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Paper 10
Entered: September 15, 2023

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*.

DECISION
Granting Institution of *Inter Partes* Review
35 U.S.C. § 314

I. INTRODUCTION

Petitioner MOM Enterprises, LLC requests *inter partes* review of claims 1 and 3–5 of U.S. Patent No. 9,066,958 B2 ("the '958 patent," Ex. 1001). Paper 2 ("Pet."). Elaine Vieth and Reinhold W. Vieth (collectively, "Patent Owner") filed a Preliminary Response. Paper 6 ("Prelim. Resp."); Paper 4, 1. Petitioner and Patent Owner respectively filed an authorized Reply and Sur-reply. Paper 8 ("Prelim. Reply"); Paper 9 ("Prelim. Sur-reply").

Considering the arguments and evidence of record, we determine that the Petition demonstrates "a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314(a). Therefore, we institute an *inter partes* review.

The following preliminary findings of fact and conclusions of law are made solely for determining whether to institute review. Any final decision will be based on the full trial record.

A. 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 4, 2.

B. 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) (the "Parallel Litigation"). Pet. 47; Paper 4, 2.

C. The '958 Patent

The '958 patent is titled "Vitamin D Compositions and Method of Administration to a Human Being." Ex. 1001, code (54).[1] 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 '958 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 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

[1] The '958 patent was filed on February 13, 2007 and claims priority to CA 2558202, filed on September 14, 2006. Ex. 1001, codes (22), (30). "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 Preliminary Response. For purposes of this Decision, we apply a September 14, 2006, priority date.

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 inventors of the '958 patent:

> 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. Various oil vehicles (canola, olive, sesame, vitamin E acetate, and medium chain triglyceride) adhered to the nipple. *Id.* at Table 1. Medium-chain triglyceride oil "was particularly desirable" because it had less "residual oily feel on the pacifier" as compared to the other oil vehicles. *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.*

D. The Challenged Claims

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

> 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 an object; and
>
> (ii) having said human being suck or lick said composition directly from said object.

Ex. 1001, 9:34–47.

Claim 3 further 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, and claim 5 recites that the "triglyceride comprises at least 95% triglycerides having a carbon-chain length selected from 8 to 10." *Id.* at 10:1–6.

E. The Asserted Grounds of Unpatentability

Petitioner asserts that claims 1 and 3–5 are unpatentable on the following grounds:

Claim(s) Challenged	35 U.S.C. §[2]	References[3]
1, 5	103(a)	Harder,[4] Wolf,[5] European Pharmacopoeia[6]
3	103(a)	Harder, Wolf, European Pharmacopoeia, Blass[7]
4	103(a)	Harder, Wolf, European Pharmacopoeia, Gartner[8]

[2] The Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) ("AIA"), amended several provisions of 35 U.S.C., including § 103. Because the September 14, 2006 priority date we apply herein for the challenged claims (*see supra* n.1) is before the effective date of the applicable AIA amendments, we refer to the pre-AIA version of 35 U.S.C. § 103.

[3] Each of the Harder, Wolf, European Pharmacopoeia, Blass, and Gartner references contain 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 numbers in the footer. For clarity, going forward in this proceeding, we encourage the parties to likewise use the footer page numbers.

[4] 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.

[5] 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.

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

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

[8] 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. Petitioner supports its contentions with evidence including the Declaration of Robert O. Williams III, Ph.D. (Ex. 1004). Patent Owner supports its contents with evidence including the Declarations of Chris Temovsky (Ex. 2004), inventor Reinhold Vieth, Ph.D. (Ex. 2008), and Warren D. Woessner, Ph.D. (Ex. 2009).

II. ANALYSIS

A. Discretionary Denial Under § 314(a)

The parties dispute whether the Board should discretionarily deny the Petition under 35 U.S.C. § 314(a) in view of the Parallel Litigation. Prelim. Resp. 55–61; Pet. 43–47.

Institution of an *inter partes* review is discretionary. *See* 35 U.S.C. § 314(a); *SAS Inst. Inc. v. Iancu*, 138 S. Ct. 1348, 1356 (2018). When determining whether to exercise discretion to deny institution in view of a parallel litigation, we consider the six factors set forth in the Board's precedential "*Fintiv*" case. *See Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 11 at 6 (PTAB Mar. 20, 2020) (precedential) ("*Fintiv*"); *see also* Memorandum, Interim Procedure for Discretionary Denials in AIA Post-Grant Proceedings with Parallel District Court Litigation (USPTO June 21, 2022) ("Memorandum").[9] We address each factor in turn below.

1. *Whether the Court Granted a Stay or Evidence Exists that One May Be Granted if A Proceeding is Instituted*

Neither party indicates that the Parallel Litigation has been stayed. Although Petitioner indicates it "intends to move to stay the counterpart district court litigation" (Pet. 43), we will not speculate as to whether the

[9] *Available at* www.uspto.gov/sites/default/files/documents/interim_proc_discretionary_denials_aia_parallel_district_court_litigation_memo_20220621_.pdf.

judge in the Parallel Litigation would grant a stay. *See Sand Revolution II, LLC v. Cont'l Intermodal Group – Trucking LLC*, IPR2019-01393, Paper 24 at 7 (PTAB June 16, 2020) (informative) ("*Sand Revolution*") ("In the absence of specific evidence, we will not attempt to predict how the district court . . . will proceed."). Accordingly, this factor is neutral. *See id.*

2. *Proximity of the Court's Trial Date to the Board's Projected Statutory Deadline for a Final Written Decision*

Patent Owner indicates that trial in the Parallel Litigation is set for October 7, 2024, while Petitioner indicates it is set for October 14, 2024. Prelim. Resp. 56–57; Pet. 44. In either case, the trial date is after the projected statutory deadline for a final written decision in this proceeding. Accordingly, this factor weighs against exercising discretion to deny institution.

3. *Investment in the Parallel Proceeding by the Court and the Parties*

Petitioner says investment in the Parallel Litigation is "minimal;" Patent Owner says it is "substantial." Pet. 44; Prelim. Resp. 59. To show substantial investment, Patent Owner asserts that "the parties have exchanged preliminary infringement and invalidity contentions; produced thousands of documents; served and responded to written interrogatories, document requests and requests for admission; [and] engaged in third-party discovery via subpoenas *duces tecum*." Prelim. Resp. 57. Patent Owner further indicates that the "Court recently entered its *Markman* claim construction decision," and fact discovery closes "on September 15, 2023, on or about the time of projected institution." *Id.*

Although the district court has entered a *Markman* claim construction decision, much work remains in the Parallel Litigation. Fact discovery is

scheduled to close on September 15, 2023; expert reports are not yet due; and substantive motion practice is yet to come. *See* Prelim. Resp. 57. Thus, although the parties and the district court have invested effort in the Parallel Litigation, further effort remains to be expended before trial.

For the reasons above, we find that this factor weighs only marginally, if at all, in favor of exercising discretion to deny institution. *See Sand Revolution*, Paper 24 at 10–11.

4. *Overlap Between Issues Raised in the Petition and in the Parallel Litigation*

Patent Owner asserts that "[a]ll of the prior art asserted by Petitioner has also been asserted in the concurrent related proceeding." Prelim. Resp. 59. Petitioner, however, asserts that it "has eliminated any risk of duplicated effort by voluntarily stipulating that if the Board institutes the present Petition, Petitioner will not pursue the same grounds asserted in this IPR petition."[10] Pet. 45 (citing Ex. 1018). Accordingly, Petitioner argues that this purported "lack of overlapping issues weigh[]s in favor of institution." *Id.* at 46.

The Memorandum states that the Board "will not discretionarily deny institution in view of parallel district court litigation where a petitioner presents a stipulation not to pursue in a parallel proceeding the same grounds

[10] Petitioner characterizes its stipulation as covering not only the same grounds raised in the Petition, but also "any grounds utilizing the primary references, Harder, Wolf, and European Pharmacopoeia Supplement 4.3." Pet. 45. The stipulation filed as Exhibit 1018, however, states only that Petitioner "will not pursue in the District Court the specific grounds raised in IPR2023-00726." Ex. 1018, 1. Contrary to Petitioner's characterization in the Petition, the stipulation as filed does not extend to "any grounds utilizing the primary references, Harder, Wolf, and European Pharmacopoeia Supplement 4.3."

or any ground that could have been reasonably raised before the PTAB." Memorandum 3. This type of stipulation is known as a "*Sotera*" stipulation. *See Sotera Wireless, Inc. v. Masimo Corp.*, IPR2020-01019, Paper 12 at 18–19 (PTAB Dec. 1, 2020) (precedential as to § II.A).

Patent Owner correctly asserts that Petitioner's stipulation does not meet the standard set forth in *Sotera*. Prelim. Resp. 60. Nevertheless, Petitioner's stipulation has the same scope as the stipulation in *Sand Revolution*, where the petitioner stipulated it would not pursue "the same grounds" in the IPR and district court litigation. *See Sand Revolution*, Paper 24 at 11–12. The Board found that such a stipulation weighed marginally against exercising discretion to deny institution, because the stipulation "mitigates to some degree the concerns of duplicative efforts between the district court and the Board, as well as concerns of potentially conflicting decisions." *Sand Revolution*, Paper 12 at 12.

Here, we similarly find that Petitioner's stipulation mitigates to some degree the concerns of duplicative efforts and potentially conflicting decisions. Thus, we find that this factor weighs marginally against exercising discretion to deny institution.

5. *Whether the Petitioner and the Defendant in the Parallel Litigation are the Same Party*

The parties are the same in this IPR and the Parallel Litigation. Pet. 46; Prelim. Resp. 60. As discussed with respect to factor 2, the currently-scheduled trial date for the Parallel Litigation is after the expected date of our final written decision. Thus, we find that factor 5 weighs against exercising discretion to deny institution.

6. *Other Circumstances that Impact the Board's Exercise of Discretion, Including the Merits*

The parties dispute whether the merits favor institution or discretionary denial. Pet. 46–47; Prelim. Resp. 60–61.

The Memorandum explains that the Board "considers the merits of a petitioner's challenge when determining whether to institute a post-grant proceeding in view of parallel district court litigation." Memorandum 4. "Where the information presented at the institution stage is merely sufficient to meet the statutory institution threshold, the PTAB has the authority, where warranted, to exercise discretion to deny institution in view of the other *Fintiv* factors." *Id.* "In contrast, where the PTAB determines that the information presented at the institution stage presents a compelling unpatentability challenge, that determination alone demonstrates that the PTAB should not discretionarily deny institution under *Fintiv*." *Id.* at 4–5.

As discussed below, we determine that Petitioner has shown a reasonable likelihood of demonstrating unpatentability of the challenged claims. Beyond that, given the facts relating to the other *Fintiv* factors in this case, we need not determine at this time whether Petitioner's showing is "compelling" in order to decide whether to exercise our discretion to deny institution in this proceeding. Therefore, we treat this factor as neutral.

7. *Conclusion*

In view of the *Fintiv* factors as presented in this case, and taking "a holistic view of whether efficiency and integrity of the system are best served by denying or instituting review" (*Fintiv*, Paper 11 at 6), we are not persuaded that the interests of efficiency and integrity of the system would be best served by invoking 35 U.S.C. § 314(a) to deny institution of a

potentially meritorious Petition. Based on the record before us, we determine the facts of this case do not warrant discretionary denial.

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.1. 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. 1014 ¶ 20) (citations omitted).

Patent Owner "agree[s] with the first sentence" 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 ¶ 32).

For purposes of this Decision, we adopt 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." We find it unnecessary to specify a particular bachelor's degree, because it does 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.

Additionally, like Patent Owner, we find that the second sentence of Petitioner's proposal is not supported. In particular, on this record Petitioner does not adequately explain for how many years and in what settings a person might obtain "related work experience in formulating compositions of and delivering 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. In particular, although we agree with Patent Owner that "the 'ordinary' nurse may have knowledge and experience in delivering medicines and nutritional supplements" (Prelim. Resp. 18), Petitioner fails to explain how a nurse would obtain "related work experience in formulating compositions."

In sum, for purposes of this Decision, we determine 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. During trial, to the extent the one or both parties disagree with this level of skill, we encourage the parties to indicate why they disagree, and to provide argument and evidence in support of any alternative proposal.

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.*

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.

Patent Owner states that after the Petition was filed, the court in the Parallel Litigation entered a Claim Construction Order. Prelim. Resp. 8–9 (citing Ex. 2005). The court adopted the parties' agreed constructions of five terms, as follows:

Claim Term	Agreed Construction
"one drop of composition consisting of . . . " ('958 patent, claims 1, 3–5)	one drop of C_6–C_{12} liquid fatty esters of glycerol sufficient to administer a nutritional or therapeutically effective dose of vitamin D
"a nutritional or therapeutic effective amount . . . " ('958 patent, claims 1, 3–5)	the amount of vitamin D in the composition of use in the practice of the invention may be readily selected to be that amount which provides suitable effects on the circulating concentration of 25-hydroxyvitamin D
"liquid triglyceride of 6 to 12 carbon chain length . . . " ('958 patent, claims 1, 3, 4)	C_6–C_{12} liquid fatty acid esters of glycerol including medium chain triglycerides which can be a mixture of 2–4 (C_6–C_{12}) fatty acids/glycerol esters
"liquid triglyceride of 6 to 12 carbon chain length . . . " ('958 Patent, claim 5)	C_6–C_{12} liquid fatty acid esters of glycerol including medium chain triglycerides which can be a mixture of 2–4 (C_6–C_{12}) fatty acids/glycerol esters, where not less than 95% of the fatty acids have 8 to 10 carbon atoms

"wherein said drop adheres to the surface of said object" ('958 patent, claims 1, 3–5)	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

Ex. 2005, 1–2. The court also construed the contested term "vitamin D." *See id.* at 2.

We determine that for purposes of this Decision, we need address only two terms, i.e., "wherein said drop adheres to the surface of said object," and "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))).

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

We adopt the parties' agreed construction of "wherein said drop adheres to the surface of said object," i.e., we construe this term to mean:

> 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.

Ex. 2005, 2. This construction is consistent with the teachings of the Specification, which indicate that determining whether a drop "adheres" to a surface is based on whether it is "sufficiently viscous so that one drop does not immediately drip or roll away from the object" yet does not "coat or

adhere" to the object "so as to prevent efficient removal" of the drop through sucking. Ex. 1001, 6:34–54; *see also id.* at Table 1, 6:34–7:27.

2. *"vitamin D"*

Although we find that construing the term "vitamin D" is not necessary for purposes of institution, to provide the parties notice, we address the district court's construction of this term. The court held a hearing and heard argument from both sides, and ultimately construed the term "vitamin D" consistent with the express definition provided in the Specification. *See* Ex. 2010, 6–21; Ex. 1001, 3:53–56.

For comity and because the district court's construction is consistent with the Specification, we adopt it herein for purposes of this Decision. Specifically, we construe "vitamin D" to mean "(5Z-7E)-(3S)-9,10-seco-5,7,10(19)-cholestatrien-3-ol also having the trivial names cholecalciferol or calciol (D3); and ergocalciferol (D2)," wherein "a person of ordinary skill in the art would understand this language to refer to either Vitamin D2 or Vitamin D3."

3. *Conclusion*

Any final written decision entered in this case may include final claim constructions that differ from these preliminary constructions, or from any discussion of claim scope provided in our analysis below. It may also include constructions for terms not construed herein. Any final claim constructions will be based on the full trial record.

During trial, to the extent the one or both parties seek a specific plain and ordinary meaning of a claim term (whether an agreed construction or otherwise), we encourage the parties to provide support as to how the proposed construction represents the plain and ordinary meaning. We caution the parties that the Board will not necessarily accept an unsupported

assertion that a particular construction represents a "plain and ordinary meaning," even if the parties agree on the proposed construction.

D. Asserted Grounds of Unpatentability

1. *Legal Standards*

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) (citing 35 U.S.C. § 312(a)(3) (requiring *inter partes* review petitions to identify "with particularity . . . the evidence that supports the grounds for the challenge to each claim")). Petitioner ultimately bears the burden of persuasion to prove unpatentability of each challenged claim by a preponderance of the evidence. 35 U.S.C. § 316(e). This burden never shifts to Patent Owner. *Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015). The Board may authorize an *inter partes* review if we determine that the information presented in the Petition and Patent Owner's Preliminary Response shows a reasonable likelihood that Petitioner will prevail with respect to at least one of the claims challenged in the petition. 35 U.S.C. § 314(a).

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 subject matter pertains. *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 determinations 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 accompanied by a reasonable expectation of achieving what is claimed in the patent-at-issue. *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.

2. *Overview of Asserted Prior Art*

a) Harder (Ex. 1007)

Harder is an excerpt of a German-language book titled "Wochenbett-betreuung in der Klinik und zu Hause," which Petitioner translates as "Childbed care in clinics and at home." Ex. 1006 (German-language document); Ex. 1007 (translation), 1. Petitioner asserts that Harder was published on January 10, 2003. Pet. 2, 11.

According to Petitioner's translation, 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 several options for administering vitamin D to prevent rickets. *Id.* at 5–7. One option 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.*

b) Wolf (Ex. 1009)

Wolf is an article titled "Rachitisprophylaxe beim Säugling," which Petitioner translates as "Prevention of Rickets in Infants." Ex. 1008 (German-language document), 4; Ex. 1009 (translation), 6. Petitioner asserts that Wolf was published on July 3, 1970. Pet. 2, 13.

According to Petitioner's translation, 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 his 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.

c) 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. Petitioner asserts that European Pharmacopoeia was published in January 2003. Pet. 2.

According to Petitioner's declarant Dr. Williams, European Pharmacopoeia "is a single reference work for the quality control of medicines," and includes official standards for substances for pharmaceutical use, including medium-chain triglycerides. Ex. 1006 ¶¶ 71–72; Ex. 1010, 5. European Pharmacopoeia defines medium-chain triglycerides as "[m]ixtures 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 medium-chain triglycerides contain a "minimum of 95.0 per cent of saturated fatty acids with 8 and 10 carbon atoms." Ex. 1010, 5. "Medium-chain triglycerides are obtained from the oil extracted from the hard, dried fraction of the endosperm of *Cocos nucifera* L. or from the dried endosperm of *Elaeis guineensis* Jacq."[11] *Id.*

d) Blass (Ex. 2022)

Blass is an article titled "Suckling- and sucrose-induced analgesia in human newborns." Ex. 1011, 6. Petitioner asserts that Blass was published in December 1999. Pet. 2–3, 18.

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.

[11] We understand that oil from *Cocos nucifera* L. and *Elaeis guineensis* Jacq. refers to coconut oil and palm oil, respectively. *See* Ex. 1003 ¶ 54 (citing Ex. 1001, 5:21–24 and explaining that where the Specification states that "[m]edium-chain triglycerides are obtained from the oil extracted from . . . *Cocos nucifera* L. or . . . *Elaeis guineensis* Jacq.," this describes medium chain triglycerides obtained from coconut oil or palm oil).

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. Bass 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.

e) Gartner (Ex. 1012)

Gartner is an article titled "Prevention of Rickets and Vitamin D Deficiency: New Guideline for Vitamin D Intake." Ex. 1012, 3. Petitioner asserts that Gartner was published on April 11, 2003. Pet. 3, 19.

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. As such, Gartner 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.*

3. *Ground 1: 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* Prelim. Resp. 20–47. After considering all of Petitioner's and Patent Owner's arguments and cited evidence (including Patent Owner's arguments and cited evidence regarding objective indicia of nonobviousness), we find that for purposes of institution, Petitioner has

shown a reasonable likelihood of establishing that claims 1 and 5 are unpatentable as obvious over Harder, Wolf, and European Pharmacopoeia.

a) Preliminary Findings Regarding Petitioner's Arguments

We begin by briefly summarizing our preliminary findings relating to Petitioner's obviousness arguments, which we arrived at after considering all of Petitioner's and Patent Owner's arguments and cited evidence.

For claim 1, Petitioner demonstrates that Harder and Wolf both teach the importance of vitamin D supplementation in infants, and the daily administration of one drop of Vigantol oil. Pet. 25–26, 28; Ex. 1004 ¶¶ 59, 62, 95; Ex. 1007, 4–6; Ex. 1009, 6–7, Table 1. Based on the translation of Harder in the record, Petitioner also demonstrates that Harder specifically discloses dispensing "1 drop of Vigantol® oil . . . to the baby from the tip of a spoon once a day." Pet. 26; Ex. 1007, 6.

Regarding the vitamin D dose recited in claim 1 ("a nutritional or therapeutic effective amount of 9 to 9000 mcg/ml vitamin D"), Petitioner shows that Wolf teaches "a composition of Vigantol oil that is 505.04 micrograms of vitamin D per milliliter." Pet. 27–28; Ex. 1009, 7–8, Table 1; Ex. 1004 ¶¶ 96, 98. This dose falls within the claimed range.

Regarding the requirement that the claimed composition consist of vitamin D and "a liquid triglyceride of 6 to 12 carbon chain length," based on the translation of Harder in the record, Petitioner shows that "Vigantol oil 'contains only one excipient as a vehicle for the fat-soluble vitamin D, namely medium-chain triglycerides.'" Pet. 28; Ex. 1007, 6; Ex. 1004 ¶ 99. Petitioner also shows that European Pharmacopoeia "teaches that medium-chain triglycerides are a 'minimum 95.0 percent of saturated fatty acids with 8 to 10 carbon atoms.'" Pet. 28; Ex. 1010, 5. Petitioner thus shows 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." Pet. 28; Ex. 1004 ¶ 104. The 8 to 10 carbon chain length of the medium-chain triglycerides taught in Harder fall within the claimed range of 6 to 12 carbon chain length.

Regarding the limitation in claim 1 that recites "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 shows, based on the translations in the record, that both Harder and Wolf teach administering one drop of Vigantol oil to an infant from a spoon, with Harder expressly teaching allowing an infant lick it off. Pet. 29; Ex. 1004 ¶ 52; Ex. 1007, 6; Ex. 1009, 7.

Finally, regarding the limitation in claim 1 that recites "wherein said drop adheres to the surface of said object," Petitioner argues that "the adhering property claimed is merely a property of the particular oil for delivery of vitamin D," and the Vigantol oil composition disclosed in Wolf and Harder "will inherently 'adhere.'" Pet. 31 (citing Ex. 1001, Table 1; Ex. 1004 ¶ 51); *id.* at 29–30 (citing Ex. 1001, 6:34–47; Ex. 1004 ¶¶ 50, 51). Petitioner also argues that based on Harder's teaching of administering Vigantol oil from the tip of a spoon, a person of ordinary skill in the art "would immediately recognize Vigantol oil's adhering properties, because Harder teaches directing the drop to the tip of a spoon, and 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." Pet. 30–31 (citing Ex. 1004 ¶¶ 52, 103; Ex. 1007, 6).

Petitioner also demonstrates that a person of ordinary skill in the art would have combined Harder, Wolf, and European Pharmacopoeia "to

provide a complete composition and dosage of Vigantol oil." Pet. 22–23; Ex. 1004 ¶ 77; Ex. 1007, 5–6. Specifically, Petitioner demonstrates that Harder teaches that Vigantol oil comprises medium chain triglycerides, and a person of ordinary skill in the art would have consulted European Pharmacopoeia to confirm that medium chain triglycerides are at least six to twelve carbon chain length. Pet. 22, 24; Ex. 1007, 5–6; Ex. 1010, 5; Ex. 1004 ¶ 84. Petitioner also demonstrates that Wolf teaches the daily dosage of Vigantol oil, while Harder further teaches how delivery should occur, e.g., by putting a drop on the tip of a spoon for an infant to lick off. Pet. 22–23; Ex. 1009, 7–8; Ex. 1007, 5–6. For purposes of institution, we determine that Petitioner has sufficiently shown that, "[g]iven the subject matter overlap between Wolf and Harder," a person of skill in the art would have been motivated "to combine Wolf and Harder to administer a composition of vitamin D oil to an infant by applying the oil to an object, such as a spoon, in a manner that would allow one to suck or lick it off." Pet. 23; Ex. 1004 ¶ 83; Ex. 1009, 7; Ex. 1007, 6.

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. Petitioner shows for purposes of institution that Harder expressly teaches that Vigantol oil contains "medium-chain triglycerides," and that a "person of ordinary skill in the art would have recognized 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 ¶¶ 58, 99; Ex. 1007, 6; Ex. 1010, 5.

At this stage of the proceeding, and after considering all of Petitioner's and Patent Owner's arguments and cited evidence, we find that

Petitioner comes forward with information sufficient to show a reasonable likelihood that claims 1 and 5 would have been unpatentable as obvious over Harder, Wolf, and European Pharmacopoeia. Pet. 22–33. Below we address Patent Owner's arguments.

b) Analysis of Patent Owner's Arguments

(1) Issues with Petitioner's Cited Art

Patent Owner raises several challenges to Petitioner's cited art. *See* Prelim. Resp. 20–34. We address each argument in turn below.

(a) Incomplete Excerpts

Patent Owner argues that Harder and European Pharmacopoeia are "incomplete and inadmissible." Prelim. Resp. 20. For example, Patent Owner asserts that Petitioner's Harder reference is an excerpt of a book that contains at least 294 pages, yet Petitioner omits "over 90% of the reference." *Id.* at 21 (citing Ex. 1005, 37). For European Pharmacopoeia, Patent Owner asserts that the eight pages of the exhibit "are not independent and include cross-references to content appearing elsewhere in the document." *Id.* at 22–23. Patent Owner argues that "a prior art reference must be read as a whole; the entire disclosure of the reference must be considered, including its teachings away from the claimed invention," and "Petitioner's failure to provide complete copies of either reference precludes consideration of them." *Id.* at 21, 23. Patent Owner further argues that Petitioner's declarant Dr. Williams has not considered the complete Harder reference, which "renders his opinion unreliable." *Id.* at 22.

On this record, Patent Owner's arguments are unavailing. It is not uncommon for parties in *inter partes* review proceedings to present as exhibits excerpts of books or other lengthy references. Patent Owner does not direct us to any rule or authority expressly prohibiting the submission of

excerpts. Patent Owner cites 37 C.F.R. § 42.6(c), which requires that "[e]ach exhibit must be filed with the first document in which it is cited except as the Board may otherwise order." Prelim. Resp. 20. This rule does not expressly require submitting an entire document.

To the extent Patent Owner contends that Dr. Williams's testimony is unreliable because he considered only excerpts of the references, or that unsubmitted portions of the references teach away, Patent Owner is free to explore these issues during trial, for example during cross-examination.

(b) Adequacy of Translations

Because both Harder and Wolf are in the German language, Petitioner relies on English-language translations of both documents. *See* Pet. 2. Our rules require that "[w]hen a party relies on a document or is required to produce a document in a language other than English, a translation of the document into English and an affidavit attesting to the accuracy of the translation must be filed with the document." 37 C.F.R. § 42.63(b).

(i) Harder Translation

For Harder, Petitioner submits a "Declaration of Accuracy of Translation," signed by David Joshua Sherman. Ex. 1007, 1. Mr. Sherman testifies that "Rebecca Amy TINWORTH performed the attached translation." Ex. 1007, 1. He also states: "I have reviewed the translation and confirm that the addition of 'to be 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." *Id.*

Patent Owner argues that "Petitioner has not submitted any declaration from 'Amy Tinworth' attesting to the accuracy of MOM-1007," but instead "has only submitted a Declaration of David Joshua Sherman,"

who "does not attest to the accuracy of the translation performed [by] Tinworth or MOM-1007." Prelim. Resp. 24–25; Prelim. Sur-reply 2 ("Sherman only attests to two words of Harder as being 'more accurate.'"). Although the record lacks a declaration from Ms. Tinworth, we disagree with Patent Owner that Mr. Sherman does not attest to the accuracy of the Harder translation as a whole. He attests that he reviewed the translation, and confirms that his addition "makes the translation a *more accurate* reflection of the German text." Ex. 1007, 1 (emphasis added). He does not limit this opinion to only the words he added. Although the Sherman declaration is somewhat unusual in that it references Ms. Tinworth's (missing) translation, on this record and for purposes of institution, it is sufficiently clear that Mr. Sherman is attesting to the accuracy of the Harder translation submitted as Exhibit 1007. *See also* Prelim. Reply 2 ("Sherman's testimony that 'the translation' is 'a more accurate reflection of the German text' is a statement 'attesting to the accuracy' of the translation required by the rule.").

Patent Owner also contends that the Harder translation is "inaccurate and manipulated" because Mr. Sherman added "the critical 'to be licked off' phrase," which Patent Owner asserts "is a blatant attempt by Petitioner to change the Harder translation to fit its litigation strategy." Prelim. Resp. 21. On this record, we have no basis to determine whether the addition of the phrase results in an "inaccurate translation" or was done in bad faith. During trial, Patent Owner is free to challenge the accuracy of the translation and Mr. Sherman's reasoning for adding the phrase.

Patent Owner also argues that (1) Petitioner translates only a portion of Harder ("less than 6 of 23 pages provided") and "has not provided a translation of the Table of Contents;" and (2) in the translation, "the

reference to Chapter 15.9 is erroneous because the table of contents (MOM-1006, pg. 10), shows Chapter 15 and section 15.9, but not chapter 15.9." Prelim. Resp. 24–25. On the current record, these issues do not prevent us from comparing the content of the Harder translation (as it currently appears in the record) with the challenged patent claims. Again, during trial, Patent Owner is free to challenge the accuracy and completeness of the translation.

Patent Owner also argues that Mr. Sherman "makes no assertion that he is familiar with the German language or has any proficiency in translating German to English." Prelim. Resp. 25–26. Rule 42.63(b) does not expressly require such assertions. In any event, during trial, Patent Owner is free to explore Mr. Sherman's familiarity with the German language and his translation proficiency, e.g., via cross-examination.

For the above reasons, on this record, we find unavailing Patent Owner's arguments that the Harder translation should be excluded or ignored.

(ii) Wolf Translation

Patent Owner argues that Wolf should be excluded because "Petitioner has not provided an affidavit attesting to the accuracy of the translations." Prelim. Resp. 24. In particular, Patent Owner argues that "the 'translator' does not profess to have knowledge of the German language or proficiency in translation services," and "only attests to accuracy to the best of the translator's knowledge." *Id.* at 26.

On this record, we find Patent Owner's arguments unavailing. The translator expressly states that he has provided "a true, full and accurate translation." Ex. 1009, 1. To the extent Patent Owner asserts that addition of the phrase "to the best of my knowledge" undercuts this assertion, Patent Owner is free to test that theory during trial, e.g., via cross-examination.

Additionally, Rule 42.63(b) does not require the translator to expressly attest to "have knowledge of the German language or proficiency in translation services." In any event, the translator testifies that he is "competent to perform this translation." Ex. 1009, 1. Again, during trial, Patent Owner is free to test that assertion, e.g., via cross-examination.

Patent Owner also asserts that although the Wolf translation affidavit states that the German excerpt is attached, there is no German attachment, and thus "there is no connection between MOM-1008 and the purported translation." Prelim. Resp. 26. We disagree. Based on our visual inspection of the translation provided at Exhibit 1009 and the German-language document provided at Exhibit 1008, on the current record it appears that Exhibit 1009 is an English translation of the German-language document provided at Exhibit 1008.

For the above reasons, on this record we find Patent Owner's arguments that the Wolf translation should be excluded or ignored are unavailing.

(c) Public Accessibility of Harder

Patent Owner argues that Petitioner fails to demonstrate Harder's public accessibility. Prelim. Resp. 27–34. At the institution stage, a petition must establish a reasonable likelihood that the reference was publicly accessible before the challenged patent's critical date. *Hulu, LLC v. Sound View Innovations, LLC*, IPR2018-01039, Paper 29 at 13 (PTAB Dec. 20, 2019) (precedential) ("*Hulu*"). A reference is "publicly accessible" if "persons interested and ordinarily skilled in the subject matter or art exercising reasonable diligence[] can locate it." *SRI Int'l, Inc. v. Internet Sec. Sys., Inc.*, 511 F.3d 1186, 1194 (Fed. Cir. 2008). "[T]he standard for public accessibility is one of reasonable diligence, to locate the information

by interested members of the relevant public." *GoPro, Inc. v. Contour IP Holding LLC*, 908 F.3d 690, 695 (Fed. Cir. 2018) (internal quotations and citations omitted).

The Petition asserts that Harder was published on January 10, 2003. Pet. 2. Petitioner also relies on a declaration from librarian June Munford. *See id.* at 12–13; Ex. 1005. According to Petitioner, Ms. Munford "explains that she is familiar with a library cataloging standard known as the 'Machine Readable Catalog' code, also known as 'MARC,' an industry wide standard for organizing library catalog information." Pet. 12 (citing Ex. 1005 ¶ 4). Ms. Munford testifies that creation of a MARC record "typically occurs during the process of preparing materials for public access," and that in her experience, "an item's MARC record indicates the date of an item's public availability." Ex. 1005 ¶ 4. She further testifies that the 008 field of a MARC record "is reserved for denoting the date of creation of the library record," and in her experience, the date in the 008 field "accurately indicates the date of an item's public availability." *Id.* ¶ 7.

Ms. Munford testifies that she accessed the online catalog of the National Library of Medicine and examined the MARC record for Harder. *Id.* ¶¶ 8, 9, Appendix HARDER01. According to Ms. Munford, field 008 of this MARC record indicates that the "the National Library of Medicine first acquired this book as of January 1, 2003," and therefore it "was made available to the public shortly after its initial acquisition in January 2003." *Id.* ¶ 4.

Patent Owner raises several issues regarding Petitioner's contentions. First, Patent Owner argues the Harder excerpt lacks any "indicia of reliability," because although the German-language version includes the text "© 2003 Hippokrates Verlag in," "[t]he Petition does not include a

translation of [that] page," and thus "Petitioner may not rely on an allegation that it is a copyright notice." Prelim. Resp. 27 (citing Ex. 1006, 3).

On this record, we do not agree with Patent Owner that the German-language version of the Harder exhibit lacks any "indicia of reliability." Even though Petitioner did not provide a translation of Harder page 3, we are still able to understand the notation "© 2003" as referring to a copyright date of 2003. Ex. 1006, 3. What's more, page 3 expressly states, in English, "Printed in Germany 2003." *Id.*; Prelim. Reply 4. Thus, the face of Harder itself indicates a publication date of 2003, which is years before the September 14, 2006, priority date.

Patent Owner questions Ms. Munford's assertions that the MARC record was created and Harder was "acquired, cataloged, and shelved on all on [sic] January 1, 2003," because this was "a Federal holiday on which the National Library of Medicine, as part of [the] Federal Government[,] was not open." Prelim. Resp. 28. For purposes of institution, we presume that Ms. Munford's declaration contains a typographical error. She bases the January 1, 2003, date on field 008 of the MARC record. *See* Ex. 1005 ¶ 9. Field 008 of the MARC record recites "030110." *See* Ex. 1005, 35. Assuming for purposes of institution that this is in the format YYMMDD, field 008 appears to show a date of January 1**0**, 2003.

Patent Owner further argues that Ms. Munford's testimony that the German-language excerpt of Harder (Exhibit 1006) is a "true and correct copy" of the book referenced in the MARC record is "not reliable," because the excerpt "is just 23 pages," whereas the MARC record shows a book having over 280 pages. Prelim. Resp. 29 (citing Ex. 1005, 35 (field 300)). On this record this argument is unavailing. Other indicia in the German-language Harder excerpt (Exhibit 1006) match the information in the MARC

record, such as title, author, and ISBN number. *See* Prelim. Reply 4 ("The MARC record and library catalog matches the indicia of publication on the face of Harder."). Accordingly, on this record we are satisfied that Exhibit 1006 is a "true and correct" excerpt of the book described in the MARC record.

Patent Owner also argues that the MARC record was revised on December 3, 2021, and as such the MARC record "cannot have existed as of its purported creation date of January 1, 2003." Prelim. Resp. 29; *see also* Prelim. Sur-reply 4 (asserting that "the MARC record did not exist prior to 2021"). On this record, we do not agree. Just because the record was updated in 2021 does not mean that the purported creation date in field 008 is inaccurate.

Patent Owner further argues that "[t]he date of record creation is unrelated to public accessibility," and "Mumford [sic] does not profess to have knowledge of the procedure used by the National Library of Medicine ('NLM') to receive publications, create records, and shelve books." Prelim. Resp. 28, 27. We agree with Patent Owner that Ms. Munford's affidavit does not appear to address NLM's specific procedures relating to receiving publications, creating records, and shelving books. Nevertheless, she testifies that since 2004, she has "served in various positions in the public library sector," and is "fully familiar with the catalog record creation process." Ex. 1005 ¶¶ 2, 3. She testifies that MARC records are created when "preparing a material for public availability." *Id.* ¶ 4. She further indicates that in her experience, the date in the 008 field of a MARC record "accurately indicates the date of an item's public availability." *Id.* ¶ 5. Thus, although Ms. Munford has not opined on the specific procedures used at the NLM, we are satisfied for purposes of institution that Ms. Munford's

experience in general library practices sufficiently demonstrates that Harder "was made available to the public shortly after its initial acquisition in January 2003," as she attests. *Id.* ¶ 9.

Patent Owner further argues that at most, Petitioner has demonstrated "technical accessibility" of Harder, but has not shown that "persons interested and ordinarily skilled in the subject matter" who were "exercising reasonable diligence" could have located it at the relevant time. Prelim. Resp. 30 (quoting *Hulu*, Paper 29, at 10–11); *see also* Prelim. Sur-reply 4. This is because, Patent Owner contends, Ms. Munford "does not explain how a POSITA would have accessed MOM-1006 prior to the critical date," for example how they could have located it "by searching the library's website." *Id.* at 30–31. Patent Owner also argues that "Petitioner makes no effort to explain how one of ordinary skill in the art of vitamin D compositions and methods of administration to a human being could, with reasonable diligence, locate Harder by having the MARC record." *Id.* at 33.

On this record, we do not find Patent Owner's arguments availing. The face of Harder bears a copyright date of 2003, a printing date of 2003, an ISBN number, and information identifying a commercial publisher. Ex. 1006, 1–3; Prelim. Reply 4. In *Hulu*, the Board found similar evidence sufficient to establish a reasonable likelihood that the disputed reference was a printed publication made available to the pertinent public prior to the critical date. *See Hulu*, Paper 29, at 19–20. Moreover, as in *Hulu*, the Munford Declaration is probative that Harder is the type of book that a medical library (such as the NLM) would have collected and catalogued. *See id.* at 20. This is different than Patent Owner's cited case, *Microsoft Corp. v. Throughputer, Inc.*, IPR2022-01566, Paper 13 (PTAB May 31, 2023) ("*Microsoft*"); Prelim. Resp. 31–33; Prelim. Sur-reply 4. The

reference at issue in *Microsoft* was a doctoral thesis that lacked "conventional markers of publication." *Microsoft*, Paper 13, at 11.

Further, "neither cataloging nor indexing is a necessary condition for a reference to be publicly accessible." *Hulu*, Paper 29, at 10 (citations omitted). Nevertheless, "[t]he MARC record . . . shows the category terms an interested researcher could use: 'postnatal care methods' and 'postpartum care.'" Prelim. Reply 5; Ex. 1005, 35. We agree with Petitioner that "[t]hese categories match the field of the '958 Patent, which includes the use of vitamin D compositions for breast-feeding infants." Prelim. Reply 5; Ex. 1001, 1:10–12.

Relatedly, Patent Owner's assertion that one of ordinary skill in the art would not look to Harder, "a general infant care book," "for the formulation of a composition for delivery of a nutritional or therapeutic effective amount of vitamin D in a single drop" is unavailing. Prelim. Resp. 33–34; Ex. 2009 ¶ 44. The person of ordinary skill in the art here is someone with, among other things, experience in delivering medicines and nutritional supplements. *See supra* Section II.B. There is no requirement that a person of ordinary skill in the art would have looked to Harder specifically for the "formulation" of a vitamin D drop, as Patent Owner contends. *See* Prelim. Resp. 33. Rather, a person of ordinary skill in the art may have looked to Harder because they are experienced in delivering medicines and nutritional supplements, and Harder concerns the neonatal care of infants in the home and in the clinic—a topic that conceivably embraces delivering medicines and nutritional supplements to infants. Ex. 1007, 4. Indeed, guidelines recommended daily vitamin D supplementation to infants for the prevention of rickets. *See, e.g.*, Ex. 1009, 6; Ex. 1012, 3.

In view of the above, we find that based on the totality of the evidence to date, Petitioner has established a reasonable likelihood that Harder is a printed publication that a publisher made available to the pertinent public prior to the September 2006 critical date.

(2) 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"

Patent Owner argues that "Harder's description of Vigantol oil . . . does not satisfy the composition limitation," because Harder equates "medium-chain triglycerides" with "vegetable oil," but a person of ordinary skill in the art would have known that vegetable oil "does not exclude the presence of long-chain triglycerides." Prelim. Resp. 45, 33–34; Ex. 2008 ¶ 29; Ex. 2009 ¶ 27. We acknowledge Dr. Vieth's testimony that "[o]ne of ordinary skill in the art would know that many vegetable oils are comprised of 'long-chain unsaturated fatty acid triglycerides,'" such as corn and flax-seed oil. Ex. 2008 ¶ 29. Nevertheless, on this record we find that for purposes of institution, Petitioner has the better argument. The translation of Harder in the record expressly states that Vigantol oil "*contains only one excipient* as a vehicle for the fat-soluble vitamin D, *namely medium-chain triglycerides* (vegetable oil)." Ex. 1007, 6 (emphasis added). On this record, we do not think the parenthetical reference to "vegetable oil," which Patent Owner and Dr. Vieth suggest *may* contain long-chain triglycerides, outweighs the teaching of a single excipient, namely medium-chain triglycerides.

Accordingly, we find that Petitioner establishes a reasonable likelihood that Harder teaches the claim limitation "a composition consisting of vitamin D in a liquid triglyceride of 6 to 12 carbon chain length."

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

Patent Owner argues that "[n]one of the references alone or in combination suggest . . . the interaction between the composition and the surface of the object." Prelim. Resp. 35. Patent Owner argues that Petitioner cannot rely on the '958 patent's experimental observations to show inherency because those observations were limited to the disclosed liquids as applied to a nipple. *See id.* at 35–36.

Patent Owner also argues that a person of ordinary skill in the art would have understood Harder as teaching to apply Vigantol "into the concave (interior) bowl of the spoon, because one of ordinary skill in the art would readily understand that medium-chain triglycerides would instantly slide off the back convex (exterior) surface of the spoon." *Id.* at 41. Patent Owner further argues Petitioner's "inherency argument was conclusively demonstrated to be false by direct observation that MCTs [medium chain triglycerides] according to claim 1 do not adhere to a spoon." *Id.* at 43 (citing Ex. 2009 ¶¶ 32–35).

Patent Owner's arguments are unavailing on this record. Petitioner has adequately shown for purposes of institution that the Vigantol oil composition disclosed in Harder and Wolf would inherently adhere to a surface, including a nipple or pacifier. *See* Pet. 29–31. "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." *Hospira, Inc. v. Fresenius Kabi*, 946 F.3d 1322, 1329 (Fed. Cir. 2020) (citation omitted); *see also id.*

("When the prior art does not expressly disclose a claim limitation, inherency may supply a missing claim limitation in an obviousness analysis.") (citation omitted).

First, we agree with Petitioner that the Specification identifies viscosity and triglyceride chain length as impacting the adhering property, 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 ¶ 50. The Specification discloses that a composition consisting of vitamin D and medium-chain triglycerides adhered to a nipple. *See* Ex. 1001, Table 1, 7:21–27. Harder discloses applying a composition consisting of vitamin D and medium-chain triglycerides to the tip of a spoon. Ex. 1007, 6. On this record, we agree with Petitioner that the results in the Specification demonstrate that the Vigantol oil in Harder—which is taught to have the same composition as that tested in the Specification—would inherently meet the "adheres" limitation of the claim. Pet. 29–31; *see also Hospira, Inc.*, 946 F.3d at 1329–30 ("[T]he work of the inventor or the patentee can be used as the evidence of inherency.").

Patent Owner argues that the '958 patent "solves the problems of adherence and delivery," whereas the "prior art never indicated any awareness of these difficulties and never solved or addressed these technical problems." Prelim. Resp. 38 (citing Ex. 2008 ¶ 5); *see also id.* at 39 ("Harder never conceived of, did not address, and never solved the problems solved by the '958 Patent."). Patent Owner also argues that nothing in Harder suggests "a drop that adheres to the exterior surface of an object, such as a pacifier, a nipple, or another object." Prelim. Resp. 39; *see also id.* at 42 ("Harder teaches nothing about the adhering property or any physical aspect of MCT or any other liquids regarding suitability.").

These arguments are unavailing. First, those of ordinary skill in the art need not have recognized the inherent characteristics or functioning of the prior art. *See In re Cruciferous Sprout Litig.*, 301 F.3d 1343, 1349 (Fed. Cir. 2002). Second, for purposes of institution, Petitioner adequately demonstrates that based on Harder's teaching of administering an infant one drop of Vigantol oil by placing it on the tip of a spoon, a person of ordinary skill in the art would have recognized Vigantol oil's adhering properties, because they would have understood that any substance that does not adhere to the surface would naturally drip off or away from the tip, rendering the disclosed delivery method ineffective. *See* Pet. 30–31; Ex. 1004 ¶¶ 52–54, 103.

Patent Owner also argues that Petitioner's "inherency argument was conclusively demonstrated to be false by direct observation that MCTs according to claim 1 do not adhere to a spoon." Prelim. Resp. 43 (citing Ex. 2009 ¶¶ 32–35). In particular, Patent Owner's declarant Dr. Woessner states:

> In connection with the prior related litigation (2017), I provided a bottle of Baby Ddrops® to Michael R. Mischnick, an attorney at Schwegman Lundberg & Woessner, P.A., who is a registered patent attorney and holds a degree in chemical engineering. I asked him to evaluate the ability of one drop of Baby Ddrops®, to adhere to a stainless-steel spoon. As described by Mr. Mischnick, one drop of Baby Ddrops® product did not adhere to a stainless steel spoon. Mischnick Decl., Ex. WW-B, page 36 of 45 (page numbers refer to numbers at the top of the page). The drop of liquid was contained by the lip of the spoon when the spoon was tipped forward slightly, but immediately flowed down the bowl of the spoon when the spoon was held level or tipped back slightly. . . .
>
> I have proven that Baby Ddrops, one drop of which is 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" as recited in claim 1, does not adhere to a spoon.

Ex. 2009 ¶¶ 32–35; *see also* Ex. 2009, 98 (Mischnick Decl. ¶ 5) (discussing spoon test). On the current record, Patent Owner's arguments are unavailing. Mr. Mischnick expressly states that one drop of Baby Ddrops "was contained by the lip of the spoon" when it was "tipped slightly downwards." Ex. 2009, 98 (Mischnick Decl. ¶ 5). Thus, this test appears to show that Baby Ddrops "adhered" to the spoon when it was tipped slightly downwards, because the drop did not immediately drip or roll away, such that no portion of the drop dripped off the spoon. Mr. Mischnick states that even "when the spoon was tipped slightly upward, the drop immediately ran down the bowl of the spoon in a thin sheet." *Id.* Here too, this test appears to show that Baby Ddrops "adhered" to the spoon, because even though the drop ran down the bowl of the spoon in a thin sheet, the drop did not drip or roll away such that any part dripped off the spoon.

Patent Owner also argues that Harder teaches applying Vigantol "into the concave (interior) bowl of the spoon," and "one of ordinary skill in the art would readily understand that medium-chain triglycerides would instantly slide off the back convex (exterior) surface of the spoon." Prelim. Resp. 41; *see also id.* at 38–39. This argument appears to be inconsistent with Harder, which teaches applying the drop to the "tip" of a spoon, not to the "bowl of the spoon."[12] Ex. 1007, 6; Pet. 12, 23. We also find unavailing Patent Owner's argument that "[t]here is no way to lick a spoon unless it is

[12] Contrary to Patent Owner's argument that "Harder does not disclose whether the drop is placed on the interior or exterior surface of the spoon" (Prelim. Resp. 46), on this record we find that the top of a spoon is an exterior surface.

turned upside down," because the tongue would be under the spoon. Prelim. Resp. 40; Ex. 2008 ¶ 19. On this record, we do not find Harder's method lacks enablement, because, for example, it appears that the tongue can be moved to the top of the spoon to lick off the drop, the drop can be sucked off the tip of a spoon, and/or the spoon can be turned over once in the infant's mouth to enable licking the drop.

Finally, Patent Owner attempts to discount Petitioner's arguments by drawing a distinction between viscosity and adherence. Prelim. Resp. 47. First, the parties' agreed construction in the Parallel Litigation indicates that viscosity impacts adherence. *See* Ex. 2005, 2. This is consistent with the '958 patent itself, which likewise indicates that viscosity can impact adherence, by teaching: "[t]he 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." Ex. 1001, 6:34–37.

(3) Secondary Considerations of Non-obviousness

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). "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 presumption of nexus for objective considerations when the patentee shows that the asserted objective evidence is tied to a specific product and that

product 'is the invention disclosed and claimed in the patent.'" *WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1329 (Fed. Cir. 2016) (citations omitted); *see also Fox Factory, Inc. v. SRAM, LLC*, 944 F.3d 1366, 1373 (Fed. Cir. 2019). Moreover, 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 unexpectedly superior results were ultimately 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 commercial success, copying, and long-felt need tied to the claimed invention, and that "[t]he Baby Ddrops® product sold by Ddrops Company embodies the claimed invention."[13] Prelim. Resp. 53–54 (citing, *e.g.*, Ex. 2004 ¶¶ 15–16)[14], 52 (citing Ex. 2004 ¶ 5).

On this record, it appears that the "Baby Ddrops® product" embodies the claimed invention. *See* Ex. 2004 ¶ 5 (discussing Baby Ddrops composition, dose, and instructions for use). Thus, to the extent Patent Owner presents similar evidence during trial, it may be entitled to a rebuttable presumption of nexus between the asserted evidence of secondary

[13] Ddrops Company appears to be a licensee of the '958 patent. *See* Ex. 2004, 8 (¶ 10). Mr. Temovsky is the co-president of Ddrops Company. *Id.* at 1 (¶ 1).

[14] Patent Owner also cites Exhibit 2004 at paragraphs 40–44, but Patent Owner's intended citation is unclear, because Exhibit 2004 does not contain any paragraphs numbered 40 through 44. *See* Prelim. Resp. 53.

considerations and the challenged claims. *See Fox Factory, Inc.*, 944 F.3d at 1373. Nevertheless, we note that "[w]here the offered secondary consideration actually results from something other than what is both claimed and novel in the claim, there is no nexus to the merits of the claimed invention." *In re Kao*, 639 F.3d 1057, 1068 (Fed. Cir. 2011). The parties are free to explore nexus during trial.

As to commercial success, Patent Owner's declarant Mr. Temovsky testifies that "[s]ince 2009, Ddrops's market share for the Patented Product in Canada has increased to approximately 60% through the end of 2016," and "[f]rom 2013 to 2016, sales of the Patented Product increased 464% in the United States." Ex. 2004, 9 (Exhibit A, at ¶¶ 15–16). On this record, Patent Owner's evidence of purported commercial success argument is almost exclusively based on these two paragraphs from Mr. Temovsky's declaration in a prior litigation (*Ddrop Co. v. iHerb, Inc.*, previously pending in the District of Minnesota and terminated on June 23, 2017 (the "*iHerb* case"), *see* Pet. 47; PO Resp. 2). Mr. Temovsky does not support this testimony with underlying evidence of record, such as market share and sales data. At this stage of the proceeding, we give this untested evidence of purported commercial success little weight.

As to copying, Patent Owner cites "Ex. 2004, pg. 9, ¶s40-44" (*see* Prelim. Resp. 53), but Patent Owner's intended citation is unclear, because none of the three Temovsky declarations of record contain any paragraphs numbered 40 through 44. *See* Ex. 2004, 1 ("Declaration of Chris Temovsky," containing paragraphs 1–9), 6 ("Declaration of Chris Temovsky" from the *iHerb* case, containing paragraphs 1–32), 65 ("Third Declaration of Chris Temovsky" from the *iHerb* case, containing paragraphs 1–36).

We observe Mr. Temovsky's assertion that "over one dozen" "competitors have copied the Ddrops patented method and product." Ex. 2004, 68 (Third Declaration of Chris Temovsky from the *iHerb* case, ¶ 13). Again, however, Mr. Temovsky does not support this testimony with underlying evidence in the record. Additionally, Mr. Temovsky's testimony appears to conflate alleged copying with alleged infringement. But "[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 v. Master Lock Co.*, 616 F.3d 1231, 1246 (Fed. Cir. 2010) (quoting *Iron Grip Barbell Co. v. USA Sports, Inc.*, 392 F.3d 1317, 1325 (Fed. Cir. 2004)). "[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." *See id.* "[A]ccess to published articles about a patented method are relevant to the analysis of objective indicia and copying." *Liqwd, Inc. v. L'Oreal USA, Inc.*, 941 F.3d 1133, 1138 (Fed. Cir. 2019). At this stage of the proceeding, we give Patent Owner's untested evidence of purported copying little weight.

As to long-felt but unresolved need, Patent Owner appears to suggest a "need for a nutritionally effective method to administer a precise amount of vitamin D in a small controlled volume of the formulation." Prelim. Resp. 37; *see also id.* at 54 (suggesting a "long-felt but unresolved need" for a "method of administering vitamin D, particularly to infants, that reliably delivers the appropriate dose"). However, a long-felt need must not have been satisfied by another before Patent Owner's invention. *See 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 . . . ."). In view of Harder and Wolf's disclosures, on the current record we find unavailing Patent Owner's contention that a long-felt need existed, because Harder and Wolf both disclose a method of administering to an infant a precise amount of vitamin D in a small controlled volume of the formulation. *See* Ex. 1007, 6; Ex. 1009, 9.

Patent Owner argues that the Board should exercise its discretion to deny institution because Petitioner did not address secondary considerations evidence (discussed above) that Patent Owner presented in publicly-filed declarations in a prior litigation against a third party. Prelim. Resp. 54–55. Patent Owner contends that "Petitioner's lead counsel and law firm in this proceeding, served as lead counsel" in the prior case, and thus this evidence "was known to lead counsel for Petitioner and a matter of public record from [this] prior related lawsuit." Prelim. Resp. 7, 2.

Under the circumstance here—including the poorly developed contentions from the prior litigation discussed above—we decline Patent Owner's invitation to require Petitioner to predict and proactively address the particular evidence of secondary considerations that Patent Owner may assert here. An investigation into secondary considerations of non-obviousness is particularly fact-intensive and may require discovery. On this record, considering that Petitioner was not a party to the prior litigation, has only now been presented with an outline of Patent Owner's secondary considerations, and has not yet been afforded an opportunity to develop countervailing evidence, we decline to hinge the outcome of a decision to institute on the incomplete record before us. *See, e.g.*, *Invata, LLC v. OPEX Corp.*, IPR2022-01604, Paper 8 at 10 (PTAB Mar. 17, 2023).

In sum, we have considered Patent Owner's evidence and arguments of secondary considerations, but find it insufficiently developed at this stage to preclude a determination that Petitioner demonstrates a reasonable likelihood of success on unpatentability. Such issues implicate genuine issues of fact that are more appropriate to resolve after development of a full trial record.

4. *Ground 2: 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. For purposes of institution, Petitioner adequately supports its contention that it was "known that an infant could suck medicine or a supplement off of a pacifier." Pet. 34; Ex. 1004 ¶ 105; Ex. 1011, 7–8. In particular, Petitioner demonstrates that Blass describes delivering a medicament to an infant by applying it to a pacifier. Pet. 34–35; Ex. 1004 ¶¶ 66–68; Ex. 1011, 7–8. On this record, Petitioner adequately demonstrates that a person of ordinary skill in the art would have looked to Blass for methods of delivering medication, such as Vigantol oil, to an infant:

> 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 ¶ 106; *see also id.* ¶¶ 85–87; Pet. 33–35.

Patent Owner argues that Blass discloses repeatedly dipping a pacifier in sugar water, and "[t]here is no indication that such a method should be used for delivering a precise dose of anything, let alone a nutritionally efficacious dose of vitamin D." Prelim. Resp. 48. On this record, this argument does not undermine Petitioner's showing that a person of ordinary skill in the art would have recognized from Harder, Wolf, and Blass that a pacifier is more likely trigger the sucking reflex than the spoon disclosed in Harder, which would ensure delivery of the complete drop that Harder teaches to administer to the infant.

Patent Owner also argues that "Blass does not satisfy the adhere limitation because the sugar water used in Blass would not adhere to a pacifier." Prelim. Resp. 48 (citing Ex. 2008 ¶ 3; Ex. 2009 ¶ 39). Petitioner, however, 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")).

5. *Ground 3: 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, 6, 9; Ex. 1004 ¶¶ 89–90; Ex. 1012, 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 ¶¶ 88–93, 107–10. For purposes of institution, we are persuaded by Petitioner's arguments.

Patent Owner argues that "Gartner does not disclose how such a [200 I.U. vitamin D] supplement should be delivered and does not disclose any mechanism for reliably delivering the proper dose of vitamin D3." Prelim. Resp. 49–50. This argument is 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.

III. CONCLUSION

For the foregoing reasons, we determine that the information presented establishes a reasonable likelihood that Petitioner would prevail in showing that at least one of the challenged claims of the '958 patent is unpatentable.

IV. NOTICES

At this preliminary stage, we have not made a final determination with respect to the patentability of any challenged claim or any underlying factual and legal issues. *See TriVascular, Inc. v. Samuels*, 812 F.3d 1056, 1068 (Fed. Cir. 2016) (noting that "there is a significant difference between a petitioner's burden to establish a 'reasonable likelihood of success' at institution, and actually proving invalidity by a preponderance of the evidence at trial"). Thus, any conclusion reached in the foregoing analysis could change upon completion of the record. Any final decision in this proceeding will be based on the full trial record.

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.

Nothing in this Decision authorizes Petitioner, in a manner not otherwise permitted by the Board's rules, to supplement the information pertaining to any ground advanced in the Petition.

V. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that, pursuant to 35 U.S.C. § 314(a), an *inter partes* review is instituted based on all grounds asserted in the Petition; and

FURTHER ORDERED that, pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, notice is hereby given of the institution of a trial commencing on the entry date of this Decision.

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