

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MOM Enterprises, LLC,
Petitioner,

v.

ELAINE AND REINHOLD W. VIETH,
Patent Owners,

Case IPR 2023-00726
Patent 9,066,958

**PATENT OWNERS' PRELIMINARY RESPONSE
UNDER 36 CFR § 42.107**

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2002	CIVIL DOCKET FOR CASE #: 0:15-cv-03981-WMW-SER, U.S. District Court, U.S. District of Minnesota (DMN), Accessed through PACER, June 23, 2023.
2003	CIVIL DOCKET FOR CASE #: 0:16-cv-04278-JNE-TNL, U.S. District Court, U.S. District of Minnesota (DMN), Accessed through PACER, June 23, 2023.
2004	Declaration of Chris Temovsky
2005	Claim Construction Order, Case 1:22-cv-00332-GBW, Ddrops Company et al v. MOM Enterprises, LLC, Gregory B. Williams, presiding, D.I. 72, Filed 06/02/23
2006	MARC STANDARDS, Library of Congress Network Development and MARC Standards Office, MARC 21 Format for Bibliographic Data, https://www.loc.gov/marc/ last accessed June 23, 2023
2007	U.S. Bureau of Labor Statistics, Occupational Outlook Handbook, Interpreters and Translators, https://www.bls.gov/ooh/media-and-communication/interpreters-and-translators.htm , last accessed June 23, 2023.
2008	Declaration of Reinhold Vieth
2009	Declaration of Warren D. Woessner
2010	Transcript of Markman Hearing, June 1, 2023, Case No. 1:22-cv-00332-GBW Ddrops Company et al v. MOM Enterprises, LLC, Gregory B. Williams, presiding
2011	Oxford English Reference Dictionary, 2 nd Edition, the Oxford University Press, 1996 (Definitions of adhere and viscosity)

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37 C.F.R. § 42.51	18, 20 24
37 C.F.R. § 42.63(b)	11, 13, 14, 22, 27

I. INTRODUCTION

On March 16, 2023, MOM Enterprises, LLC, d/b/a Mommy's Bliss ("Petitioner") filed an *inter partes* review petition ("IPR") of U.S. Patent No. 9,066,958 ('958 Patent) (MOM-1001) challenging the validity of claims 1 and 3-5 ("Challenged Claims") as obvious. Petitioner takes a shotgun approach rather than a rigorous application of the *Graham v John Deere Co.*, 383 U.S. 1 (1966), *hereafter Graham* analysis.

The Petition relies on documents that are not properly qualified as prior art. Thus, the petition fails the first *Graham* factual inquiry (determining the scope and content of the prior art.) The so-called prior art includes incomplete documents, preventing an evaluation of what a document as a whole would teach one of ordinary skill in the art and irregular and unattested translations. The primary reference in all combinations has not been shown to have been accessible to those of ordinary skill in the art.

Second, even if the Board considers the documents as prior art, Petitioner's obviousness argument fails because it does not properly address the second *Graham* factual inquiry (ascertaining the differences between the claim and the prior art). Specifically, the prior art lacks *at least* the material limitation in claim 1 requiring "wherein said drop adheres to the surface of said object".

The petition asserts only conclusions rather than undertaking a meaningful analysis of the third *Graham* factuality inquiry (resolving the level of ordinary skill in the art). The petition asserts a grossly understated alternative level of skill. Then, in a classic use of impermissible hindsight, the petition looks to the patent itself for the justification for modifying the prior art. None of the prior art relied upon discloses a composition and an object, wherein the composition adheres to the object.

Finally, to complete the superfecta, Petitioner fails to address the fourth *Graham* factuality inquiry (consider evidence of secondary indicia of non-obviousness). Here, the evidence of secondary indicia (copying by competitors, commercial success, industry praise, and long felt but unresolved need) was known to lead counsel for Petitioner and a matter of public record from a prior related lawsuit. But Petitioner never bothered to submit this known evidence to the Board or to address it.

Because the Petition fails to address, let alone satisfy, the four factual inquiries mandated by *Graham*, the prior art is unreliable. The Patent Owners, therefore, respectfully request that the Board exercise its discretion to deny institution. The public would be better served if the Board used its resources to address other petitions that properly address all of the *prima facie* elements of

obviousness, which are not filed on the last possible day in the midst of concurrent litigation by counsel who was aware of and previously asserted the primary reference as supporting grounds for invalidating the same claims in a prior related lawsuit almost six years earlier.

A comparison of the first sentence of the Petition to claim 1 of the '958 Patent demonstrates a basic deficiency. Specifically, the Petition erroneously states, "The purported invention disclosed in the '958 Patent is having someone 'lick or suck' a certain substance from an object. *See* MOM-1001." The glaring flaw here and throughout the petition is that this is not what the claims actually state. Claim 1 of the '958 Patent requires, *inter alia*, applying a drop of a certain substance "to an exterior surface of an object, wherein said drop adheres to the surface of said object." The claim only applies when the object is such that the drop of the certain substance adheres to it.

II. THE '958 PATENT

A. Overview

According to the National Institutes of Health (NIH) Office of Dietary Supplements (ODS), the Recommended Dietary Allowance (RDA) for Vitamin D for infants is 10 mcg (400 IU). Breast milk alone does not provide infants with an adequate amount of vitamin D, and excessive intakes of vitamin D are toxic. MOM-1001, 1:60-2:12. In 2005, pediatric associations in the U.S. strongly

recommended starting vitamin D supplementation from birth onwards. The previous recommendation had been that vitamin D supplementation should start at around 2 months of life. The need to provide vitamin D at an earlier age created challenges. First, smaller infants are more difficult to handle. Second, breast-feeding mothers often do not want to give their infants foreign liquids or compounds that are not natural for them to be taking. Moreover, the pediatric associations did not provide any explanation of how to deliver vitamin D to the breast-feeding infant. They simply left it to the parents to figure out on their own. *Id.*, 2:13-36.

The inventors of the '958 Patent, Reinhold Vieth and Elaine Vieth, realized problems existed with existing vitamin D products; critically, there was the lack of an appropriate and effective method of delivery. The prior art products tasted bad with an unpalatable texture, which caused infants to spit out the liquid. These problems resulted in under-dosing and ineffective treatment. Additionally, the prior art products had a short shelf-life and a greasy feel. *Id.*, 2:37-52.

Recognizing the need for a solution to these problems and the lack of scholarly information and studies regarding the efficacy, use, and administration of nutritional supplement vitamins (especially vitamin D) to infants/babies, Reinhold Vieth and Elaine Vieth undertook experimentation in the early 2000's, testing and

analyses to develop a new, useful and innovative product and method for efficaciously administering vitamin D to babies. *Id.*, 2:53-3:17.

Through experimentation, the Vieths discovered that indirect application of a particular composition of vitamin D to a pacifier or nipple resulted in only about a 4% loss, which is deemed acceptable for dosing a supplement product. *Id.*, 4:50-57. The Vieths also discovered that a vitamin D composition consisting of a liquid triglyceride of 6 to 12 carbon chain length had other, numerous advantages over the prior art vitamin D products, including a longer shelf-life. It is tasteless, has a non-greasy feel and adheres to the surface of a nipple or pacifier.

B. Challenged Claims

Petitioner challenges claims 1 and 3-5 of the '958 Patent. Claim 1 is independent. Claims 3-5 depend from claim 1. Claim 1 is directed to a method of delivering a nutritional or therapeutic amount of vitamin D to a human being. Claims 3-5 recite refinements to the method of claim 1.

C. Prosecution History

The '958 Patent issued from U.S. Patent Application No. 11/674,234, filed February 13, 2007, which claims priority to Canadian Application 2558202, filed September 16, 2006, MOM-1001, pg. 1.

The last prior art rejection of claim 1 (prosecuted as application claim 13) before allowance was based on a combination of references that included Blass *et al.* (MOM-1011). MOM-1002, pg. 75.

The Examiner's statement of Reasons for Allowance was:

The cited references in combination fail to teach, motivate or suggest a vitamin D composition consisting of vitamin D and a liquid triglyceride of 6 to 12 carbon chain length and a method of delivering the vitamin D composition wherein a single drop of a vitamin D composition consisting of vitamin D in a liquid triglyceride is applied to a surface so that the single drop would adhere to the object, until it is sucked or licked off of the surface, and thus effectively administer the desired level of vitamin D to the user. One skilled in the art would not be motivated to apply a single drop of the vitamin D composition to the exterior surface of an object including an arm or a hand because it may drip off or get contaminated. Thus, the claimed method is novel and non-obvious over the prior art.

MOM-1002, pg. 28. The Examiner's statement confirms that Blass would not have motivated one of ordinary skill in the art to apply a single drop of the vitamin D composition to an object to which it would adhere.

III. RELATED PROCEEDINGS

Patent Owner and Petitioner are parties to a concurrent civil action, *Ddrops Company, et al, v. MOM Enterprises, LLC*, filed March 16, 2022, pending in the

United States District Court for the District of Delaware (the “concurrent related proceeding”).

The ‘958 Patent was asserted in two prior actions in the United States:¹.

1. *Ddrops Company, et al. v. Walgreen Co., et al*, 15:CV-03981, filed 10/30/2015 in the U.S. District of Minnesota; Terminated 06/01/2016. Ex. 2002.
2. *Ddrops Company, et al. v. iHerb, Inc. et al.*, 16:CV-04278, filed 12/198/2016 in the US District of Minnesota; Terminated 06/23/2017 (the “prior related proceedings” or “iHerb Case”). Ex. 2003.

Significantly, Petitioner’s lead counsel and law firm in this proceeding, served as lead counsel in the iHerb Case. *Id.*, pgs. 2-3.

A motion for a preliminary injunction, *see id. D.I. 33*, was fully briefed before the iHerb Case settled. The briefing developed substantial evidence of secondary indicia of non-obviousness. This evidence was disclosed in a supporting declaration. That evidence is attached as exhibits to the declarations of Chris

¹ The Canadian equivalent of the ‘958 Patent has been successfully prosecuted in numerous actions in Canada.

Temovsky, Ex. 2004 and Warren Woessner, Ex. 2009. As specified below, the evidence that was previously developed and disclosed included:

- Evidence showing that the Ddrops product embodied the claim.
- Evidence of copying by competitors.
- Evidence of commercial success.
- Evidence of industry praise including awards.
- Evidence of long felt but unresolved need was developed.
- Evidence of long felt and unresolved need is set forth in the patent specification.

IV. CLAIM CONSTRUCTION

In the concurrent related proceeding, the court entered a Claim Construction Order on June 2, 2023, following a *Markman* hearing. Ex. 2005. The Order adopted agreed constructions as follows:

<u>AGREED CONSTRUCTIONS</u>	
1	“one drop of composition consisting of . . . ” has its plain and ordinary meaning, which is “one drop of C ₆ -C ₁₂ liquid fatty esters of glycerol sufficient to administer a nutritional or therapeutically effective dose of vitamin D” (‘958 Patent, claims 1, 3-5)

<u>AGREED CONSTRUCTIONS</u>	
2	“a nutritional or therapeutic effective amount . . . ” has its plain and ordinary meaning, which is “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” (‘958 Patent, claims 1, 3-5)
3	“liquid triglyceride of 6 to 12 carbon chain length . . . ” as used in claims 1, 3, and 4 has its plain and ordinary meaning, which is “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” (‘958 Patent, claims 1, 3-4)
4	“liquid triglyceride of 6 to 12 carbon chain length . . . ” as used in claim 5 has its plain and ordinary meaning, which is “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” (‘958 Patent, claim 5)

<u>AGREED CONSTRUCTIONS</u>	
5	“wherein said drop adheres to the surface of said object” has its plain and ordinary meaning, which is “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” (‘958 Patent, claims 1, 3-5)

The court construed “vitamin D”, which was contested by the parties, 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).” (‘958 Patent, claims 1, 3-5). It further clarified in a footnote: “As stated during the hearing, ‘a person of ordinary skill in the art would understand [this] language to refer to either vitamin D2 or vitamin D3.’” Ex. 2005, pg. 2; *see also* Hearing Transcript, Ex. 2010, pg. 17.

V. PRIOR ART

The proposed grounds for obviousness asserted by the Petitioner, i.e., Grounds 1-3, rely on the following.

A. Harder

Harder (MOM-1006), and its purported translation (MOM-1007), should be stricken from the record. The purported MARC record for Harder shows that it should have 12 pages of front matter and 282 pages of main text. MOM-1005, pg. 35, field 300. See MARC Format for Bibliographic Data, *Field 300 – Physical Description* (Ex.2006, pg.5) issued by The Library of Congress – Network Development and MARC Standards Office. However, MOM-1006 is only 23 pages long; petitioner omitted over 90% of the book. Without the entire book, the Petitioner's cherry-picked excerpt cannot be read in context, and the Board cannot determine if one of ordinary skill in the art would even consider this document. Moreover, other portions of Harder may in fact teach away from the claimed invention.

Petitioner asserts that MOM-1007 is a translation of Harder. However, MOM-1007 does not attest to the accuracy of the translation. MOM-1007 does not qualify as a translation of all of MOM-1006. The 7 pages attached to the Declaration are in English, but appear to correlate to less than 6 of the 23 pages of MOM-1006 that were supplied. Sherman, the declarant of MOM-1007, states "1. Rebecca Amy TINWORTH performed the attached translation from German into English of Chapter 15.9 of 'Wochenbettbetreuung in der Klinik und zu Hause'

[Childbed care in clinics and at home] (also attached).” However, the pages asserted to be (“also attached”) are not present. The reference to Chapter 15.9 is erroneous because it appears from the table of contents of MOM-1006 (not translated) that there is a Chapter 15 and perhaps a section 15.9, but not a chapter 15.9.

MOM-1007 asserts Tinworth “is competent to perform this translation”. Significantly, there is no affidavit attesting to the accuracy of the Tinworth translation. Sherman, who did not perform the translation himself, declares, “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.” (Emphasis added). Obviously, this is code for “massaging” the translation to more closely align with the Petitioner’s legal arguments. This is confirmed in paragraph 2 by the admission that Tinworth’s original translation did not include the critical “to be licked off” phrase. MOM-1007, therefore, is not a translation prepared by Tinworth, but rather a translation manipulated by Mr. Sherman to add the critical “to be licked off” phrase.

Moreover, Sherman never states that he is competent or qualified to translate German to English. He provides no qualifications or credentials and does not even

claim proficiency in the English language, the German language, or providing translation services.

According to the United States Bureau of Labor Statistics, Occupational Outlook Handbook for Interpreters and Translators (Ex. 2007), “Interpreters and Translators typically need at least a bachelor’s degree to enter the occupation. They also must be proficient in English and at least one other language, as well as in the interpretation or translation service they intend to provide.” Sherman has not attested to the accuracy of the translation attached to MOM-1007 and does not claim he is qualified to do so. MOM-1006 and MOM-1007 therefore should be rejected under 37 C.F.R. § 42.63(b).

Even if the panel overlooks the improper and inadmissible hearsay revision of a translation that Petitioner has not submitted, Harder fails to teach (and no other reference teaches) one of the critical elements of claim 1, namely, administering a drop of the composition by placing it on an exterior surface of the object wherein the composition adheres to the object. Nothing in Harder indicates that Vigantol oil adheres to a spoon (the object identified by Harder).

B. Wolf

Wolf recommends daily administration of 500 IU of vitamin D3 and teaches to administer vitamin D3 “at least for the first year of life from the newborn

phase”. MOM-1009, pg. 7, ¶3. Wolf does not disclose the composition of Vigantol oil except to claim it is a pure vitamin D3 preparation. Wolf does not describe what “pure” means.

While the teaching of Wolf has little to no non-cumulative value, it should still be rejected as prior art. The purported Translator’s Declaration for Wolf (MOM-1009, pg. 1), is lacking. Rather than being an “affidavit attesting to the accuracy of the translation”, as required by 37 C.F.R. §42.63(b). MOM-1009 qualifies the accuracy of the translation by “to the best of my knowledge.” The only basis given for “knowledge” is that the declarant has a BS degree in physiology, a PhD in biochemistry and “have worked in Germany following my studies.” MOM-1009, ¶3. The declarant does not claim to have knowledge of German (or English) and does not claim any proficiency in translation of German to English. The “translator” does not claim to have any of the proficiencies identified in Ex. 2007, and thus should be refused consideration.

C. *European Pharmacopeia, Supplement 4.3*

Petitioner provided only a copy of the cover, title page, table of contents, and pages 3148-3151 of Supplement 4.3 to *EUROPEAN PHARMACOPEIA*, FOURTH EDITION. MOM-1010. According to the Table of Contents, pages 3148-3150 are from the MONOGRAPHS section of the document. Page 3151 is

unrelated and not relied upon by Petitioner. Petitioner has not provided a “complete copy” of the document with the Petition.

For example, there are references to testing of unknown solutions:

“Appearance. The substance to be examined is clear (2.2.1) and not more intensely colored than reference solution Y3 (2.2.2, Method 1).” There is no indication of what 2.2.1 is; no indication of what solution Y3 is; and no description 2.2.2, Method 1. It is impossible to consider what the reference as a whole discloses or what the sections provided even mean without the remainder of the document.

In *Shenzhen Aurora Tech. Co. Ltd. v. Potco, Inc.*, IPR 2022-00670, Paper 10, the Board denied institution and refused to consider an incomplete machine translation filed without any affidavit attesting to the accuracy of a foreign reference. MOM-1010 might as well be in a foreign language because its contents are impossible to interpret without the missing information. MOM-1010 should not be considered.

Moreover, as discussed below, even if MOM-1010 were considered, it discloses nothing more than an inactive component that might be used in medical formulations. There is no suggestion of how or why or administration techniques. Thus, even if considered, it is cumulative to the disclosure in the ‘958 Patent, Example 6 that USP grade medium-chain triglycerides were available to use.

D. Blass

The Blass article, MOM-1011, is entitled “Suckling- and sucrose-induced analgesia in human newborns.” The Examiner considered Blass and relied on it to initially reject claims during the prosecution. Blass stands for the unremarkable principle that the effects of “sucking induced analgesia” are enhanced if an infant sucks with greater vigor and that dipping a pacifier in sugar water before giving it to an infant induces more vigorous sucking. Blass does not address administration or dosing of vitamins or adhesion of any liquids to objects. Blass reports on the results of an experiment where some infants were given a pacifier dipped in sugar water every 30 seconds to increase the amount of sucking. Blass does not disclose or suggest that it has any interest in precise dosing of any substance. Ex. 2008, ¶s 39, 40.

Neither MOM-1008 nor MOM-1010 give any reason why a person of ordinary skill in the art would apply the method of dipping a pacifier into a contain of sugar water to administer vitamin D. Unlike sugar water, an overdose of vitamin D is toxic to infants. A person of ordinary skill in the art would certainly deem the Blass method to administer vitamin D to infants reckless and unsafe.

E. Gartner

The Gartner article is titled, “Prevention of Rickets and vitamin D Deficiency: New Guidelines for Vitamin D Intake.” MOM-1012. The Petition truncates the title, presumably because Petitioner does not like the reference to “new.” Gartner merely addresses guidelines issued by the National Academy of Sciences and recommends a supplement of 200 IU of vitamin D per day. Gartner does not disclose how such a supplement should be delivered and does not disclose any mechanism for reliably delivering a proper dose of vitamin D.

VI. PERSON OF ORDINARY SKILL IN THE ART

According to the Petition page 6:

A POSITA 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. A person skilled in the art would also have knowledge of published publications relevant to formulating compositions of and delivering medications and nutritional supplements to humans.

For the purpose of this Preliminary Response, Patent Owners agree with the first sentence, but do not agree with the remainder of the description. The alternative formulation allows that a nurse may be a person of ordinary skill in the relevant art. This is not correct. The patent specification is a relevant source of information regarding the skills required for one of “ordinary skill.” The ‘958 Patent demonstrates that one of ordinary skill in the art must have knowledge of the benefits and risks attendant to the administration of vitamin D as well as the nature, chemistry, and characteristics of various vehicles for delivery of pharmaceuticals and nutritional supplements, and procedures and equipment detecting and measuring the relevant chemicals, including the efficacy and uptake of vitamin D. MOM-1001, 7:31-34 and 8:27-31. While the “ordinary” nurse may have knowledge and experience in delivering medicines and nutritional supplements, they do not have the skills required of a person of ordinary skill in the art relevant to the ‘958 Patent. *See also* Declaration of Reinhold Vieth (Ex. 2008), ¶32. (“Based on my experience, including attending conferences and giving lectures to audiences that included nurses and midwives, it is my opinion that a nurse does not satisfy the minimum requirements for a person of ordinary skill in the art pertinent to the ‘958 Patent. The ‘958 Patent identifies skills that a person of ordinary skill in the art would have beyond those that an ‘ordinary nurse’ would

possess. For example, selecting excipients appropriate for vitamin D, MOM-1001, 1:10-12, understanding the metabolic steps that vitamin D goes through, *id.* 1:40-50; understanding and measuring absorption rates, *id.* at 2:58-66; the skill to understand that efficacious administration of vitamin D must have suitable effects on the circulating concentration of 25-hydroxyvitamin D and how to make that determination, *id.* 4:63-5:7, and others.”)

VII. OBJECTIVE INDICIA OF NON-OBVIOUSNESS

Petitioner, through its lead counsel, knew of evidence of objective indicia of non-obviousness, but failed to address it in its Petition. Objective indicia must be considered in every case where such evidence exists. The objective indicia of non-obviousness was known to lead counsel to Petitioner from his and his firm’s representation of the defendants in the iHerb Case. *See* Civil Docket, Case 0:16-CV-04278-JNE-TNK, accessed June 23, 2006, PACER (Ex. 2002). The evidence was not restricted by a Protective Order in the prior related proceeding and was publicly available for download through PACER. *Id.*

VIII. SPECIFIC REASONS WHY *INTER PARTES* REVIEW SHOULD NOT BE INSTITUTED

Each petition must contain a “full statement of the reasons for the relief requested, including a detailed explanation of the significance of the evidence”. 37 C.F.R. §42.22(a) (2). “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). 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).

A. The Petition does not Demonstrate a Reasonable Likelihood that the Petitioner will Prevail as to any Claim under Ground 1.

Petitioner has not established that it may rely on Harder (MOM-1006); Supplement 4.3 of the *European Pharmacopoeia*, Fourth Edition (MOM-1010); or Wolf (MOM-1008).

1. Harder (MOM-1006) and Supplement 4.3 of the *European Pharmacopoeia*, Fourth Edition (MOM-1010) are incomplete and inadmissible.

37 CFR §42.6(c) requires that, “Each exhibit must be filed with the first document in which it is cited except as the Board may otherwise order.” Petitioner has only filed highly selected excerpts of Harder and *European Pharmacopoeia* Supplement 4.3. MOM-1006 and MOM-1010 are incomplete and insufficient to establish the teachings disclosed therein. As discussed in Section IV. A. & C., *supra*, the portions of Harder and *European Pharmacopoeia*, Supplement 4.3 included in MOM-1006 and MOM-1010 are insufficient to satisfy the requirements of 37 CFR §42.6(c) and thus should be excluded.

Petitioner and its expert (MOM-1004), rely on MOM-1007 as a basis for all asserted Grounds. However, 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. Petitioner alleges that MOM-1007 is an English translation of Harder (MOM-1006). That is false. MOM-1007 is not an accurate translation of Harder. MOM-1007 is a Declaration of Mr. Sherman, in which he attempts to justify revising the original translation by adding the critical “to be licked off” phrase, because he believes it is “a more accurate reflection of the German text.” MOM-1007. This is a blatant attempt by Petitioner to change the Harder translation to fit its litigation strategy. MOM-1006 is an inaccurate and manipulated translation and therefore should be rejected by the Board.

Harder, according to the MARC record attached to the Declaration of Petitioner's Library expert (MOM-1005, pg. 37), includes at least 294 pages (12 pages of front matter and 282 pages of main text). Harder is the cornerstone of Petitioner's arguments and its omission of over 90% of the reference is entirely improper.

The author of Harder purports to have been a midwife. Whether a doctor with a degree in pharmaceuticals or a related field with years of experience in formulating compositions of, and delivering, medicines would consider a guide

written by a midwife is a significant question that cannot be answered without a complete copy of Harder. Interestingly, Petitioner's expert bases his opinions solely on MOM-1007, which is the revised translation of Harder §15.9, but MOM-1007 only covers 6 pages of the 23-page excerpt filed. In other words, Williams has not reviewed or considered 276 pages of Harder. This renders his opinion unreliable. Williams apparently assumes, and expects the Board to assume, that 97% of Harder is irrelevant and may be ignored.

Petitioner has failed to meet its burden of proof and the Board should not rely on Harder. Because Harder is the primary reference for all asserted grounds, the failure to establish the scope and content of the prior art makes it impossible for Petitioner to establish a reasonable likelihood of success on any ground asserted in the Petition. *Shenzhen Aurora Tech. Co. Ltd. v. Potco, Inc.* (PTAB August 27, 2020) IPR 2020-00670, Paper 10.

The 8 pages in MOM-1010 are from a supplement to the Fourth Edition of *European Pharmacopoeia*. MOM-1010 are pages from monthly Supplement 4.3. The 8 pages are not independent and include cross-references to content appearing elsewhere in the document. The MARC records show that the *European Pharmacopoeia* 4th Edition has 18 pages of forward material, 2416 pages of main text, and two prior supplements. MOM-1005, pg. 69, Field 300. The Identification

and Tests sections in MOM-1010, pgs. 6 and 7, refer to other material that is not provided. For example, Identification A refers to 2.5.1, not provided, and Identifications B and C refer to Tests. The Tests section refers to 2.2.2, Method I; 2.2.5; 2.2.6; 2.2.9; 2.5.1; 2.5.3, Method A; 2.5.6; 2.5.7; 2.4.22, Method C; and 2.2.23, Method II (4 references). None of referenced material from the Tests section are provided. According to the table of contents (MOM-1010, pg. 4), only 2.2.6 was included in the Supplement (but not in MOM-1010). *See* Ex. 2009, ¶s26-27.

Petitioner's failure to provide complete copies of either reference precludes consideration of them. For this reason, alone, the Petition fails to establish a likelihood of success for any claim under all of the grounds.

2. Harder (MOM-1007) and Wolf (MOM-1009) should be Excluded for Failure to Provide an Affidavit Attesting to the Accuracy of the Translation.

When a party relies on 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. 37 CFR §42.63(b). The Patent Trial and Appeal Board Consolidated Trial Practice Guide November 2019, (I)(F)(1)(c), page 22 states:

Document Translation: All proceedings before the Board will be conducted in English. Translations therefore must be provided for:

(1) those documents produced in discovery under 37 C.F.R. § 42.51; and (2) all documents relied on, or otherwise used, during the proceedings. Unless accompanied by an English language translation, such documents in a language other than English will not be considered by the Board.

Petitioner has not provided an affidavit attesting to the accuracy of the translations in MOM-1007 and MOM-1009. It has not submitted a certified translation of Harder (MOM-1006). Even if the excerpt from Harder is accepted, MOM-1006 is in German and the purported translation in MOM-1007 is insufficient.

At most, MOM-1007 is a revision of an unsubmitted translation of only a portion of MOM-1006 (less than 6 of 23 pages provided). No translation of the remainder of Harder was provided. Petitioner did not even provide an entire chapter.

Furthermore, no basis exists for relying on MOM-1007 as an accurate translation of the excerpt of MOM-1006. Petitioner asserts that MOM-1007 is the “Translation of Harder by Amy Tinworth (“Harder Tr.”)”. *See* Petition, pg. iii. On its face, MOM-1007 only refers to section 15.9 of Harder and not to MOM-1006 or “Harder” as a whole. Additionally, Petitioner has not submitted any declaration from “Amy Tinworth” attesting to the accuracy of MOM-1007.

Petitioner has only submitted a Declaration of David Joshua Sherman as part of MOM-1007. However, Sherman does not attest to the accuracy of the translation performed Tinworth or MOM-1007. To the contrary, he suggests that Tinworth's unsubmitted translation was not accurate. Sherman states, "1. Rebecca Amy TINWORTH performed the attached translation from German into English of Chapter 15.9 of 'Wochenbettbetreuung in der Klinik und zu Hause' [Childbed care in clinics and at home] (also attached)."

(Emphasis added.) However, Petition did not provide Tinworth's original purported translation. Also, 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. Petitioner has not provided a translation of the Table of Contents either.

Sherman asserts "Rebecca Amy Tinworth is competent to perform this translation." Sherman does not attest that the translation is accurate, gives no clue why the Petitioner contends the translation was made by Tinworth, or what he means by "the addition". Clearly, "to be licked off" did not appear in the translation made by Tinworth. Sherman does not provide any explanation of his conclusion that the translation prepared by Tinworth needs to be improved by changing words, which clearly was done to benefit Petitioner's arguments. Sherman makes no assertion that he is familiar with the German language or has

any proficiency in translating German to English. He gives no facts to support his conclusion. His opinion therefore should be given no consideration.

Even if his opinion is considered, Sherman does not opine or conclude that his revised *interpretation* of Tinworth's translation is accurate. Because of the irregularities, MOM-1007 should not be considered a translation of Harder and according to the Trial Practice Guide and the Rules, Harder should not be considered.

Wolf (MOM-1008) should also be excluded because MOM-1009 is not an affidavit attesting to the accuracy of the translation "as required" under 37 C.F.R. § 42.63(b). According to the United States Bureau of Labor Statistics, a translator "must be proficient in English and at least one other language, as well as in the translation service they intend to provide." Ex. 2007 (Accessed June 24, 2023). The Declaration of Translation for Wolf (MOM-1009), only attests to accuracy to the best of the translator's knowledge. But the "translator" does not profess to have knowledge of the German language or proficiency in translation services. The declaration does not have an "attached German document," so there is no connection between MOM-1008 and the purported translation.

These omissions and irregularities support Patent Owners' request that the Board disregard Harder, Supplement 4.3 of *European Pharmacopoeia*, and Wolf.

The Board should deny institution because Harder, Wolf, and Supplement 4.3 are all required for every asserted ground. Without the complete references or proper, admissible translations, Petitioner has failed to carry its burden of establishing the scope and content of the prior art and its burden to establish a reasonable likelihood of success.

3. The Petition Fails to Demonstrate Public Accessibility of Harder (MOM-1007)

The Petition relies on the combination of Harder and other references for all grounds challenging the claims. It relies on Mumford (MOM-1005), to establish that the Harder “book was available to the public shortly after” January 1, 2003. But Harder is a partial, truncated excerpt of a document. Page 3 of MOM-1006 is in German and includes “© 2003 Hippokrates Verlag in” and other text. The Petition does not include a translation of page 3 and thus may not rely on an allegation that it is a copyright notice. Thus, there are no indicia of reliability. *See Shenzhen*, IPR 2020-00670, Paper 10 at 5. Mumford 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. Mumford has no knowledge of the German language.

Mumford states that Field 008 of the MARC record “is reserved for denoting the date of creation of the library record itself.” Her opinion that Field 008

“accurately indicates the date of an item’s public availability” is premised on her statement that Field 008 is reserved for denoting the creation of the library record itself.” Even if Field 008 denotes the date that NLM created the MARC record, her logic to support the conclusion of public accessibility is flawed. MOM-1005 states that the fact that no other dates state the date “of inclusion of said materials within the library collection” is insufficient. The date of record creation is unrelated to public accessibility.

Even if Field 8 could be relied upon to show technical accessibility, the fact that no other dates show the date of inclusion means only that the MARC record does not show the date on inclusion of the material in the library collection. Munford also claims that Field 008 indicates that the library acquired the book on January 1, 2003. MOM-1005, ¶9. Therefore, according to Munford, the book was acquired, the MARC record was created, and the book was available all on January 1, 2003. There is no explanation of how a document supposedly bearing a 2003 copyright date could have been acquired, cataloged, and shelved on all on January 1, 2003, a Federal holiday on which the National Library of Medicine, as part of Federal Government was not open.

Munford further states, “In comparing Exhibit MOM-1006 to Appendix HARDER01, it is my determination that Exhibit MOM-1006 is a true and correct

copy of Wochenbettbetreuung in der Klinik und zu Hause, Hippokrates Verlag by Ulrike Harder.” This is not reliable. Appendix HARDER01 (MOM-1005, pg. 35), is purportedly the MARC record, including Field 300, which shows 12 pages of foreword and 282 pages of main text. See Ex. 2006, pgs. 5-6. However, MOM-1006 is just 23 pages. Additionally, the MARC record provided bears a revision date in Field 005 showing that the record reproduced in Appendix HARDER01 was not in existence prior to the critical date. Field 005 shows a December 3, 2021, revision date. See Ex. 2006, pg. 4. The MARC STANDARDS issued by the Library of Congress – Network Development and MARC Standards Office, specify that Field 005 is for date and time of latest transaction, “Sixteen characters that indicate the date and time of the latest record transaction. ... The date requires 8 numeric characters in the pattern *yyyymmdd*” followed by 8 characters specifying the time to the tenth of a second. Ex. 2006, pg. 4. According to the MARC record provided, it was last revised on 20211203220242.0, meaning December 3, 2021, at 42 seconds past 10:02 p.m. Thus Appendix HARDER01 (MOM-1005, pg. 35), cannot have existed as of its purported creation date of January 1, 2003. Munford does not explain these inconsistencies. Thus, Munford’s Declaration falls short of establishing that Ex. 1006 was in fact publicly available as of the critical date.

Even if the Board were to overlook the fact Appendix HARDER01 does not establish the date of inclusion in the NLM collection, the Petition still falls far short of meeting the institution-stage standard set by *Hulu v. Soundview Innovations, LLC*, IPR2018-01039, Paper 9 (PTAB Dec. 20, 2019) (precedential). for establishing public accessibility: “[A]t the institution stage, the petition must identify, with particularity, evidence sufficient to establish a reasonable likelihood that the reference was publicly accessible before the critical date of the challenged patent and therefore that there is a reasonable likelihood that it qualifies as a printed publication.” *Id.* In *Hulu*, the Board held that “[p]ublic accessibility requires more than technical accessibility.” *Id.* at 10. Under *Hulu*, a reference is deemed “publicly accessible” only upon a satisfactory showing that the document was made available to the extent that “persons interested and ordinarily skilled in the subject matter” who are “exercising reasonable diligence” could locate it at the relevant time. *Hulu* at 10-11.

Petitioner makes only a conclusory assertion that Harder “was made available to the public shortly after” its acquisition in January 2003.” Critically, Munford does not explain how a POSITA would have accessed MOM-1006 prior to the critical date. For example, she does not testify that a POSITA could have found MOM-1006 by searching the library’s website prior to the critical date,

much less *how*. Munford does not make even a conclusory assertion of when the NLM MARC record was incorporated in a publicly accessible database prior to the critical date. Indeed, MOM-1005 is bereft of any suggestion that a POSITA could have found Harder with the exercise of reasonable diligence. Munford simply avers that MOM-1006 was publicly available in 2003. But that is at best a classic example of technical accessibility, which is insufficient to meet *Hulu*'s public accessibility requirement. *Hulu* at 10.

The Board's decision denying institution in *Microsoft Corp. v. Troughputter, Inc.*, IPR2020-01566, paper 13 (PTAB May 31, 2023) is particularly instructive. The Petitioner in *Microsoft* was represented by the same law firm as Petitioner here and the same Ms. Munford proffered a virtually identical (save for the name of the references and dates) declaration as submitted here.

In *Microsoft*, the Board held:

For a reference to qualify as a printed publication, it "must have been sufficiently accessible to the public interested in the art." *In re Lister*, 583 F.3d 1307, 1311 (Fed. Cir. 2009) (quoting *In re Cronyn*, 890 F.2d 1158, 1160 (Fed. Cir. 1989)). The touchstone is "public accessibility," and this "is determined on a case-by-case basis based on the 'facts and circumstances surrounding the reference's disclosure to members of the public.'" *Id.* (quoting *In re Klopfenstein*, 380 F.3d 1345, 1350 (Fed. Cir. 2004); *In re Hall*, 781 F.2d 897, 898–99 (Fed.

Cir. 1986)). “A given reference is ‘publicly accessible’ upon a satisfactory showing that such document has been disseminated or otherwise made available to the extent that persons interested and ordinarily skilled in the subject matter or art[,] exercising reasonable diligence, can locate it.” *SRI Int’l, Inc. v. Internet Sec. Sys., Inc.*, 511 F.3d 1186, 1194 (Fed. Cir. 2008) (quoting *Bruckelmyer v. Ground Heaters, Inc.*, 445 F.3d 1374, 1378 (Fed. Cir. 2006)).

“When a reference is uploaded to a website or deposited in a library, the fact that the reference is indexed or cataloged in some way can indicate that it is publicly accessible.” *Samsung Elecs. Co. v. Infobridge Pte. Ltd.*, 929 F.3d 1363, 1369 (Fed. Cir. 2019). “In certain situations, particularly for manuscripts or dissertations stored in libraries, courts may inquire whether a reference was sufficiently indexed, catalogued, and shelved.” *Hulu v. Soundview Innovations, LLC*, IPR2018-01039, Paper 29 at 9 (PTAB Dec. 20, 2019) (precedential). There is no strict requirement for indexing, searchability, cataloging, or shelving. *See, e.g., Samsung*, 929 F.3d at 1369; *Jazz Pharms., Inc. v. Amneal Pharms., LLC*, 895 F.3d 1347, 1359 (Fed. Cir. 2018). But it is “critical” that there be “some evidence that a person of ordinary skill could have reasonably found” the reference. *Samsung*, 929 F.3d at 1369. ... “[T]here is no presumption in favor of institution or in favor of finding a reference to be a printed publication.” [*Hulu*, IPR 2018-01039, Paper 29 at 16.]

Petitioner’s entire argument for qualifying HARDER as a printed publication is, “The 008 field of the MARC record indicates this book was first

acquired by the National Library of Medicine on January 1, 2003, and therefore, indicates the book was available to the public shortly after that date.” Petition, pg. 13. As in *Microsoft*, Paper 13 at 11, this contention is “not sufficient to establish its *accessibility* to an ordinary artisan. See *Acceleration Bay, LLC v. Activision Blizzard Inc.*, 908 F.3d 765, 773 (Fed. Cir. 1998) (“‘[P]ublic accessibility’ requires more than technical accessibility.”).” (Emphasis in original.) 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.

Moreover, Harder appears to be a general infant care book. Petitioner has not submitted a complete copy of Harder along with a translation and affidavit attesting to the accuracy of a translation of the complete copy (or even a certified translation of the title of Harder). One of ordinary skill in the art would not look to such a book for the formulation of a composition for delivery of a nutritional or therapeutic effective amount of vitamin D in a single drop. This is particularly apparent from the fact that the composition of Vigantol oil is not described in Harder and that the description of a component of Vigantol oil is given by Harder as a “medium-chain triglycerides (vegetable oil)”. One of ordinary skill in the art pertinent to the ‘958 Patent would know that vegetable oil as referred to in MOM-

1007, pg. 6, does not exclude the presence of long-chain triglycerides. One of ordinary skill in the art would not look to a general book on post-natal child care such as Harder. Ex. 2009, ¶44. Clearly, one of ordinary skill in the art would not expect to find anything useful, and to the extent the book contained one phrase out of 284 pages, it would likely be nonsensical as in Harder (medium chain triglycerides that might be long-chain triglycerides). Thus, even if indexed, Harder was not accessible to one of ordinary skill even through a search performed with reasonable diligence. Moreover, Petitioner has not presented evidence of the content of the MARC record for Harder on or before the critical date.

4. Claims 1 and 5 are not Obvious even if the purported prior art is considered.

Petitioner argues that Harder, Wolfe, and *European Pharmacopoeia* Supplement 4.3 in combination renders claims 1 and 5 obvious. Petitioner has not established the scope and content of the prior art, because the Board should not consider Harder, Supplement 4.3, and Wolf as previously established. Even if the references are considered, the differences between claim 1 and the prior art are such that they would not have been obvious.

Claim 1, step (i) recites, “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.” This element has four parts

1. amount (“applying one drop”);
2. of a particular composition (“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”);
3. site (“to the exterior surface of an object”); and
4. the nature of the interaction between the composition and the site (“wherein said drop adheres to the surface of said object”).

None of the references alone or in combination suggest at least part 4, specifying the interaction between the composition and the surface of the object.

The claim recites “wherein said drop adheres to the surface of said object”. This is satisfied when the object and the composition are chosen to satisfy the wherein limitation. The Petition incorrectly asserts that the MCT disclosed will adhere based on the properties of MCT. The ‘958 Patent never says that. Petitioner points to Table 1 to support its conclusion. However, Table 1 suggests no such thing. Table 1 of the ‘958 Patent reports the results of “Experimental observation of potential liquids for suitability for nipple vitamin D.” The ‘958 Patent states, “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. The results of these experimental observations are presented in Table 1 along with further considerations regarding the parameters desired for this invention.” The results reported in the second column of Table 1 are “Experiment drop behavior on nipple”.

MOM-1004, ¶51 ,incorrectly states “the applicants conducted experiments to demonstrate that the ‘vehicle[s] for vitamin D’ listed in Table 1 had sufficient viscosity such that they will adhere to the surface of an object.” Contrary to this conclusion, Table 1 reports which vehicles tested adhere to a particular type of object, for example a nipple, not any object. The ‘958 Patent does not state that the experiments were done to demonstrate sufficient viscosity to adhere. Table 1 does not report viscosity of the vehicles tested. MOM-1004, ¶52 states an over-generalized premise that, “For a drop of vitamin D to be delivered to an infant in the manner described in the ’958 Patent, it needs to be combined with a carrier ‘vehicle’ that will make it sufficiently viscous to adhere to an object.” Ex. 2009, ¶30.

The plain meaning of “adhere” in physic or chemistry is for two or more dissimilar substances to be united by a molecular force acting in the area of contact. *Oxford English Reference Dictionary*, 2nd ed. (Oxford University Press, 1996) (Ex. 2011, pg. 3). Viscosity of a fluid is internal friction, resistance to flow.

Id. at 4. Thus, viscosity is a property of a single substance, while “adhere” is a property of the interaction between two substances.

The Petition incorrectly focuses on viscosity, while the patent claim recites “adhere”. Thus, the Petition’s logic fails in its entirety. Thus, the method of claim 1 involves an object having properties that will adhere to the MCT. MOM-1004, ¶52 then makes the leap that, “The applicants *appear to suggest* that they discovered that medium chain triglycerides satisfy this criterion, whereas water and ethanol would drip off.” The tip-offs are the words “appear” and “suggest”. The Petition incorrectly assigns a meaning that is not stated in the patent. In fact, the ‘958 Patent claims explicitly set forth the invention. Moreover, MOM-1001, Table 1 reports those vehicles that adhere to a nipple, not viscosity.

The Petition and Williams Declaration (MOM-1004) reflect an erroneous understanding and a fundamental error regarding “Vigantol” oil and Harder, and more critically the problems and issues which the ‘958 Patent addresses and solves. Ex. 2008, ¶4.

The goal of the ‘958 Patent was to meet the need for a nutritionally effective method to administer a precise amount of vitamin D in a small controlled volume of the formulation. Ex 2009, ¶s13, 14. Such a method is medically important because the minimal daily requirement can be met by very small quantities of

vitamin D, *i.e.*, 10 µg of vitamin D3 per day for an infant. MOM-1001, 3:53-6:5.

While low doses of vitamin D can prevent the onset of rickets in infants, higher doses can cause hypercalcemia and related toxic effects. MOM-1008; MOM-1009.

The method must be simple and reproducible by the consumer, such as the care provider of an infant. MOM-1001, 7:60-8:23. The difficulty posed by dropping one drop of a liquid onto a small surface like a nipple, pacifier, or finger is that much of the drop rolls off. If that drop stays put on that small surface, then it might not be easy to suck or lick from that surface. For example, an attempt to suck a drop of vegetable oil from a finger will leave enough oil behind to require washing. The '958 patent solves the problems of adherence and delivery, there can be no viable product. The prior art never indicated any awareness of these difficulties and never solved or addressed these technical problems (among others). Ex. 2008, ¶5.

The Petition (and Williams), do not understand, or simply misconstrue, the Harder reference, on which they place so much emphasis. The Petition and Williams' opinion is premised upon the idea that if you can place a dose of a liquid into the bowl of a spoon, then it is obvious that you can put a single drop of a liquid onto a nipple or pacifier without having it drip off, and still be able to consume at least 90% of that dose by sucking. Their thinking is simply wrong. The Petition (and Williams), are confusing the interior, concave, bowl side of a spoon

with the exterior side of a convex surface like a pacifier or mother's nipple. Ex.

2008, paragraph 16.

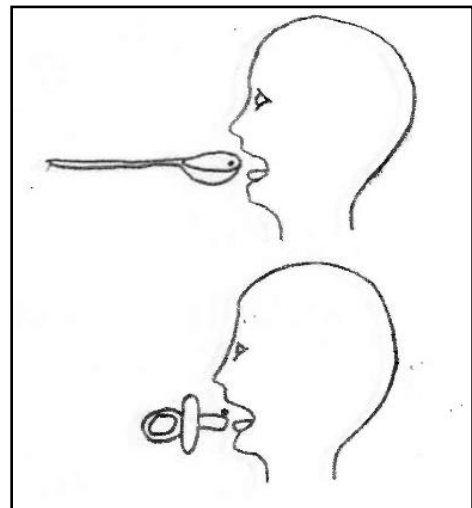
Harder discusses the conventional use of a spoon. The '958 Patent does not deal with the use of a spoon. Harder never states that MCT is uniquely necessary to provide the vitamin D. It just happens that the brand name of the MCT oil she used is "Vigantol". There certainly is nothing in Harder to suggest that a drop that adheres to the exterior surface of an object, such as a pacifier, a nipple, or another object with characteristics that allow the drop of MCT and vitamin D to adhere to the object. is equivalent to administering a dose of vitamin D in MCT by use of a spoon. Ex. 2008, ¶17.

Harder never conceived of, did not address, and never solved the problems solved by the '958 Patent. She never showed whether a drop would stick and not drip from a small exterior surface like a pacifier or nipple. Harder used a spoon, which is by definition a long handle with a bowl that holds any liquid. She never addressed the question of how much of the dose was left on the spoon when it was removed from the baby's mouth. She also recognized the significant risk that a spoon has capacity for many drops, and the risk of overdose that posed. Ex. 2008, ¶18.

Moreover, when a spoon enters a person's mouth, the tongue is underneath it. There is no way to lick a spoon unless it is turned upside down, and that does not make sense in the context of Harder's suggestion. Furthermore, the shape of a spoon is not something that an infant would readily suck on. A spoon is more likely to annoy an infant than stimulate licking. Harder only mentions "lick" and does not mention "suck." Ex. 2008, ¶19.

The following drawing simplifies, but makes clear, the substantial and significant differences between Harder and the '958 Patent:

Figure legend. Methods of giving vitamin D to an infant. Top, Harder suggestion; Below '958 Patent method. The dot represents the location of the dose, which in reality is not a bead, but which spreads as a film coating the surface. Harder places the drop into the bowl of a spoon, which is not a size or shape that an infant can naturally



suck on, and because the baby's tongue is under the spoon, the Harder method makes it impossible to actually lick the dose. In contrast, '958 Patent places the drop on the exterior of a size, shape and material that the infant will naturally suck on. Ex. 2008, ¶20.

Harder thus teaches away from the method claimed in the '958 Patent by focusing on an interior, bowl-shaped surface instead of an exterior surface. Harder teaches away from the use of application of one single drop onto a small, convex exterior surface. Harder should be understood to mean to place the vitamin D composition 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 and therefore could not be administered in that manner. One or more drops can be retained inside the bowl-shaped part of a spoon without concern relating to adherence or viscosity. Indeed, Harder represented that water will work as well as a delivery vehicle. Ex. 2008, ¶21.

The Petition seems to argue either that the interior, bowl side of a spoon is the same thing as the exterior surface of a mother's breast or a pacifier, or that somehow the composition (Vigantol oil) will adhere to the back side of the spoon. This basic premise of such an argument is absurd. Harder never validated her suggested approach as one that can deliver the full dose of vitamin D. In fact, much of the dose will remain stuck on the spoon. Moreover, if Harder's suggested approach was widely used, there would be news reports that rickets (a vitamin D

deficiency) was occurring despite giving vitamin D to infants with a spoon. Ex. 2008, ¶22.

The nature of a spoon as used in Harder is different from an object to which the composition will adhere. A spoon will not administer an efficacious dose of vitamin D and MCT composition, because the single drop of the composition will spread out and coat the spoon. After administration, the residue on the spoon is a substantial portion of the intended dose. Moreover, MOM-1004, ¶50, incorrectly reads the '958 Patent as recognizing only viscosity as important in adherence of a liquid to an object and does not confront directly whether the Harder composition adheres to the spoon. It does not. Ex. 2009, ¶30.

The Petition presents the conclusory and circular argument, MOM-1004 ¶54, Petition, pg. 29, that because claim 1 recites the claim limitation “wherein the drop [of the composition] adheres to the surface of said object,” the disclosure in Harder that “[one] drop of Vigantol® oil is given to the baby from the tip of a spoon,” combined with the unsupported opinion in MOM-1004 that all MCTs are universally adherent to all surfaces, renders the selection of C6-C12 MCTs that will adhere to a given surface as an inherent property of the composition recited in claim 1. Ex. 2009, ¶31. However, Harder teaches nothing about the adhering property or any physical aspect of MCT or any other liquids regarding suitability.

Harder's suggestion of putting a dose onto a spoon is absolutely conventional, but that is not what the patent claim says. Ex. 2008, ¶24.

Furthermore, this inherency argument was conclusively demonstrated to be false by direct observation that MCTs according to claim 1 do not adhere to a spoon. Ex 2009, ¶s32-35. Harder's single sentence to put a drop in a spoon, in the context of the risk of overdose, would not suggest using an object to which the composition adheres as a safe and effective method of administering an efficacious dose of vitamin D₃ according to claim 1. Ex. 2008, ¶25.

The Petition's reliance on MOM-1010, Supplement 4.3 of *European Pharmacopoeia* is also misplaced because it relates only to MCT and does not mention any active ingredient, vitamin D or otherwise. Ex. 2008, ¶26; Ex. 2009, ¶36.

Harder does not disclose the composition limitation of claim 1. Harder discloses applying a drop of Vigantol oil to a spoon. Harder does not disclose that the drop adheres to the surface of the spoon. Harder does not disclose even that the drop is applied to the exterior surface of the spoon. Ex. 2009, ¶s17, 18.

Wolf includes recommendations of several supplements to provide a dose of vitamin D. In particular, Wolf discloses a recommendation to administer a single drop of Vigantol oil. Wolf does not disclose the composition limitation of claim 1

or the administration limitations of claim 1. The administration limitations are applying the drop to an exterior surface of an object and wherein said drop adheres to the surface of said object. *Id.*, ¶20.

The *European Pharmacopoeia* Supplement 4.3 discloses certain aspects of the nature of medium chain triglycerides. Supplement 4.3 does not disclose administering a composition of vitamin D and thus, does not disclose (a) applying a drop; (b) the composition limitation of claim 1; (c) that the drop is applied to an exterior surface of an object; and (d) that the nature of the drop and the object are such that the drop adheres to the surface of the object. Ex. 2009, ¶s18, 31, 36.

Having considered the differences between claim 1 and the prior art, there is no rational reason to modify the prior art in order to yield the claim limitations. Both Harder and Wolf refer to Vigantol oil. Petitioner has not provided any reliable evidence of the composition of Vigantol oil. Petitioner has presented no facts from which one would conclude that MCT will adhere to a spoon. Ex. 2008, ¶29.

If improperly considered, Harder perhaps discloses that “Vigantol oil is a prescription-only medicine.” Harder states that the oil “contains only 1 excipient as a vehicle for the fat-soluble vitamin D, medium-chain triglycerides (vegetable oil). There is no indication why Harder believed at the time she wrote the book that

Vigantol oil contained only 1 excipient as a vehicle for the fat-soluble vitamin D. There is no indication why Harder believed that medium-chain triglycerides (vegetable oil) were the composition of Vigantol oil. Petitioner has not presented any direct evidence of the composition of Vigantol oil. Ex. 2009, ¶27.

Claim 1 recites one drop “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.” Harder’s description of Vigantol oil, even if considered, does not satisfy the composition limitation. Ex. 2008, ¶29; Ex. 2009, ¶27. Petitioner makes no effort to address the “consisting of” limitation for the composition recited in claim 1. Even if one of ordinary skill in the art would believe that Vigantol oil contains “only a single excipient as a vehicle for the fat-soluble vitamin D”, this is far from establishing that Vigantol oil consisted of only vitamin D in a liquid triglyceride of 6 to 12 carbon chain lengths.

None of the 3 references relied upon suggest administering a drop of any kind of vitamin D composition by placing the drop on an object where the nature of the composition and of the object are such that the drop adheres to the object. Thus, the combination of references cannot render claim 1 obvious.

Harder discloses putting a drop of something in a spoon, but does not include any indication that the drop adheres to the spoon. Petitioner argues that the

limitation of the drop adhering to the exterior surface of an object is inherent in Harder's disclosure of administering a drop of Vigantol oil by a spoon. Harder does not disclose whether the drop is placed on the interior or exterior surface of the spoon. Ex. 2009, ¶30. However, as discussed above, MCT will not adhere to a spoon. *Id.* Therefore, the only possible interpretation of Harder is that the drop would not adhere to the spoon and would immediately run off.

No reason exists to conclude that a drop of Vigantol oil necessarily adheres to a spoon. In fact, the evidence developed in prior litigation demonstrates that a composition, as required by claim 1, does not adhere to the tip of a stainless-steel spoon. Ex. 2009, ¶32. Petitioner relies on the Williams declaration (MOM-1004), for its assertion that Vigantol oil had to be sufficiently viscous to adhere to the tip of a spoon to allow for an infant to be able to lick it off. Petitioner and Williams' conclusion is flawed because they do not recognize that the nature of the composition as well as the nature of the object are the variables required for adherence. Ex. 2008, ¶18.

They also do not recognize that application of the drop as described by Harder to the interior surface of a spoon will not permit the drop to be retained on the spoon so that it can be licked or sucked away. The Petition, pg. 31, cites to MOM-1004, ¶54 to support the assertion that "the medium chain triglycerides in

Vigantol oil had to be sufficiently viscous to adhere to the tip of a spoon to allow for an infant to be able to lick it off.” MOM-1004, ¶54 contains no such conclusion. MOM-1004, ¶54 states the opinion that ““medium chain triglycerides (vegetable oil)’ taught by Harder would be sufficiently viscous to adhere to the surface of an object (*e.g.*, nipple).” Williams does not conclude that the composition disclosed by Harder would adhere to a spoon as asserted by the Petition, pg. 31. None of the references relied upon in ground 1 teach the limitation of an object and a composition where the composition adheres to the object.

Furthermore, the Petition is inconsistent with the claim language in so far as viscosity and adherence are fundamentally different concepts. Claim 1 calls for adherence, which is the nature of the interaction between two substances, while viscosity is the nature of a single substance. Ex. 2011, pgs. 3-4. Claim 5 depends from claim 1 and therefore incorporates all the limitations of claim 1. Claim 5 is not obvious on ground 1 for the same reason that claim 1 is not obvious on ground 1. Ex. 2009, ¶40.

B. The Petition Does Not Establish a Reasonable Likelihood of Success Under Ground 2.

The Petitioner asserts that claim 3 is obvious over the references applied against claim 1 and Blass (MOM-1011). Claim 3 recites the additional limitation of “wherein said human being is an infant and said object is a woman’s nipple or the

external surface of a pacifier.” The Petitioner confuses a motivation to combine with a conclusion of obviousness. Even if one of ordinary skill in the art were motivated to combine Blass with the other references, that is not sufficient to establish that such a person would have combined the references to achieve the claimed limitations.

Blass was used by the Examiner in a rejection of certain claims. It discloses using a pacifier dipped in sugar water to enhance sucking by an infant during an experiment. Contrary to the Petition, a person of ordinary skill in the art would not consult Blass “to identify additional methods of delivery a liquid vitamin D supplement like Vigantol oil.” Blass at best discloses that the pacifier is repeatedly dipped in sugar water. There 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.

Blass does not satisfy the adhere limitation because the sugar water used in Blass would not adhere to a pacifier. The agreed construction of “wherein said drop adheres to the surface of said object” is “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. Blass states the infant either swallowed 2-mL of solution delivered slowly over 2 minutes by syringe or sucked a pacifier dipped in the assigned solution every 30s for the 2 min treatment. MOM-1011, pg. 8. Blass administers a sugar-water solution by coating (dipped in the solution) the pacifier, not by a single drop adhering to a pacifier. Therefore, Blass also fails to disclose the “adheres” limitations of claim 1. Accordingly, claim 3 is also not obvious based on the combination of Harder, Wolf, *European Pharmacopoeia* Supplement 4.3 and Blass. Ex. 2008, ¶3, Ex. 2009, ¶39.

C. The Petition Does Not Establish a Reasonable Likelihood of Success Under Ground 3.

Ground 3 asserts that claim 4 is obvious over Harder, Wolf, *European Pharmacopoeia* Supplement 4.3, and Gartner. Claim 4 depends from claim 1 and recites the additional limitation that “the composition consists of from 150 to 450 mcg per mL vitamin D in a liquid triglyceride of 6 to 12 carbon chain length.” The Petitioner does not assert that the addition of Gartner supplements the above-noted deficiencies in Ground 1. Therefore, claim 4 is not obvious for the same reasons as claim 1.

In addition, while Gartner discloses and recommends a supplement of 200 IU per day, this was already disclosed as prior art in the background section of the patent. MOM-1001, 2:13-18. Gartner does not disclose how such a supplement

should be delivered and does not disclose any mechanism for reliably delivering the proper dose of vitamin D3.

D. Secondary Indicia of Non-Obviousness Defeats Petitioners' Attempt to Establish a Reasonable Likelihood of Success on any Challenged Claim.

Not surprisingly, the Petition attempts to discount the presence of secondary considerations of non-obviousness that surround the '958 Patent. As a safeguard against hindsight bias and to avoid reading the teachings of the invention at issue into the prior art, the Board must consider objective indicia of non-obviousness. *Graham v. John Deere Co.*, 383 U.S. 1, 36 (1966). Here, the claims of the '958 Patent are supported by compelling indicia, such as the massive commercial success of products that embody the claimed invention, copying by competitors, and long felt but unresolved needs.

The proponent of obviousness must address four factors, including objective evidence of secondary considerations. *Id.* at 17-18. "A determination of whether a patent claim is invalid as obvious under § 103 requires a consideration of all four *Graham* factors, and it is error to reach conclusion of obviousness until all those factors are considered." *Apple, Inc. v. Samsung Elecs. Co.*, 839 F.3d 1034, 1048 (Fed. Cir. 2016). "[E]vidence of secondary considerations may often be the *most probative* and cogent evidence in the record. It may often establish that an

invention appearing to have been obvious in light of the prior art was not.”

Transocean Offshore Deepwater Drilling, Inc. v. Maersk Drilling USA, Inc., 699 F.3d 1340, 1349 (Fed. Cir. 2012) (emphasis added). Secondary considerations can be the most reliable evidence to avoid the trap of hindsight bias in the obviousness analysis.

With respect to the secondary consideration of commercial success, 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. v. Teva Pharms. USA*, 395 F.3d 1364, 1376 (Fed. Cir. 2005). In this way, evidence of commercial success is probative of whether an invention was non-obvious. *Id.*; see also *Demaco Corp. v. F. Von Langsdorff Licensing Ltd.*, 851 F.2d 1387, 1392 (Fed. Cir. 1988).

While any objective evidence of non-obviousness must have nexus to the claimed invention, that nexus need only be “reasonably commensurate,” and the case law cautions against unduly “strict requirements” in evaluating nexus.

Rambus Inc. v. Rea, 731 F.3d 1248, 1257 (Fed. Cir. 2013). This is true with respect to objective considerations of commercial success, whereby a patent owner must establish a “nexus” between the claimed invention and the commercial success of the product. *Cable Elec. Prods., Inc. v. Genmark, Inc.*, 770 F.2d 1015, 1027 (Fed.

Cir. 1985). A presumption of nexus applies “when the patentee shows ... that [the] product embodies the claimed features, and is coextensive with them.” *Polaris Indus., Inc. v. Arctic Cat, Inc.*, 882 F.3d 1056, 1072 (Fed. Cir. 2018); *see also* *WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1330-31 (Fed. Cir. 2016) (“the patent owner can show that it is the claimed combination as a whole that serves as a nexus for the objective evidence”); *J.T. Eaton & Co. v. Atl. Paste & Glue Co.*, 106 F.3d 1563, 1571 (Fed. Cir. 1997) (“When a patentee can demonstrate commercial success, usually shown by significant sales in a relevant market, and that the successful product is the invention disclosed and claimed in the patent, it is presumed that the commercial success is due to the patented invention.”).

During the prior related proceeding, Patent Owners developed and disclosed substantial evidence of secondary consideration and their nexus to the claims, including the novel aspect of the claims, *i.e.*, the adheres limitation, even at that point in time. The Baby Ddrops® product sold by Ddrops Company embodies the claimed invention. It is a composition consisting of vitamin D (D3) and includes packaging with directions for administration of Baby Ddrops exactly satisfying all of the limitations of claims 1 and 3-5. Ex. 2004, ¶5. The evidence of the Baby Ddrops product and Patent Owners' position that it embodies the claims was developed in the prior related proceeding, openly available through PACER, and

known to Petitioner by virtue of its lead counsel and law firm in this proceeding having been lead counsel and law firm in the prior related proceeding. The Temovsky Declaration in the prior related proceeding disclosed Patent Owners position. Ex. 2004, ¶s10-12.

Petitioner was also aware of the commercial success of the invention because the sales and market share of the Baby Ddrops product was known to Petitioner's lead counsel and law firm from the prior related proceeding. Ex. 2004, ¶s15, 16 (showing substantial market share growth after introduction of patented product). As with the discussion of commercial success, evidence of copying by others exists, including the defendant's products at issue in the prior related proceeding that support a finding of non-obviousness. The evidence of copying was disclosed in the prior related proceeding and was known by Petitioner. Ex. 2004, pg. 9, ¶s40-44 (showing copying by the defendant in the prior related proceeding).

The high level of sales of Patent Owners' products supports a finding of commercial success and weighs strongly against a finding of obviousness. *See Telebrands Corp. vs. Tinnus Enterprises, LLC*, No. PGR2016-00031 (Paper 88, Final Written Decision) (P.T.A.B. Feb. 7, 2018) (finding undisputed sales of "over 25 million units and \$136 million dollars as significant," even in the absence of

market share data) (citing *Tec Air, Inc. v. Denso Mfg. Mich. Inc.*, 192 F.3d 1353, 1361 (Fed. Cir. 1999) (“sales figures alone are also evidence of commercial success.”)).

The patented invention presents a novel method of administering vitamin D, particularly to infants, that reliably delivers the appropriate dose. As evidenced by the prior art at the time (including the art cited in the Background of the ‘958 Patent), there was a long-felt but unresolved need that existed at the time which was filled by the revolutionary ‘958 Patent.

These factors, taken alone or in totality, serve to rebut the grounds of unpatentability raised by the Petition. The Petition thus fails to demonstrate a reasonable probability of success by virtue of its failure on all four *Graham* factors. For these reasons, Patent Owners request that institution be denied on the merits.

IX. THE BOARD SHOULD EXERCISE ITS DISCRETION TO DENY INSTITUTION.

A. The Board should Exercise its Discretion to Deny Institution for Failure to Address Compelling Evidence of Secondary Consideration

Petitioner, through counsel, is aware of compelling evidence of secondary indicia of non-obviousness, but has not addressed such indicia. Petitioner’s failure to address previously-disclosed and developed evidence of secondary indicia

dooms the petition. The previously-developed evidence includes commercial success, copying and long felt but unresolved need. The secondary indicia supporting validity of the claims are address above.

B. The Board Should Exercise its Discretion to Deny Institution due to Parallel Litigation.

Pursuant to 35 U.S.C. §314(a), the statute contains “no mandate to institute review.” The Director has discretion to deny a petition. *Cuozzo Speed Technologies, LLC v Lee*, 579 U.S. 261, 273 (2016). Even if the Board were to find one potentially meritorious basis for a challenge, instituting an IPR would improperly reward Petitioner’s gamesmanship in waiting to the last possible day to file its Petition while still challenging the ‘958 Patent in the concurrent related proceeding, and its deliberate choice not to address the evidence of secondary considerations that were public and of which it was fully aware. Accordingly, the Board should exercise its discretion not to institute an IPR.

Even if the Board concludes that Petitioner has established a reasonable likelihood to prevail on any challenged claim, it should exercise its discretion to deny institution. Petitioner delayed filing the Petition until the last possible day. The only justification offered was the potential for settlement. However, Petitioner offers no evidence or fact-based argument to show that the parties were close enough to settlement to justify the delay.

Petitioner acknowledges that there is ongoing parallel district court litigation, but the *Finitiv* factors, as explained in the Interim Procedures For Discretionary Denials in AIA Post-Grant Proceedings with Parallel District Court Litigation, do not mitigate against a discretionary denial. In this case, the concurrent related proceeding lack of a stay, proximity to trial, investment of the parties, the overlap of issues, identity of the parties, and failure to issue a *Solterra* stipulation all weigh heavily in favor of a discretionary denial. Petitioner has not established any facts that mitigate against a discretionary denial.

1. *Finitiv* factor 1: Whether the Court Granted a Stay or Evidence Exists that One May be Granted if a Proceeding is Instituted.

No stay has been granted in the concurrent related proceeding and none has been requested. Petitioner has not identified any evidence that a stay may be granted if this proceeding is instituted.

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

The expected statutory deadline for a final written decision in this IPR is the petition in this proceeding is September 16, 2024. The trial in the concurrent

related proceeding is set for October 7, 2024, a mere three weeks following the projected statutory deadline. This factor favors discretionary denial.

3. *Finitiv* Factor 3: Investment in the Parallel of Proceedings by the Court and the Parties

Petitioner grossly understates the parties' investment in the concurrent litigation. The District Court entered a Scheduling Order which requires the parties to close fact discovery on September 15, 2023, on or about the time of projected institution. Since commencement of the concurrent related proceeding, 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; engaged in third-party discovery via subpoenas *duces tecum*; and briefed and argued claim construction issues. The Court recently entered its *Markman* claim construction decision, thereby setting the final dates for the remainder of the action. The parties have and will continue to make substantial investments in the concurrent related proceeding during the pendency of this IPR. The Court in the concurrent related proceeding will be on the doorstep of trial commencing October 7, 2024, a mere 3 weeks before the projected statutory written decision deadline.

Preliminary infringement contentions were served on December 1, 2022. Plaintiffs' First Set of Document Requests and Interrogatories were served

December 13, 2022. Petitioner served Invalidity Contentions on January 3, 2023. Defendants served Responses to Plaintiffs' Request for Production Nos. 1-52 and Responses to Plaintiffs' Interrogatories 1-15 on January 26, 2023. Defendants served interrogatories and requests for production on February 3, 2023. Defendants supplemented its Objections and Responses to Plaintiffs' First Set of Interrogatories. Ex. 2001. All of the foregoing occurred prior to the IPR filing date and represents more than a minimal investment as characterized by the Petition.

Since filing the Petition, the Plaintiffs have responded to a First Set of Document Requests, answered Defendants' First Set of Interrogatories, issued a second set of document requests; issued third-party subpoenas, responded to Defendants' Second Set of Interrogatories, issued a third set of requests for documents and served Amended Answers to Defendants' First Set of Interrogatories. *Id.* The parties completed *Markman* briefing, the court conducted a *Markman* hearing, and issued a Claim Construction Order. Further, since filing the Petition, Petitioner has served second sets of document requests and interrogatories.

Remarkably, the Petition claims minimal investment in the litigation and substantial investment in the IPR and characterizes its last-day submission of the Petition as only "close" to the deadline. The Petition offers the excuse of

settlement discussions, while simultaneously admitting that initially there were no discussions, followed by the parties being “so far apart that settlement proved an untenable option.” Petition, pg. 45.

Furthermore, all of the references relied upon were the subject of invalidity contentions filed in the concurrent related proceeding two and a half months before the Petition was filed. Ex. 2001, D.I. 33. All but one of the references relied upon in the Petition were asserted as part of the grounds of invalidity and briefed either in opposition to a motion for a preliminary injunction in the iHerb Case, which principally relied on Harder, Blass and a declaration by the same Dr. Williams who is offering testimony (MOM-1004) in this Petition. Far from favoring institution, the substantial investment in the litigation and Petitioner waiting until the last possible day to file weigh in favor of denial.

4. *Finitiv* Factor 4: Overlap of Issues Between the Petition and in the Parallel Proceedings.

All of the prior art asserted by Petitioner has also been asserted in the concurrent related proceeding. The substantial overlap weighs in favor of denial. Contrary to the Petition, pg. 45, the Stipulation (MOM-1018), does stipulate that Petitioner will not pursue any grounds utilizing the primary references, Harder, Wolf, and *European Pharmacopoeia* Supplement 4.3. The stipulation does not even state that it will not pursue any grounds that could have been brought in the

IPR. The Stipulation does not satisfy the *Solterra Wireless* requirement that Petitioner not pursue in the parallel proceedings the same grounds or any ground that could have reasonably been raised before the PTAB. Petitioner's Stipulation is meaningless because it does not satisfy the requirements of *Solterra Wireless* and does not comply with the interim procedures to avoid a discretionary denial.

5. *Finitiv* Factor 5: Whether Petitioner and Defendant in the Parallel Proceedings Are the Same Parties.

Petitioner and Patent Owners in this proceeding are the same parties in the Parallel Proceeding. The other circumstances (*Solterra Wireless*) do not mitigate against a discretionary denial.

6. *Finitiv* Factor 6: Other Circumstances

Petitioner in this proceeding has not presented any stipulation that is consistent with a *Solterra Wireless* stipulation. As shown in MOM-1018, the Petitioner only stipulates that if the PTAB Institutes this *inter partes* review based on the grounds and claims asserted in the Petition, it will not pursue in the District Court those specific grounds. The so-called stipulation reserves the right to assert invalidity on denied grounds and its right to continue to assert grounds other than the instituted grounds in the District Court.

7. Petitioner has not Established Compelling Merits for Any Ground.

Far from establishing compelling merits, the Petition fails on all four *Graham* factors. Petitioner argues that its grounds have merit because it asserts three new grounds. However, none of the reference show at least one of the critical limitations of independent claim 1, *i.e.*, that vitamin D is delivered in a nutritionally effective one drop dose that adheres to the object delivering the vitamin D. Additionally, the failure to address known evidence of secondary indicia of non-obviousness, one of the required elements of a *prima facie* showing of obviousness, dooms any argument that Petitioner has presented compelling evidence of unpatentability.

X. CONCLUSION

Petitioner has not established a reasonable likelihood that it will prevail in establishing that the Challenged Claims of the '958 Patent are invalid as obvious. Patent Owners accordingly request that the Board deny institution of *inter partes* review of the '958 Patent.

Dated: June 29, 2023.

Respectfully submitted,

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Patent Owners' Preliminary Response
U.S. Patent No. 9,066,958
IPR 2023-00726

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CERTIFICATE OF COMPLIANCE

The undersigned hereby certifies that the foregoing Patent Owners' Preliminary Response includes fewer than 14,000 words, as measured by the word-processing system used to prepare this system.

/Mark E. Ungerman/
Mark E. Ungerman
(Reg. No. 32,070)

CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6(e), the undersigned certifies that the foregoing Patent Owner's Preliminary Response is being served on June 29, 2023, by filing this document through the Patent Trial and Appeal Case Tracking System (P-TACTS) and by electronic mail as directed by Petition upon the following counsel of record for Petitioners:

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