 2.

We find that the information the parties seek to seal is the type of information that businesses typically keep confidential, to avoid competitive harm. Accordingly, for the above reasons, we find that the parties have established good cause to seal the requested portions of the Patent Owner Sur-reply, and grant the parties' joint motion to seal this document.

B. Joint Renewed Motion to Seal (Paper 107)

The parties previously filed motions to seal the Patent Owner Response (with various redacted versions filed under seal at Papers 61, 84, and 87). *See* Papers 62, 83, 85. In earlier Orders (Papers 73, 101, 102), we noted that Petitioner and Patent Owner had filed conflicting redacted versions of the Patent Owner Response and ordered that, to the extent either party maintained its request to seal any portion of the Patent Owner Response, the parties file a joint renewed motion to seal, together with a joint redacted version of the Patent Owner Response.

[36] Patent Owner previously filed, at Paper 92, a different redacted version of the Sur-reply. Paper 106 has fewer redactions than Paper 92.

The parties filed a joint renewed motion to seal the Patent Owner Response, together with a joint redacted version of the document. *See* Paper 107 (motion); Paper 108 (redacted Patent Owner Response).

Petitioner seeks to redact confidential information (at pages 48 and 63) relating to its product composition, formulation development, marketing strategy, and sales data, including through reference to exhibits we previously sealed. Paper 107, 4. Patent Owner seeks to redact the terms of confidential settlement agreements (pages 53–54) and confidential market share information (pages 62–64). *Id.*

We find that the information the parties seek to seal is the type of information that businesses typically keep confidential, to avoid competitive harm. The parties' counsel certifies "that the information sought to be sealed has not, to their knowledge, been published or otherwise made public." Paper 107, 5.

Accordingly, for the above reasons, we find that the parties have established good cause to seal the requested portions of the Patent Owner Response, and grant the parties' joint motion to seal this document. Given that several redacted versions of this document appear in the record, for clarity, we reiterate that the authorized redacted version of the Patent Owner Response (Paper 61) is at Paper 108.

C. Petitioner's Renewed Motion to Seal (Paper 109)

Petitioner previously filed a Motion to Seal portions of Patent Owner's Motion for Additional Discovery (Paper 49). Paper 85, 1. In a prior Order (Paper 102), we denied that motion, because some of the material Petitioner sought to seal appeared to have been published or

otherwise made public.[37] Petitioner now renews its motion to seal portions of Patent Owner's Motion for Additional Discovery (Paper 49). *See* Paper 109. With the present renewed motion, Petitioner filed a modified redacted version (Paper 110), which removes some of the previously-requested redactions. Patent Owner did not file an opposition to the motion.

Petitioner asserts that the information it seeks to seal is "confidential MOM information relating to marketing and business strategy." Paper 109, 3. We find that the information the Petitioner seeks to seal is the type of information that businesses typically keep confidential, to avoid competitive harm. Petitioner's counsel certified "that the information sought to be sealed has not, to their knowledge, been published or otherwise made public." *Id.*

Accordingly, we find that Petitioner has established good cause to seal the requested portions of Patent Owner's Motion for Additional Discovery (Paper 49), and thus grant Petitioner's renewed motion. Given that multiple redacted versions of this document appear in the record, for clarity, we reiterate that the authorized redacted version of Patent Owner's Motion for Additional Discovery (Paper 49) is at Paper 110.

D. Notice of Unsealing of Exhibits 1036 and 1037

Petitioner filed Exhibits 1036 (Horowitz Deposition Transcript) and 1037 (Reid Deposition Transcript) under seal. Both parties subsequently confirmed that these documents do not contain confidential information and

[37] At the time of our prior Order (Paper 102), two identical redacted copies of Patent Owner's Motion for Additional Discovery (Paper 49) existed in the record, (1) as an appendix to Paper 48; and (2) as Paper 86.

do not need to be sealed. *See* Tr. 69:17–70:8. Ten business days after entry of this Final Written Decision, the Board will unseal these exhibits.

E. Instructions and Additional Guidance Regarding Confidentiality

This Final Written Decision is entered as a non-public version because it may reference sealed information. No later than ten business days after entry of this Final Written Decision, the parties shall jointly submit, as an Exhibit, a proposed redacted version of the Final Written Decision that will be publicly available, together with a joint Paper specifically identifying where (i.e., in which Order(s)) the Board previously sealed the specific information sought to be redacted, or establishing good cause for why the materials should be sealed in the first instance. Alternatively, if the parties agree that the Final Written Decision can be made publicly available without any redactions, within ten business days after entry of this Final Written Decision they shall jointly notify the Board via email stating as such. In the absence of any communication from the parties about any alleged confidentiality in the Final Written Decision within the time frame set forth above, the Board will make this Final Written Decision publicly available.

The parties are reminded that confidential information that is subject to a protective order ordinarily becomes public 45 days after final judgment[38] in a trial. *See* TPG 21–22. There is an expectation that information will be made public where the existence of the information is identified in a final written decision. *Id.* at 22. A party seeking to maintain the confidentiality of information, however, may file a motion (after final

[38] For present purposes, this panel interprets "final judgment" to include the resolution of appellate proceedings, if any.

judgment) to expunge the information from the record prior to the information becoming public. *See* 37 C.F.R. § 42.56.

V. CONCLUSION[39]

Based on the information presented, we conclude that Petitioner has demonstrated by a preponderance of the evidence that claims 1 and 3–5 of U.S. Patent No. 9,066,958 B2 are unpatentable.

In summary:

Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis	Claims Shown Unpatentable	Claims Not shown Unpatentable
1, 5	103(a)	Harder, Wolf, European Pharmacopoeia	1, 5	
3	103(a)	Harder, Wolf, European Pharmacopoeia, Blass	3	
4	103(a)	Harder, Wolf, European Pharmacopoeia, Gartner	4	
Overall Outcome			1, 3–5	

[39] 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).

VI. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that Petitioner has demonstrated by a preponderance of the evidence that claims 1 and 3–5 of U.S. Patent No. 9,066,958 B2 are unpatentable;

FURTHER ORDERED THAT Patent Owner's Motion to Exclude (Paper 94) is denied in part and dismissed as moot in part;

FURTHER ORDERED THAT Petitioner's Motion to Exclude (Paper 95) is denied in part and dismissed as moot in part;

FURTHER ORDERED THAT Patent Owner's Motion to Seal (Paper 93) is granted in part and denied in part, and Patent Owner shall follow the instructions provided above in Section IV.A.1;

FURTHER ORDERED THAT the parties' Joint Renewed Motion to Seal (Paper 107) is granted;

FURTHER ORDERED THAT Petitioner's Renewed Motion to Seal (Paper 109) is granted;

FURTHER ORDERED THAT the Board will unseal Exhibits 1036 and 1037 ten business days after entry of this Final Written Decision;

FURTHER ORDERED THAT the parties shall jointly inform the Board regarding confidentiality in this Final Written Decision as directed in Section IV.E above; 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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