

HIGHLY CONFIDENTIAL – ATTORNEYS EYES ONLY

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' RESPONSE
UNDER 36 CFR § 42.120**

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2001	Docket Sheet: 1:22-cv-00332-GBW Ddrops Company. et al. v. MOM Enterprises, LLC, Gregory B. Williams, presiding, Date filed: 03/16/2022, Date of last filing: 06/22/2023. Accessed through PACER, June 23, 2023.
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, dated June 28, 2023, with attached Exhibits A-D
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, dated June 28, 2023, with attached Exhibits A-B

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2009 WITHDRAWN	Declaration of Warren D. Woessner WITHDRAWN
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)
2012	DECLARATION IN SUPPORT OF PATENT OWNERS' MOTION FOR PRO HAC VICE ADMISSION OF ALAN M. ANDERSON
2013	DECLARATION IN SUPPORT OF PATENT OWNERS' MOTION FOR PRO HAC VICE ADMISSION OF L. REAGAN FLORENCE
2014	DECLARATION IN SUPPORT OF PATENT OWNERS' MOTION FOR PRO HAC VICE ADMISSION OF MATTEW PALEN
2015	Transcript of 27 Oct. 2023 Board Conference Call
2016	EXPUNGED
2017	EXPUNGED
2018	[Proposed] PROTECTIVE ORDER
2019	REDLINE OF [Proposed] PROTECTIVE ORDER AGAINST DEFAULT PROTECTIVE ORDER
2020	[REVISED PROPOSED STIPULATED] PROTECTIVE ORDER
2021	REDLINE OF [REVISED PROPOSED STIPULATED] PROTECTIVE ORDER AGAINST DEFAULT PROTECTIVE ORDER
2022	Rule 30(b)(6) Deposition Transcript of Innovative Labs, taken September 6, 2023, and Exhibits 1-23

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2023	Deposition Transcript of Stephen Benyunes, taken December 5, 2023
2024	Deposition Transcript of David J. Sherman, taken December 5, 2023
2025	Deposition Transcript of Robert O. Williams, III, taken December 7, 2023
2026	Deposition Transcript of Yasmin Kaderali, taken January 30, 2024
2027	Deposition Transcript of Stephanie Medina, taken February 1, 2024
2028	Benyunes Deposition Ex. 5
2029	Benyunes Deposition Ex. 6
2030	Benyunes Deposition Ex. 7
2031	Benyunes Deposition Ex. 8
2032	Sherman Deposition Ex. 9
2033	Sherman Deposition Ex. 10
2034	Sherman Deposition Ex. 11
2035	Sherman Deposition Ex. 12
2036	Sherman Deposition Ex. 13
2037	Sherman Deposition Ex. 14
2038	Sherman Deposition Ex. 15
2039	Sherman Deposition Ex. 16
2040	Williams Deposition Ex. 18
2041	Williams Deposition Ex. 23
2042	Kaderali Deposition Ex. 24
2043	Kaderali Deposition Ex. 25
2044	Kaderali Deposition Ex. 26

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2046	Kaderali Deposition Ex. 28
2047	Kaderali Deposition Ex. 29
2048	Kaderali Deposition Ex. 30
2049	Kaderali Deposition Ex. 31
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2057	Kaderali Deposition Ex. 39
2058	Kaderali Deposition Ex. 40
2059	Medina Deposition Ex. 41
2060	Medina Deposition Ex. 42
2061	Medina Deposition Ex. 43
2062	Medina Deposition Ex. 44
2063	Medina Deposition Ex. 45
2064	Medina Deposition Ex. 46
2065	Medina Deposition Ex. 47
2066	Medina Deposition Ex. 1027
2067	Email Chain, dated November 10 & 11, 2020
2068	Declaration of Reinhold Vieth, dated February 3, 2024, and Exhibits A-F

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Exhibit Number	Description
2069	Declaration of Paul Horowitz, dated February 5, 2024, and Exhibits A-M
2070	Declaration of Casey MacKenzie, dated February 7, 2024, and Exhibits A-B
2071	Declaration of Chris Temovsky, dated February 8, 2024, and Exhibits A-X
2072	Declaration of Steven M. Reid, dated February 9, 2024, and Exhibits A-B

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<i>Apple, Inc. v. Samsung Elecs. Co.</i> , 839 F.3d 1034 (Fed. Cir. 2016)	44, 54, 59
<i>Dynamic Drinkware, LLC v. Nat’l Graphics, Inc.</i> , 800 F.3d 1375 (Fed. Cir. 2015)	27
<i>Fox Factory, Inc. v. SRAM, LLC</i> , 944 F.3d 1366 (Fed. Cir. 2019)	46
<i>Google Inc. v. EveryMD.com LLC</i> , IPR2014-00347, Paper 9 (PTAB May 22, 2014)	27
<i>Graham v. John Deere Co.</i> , 383 U.S. 1 (1966)	28, 44
<i>Harmonic Inc. v. Avid Tech., Inc.</i> , 815 F.3d 1356 (Fed. Cir. 2016)	27
<i>Howard v. City of Durham</i> , 2021 U.S. Dist. LEXIS 211307 (M.D.N.C. Nov. 2, 2021)	26
<i>In re Magnum Oil Tools Int’l, Ltd.</i> , 829 F.3d 1364 (Fed. Cir. 2016)	28
<i>Institut Pasteur & Universite Pierre Et Marie Curie v. Focarino</i> , 738 F.3d 1337 (Fed. Cir. 2013)	49, 59
<i>Iron Grip Barbell Co. v. USA Sports, Inc.</i> , 392 F.3d 1317 (Fed. Cir. 2004)	49
<i>J.T. Eaton & Co. v. Atl. Paste & Glue Co.</i> , 106 F.3d 1563 (Fed. Cir. 1997)	62
<i>KSR Int’l Co. v. Teleflex Inc.</i> , 550 U.S. 398 (2007)	28
<i>Lectrosonics, Inc. v. Zaxcom, Inc.</i> , IPR2018-01129, Paper 33 (PTAB Jan. 24, 2020)	46, 60
<i>Liqwd, Inc. v. L’Oreal USA, Inc.</i> , 941 F.3d 1133 (Fed. Cir. 2019)	45, 49

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<i>Michalic v. Cleveland Tankers, Inc.</i> , 364 U.S. 325 (1960)	49
<i>Polaris Indus., Inc. v. Arctic Cat, Inc.</i> , 882 F.3d 1056 (Fed. Cir. 2018)	46
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<i>Rambus Inc. v. Rea</i> , 731 F.3d 1248 (Fed. Cir. 2013)	46
<i>Ross v. City of Rockford</i> , 2018 U.S. Dist. LEXIS 51398 (N.D. Ill. Mar. 27, 2018)	26
<i>Tec Air, Inc. v. Denso Mfg. Mich. Inc.</i> , 192 F.3d 1353 (Fed.Cir. 1999)	62
<i>WBIP, LLC v. Kohler Co.</i> , 829 F.3d 1317 (Fed. Cir. 2016)	46
<i>Wilson Elec., LLC. v. Cellphone-Mate, Inc.</i> , IPR2018-01778, Paper 10 (PTAB Apr. 23, 2019)	28

I. INTRODUCTION

Elaine and Reinhold Vieth (“Patent Owners” or “the Vieths”) respectfully submit this Response to the Petition (Paper 2) filed by Petitioner MOM Enterprises, LLC (“Petitioner”). Contrary to Petitioner’s arguments, claims 1, 3, 4 and 5 of U.S. Patent No. 9,066,958 (the “’958 Patent”) are valid.

The cornerstone of Petitioner’s invalidity contentions is a cherry-picked excerpt from the German-language Harder-edited book, which was neither written by nor for a person of ordinary skill in the art. The translation of the single sentence Petitioner relies upon from this book is essential to its arguments. In fact, if the translation does not include the word “licked,” then Petitioner’s expert has no obviousness opinion. The first translation Petitioner obtained of Harder does not include the word “licked.” In a desperate attempt to correct this fatal flaw, Petitioner’s counsel obtained several additional translations of Harder after demanding they include the word “licked.” Because Petitioner and its expert rely heavily on manipulated translations, they cannot meet their burden of proof. At a minimum, the Board should find that Harder is ambiguous and thereby insufficient to support a finding of obviousness.

The Board should give little weight to the opinions of Petitioner’s expert. Petitioner’s counsel provided him with the prior art references and asserted

combinations and even wrote the first draft of his expert report. Petitioner's expert is little more than a rubber stamp for the arguments of Petitioner's counsel.

Moreover, Petitioner's obviousness opinion is legally flawed because he failed to consider secondary indicia of non-obviousness. When asked to explain why he failed to consider secondary indicia of non-obviousness, Petitioner's counsel instructed him not to answer the question.

Petitioner has failed to meet its burden of proof because its prior art combinations do not prove that the claims in issue are obvious. There are significant gaps in the Petitioner's prior art references. For example, none of them address the critical issues of adherence and providing a therapeutically-effective dose of vitamin D. Petitioner's expert, a self-described person of ordinary skill in the art, admitted that nothing in the prior art addresses how many licks or how to obtain an efficacious dose of vitamin D from the surface of a spoon.

Finally, substantial evidence of secondary indicia strongly supports the validity of claims 1 and 3-5 of the '958 Patent. Petitioner's expert has not offered an opinion on secondary indicia. The necessary nexus exists between Ddrops' product that embodies the patented composition and method and Petitioner's product. Objective and clear evidence shows that Petitioner – and other competitors – copied Ddrops' commercial product. Petitioner's internal documents

disclose a deliberate plan to copy the commercial embodiment in order to “steal” market share from Ddrops. The ‘958 Patent also solved a long-felt but unmet need. Ddrops’ commercial embodiment has received numerous industry awards and praise from researchers, physicians and customers. Finally, Ddrops’ commercial embodiment has been highly successful in the market. Not surprisingly, after Petitioner made a single change in 2020 to complete its embodiment of the ‘958 Patent, its reformulated product also has achieved commercial success. Thus, claims 1 and 3-5 of the ‘958 Patent are valid, contrary to Petitioner’s assertions.

II. THE ‘958 PATENT AND THE PROBLEM IT SOLVED

Insufficient vitamin D in infants, children and adults leads to rickets, a debilitating and potentially deadly disease. The need for supplemental vitamin D in humans goes back hundreds of years. Exposure to sunlight, cod liver oil, and vitamin D tablets were all used as suboptimal means and methods. But vitamin D is very potent. It is administered in micrograms. Even a small overdose can cause toxic responses. Ex. 2068, ¶s 7-18. *See also* Ex. 1001, 1:60-2:12. The need to provide vitamin D at an early age created further challenges. First, infants are more difficult to handle and their actions are driven by reflexes rather than instructions. Second, breastfeeding mothers often do not want to give their infants foreign liquids or compounds that are not natural for them. Moreover, pediatric

associations did not provide any clear or consistent guidance regarding a suitable method to deliver vitamin D to the breastfeeding infant. They simply left it to the parents to figure it out on their own. *Id.*, 2:13-36.

Patent Owners realized the multiple problems that existed with both then-existing vitamin D products and the lack of a functional and effective method of delivery. Existing products tasted bad with an unpalatable texture, which caused infants to reflexively spit out the liquid. This resulted in under-dosing and ineffective treatment. Additionally, the prior products had a short shelf-life and a greasy feel. *Id.*, 2:37-52. There was “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.” There also was a need “for adults to be able to deliver a dose of vitamin D efficiently by sucking a vitamin D supplement from a surface, instead of directly placing the supplement directly into the mouth.” *Id.*, 3:43-49.

The problem addressed by Patent Owners in the early 2000s was: *How do you reliably deliver vitamin D to a human being or an infant, in a form and method that is reliably safe and nutritionally effective, amenable and acceptable to the recipient?* This is an exceedingly complex problem, involving five inter-related variables: (a) a single drop; (b) the correct concentration; (c) the proper carrier; (d)

the delivery means; and (e) the method of administration. The solution is not trivial. The Board cannot use hindsight to evaluate whether the invention disclosed in the '958 Patent was obvious at the time of invention. Despite all the efforts in the medical and pharmaceutical community since the 1800s, the problem of addressing vitamin D deficiency and supplementation remained unresolved. When the Vieths began investigating and researching to solve this complex problem, they did not believe they would succeed. The invention did not materialize in a dream after a weekend of tinkering. Rather, the Vieths engaged in years of experimentation, research and analysis before achieving the innovative single-drop solution. Ex. 2068, ¶s 29-46, Ex. C. *See* Ex. 1001, 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, no taste, and a non-greasy texture. Critically to the function of the invention, it also has suitable adhesion properties to prevent the vitamin D from running down, dispersing along,

or dripping off the surface of a nipple or pacifier. *Id.*, 6:40-47. *See* Ex. 2068, ¶s 29-53.

Critically, the Vieths discovered through experimentation that the medium chain triglycerides (“MCT”) oil used in the invention “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. The liquid *does not coat or adhere* to the pacifier so as to prevent efficient removal of the vitamin D from the nipple or pacifier through sucking.” Ex. 1001, 6:36-39 (emphasis added). This is a key element of the ‘958 Patent claims.

The Examiner’s statement of Reasons for Allowance, after over eight years of prosecution, 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.

Ex. 1002 at 28. None of the combinations proffered by Petitioners teach or suggest the innovative solution to the complex, inter-related problem solved by the Patent Owners.

III. LEVEL OF ORDINARY SKILL IN THE ART

In its Decision granting *inter partes* review, the Board determined that a person of ordinary skill in the art (“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.” Paper 10 at 13. In reaching this determination, the Board rejected the Petitioner’s attempt to expand the scope of a POSITA to include a nurse. *Id.*

Patent Owners agree with the Board’s determination. The field of the ‘958 Patent requires education and experience in both chemical formulation and methods of administering supplements to humans. The relevant prior art concerns formulations of medicaments or nutritive supplements to humans and particularly infants. The sophistication of a person who addresses the problems and risks

involved with developing formulations safe for human consumption requires both an advanced degree and related experience. Ex. 2072, ¶52. *See* Ex. 1001, 7:31-34, 8:27-31; Ex. 2008, ¶32. *See also* Ex. 2069, ¶6(f). A nurse’s skillset does not include developing medicaments, formulations, or the considerations relating to such development. Similarly, a POSITA does not include a midwife or doula, whose training and experience is typically below that of an average nurse. Ex. 2072, ¶53.

Moreover, as the Board noted, Petitioner failed to explain the “related work experience” it proposed for a nurse as part of its POSITA description. Paper 10 at 13. Petitioner’s purported expert, Williams, was instructed not to answer whether the description of a POSITA contained in his declaration was provided by counsel. Ex. 2025, 64:8-22. Williams had never seen the Decision, even though the Board issued it months before his testimony was taken. He was not aware the Board had rejected the second sentence of “his” description of a POSITA. *Id.*, 66:18-67:6. When asked if he had been asked to consider the points raised by the Board in its Decision, he was again instructed not to answer. *Id.*, 67:8-17. He testified that he had not reevaluated his alleged opinion in view of the Board’s decision. *Id.*, 70:10-14. Thus, Petitioner has offered no support for its proposed description of a POSITA. In light of the instructions not to answer and Williams’ testimony,

Petitioner should be barred from providing any further argument or explanation for its lawyer-written description of a POSITA. The Board should confirm its prior description of a POSTIA.

IV. CLAIM CONSTRUCTION

The parties previously agreed to various claim constructions in the underlying District Court action, and the District Court adopted those constructions. *See* Paper 10 at 14-15; Ex. 2005, 1-2. In its Decision, the Board adopted the District Court’s claim construction for “wherein said drop adheres to the surface of said object” and “vitamin D.” Paper 10 at 15-16. Patent Owners agree with these constructions, as well as the constructions agreed and issued by the District Court. *See* Ex. 2072, ¶s 22-26.

Regarding the construction of “wherein said drop adheres to the surface of said object”, the part of the construction, “The drop does not coat or adhere to the object so as to prevent efficient removal of the drop from the object”, deserves explication. As explained by Patent Owners’ expert, Dr. Reid:

The phenomenon of adherence or, equally, adhesion, in this context invokes a relationship between two characteristics, namely the nature of the liquid triglyceride and the nature of the exterior surface. It is not enough for the vitamin D composition simply to adhere to an exterior

surface in the sense that it merely does not drip off, *i.e.*, the drop remains attached somehow no matter where to the surface. Rather, the drop adheres so as to remain localized to facilitate its removal from the surface so that a nutritional or therapeutic effective dose of vitamin D is delivered to a human. Thus, the drop does not spread out, coat, or form a film on the surface because any of these actions would compromise removal of the drop and, hence, delivery of the dose of vitamin D. The liquid triglyceride is a carrier oil of sufficient viscosity so as to not drip off the surface, in contrast, for example, to aqueous and alcoholic preparations. *See* Ex. 1001 at 7:1-22. The surface is one to which the drop adheres within the meaning above; this does not include, for example, a spoon.... Therefore, not just any liquid triglyceride and not just any surface will suffice: the combination of the two establishes a relationship of adherence so that a nutritional or therapeutic effective dose is administered to a human by licking or sucking.

Ex. 2072, ¶26.

Although he understood that claims must be interpreted as they would have been by a POSITA at the time of the invention, Petitioner's alleged expert did not

construe the asserted claims in reaching “his” opinions. Other than what he was fed by Petitioner’s counsel, Williams does not provide any indication of the claim construction he applied. Ex. 2025, 70:15-71:19. Petitioner has not proposed any different constructions to those determined by the District Court or the Board. Petitioner should be barred from offering any new or different constructions now.

V. THE PRIOR ART RELIED ON BY PETITIONER

Petitioner relies on five prior art references to argue that claims 1 and 3-5 of the ‘958 Patent are invalid as obvious. However, to achieve that result, Petitioner resorted to surprising efforts to ensure “the fix is in.” Petitioner took three bites at the translation apple before finally obtaining a translation of the so-called Harder reference that aligns with its legal arguments. It also grossly mischaracterizes what the prior art teaches.

A. Harder

1. Petitioner Obtained Multiple, Inconsistent Translations of Harder

Petitioner has submitted not one, not two, not three, but four different translations of all or parts of §15.9 of the Harder reference. See Exs. 1007, 1021,

1022, 1023.¹ These multiple translations are not simply an example of the proverbial “gang that couldn’t shoot straight.” Rather, they show a coordinated effort between Petitioner, its counsel, and its experts to twist the evidence to fit their legal arguments. The original – untainted translation – is missing the phrase “to be licked off.” Williams admitted at his deposition that he cannot give his obviousness opinion without that phrase in the Harder translation. *See* Ex. 2025, 99:5-100:21; 120:10-19. Petitioner’s attorneys engaged in a deliberate campaign to obtain the necessary translation. Without the doctored translation, this proceeding is over.

In connection with a prior infringement action brought by Ddrops against infringing distributors that copied its product and patented method, Petitioner’s counsel – representing the infringers in that action – obtained a certified translation of §15.9 of Harder in 2017. *See* Ex. 1021. The translator, Tinworth, declared under penalty of perjury that her translation was “a true, full and accurate translation of” §15.9 of Harder. She declared her competency to perform the translation. *Id.*, ¶s 2-3. Her certified and quality-controlled translation states in critical part: “1 drop of

¹ Petitioner’s counsel additionally obtained single-sentence re-translation of Harder in 2017. *See* Ex. 2024, 23:17-24:10; 25:16-26:6; Ex. 2032.

Vigantol® is given to the baby from the tip of a spoon once a day before a breastfeed or a meal.” *Id.*, p. 5. Tinworth’s translation was peer-reviewed by another qualified translator before she executed her declaration. Ex. 2024, 22:9-24. Her then-manager agrees she was competent and qualified to provide a true, full and accurate translation. *Id.*, 26:20-22; 27:9-19.

However, Petitioner’s counsel was not happy with Tinworth’s translation. It recognized that her translation left a critical gap in its invalidity arguments. An attorney at the law firm retained by Petitioner,² called the translation service and complained. She asked that a “certain passage” be reviewed because she thought some words needed to be added. Ex. 2024, 29:1-30:1; 30:25-31-8; Ex. 2032 at 2; Ex. 2033 at 1. Rather than say “no” to a significant client with its own Key Account Manager, the service asked Sherman to review a single sentence in Harder. The only reason Sherman reviewed a single sentence in Tinworth’s translation was because of the request by Petitioner’s counsel. Ex. 2024, 24:7-28:12; 33:1-9, 35:2-7; Ex. 2032. Translating a single sentence in a document is

² Martina Tyreus Hufnal made the request. She remains an attorney with Petitioner’s counsel. See <https://www.fr.com/team/martina-tyreus-hufnal/> (accessed Feb. 6, 2024).

improper; context is important. Ex. 2023, 73:23-74:3. However, in June 2017, Sherman complied with Petitioner counsel's request, reviewed a single sentence, and signed a declaration drafted by Petitioner's counsel that added "to be licked off" to Tinworth's original certified translation, allegedly to make it "a *more accurate reflection* of the German text." Ex. 2024, 33:1-9; 35:2-7, 8-18; 45:5-10; 67:17-24; 72:2-73:2; Ex. 1007, ¶3 (emphasis added). Sherman's 2017 declaration did not state that Tinworth's translation was wrong or erroneous or not accurate. He simply, as requested by Petitioner's counsel, added four words that counsel wanted, and then signed a declaration that had been drafted by Petitioner's counsel. The phrase "a more accurate reflection" was provided by Petitioner's counsel. Ex. 2024, 25:1-28:12, 71:23-72:2; Ex. 1007. *See* Ex. 2072, ¶42.

Four years later, in connection with this proceeding, Petitioner's counsel, now representing Petitioner, needed a new declaration. After much effort, it got Sherman to resign the same declaration he had signed in June 2017. *See* Ex. 2024, *Compare* Ex. 2033 at 4-11 (2017 declaration) *with* Ex. 1007 (2023 declaration). Williams relied on Sherman's February 2023 restatement of his June 2017 declaration in stating his opinions in his declaration. Ex. 2025, 24:8-11.

In a desperate attempt to distance themselves from the original Tinworth translation, Petitioner's counsel then requested another translator for a translation

of §15.9 of Harder. The translation service selected Benyunes to do the latest translation. However, he did not do an original, from scratch, translation of §15.9 of Harder. Contrary to his standard practice, Benyunes inexplicably used Tinworth's original translation as his starting point. He simply copied Tinworth's translation to the extent he would have essentially chosen the same words. Ex. 2023, 59:21-60:16; 81:4-15. Benyunes translated the key sentence in §15.9 as "Once a day before breastfeeding or a meal, the baby is given 1 drop of Vigantol® oil on the tip of a spoon *to lick off*." Ex. 1023 at 5. Benyunes' translation thus is the third different translation of one sentence in Harder. Benyunes also was given a draft declaration drafted by Petitioner's counsel to sign. Ex. 2023, 53:11-22. See Ex. 2072, ¶s 41, 43-44.

Thus, three different translations exist of Harder: Tinworth (Ex. 1021); Sherman (Exs. 1007; 1022); and Benyunes (Ex. 1023). Only Tinworth is untainted by the manipulations of Petitioner's counsel. Only Tinworth is a full, original translation. Ex. 2072, ¶45. Any analysis of Harder, therefore, should be based on Tinworth's untainted translation.

2. Regardless of the Translation, Harder Provides Little or No Useful Teaching

Section 15.9 of Harder is a single sub-section in a single chapter of an edited volume written by midwives for midwives. The book offers practical solutions for midwives to typical problems that might be faced in the first months of an infant's life. See Ex. 2070, ¶s 1-5; Ex. B. Section 15.9 presents four alternative approaches to administering vitamin D to infants to prevent rickets. Option 1, the "most reliable option," crushes vitamin D tablets into a spoonful of water that is then drunk from a spoon. Option 2, instead of Option 1, proposes exposing an infant to sunlight. Option 4, which Harder characterizes as "problematic," involves administering synthetically produced vitamin D to an infant. Ex. 1021 at 3-6.

Option 3 is suggested in the limited case when a child is susceptible to allergies or where Option 1 (tablets in water), results in increased bloating. According to Tinworth, under special-case Option 3, a single drop of Vigantol® oil is "given to the baby from the tip of a spoon once a day before a breastfeed or a meal." Ex. 1021 at 4. Sherman modifies this sentence to read that the single drop of Vigantol® oil is "given to the baby *to be licked off* from the tip of a spoon once a day before a breastfeed or a meal." Ex. 1007 at 6 (emphasis added). Benyunes claims Option 3 states, "Once a day before breastfeeding or a meal, the baby is

given 1 drop of Vigantol® oil on the tip of a spoon *to lick off*. Ex. 1023 at 5 (emphasis added). Harder critically cautions against allowing even one drop more to fall into the spoon due to the high risk of vitamin D toxicity. She states that if two drops fall in, the spoon should be immediately washed and the process restarted. Ex. 1021 at 5.

Harder provides no information regarding the composition of the oil she used – Vigantol® oil – a product that is not available in the U.S. or Canada and is only available by prescription in a few European countries. *See* Ex. 2069, ¶6(h). Her stark warning about the risk of giving an infant a toxic overdose using Option 3 militates against using that option as the starting point – or any point – for research.

Regardless of the translation used, Harder’s Option 3 shows an astonishing lack of knowledge and understanding of an infant’s feeding mechanics and inability to “lick” anything for purposes of ingestion. Infants do not and cannot lick a substance off any surface for purposes of feeding. An infant uses its tongue as part of rooting method to find a mother’s nipple for suckling. If Harder used the verb “lick,” it is an inaccurate description of how an infant uses its tongue. She does not understand that fact. Further, Pediatricians advise against inserting any object, such as a spoon, into an infant’s mouth. Harder also does not understand

that fact. Ex. 2068, ¶s 46-52, 60-71, 93, Exs. D-F; Ex. 2069, ¶7; Ex. 2072, ¶s 77-78. Simply put, Harder’s suggestion is incompetent.

Harder also does not address the critical issue of adherence or providing a therapeutically-effective dose of vitamin D. Harder ignores the fact that some amount of the oil will adhere and remain in the spoon. Harder does not mention or address viscosity or adherence. Ex. 2025, 130:10-15. Williams admits that Harder teaches nothing about the number of licks an infant would have to make to obtain a therapeutically effective dose of vitamin D. *Id.*, 137:4-18; 138:1-24; 139:1-6; 139:23-140:10. Williams admitted he would have to consult with a medical professional or clinician to determine this key issue. *Id.*

Thus, contrary to the arguments of Petitioner, and regardless of the competing translations used, Harder discloses little of relevance to seeking a solution to the long-standing problem solved by the ‘958 Patent. Ex. 2072, ¶s 76-81. Harder’s Option 1, the “most reliable option – administering vitamin D tablets in water – teaches away from the ‘958 Patent. A POSITA would more likely recognize that option rather than the one presented specifically for a child susceptible to allergies that possesses a higher risk of toxic overdose. Harder provides no useful teaching toward solving that problem.

B. Wolf

The Wolf reference (Ex. 1008) is a German-language “Current therapy” note for which Petitioner has provided a translation. *See* Ex. 1009. Unlike the Harder reference, Petitioner did not obtain multiple translations. Significantly, Wolf *teaches away* from the claimed inventions.

Wolf discloses a prophylaxis of rickets in infants by recommending daily administration of 500 I.U. of vitamin D. Ex. 1009, 7; Ex. 2072, ¶46. Wolfe cites various “pure vitamin D preparations” that are tablets or liquids and “vitamin preparations containing vitamin D₂ or D₃” that are also tablets or liquids. Ex. 1009, 8-9; Ex. 2072, ¶46. There are many liquid vitamin D options listed, most of which are not or were not dissolved in MCT. Ex. 2068, ¶79. Wolf says that Vigantoletten® and Vigorsan® are the most suitable “pure vitamin D₃ preparations.” Ex. 1009, 9; Ex. 2072, ¶46. Wolf lists Vigantol® among the various vitamin D₃ preparations, but does not disclose the composition or chemical properties of the product. *See* Ex. 1009, 8. Wolf does not define or describe what he means by “pure” in reference to vitamin D₃ preparations. Ex. 2072, ¶46.

Contrary to Petitioner’s arguments, Wolf teaches away from the inventions claimed in the ‘958 Patent. Ex. 2072, ¶s 84-85; Ex. 2068, ¶s 79-83. Wolf states, “Drops or tablets should not be added to the bottle, but administered to the baby on

a spoon with some liquid.” Ex. 1009, 7. Contrary to the claim language, the fact Wolf adds some amount of additional liquid so that there is no single-drop and the composition does not consist of vitamin D and MCT. Wolf recognizes the difficulty in efficiently delivering a full dose from a surface, but goes in the opposite direction than the inventors’ effort to address this difficulty. By adding extra liquid, Wolf discloses a method for diluting a vitamin D dose. Ex. 2072, ¶85; Ex. 2068, ¶81. He does not address the fact that some of the dose is left behind on the surface of the spoon and not administered. *Id.* See Ex. 2072, ¶s 82-85.

Williams was instructed not to answer what he was told about the significance of the Wolf reference when it was provided to him by Petitioner’s counsel. Ex. 2025, 129:18-22. However, he agrees that a POSITA would understand Wolf as teaching putting a drop or tablet on a spoon with some additional liquid. *Id.*, 132:5-22. He agreed that Wolf does not teach or suggest anything regarding adherence or viscosity or having an infant or child lick something off an object. *Id.*, 130:16-129:2.

C. *European Pharmacopeia*

Petitioner relies on a highly truncated excerpt from Supplement 4.3 of the fourth edition of *European Pharmacopeia*. Ex. 1010. The excerpt is a monograph on medium chain triglycerides (“MCT”) that describes the acid origins and MCT

composition of octoanic and decanoic acids, methods for identifying MCT and maximum levels and assays for determining impurities. *Id.* at 5-6. *See* Ex. 2072, ¶47. The reference does not disclose any active ingredient for MCT, such as vitamin D or anything else. Ex. 2068, ¶87. While some of the characteristics of MCT are stated by reference to standards and tests, none of them are contained in the referenced excerpt from supplement 4.3 to *European Pharmacopoeia*. Ex. 2068, ¶88.

D. Blass

The Blass reference is an article entitled, “Suckling- and sucrose-induced analgesia in human newborns.” Ex. 1011. Blass examined the examined sucrose-induced non-pharmacological “analgesia” in newborn infants subjected to heel lance blood collection. *Id.* at 6. In Blass, comparative experiments were conducted either (a) giving an infant 2 mL of a sucrose solution or (b) a pacifier dipped in a sucrose solution every thirty seconds during a two-minute period while the infant received a heel prick. *Id.* at 8. *See* Ex. 2072, ¶48.

Based on observations that the infant did not cry or grimace as much under either scenario, particularly (b), Blass presented a theory that a synergy “between orogustatory and orotactile mechanisms” results in some non-pharmacological analgesia. Ex. 1011 at 14. Blass does not suggest that sucrose is a

pharmaceutically-active agent. He also does not indicate any particular dose of sucrose is necessary. Blass emphasizes that “sweet taste [is] an analgesic agent.” *Id.* at 15. He concluded, “Behaviorally induced analgesias either through taste, flavor, suckling, or contact offer very promising, effective, and safe, noninvasive and nonpharmacological treatments.” *Id.* at 16. *See* Ex. 2072, ¶s 48-50.

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. Basically, Blass presents a method of distracting an infant from the pain it is otherwise feeling. Blass does not address administration or nutritionally-sufficient dosing of vitamins or adhesion of any liquids to surfaces of objects. Ex. 2068, ¶96.

Furthermore, the Examiner carefully considered Blass and relied on it to initially reject claims during the prosecution. However, based on the arguments presented by Patent Owners during prosecution distinguishing Blass from the claimed inventions, he ultimately allowed issuance of the claims. *See* Ex. 1002 at 28, 60-66.

E. Gartner

Gartner is a clinical report on a new National Academy of Sciences recommendation that infants, children and adolescents have 200 I.U. of vitamin D for prophylaxis of rickets. *See* Ex. 1012, 3. Gartner warns that “[c]urrently available solitary vitamin D preparations (containing up to 8000 IU/mL) are too concentrated to be safe for routine home use.” *Id.* at 4. *See* Ex. 2072, ¶51. Gartner does not suggest anything about the delivery of vitamin D other than “currently available” multivitamins that include vitamin D or vitamin D-fortified milk or formula. Gartner does not recognize that there is a problem with or difficulty with how to effectively administer a nutritionally-sufficient dose of vitamin D to a human being, including an infant. Ex. 2068, ¶97.

VI. WILLIAMS’ OPINIONS SHOULD BE DISREGARDED OR GIVEN LITTLE WEIGHT

The testimony of Petitioner’s expert, Williams, revealed that his opinions set forth in his declaration should be disregarded or given little weight. Williams revealed that he did little if any no work regarding his opinions or his report himself. Rather, Petitioner’s counsel spoon-fed it to him. Further, Williams revealed significant defects in his opinions. The Board should disregard or give Williams’ declaration and opinions no or little weight because they lack credibility.

Petitioner's counsel identified and provided Williams with the five prior art references identified in his report. Petitioner's counsel told Williams the three prior art combinations used to contend that claims 1 and 3-5 are invalid as obvious. Petitioner's counsel wrote the first draft and subsequent drafts of Williams' report, parts of which clearly were copied from a report Williams prepared in 2017 for use in a different patent infringement action brought by Ddrops against distributors then-represented by Petitioner's counsel for violating the '958 Patent. *See, e.g.*, Ex. 2025, 19:24-20:1-24; 21:4-10; 22:1-23:9; 30:13-31:8; 37:16-24; 45:22-46:2; 46:16-47:16; 51:10-16.

Petitioner's counsel repeatedly instructed Williams not to answer essential questions based on bogus claims of privilege. Williams was not allowed to testify regarding what he was told on essential facts and issues. He was instructed not to answer questions regarding what he was told regarding the prior art references or the combinations provided to him by Petitioner's counsel. Williams was instructed not to answer questions regarding how much of his declaration actually was prepared by Petitioner's counsel. He was instructed not to answer questions regarding the inconsistencies between his opinions expressed in his declaration under penalty of perjury signed in 2017, and those given in his declaration here. He was instructed not to answer questions regarding the differences between the

competing translations of the Harder reference and what he was told regarding them. Petitioner's counsel instructed he not answer questions about what he was told regarding the Wolf reference. Williams was also instructed not to state who provided him with a document to review that is not cited or referenced in his declaration. He was instructed not to answer important questions so many times that the transcript of his testimony is more a recitation of instructions not to answer than substantive answers. The index to his testimony indicates that he was instructed not to answer approximately ninety (90) times. *See, e.g., id.*, 43:6-16; 48:2-8; 49:5-11; 51:10-16; 58:7-13; 61:12-62:4; 63:17-22; 68:8-15; 67:8-13; 75:12-16; 76:6-19; 77:8-11; 79:6-11; 81:9-16.

On the rare occasion that Williams was allowed by Petitioner's counsel to answer a deposition question, his answers reveal significant fundamental deficiencies in his opinions. For example, Williams has never reviewed the Petitioner's Petition or the Board's Decision instituting this proceeding. *Id.*, 66:15-23. Williams testified that without the subsequent doctored translations of Harder that added the critical "lick off" words, he cannot render his opinions regarding obviousness. *Id.*, 99:5-100:21; 120:10-19. Despite the importance of licking to his opinions, Williams admitted that he is unqualified to give an opinion as to the number of licks an infant would have to make to receive a nutritionally-sufficient

dose of vitamin D from a spoon or surface. Williams repeatedly disqualified himself by stating he would have to speak with a clinician, such as a physician, despite claiming he was a POSITA. *Id.*, 138:17-24; 139:1-6; 139:23-140:10; 144:23-145:3; 145:21-146:6. Williams even admitted that he never considered the efficacious dose requirement in the claims of the ‘958 Patent. *Id.*, 137:4-138:9.

Williams declaration, opinions and testimony are so riddled with gaps, deficiencies and refusals to answer legitimate questions that the Board should entirely disregard his evidence. The Board should not permit Petitioner’s counsel to so blatantly stonewall the obtainment of important testimony – undoubtedly because the truth would be more damning than a non-answer. At a minimum, the Board should significantly discount and not give much, if any, weight to Williams’ evidence. *Cf. Howard v. City of Durham*, 2021 U.S. Dist. LEXIS 211307, *23 (M.D.N.C. Nov. 2, 2021) (Fed. R. Civ. P. 26 bars “counsel from “ghost writing” an expert’s report”); *City of Ross v. City of Rockford*, 2018 U.S. Dist. LEXIS 51398, *4-5 (N.D. Ill. Mar. 27, 2018) (discovery permitted to identify facts or data provided to expert by attorney considered by expert in forming opinions; discovery permitted as to attorney-expert communications to identify assumptions provided by attorney to expert). *See also Acco Brands Corp. v. Think Products, Inc.*,

IPR2015-01168, Paper 40 at 30-31 (PTAB Oct. 11, 2016) (in reaching decision, Board “determined and ascribed the appropriate weight to all proffered evidence”).

VII. PETITIONER’S PRIOR ART COMBINATIONS DO NOT PROVE THAT THE CLAIMS IN ISSUE ARE OBVIOUS

A. Obviousness Standard

“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)). The burden of persuasion in an IPR “never shifts to the patentee.” *Dynamic Drinkware, LLC v. Nat’l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015). Moreover, a petitioner should not “place the burden on [the Board] to sift through the information presented by [the] Petitioners, determine where each element [of the challenged claims] is found in [the cited references], and identify any differences between the claimed subject matter and the teachings of [the cited references].” *Google Inc. v. EveryMD.com LLC*, IPR2014-00347, Paper 9 at 25 (PTAB May 22, 2014).

A claim is unpatentable under §103(a) if the “differences between the subject matter sought to be patented 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.” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of 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 skill in the art; and (4) when in evidence, objective indicia of non-obviousness (i.e., secondary considerations). *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966).

“To satisfy its burden of proving obviousness, a petitioner cannot employ mere conclusory statements. The petitioner must instead articulate specific reasoning, based on evidence of record, to support the legal conclusion of obviousness.” *In re Magnum Oil Tools Int’l, Ltd.*, 829 F.3d 1364, 1380 (Fed. Cir. 2016). A petition seeking to establish obviousness based on more than one reference, as here, “must articulate sufficient reasoning with rational underpinnings to combine the teachings.” *Wilson Elec., LLC. v. Cellphone-Mate, Inc.*, IPR2018-01778, Paper 10 at 15 (PTAB Apr. 23, 2019) (citing *KSR Int’l*, 550 U.S. at 418). Petitioner cannot meet its burden to establish that any of the claims in issue are invalid as obvious in light of the asserted combinations and the substantial evidence of secondary indicia.

B. Claims 1 & 5 are Not Obvious in Light of Harder, Wolf & *European Pharmacopoeia*

Petitioner argues that Harder, Wolfe, and *European Pharmacopoeia* Supplement 4.3 in combination renders claims 1 and 5 obvious. Before the Board can even consider the merits of Petitioner’s argument, it must first clear multiple preliminary hurdles. A failure to resolve any of these hurdles in Petitioner’s favor ends the Board’s inquiry regarding claims 1 and 5 and this proceeding entirely, because claims 3 and 4 depend from claim 1.

First, the Board must decide whether a POSITA would even consider Harder. Because Harder is an edited practical volume by midwives for midwives, no POSITA working to solve the problem addressed in the ‘958 Patent would consider Harder pertinent or relevant or a useful source for any purpose. If the Board decides that a POSITA would consider Harder relevant prior art, then it must address the multiple, inconsistent translations proffered by Petitioner in its attempt to game the system. If the Board concludes that the only unadulterated, untainted initial translation by Tinworth is what a POSITA would consult, then its work is again finished. Petitioner’s expert admitted that without the words subsequently added to Tinworth’s translation at the instigation and insistence of

Petitioner’s counsel, he cannot render the opinions he has given regarding obviousness.

Only if these preliminary issues are resolved favorably to Petitioner does the Board need to address the proposed combination of Harder plus Wolf plus *European Pharmacopoeia*. Regardless of the translation of Harder used, that combination does not teach or suggest all the elements of claims 1 or 5. Properly read and understood, Harder would be of little or no use to a POSITA, and combined with Wolf, teaches away from the innovative and elegant solution to the long-standing problem solved by the ‘958 Patent.

1. A POSITA Would Not Have Considered Harder

A POSITA, as previously defined, would not consult a document such as Harder in attempting to address the problems solved by the ‘958 Patent. A POSITA – a person with “a doctorate degree in Pharmaceutics or a related field with several years of experience in formulating compositions of and delivering medicines and nutritional supplements” – would consult authorities in the fields of pharmaceutics and the delivery of medicants. They would consider materials written by similarly-situated individuals, such as textbooks and peer-reviewed articles. A POSITA would have considered the collective wisdom and experience

of similarly educated individuals. Ex. 2072, ¶s 52-53; Ex. 2068, ¶s 58-59; Ex. 2069, ¶6(f).

A POSITA would not have consulted or likely even found Harder. Harder is a collection of practical and “how-to” chapters written by midwives. The target audience for Harder is midwives. Ex. 2070, Ex. B. A midwife is not a POSITA. Ex. 2072, ¶53. Harder herself distinguishes her co-edited book from “obstetric textbooks.” Ex. 2070, Ex. B. The Table of Contents of Harder shows that none of the chapter subjects would be of interest to a POSITA working in the field of the ‘958 Patent. *See id.*; Ex. 2072, ¶s 55-57. Harder may be a useful reference for midwives looking for practical tips, but it would have no value to a POSITA.

Nothing in §15.9 addresses or considers a solution to the problem of efficiently and effectively delivering a nutritionally therapeutic dose of vitamin D to an infant, much less a human being. Ex. 2072, ¶s 58-60. No POSITA seeking to solve the complex problem addressed by the ‘958 Patent would consider Harder as pertinent or relevant. *Id.*, ¶60; Ex. 2068, ¶s 58-59; Ex. 2068, ¶6(f). Without Harder, Petitioner’s obviousness arguments completely fail.

2. The Only Trustworthy Translation of Harder is Tinworth

The keystone of Petitioner’s obviousness arguments is a single section in a single chapter from the Harder reference. Without the desired translation of

Harder, Petitioner's obviousness arguments fall like a house of cards. To obtain the language it needed to make its obviousness arguments, Petitioner complained about the original, untainted translation and convinced the translation service to get a different translator to change a few words in a single sentence. That changed translation is critical to Petitioner's obviousness arguments.

The original translation by Tinworth (Ex. 1021) is the only untainted, complete translation of Harder. The translation by Tinworth is the only translation free from interference by Petitioner's counsel. Sherman's "modification" of Tinworth is similarly tainted, as shown above. Benyunes' late translation, submitted by Petitioner after the completion of Williams' opinions, is also the result of improper interference. It does not represent a fresh look at Harder; it is primarily based on Tinworth. Williams did not look at it until the night before his deposition. Ex. 2025, 169:17-170:20.

The words added by Sherman (or Benyunes) are critical. Williams admitted that absent the changed translation, he could not give the obviousness opinions he has stated. Ex. 2025, 99:5-100:21; 120:10-19. The Board should not countenance gamesmanship by considering any translation other than the untainted original Tinworth translation. See Ex. 2072, ¶s 61-64. Indeed, a POSITA surely would not obtain multiple translations of a foreign language document until they got a version

that suited them. The Tinworth translation is the only proper translation and use of it ends the obviousness analysis based on Williams' admissions.

3. Regardless of the Translation, Harder, Wolf and *European Pharmacopoeia* in Combination Do Not Render Claims 1 and 3 Invalid as Obvious

Even if Harder teaches a drop of Vigantol® oil to be licked off a spoon by a baby, according to the tainted Sherman or Benyunes translations, Harder in combination with Wolf and *European Pharmacopoeia* still would not have suggested to a POSITA the method of claims 1 and 5 of the '958 Patent. Two reasons exist for this conclusion. First, a drop of MCT oil containing 400 IU of vitamin D, when placed on the tip of a spoon, in fact coats or adheres to the spoon, thereby preventing the efficient removal of the drop either through licking (assuming an infant could lick) or through sucking. Second, although Petitioner relies on Wolf for teaching the composition and dosage of Vigantol® oil, Wolf in fact teaches away from claims 1 and 5 of the '958 Patent. Additionally, a POSITA would not consider Wolf as combinable with Harder and *European Pharmacopoeia*. Ex. 2072, ¶63.

Dr. Reid, Patent Owners' expert, performed a test to determine whether a drop of a 400 IU solution of MCT oil, when applied to the tip of a spoon, would remain on the tip or spread out and coat the bowl, i.e., concave surface, of the

spoon. He used Ddrops’ baby vitamin D product because Vigantol® oil is not available in the U.S. As described in detail in his declaration, Dr. Reid conducted a fair and repeatable test. His test showed that the drop, under two different angles, immediately rolled toward the bottom of the spoon and left a film or coating on the spoon. He also determined that under either scenario, the drop never remained on the tip of the spoon, but coated the spoon with a film of the oil. Ex. 2072, ¶s65-75, Ex. B.

These results contradict Williams’ assertion that an oil has “sufficient viscosity to adhere to and not immediately drip or roll away from an object each and every time. Ex. 1004, ¶50. Williams never tested adherence of any substances mentioned in his declaration. Ex. 2025, 111:5-9. Dr. Reid’s experiment proves the fallacy of Williams’ assertion. *See* Ex. 2072, ¶74.

Second, the results of Dr. Reid’s experiment show that a drop of MCT oil placed on the tip of a spoon does not teach or suggest the “efficient removal of the drop” from a surface, particularly where the removal occurs through sucking. Paper 10 at 15, 16. A POSITA would know that the curved shape of a spoon does not facilitate, and may prevent, sucking. A POSITA – unlike Harder – also would have known that an infant does not, and is simply unable to, suck a spoon or even

lick it. Ex. 2068, ¶s 47-52, 65-69, Exs. D, E, F; Ex. 2069, ¶6(h), Ex. K; Ex. 2072, ¶75.

Additionally, even if Harder provided that a drop of oil placed on the tip of a spoon “to be licked off” or “to lick off,” a POSITA would not appreciate, and in fact would disagree, that the drop could undergo “efficient removal” from the spoon or object. Dr. Reid’s experiment proved that a drop of MCT oil rolls away from the tip of a spoon and leaves a film or coating. A POSITA would understand that an infant could not remove a drop of MCT oil from a spoon and receive a nutritionally therapeutic or effective dose of vitamin D. A substantial portion would roll away from the tip of the spoon, and an infant has no ability to lick or suck a spoon, much less in a manner to reach the oil pooled in the bowl of a spoon. Ex. 2072, ¶76; Ex. 2068, ¶s 46-49, 64, 68, 100; Ex. 2069, ¶7(a). Harder does not suggest that an infant receives any amount of vitamin D, despite claiming the use is “simple.” A spoon does not facilitate infant sucking. A drop of oil could not be efficiently removed from the spoon. Ex. 2072, ¶s 76-77. An infant does not possess the ability to lick anything from surfaces, including spoons. Further, an infant could not lick anything from a spoon because the tongue would be depressed below the spoon. Ex. 2068, ¶s 46-52, 60-71, 93.

Further, nothing in Harder suggests how many licks an infant would need to make to receive an efficacious dose of vitamin D. Williams does not know, and indeed did not even “consider the efficacious part.” Ex. 2025, 138:1-24; 139:1-6; 139:23-140:4. If Harder does not disclose or suggest to Williams, a self-described POSITA, solutions to the issues of how many licks or how to obtain an efficacious dose, then it surely does not teach or suggest that key aspect of the invention to any other POSITA. Ex. 2072, ¶79.

Even if a POSITA would consider Harder as disclosing a method of administering a drop of Vigantol® oil to an infant to be licked off the tip of a spoon, the fact a drop rolls away reveals Harder does not teach or suggest anything about how to deliver a “nutritional or therapeutic amount of vitamin D.” Ex. 1001, 9:34-35. A POSITA would have no reasonable expectation of success that an infant would lick or suck a spoon to receive a full dose of vitamin D. Ex. 2072, ¶80.

Wolf does not fix the deficiency in Harder. Wolf teaches the administration of vitamin D by a spoon. It says nothing about licking or sucking. If the original Tinworth translation is used, Wolf and Harder, in combination with *European Pharmacopoeia*, do not suggest the innovative method in claims 1 and 5 of the ‘958 Patent. Ex. 2072, ¶s 81, 85-86.

Even if the tainted Sherman or Benyunes translations of Harder are considered, Wolf does not address or solve the problem of efficient removal of a drop, even by licking, because the drop rolls away from the tip of a spoon and leaves a coating behind. Williams admits that Wolf says nothing about viscosity or adherence. Ex. 2025, 130:16-23.

Wolf teaches away from claims 1 and 5 because it teaches that drops “should be administered to the baby on a spoon *with some liquid*.” Ex. 1009, 7 (emphasis added). A POSITA therefore would understand that Wolf teaches diluting a drop of Vigantol® oil with a liquid prior to administering the combination to an infant. Williams admits this is how a POSITA would understand Wolf. Ex. 2025, 132:9-22. Wolf does not suggest that a single drop of a vitamin D-containing oil should be or could be administered to an infant; it teaches the opposite – add liquid to a drop before administering. Ex. 2072, ¶84.

Harder, again regardless of the translation used, also teaches away from providing a single drop to an infant. Harder’s first, “most reliable option,” crushes vitamin D tablets into a spoonful of water, similar to Wolf. Given the limited alternative-use options and the strict warning concerning Option 3, Harder teaches away from using a single drop. A POSITA would reasonably understand Harder as preferring the tablet-plus-water method. *See* Ex. 2025, 127:24-128:23 (stating he

would have to ask a clinician to see if a POSITA would understand Harder as teaching away from using Vigantol® oil for administering vitamin D to infants or children).

Thus, Wolf teaches away from the method of claims 1 and 5. Harder also teaches away. Wolf clearly advocates for liquid compositions of vitamin D – as was the state of art in the marketplace when Ddrops’ product embodying the ‘958 claims entered the market. See Ex. 2071, ¶s 36-50; Ex. 2046 at 8. Harder also recommends putting vitamin D tablets in liquid. Even if Harder is read to suggest the administration of single drops, it is contrary to scientific fact regarding the inability of infants to lick much less suck on an object such as a spoon. Neither of these references say anything about efficient administration of a nutritionally or therapeutically dose of vitamin D. Petitioner glosses over these critical deficiencies in Wolf and Harder. *European Pharmacopoeia* adds nothing to this combination. Thus, the combination of Harder, Wolf and *European Pharmacopoeia* does not render claims 1 and 5 obvious to a POSITA. Ex. 2072, ¶s 85-86.

C. Claim 3 is Not Obvious in Light of Harder, Wolf, *European Pharmacopoeia* & Blass

Petitioner adds Blass to Harder, Wolf and *European Pharmacopoeia* to argue that claim 3 is obvious. 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.” Petitioner confuses a motivation to combine with a conclusion of obviousness. Even if a POSITA was 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.

Williams relies upon Blass for the unremarkable proposition that a pacifier “would more likely trigger the sucking reflex” of an infant and for the erroneous notion that a person of ordinary skill in the art would have consulted Blass for “methods of delivering medication”. Ex. 1004, ¶s 87, 106. Williams asserts that a POSITA would use Blass to “improve the method of delivery of a liquid . . . *like that disclosed in Harder.*” *Id.* at ¶106 (emphasis added). However, Blass does not suggest anything of the sort to a POSITA. Ex. 2072, ¶87; Ex. 2068, ¶85.

As previously discussed, Blass simply conducted an experiment and determined that antinociception during heel lancing of infants is most pronounced in a synergy realized “between orogustatory and orotactile mechanisms.” Ex. 1011 at 14. In other words, a POSITA would understand mouth-taste and mouth-feel combine to “offer very promising, effective, and safe, noninvasive and nonpharmacological treatments.” *Id.* at 16. Blass realized synergy between the

orogustatory and orotactile mechanisms by providing infants a pacifier dipped repeatedly in a 12% sucrose solution. Ex. 2072, ¶88; Ex. 2068, ¶84.

A POSITA would know that sucrose is not an active pharmaceutical ingredient. Blass does not describe it as such, and emphasizes throughout that it is the sweet *taste* of sucrose and the role of taste and/or orotactility as the “nonpharmacological treatments.” Ex. 1011 at 16. Blass is unconcerned with delivery of a certain dose of a sucrose solution to an infant. Blass only demonstrated that maintenance of a sweet taste in an infant’s mouth is the objective to be achieved, by periodic dipping of a pacifier in a 12% sucrose solution over a 2-minute period. *Id.* at 8. Ex. 2072, ¶s 87-90.

Contrary to Williams and Petitioner’s assertion, a POSITA would not “consult Blass for methods of delivering medication,” because Blass has nothing to say about delivering medication. *See* Ex. 1004, ¶85. A POSITA also would not consult Blass “for other methods of delivering liquids (*i.e.*, sucrose solution)” (*id.* at ¶105), because Blass is focused solely on orogustatory and orotactile mechanisms of analgesia, not delivery of liquids. Ex. 2072, ¶91.

Moreover, Blass discloses dipping a pacifier in a 12% sucrose solution. Ex. 1011 at 8. A POSITA would recognize that dipping a pacifier is not a method to meter a dose of anything. Dipping a pacifier into a 12% sucrose solution is a

method to maintain a sweet taste in an infant’s mouth to engage the orogustatory mechanism of analgesia. Thus, Blass is unconcerned with the amount of sucrose transferred from the pacifier to the infant. Ex. 2072, ¶91; Ex. 2068, ¶96.

In contrast, Harder emphatically stresses the risk of a Vigantol® overdose when “2 drops fall onto the spoon,” warning that the spoon must be washed and starting over with a single drop. *See* Ex. 1021 at 5. *See also* Ex. 1007 at 6. The care and attention that Harder attaches to administration of a single drop of Vigantol®, even if that was possible, puts into sharp relief the comparatively haphazard pacifier-dipping methodology of Blass. Thus, a POSITA would not have looked to Blass for suggesting an alternative method of delivering a medicament, such as Vigantol®. Ex. 2072, ¶91.

Any of the Harder translations and Wolf suggest use of a spoon to administer a drop of Vigantol® combined with more liquid to an infant for prevention of rickets. This further militates against any motivation that a POSITA might have found to modify Harder and Wolf with Blass, who is unconcerned with rickets or any other medical indication, medicaments, or their delivery to infants. Further, in connection with “skeptical parents [who] are more likely to be accepting of administering drops on a daily basis”, Harder discloses that “[u]se of the oil is simple. . . .” Ex. 1021 at 5; Ex. 1007 at 6; emphasis in original). The

person so advised by Harder would have understood that administration of a single drop of Vigantol® to an infant by spoon constitutes not a problem to be solved, but a simple use to be enacted by parents. Therefore, a POSITA would have had no reason to combine Harder and Wolf with Blass. Ex. 2072, ¶94.

Blass also 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 a 2-mL of solution delivered slowly over 2 minutes by syringe or sucked a pacifier dipped in the assigned solution every 30 seconds for the 2 minute treatment. Ex. 1011 at 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.

Finally, Blass was carefully considered by the examiner during prosecution. He allowed the claims even though he initially based his rejection on arguments similar to those of Petition. See Ex. 1002 at 28, 60-66. This is strong evidence that

Blass in combination with other references does not suggest the limitations of claim 3.

Accordingly, claim 3 is not obvious based on the combination of Harder, Wolf, *European Pharmacopoeia* and Blass for the same reasons claims 1 and 5 are not obvious based on Harder, Wolf and *European Pharmacopoeia* previously stated. Ex. 2072, ¶s 30, 87-94; Ex. 2068, ¶s 84-86, 96.

D. Claim 4 is Not Obvious in Light of Harder, Wolf, *European Pharmacopoeia* & Gartner

Petitioner asserts that claim 4 is obvious in light of Harder, Wolf, *European Pharmacopoeia* Supplement 4.3, and Gartner. Petitioner claims that adding Gartner to the mix of Harder, Wolf and *European Pharmacopoeia* makes it “obvious to a POSITA to reduce the concentration of Vigantol oil as needed to meet recommended dosages for delivering a nutritional and therapeutic amount, without risking an overdose, which would fall within the range disclosed in Claim 4.” Ex. 1004, ¶107. Petitioner does not assert that the addition of Gartner supplements the previously-noted deficiencies in its contention that claims 1 and 5 are obvious in light of Harder, Wolf and *European Pharmacopoeia*. See Petition at 35-39. Therefore, claim 4 is not obvious for the same reasons previously stated as claims 1 and 5, regardless of whether one considers the untainted Tinworth

translation of Harder or one of later, lawyer-induced, revisions of Tinworth. Ex. 2072, ¶s 95-97; Ex. 2068, ¶97.

Additionally, 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. Ex. 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 D to a human being. Ex. 2068, ¶97. D. Claim 4 therefore is not obvious in light Harder, Wolf, European Pharmacopoeia & Gartner. Ex. 2072, ¶s 95-97.

VIII. OBJECTIVE INDICIA OF NON-OBVIOUSNESS

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*, 383 U.S. at 36. 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). *See Liqwd, Inc. v. L’Oreal USA, Inc.*, 941 F.3d 1133, 1136-37 (Fed. Cir. 2019). Thus, secondary considerations can be the most reliable evidence to avoid the trap of hindsight bias in the obviousness analysis.

Petitioner recognizes the need to consider secondary indicia of non-obviousness. It told its alleged expert, Williams, of the requirement to consider them in determining obviousness. Ex. 1004, ¶31. However, Williams did not consider any secondary indicia of non-obviousness in reaching his opinions. Ex. 2025, 75:20-76:4. When asked why he did not do so, whether he was told there were secondary considerations but should not consider them, or whether he was given any information or documents relating to secondary indicia, Williams was instructed not to answer. *Id.*, 76:6-77:11. Petitioner’s obviousness arguments, therefore, are fatally flawed. It knowingly failed to consider this critical requirement.³

³ Petitioner’s counsel was well-aware of the existence of secondary indicia from its prior representation of the defendant in earlier litigation brought by Ddrops. Paper

Here, the claims of the ‘958 Patent are supported by compelling secondary indicia, including copying, long-felt but unmet need, industry praise and recognition, and commercial success. The secondary objective indicia alone establish that the asserted claims in the ‘958 Patent are not obvious.

A. Nexus

While any objective evidence of non-obviousness must have a nexus to the claimed invention, that nexus need only be “reasonably commensurate.” Case law cautions against unduly “strict requirements” in evaluating nexus. *Rambus Inc. v. Rea*, 731 F.3d 1248, 1257 (Fed. Cir. 2013). 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, e.g., Fox Factory, Inc. v. SRAM, LLC*, 944 F.3d 1366, 1373 (Fed. Cir. 2019). *See also WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1330-31 (Fed. Cir. 2016). *See generally Lectrosonics, Inc. v. Zaxcom, Inc.*, IRP2018-01129, Paper 33 at 31-34 (PTAB Jan. 24, 2020). Here, both Ddrops’ Baby Ddrops®

6 at 19, 54-55. Indeed, the untainted Tinworth translation was filed by Petitioner’s counsel in the earlier action. *See* Ex. 1021.

product and method (“Patented Product”) and Petitioner’s product embody the ‘958 Patent claims.

1. Ddrops’ Product Embodies the Patent Claims

Ddrops’ Baby vitamin D drops contains 400 IU vitamin D₃ per drop (Exhibit B, panels 1-2) in organic fractionated coconut oil (MCT), which computes to 303 mcg/mL vitamin D₃ in MCT. Therefore, the Baby Ddrops formulation, as with MOM’s formulations, is a composition of 9 to 9000 mcg/mL vitamin D C₆-C₁₂ liquid fatty acid esters of glycerol including medium chain triglycerides which can be a mixture of 2-4 (C₆-C₁₂) fatty acids/glycerol esters in accordance with claim 1 of the ‘958 patent. Ex. 2072, ¶104. Ddrops conducts tests to confirm that the batches of its product conform to the specifications and concentrations listed on its packaging, and thereby contains a composition conforming to one or more claims of the ‘958 Patent. Ex. 2071, ¶s 19, 26-28, 31, Ex. B.

Additionally, Ddrops’ Baby vitamin D drops product packaging includes instructions for use consistent with claims 1 and 3 of the ‘958 Patent. *Id.*, ¶s 32-34; Ex. C. Thus, the Patented Product embodies the claims of the ‘958 Patent. See Ex. 2072, ¶s 104-105.

2. Petitioner's Product Embodies the Patent Claims

The analyses of Petitioner's product conducted by its manufacturer confirm that its product embodies the compositions described in claims 1 and 3-5 of the '958 patent. MOM's manufacturer determined that three lots of MOM's vitamin D formulation were determined to contain [REDACTED] vitamin D₃ per serving (drop) in organic coconut MCT oil. *See* Ex. 2022, 49:22-54:11; 55:6-11, Exs. 13, 14, 15. Using the conversions of 0.025mcg/IU and 1 drop/0.033 mL (*see* Ex.1009 at 8), these amounts of vitamin D compute to [REDACTED], respectively. Each of MOM's formulations is therefore a composition of 9 to 9000 mcg/mL vitamin D C₆-C₁₂ liquid fatty acid esters of glycerol including medium chain triglycerides which can be a mixture of 2 - 4 (C₆-C₁₂) fatty acids/glycerol esters in accordance with claim 1 of the '958 patent. MCT oil is a mixture of triglycerides of at least 95% C₈ and C₁₀ saturated fatty acids. *See* Ex. 1010 at 5; *see also* Ex. 1001, 5:21-27. Ex. 2072, ¶s 103, 105. *See also* Ex. 2022, Ex. 21 (product technical specifications showing Petitioner's current product meets all composition elements); Ex. 2061 at 3.

Additionally, Petitioner's product includes directions for use instructing its customers to "Place one drop daily onto mother's nipple or a pacifier...." Ex.

2027, 79:24-80:4; Ex. 2061 at 3. Thus, the Petitioner’s product embodies the ‘958 Patent claims. Ex. 2072, ¶s 103, 105. See Ex. 2071, ¶s 104-107, Ex. X.

B. Copying

“Copying by a competitor is a relevant consideration in the objective indicia analysis.” *Liqwd*, 941 F.3d at 1137 (citing *Iron Grip Barbell Co. v. USA Sports, Inc.*, 392 F.3d 1317, 1325 (Fed. Cir. 2004)). Copying is evidence of the non-obviousness of the patented invention. *Liqwd*, 941 F.3d at 1137. “Copying requires duplication of features of the patentee’s work based on access to that work...” *Institut Pasteur & Universite Pierre Et Marie Curie v. Focarino*, 738 F.3d 1337, 1347-48 (Fed. Cir. 2013). “Evidence of copying may include internal documents, direct evidence such as photos of patented features or disassembly of products, or access and similarity to a patented product.” *Liqwd*, 941 F.3d at 1137. See *Iron Grip Barbell*, 392 F.3d at 1325. Access to the patented product and substantial similarity is sufficient to establish copying by a competitor. *Medtronic, Inc. v. Teleflex Innovations S.A.R.L.*, 70 F.4th 1331, 1340 (Fed. Cir. 2023). Circumstantial evidence of copying is “not only sufficient, but may also be more certain, satisfying and persuasive than direct evidence.” *Michalic v. Cleveland Tankers, Inc.*, 364 U.S. 325, 330 (1960). Here, direct and circumstantial evidence clearly shows that Petitioner copied the patented Ddrops product and method. Indeed,

numerous other competitors have copied the patent invention since its introduction into the market, and in every case, were forced to cease sales of their knock-off product.

1. Petitioner’s Copying

Petitioner’s copying was a two-step process. It first copied all aspects of the patented invention in 2016-17 except for the chemical composition. In 2020, it urgently changed to MCT as the vitamin D carrier, just like the patented invention. That change completed the Petitioner’s copying. Its product then became essentially identical to the Patented Product.

Petitioner became aware of Ddrops’ product in 2010, when it first considered developing a baby vitamin D product. Ex. 2026, 24:19-23; Ex.2043. Petitioner’s CEO does not recall why she was then interested in pursuing a new baby vitamin D product. Ex. 2026, 29:24-30:5; 41:5-42:5. However, she recalls seeing the Ddrops baby vitamin D product on a store shelf in 2010. *Id.*, 33:15-19. Petitioner does not recall why it did not introduce a baby vitamin D product in 2010. *See id.*, 46:14-22.

Petitioner introduced a baby vitamin D product in 2016-2017. At that time, it was well aware of Ddrops’ patented product. In fact, in its “2017 N[ew] P[roduct] D[evelopment]” PowerPoint, Petitioner compared four competing baby vitamin D

products then in the market: Enfamil’s D-Vi-Sol, Wellbaby by Upspring, Zarbees, and Ddrops. *Id.*, 71:13-19; Ex. 2046 at 8-9. Of the four competing products, only Ddrops featured a one-drop serving. The Ddrops product also was the only one packaged in a 90-serving size. The Ddrops product was the only one actually shown in a photo. Kaderali, 73:19-74:11. *See* Ex. 2046 at 8-9. Thus, Petitioner had acquired a sample Ddrops product at that time.

The new product that Petitioner introduced was a one-drop serving in a 90-serving size, just like Ddrops’ Patented Product. *See* Ex. 2046 at 9. The instructions for use were also identical to Ddrops’ product. The instructions told the user, “Place one drop daily onto the mother’s nipple or a pacifier....” Ex. 2060. The only difference from the patented invention was the use of sunflower oil and another ingredient as the vitamin D carrier. *See id.* Petitioner’s CEO, who made the decision to introduce the near-knock off product in 2016-17, has no recollection of any discussions regarding the Ddrops product, the decision to introduce a one-drop product in a 90-serving size, or whether any other ingredient than sunflower oil was considered. Ex. 2026, 48:10-11; 66:20-23; 67:19-22; 68:19-22. The one-drop serving, 90-dose supply, and application instructions were all “key facts” that Petitioner used in marketing its partial copy. Petitioner even used a marketing catch-phrase from Ddrops’ product, “the sunshine vitamin.” *Id.*, 83:19-85:25; 88:6-

89:8; 88:22-90:7; Ex. 2027, 40:25-41:3; 52:11-23; 56:6-23; Exs. 2047, 2048, 2060.

See Ex. 2072, ¶s 106-108.

Step two in Petitioner's copying occurred in 2020. At that time, Petitioner suddenly was confronted with a problem: its new packaging for its baby vitamin D product using sunflower oil and vitamin E as ingredients would result in rancidity and instability. It needed to fix that problem. See Ex. 2027, 62:5-9; Ex. 2026, 92:11-23; 93:3-8. Petitioner decided to reformulate its product to use only MCT. Ex. 2027, 81:23-82:11. At the time, Petitioner was aware that Ddrops' Patented Product was made with MCT. *Id.*, 65:6-66:9. Petitioner instructed its manufacturer to only test and consider changing to MCT oil. That was the only new formulation Petitioner considered and had its manufacturer test. *Id.* 64:5-9; 76:4-20; 77:6-10; Ex. 2022, 32:1-24. This was the *only change* made to Petitioner's product in 2020. Ex. 2026, 122:24-123:6. Once the change occurred and the reformulated product was introduced in 2021, Petitioner featured MCT as a key aspect of its baby vitamin D product. Ex. 2027, 81:2-12; Ex. 2062. See Ex. 2072, ¶s 109-111; Ex. 2071, ¶s 102-109.

Thus, direct and circumstantial evidence clearly establishes that Petitioner had access to Ddrops' Patented Product and produced a substantially similar

product. In early 2021, when it introduced its reformulated product, Petitioner had completed copying Ddrops' Patented Product in all essential features.

2. Copying by Others

Competitors quickly noticed the innovation in the Patented Product and also simply copied it. Almost immediately upon introduction in Canada, competitors copied Ddrops' product. Ddrops commenced proceedings to force them to stop, and in every instance, obtained judgments and settlements stipulating to the validity, enforceability and infringement of the Canadian patent corresponding to the '958 Patent. Each Canadian copyist ceased sales of its infringing products. Ex. 2071, ¶s 86-93.

Shortly after introducing its Patented Product in the U.S., Ddrops again faced-off against copyists, now its own distributors. Walgreens and Drugstore.com first copied Ddrops' product. As distributors, they had access to the product and, likely seeing the substantial sales of the innovative product, copied it to sell under their own brands. Ddrops commenced an action against them for patent infringement. Before a motion for a preliminary injunction could be heard,

[REDACTED]

[REDACTED]. *Id.*, ¶s 94-98, Ex. U.

Another set of distributors, iHerb and Madre Labs, also decided to copy Ddrops' Patented Product in effect to cut-out the manufacturer to increase their profits. Again, Ddrops commenced an action for patent infringement. Again,

[REDACTED]

[REDACTED]. Ex. 2071, ¶s 99-101, Ex. V.

Thus, the innovative combination of elements claimed in the '958 Patent have been copied by Petitioner and other competitors, including very large, international entities such as Walgreens and iHerb. After completing its two-step process, with undisputed access to Ddrops' product, Petitioner achieved a substantially similar product to allow it to directly compete against Ddrops' market-leading product. Other entities, in Canada and the U.S., similarly recognized the innovation behind Ddrops' product and simply copied them before quickly agreeing to stop their wrongful conduct. This clear evidence of copying supports the non-obviousness of claims 1 and 3-5 of the '958 Patent.

C. Long-Felt But Unmet Need

“Evidence of a long-felt but unresolved need can weigh in favor of the non-obviousness of an invention because it is reasonable to infer that the need would not have persisted had the solution been obvious.” *Apple*, 839 F.3d at 1056. Here, substantial evidence exists that the '958 Patent solved a long-felt but unmet need

that had existed for centuries. The undisputed fact is that prior to the ‘958 Patent and Ddrops’ product that embodies its claims, the state of the art was exceptionally different. No one had conceived of the innovative solution to a complex problem before the ‘958 Patent.

Insufficient vitamin D in infants, children and adults leads to rickets, a debilitating and potentially deadly disease. The need for supplemental vitamin D goes back hundreds of years. Exposure to sunlight causes the human body to produce vitamin D, but sunlight is not always available and itself can cause harm. Cod liver oil was used early-on as a supplement, unknowingly, to address this need. However, cod liver oil tastes awful and goes rancid. It also does not deliver a uniform or standard dose of vitamin D. This made cod liver oil particularly unsuitable for use with infants. Vitamin D is very potent. Much like fentanyl, a small excess amount can lead to an overdose and death. Indeed, vitamin D is a highly effective rat poison. Ex. 2068, ¶s 7-18; Ex. 2069, ¶6; Exs. I, J.

As late as the 1940s, cod liver oil was still the state of the art for providing vitamin D to adults or infants. By the 1950s, tablets were developed to provide vitamin D. However, infants and children often would not take the tablets. A risk of toxic overdose existed due to the high potency of vitamin D. Liquid concoctions then were developed, often administered by a spoon or an eyedropper. But a spoon

could not be used with an infant, except for trying to pour the liquid into the infant's mouth, with attendant risks of choking, gagging or spitting it out. Further, with a spoon, some amount of the liquid would remain on its surface. This would produce a wide variation in the amount of vitamin D actually ingested. An eyedropper, like a spoon, required careful measurement, and also left some amount of the dose behind. Ex. 2068, ¶s 19-26; Ex. 2069, ¶5; Ex. 2071, ¶s 36-42.

By the 1970s, various syrup-based products existed for supplemental vitamin D. The market-leading product – then as well as at the time Ddrops introduced its product that embodied the claims of the '958 Patent – was Enfamil® D-Vi-Sol®, made by Mead Johnson, a global company focused primarily on pediatric nutrition. D-Vi-Sol is a synthetic, glycerin product not soluble in water. It includes an emulsifier – essentially soap. D-Vi-Sol requires use of a syringe to carefully administer 1 milliliter (mL) to an infant or into food. It has a distinct odor, greasy texture and bad flavor. Adults will not take it. Ex. 2069, ¶s 27-28; Ex. 2071, ¶s 44-46, Exs. D, E.

Other products on the market made using other substances such as sunflower oil, fish oil or olive oil also had difficulties. Those oils also had their own smell and flavor profiles. Zarbees baby vitamin D product used MCT oil, but it required

use of a syringe to administer 0.25 mL directly into the mouth or mixed with food or drink. Ex. 2071, ¶s 37-43, 47-49, Ex. F. See Ex. 2046 at 8.

The problem *addressed by the Patent Owners in the early 2000s was: How do you reliably deliver vitamin D to a human being or an infant, in a form and method that is reliably safe and nutritionally effective, amenable and acceptable to the recipient?* This is an exceedingly complex problem, involving five inter-related variables. The solution is not trivial. Despite all the efforts in the medical and pharmaceutical community since the 1800s, the problem of addressing vitamin D deficiency and supplementation still existed. When the Vieths undertook research to see if they could solve this complex problem, they did not believe they would succeed. But after considerable experimentation and analysis, they did. Ex. 2068, ¶s 29-46, Ex. C.

When Ddrops introduced its product that embodies the claims of the ‘958 Patent, the state of the art still involved products comprised of different oils as carriers for vitamin D, different methods of administration, and not a single product that instructed that one drop could be effectively given by placing one drop on an object or a mother’s nipple or pacifier. Ex. 2071, ¶s 35-53. In fact, when Petitioner first became desirous of introducing a baby vitamin D supplement in

2010, its current CEO suggested using fish oil to its supplier – the centuries-old substance. Ex. 2026, 44:23-45:2; Exs. 2043, 2044.

Six years later, when Petitioner proceeded with its new product, its own research and decision-making was based on looking at four products: D-Vi-Sol, Zarbees, Wellbaby by Upspring, and Ddrops. *See* Ex. 2046 at 8-9. Of those existing products, only Ddrops had the unique combination of a one-drop dose, MCT as the carrier for vitamin D, and instructions to place one drop on a surface, such as a mother’s nipple or pacifier. Ex. 2026, 71:13-19; 73:19-74:1; Ex. 2046 at 8-9; Ex. 2047 at 22; Ex. 2048 at 1-9.

Interestingly, when it was developing its new product in 2016-2017, Petitioner wanted “innovation.” Ex. 2026, 50:7-12. Key problems that it sought to solve in 2016-17 were ease of administration and having a product an infant would not spit up. Ex. 2027, 25:6-16; 27:7-21; 27:23-28:12. Thus, even in 2016-2017, the problems solved by the ‘958 Patent still existed. The unique solution to those (and other) long-standing problems, was not obvious to Petitioner. Rather than conduct their own research, they simply embarked on their two-step process to copy Ddrops’ product that embodies the ‘958 Patent.

Given the long-standing existence and awareness of the problem of administering an efficacious and safe dose of supplemental vitamin D to a human

being, particularly an infant or small child, the innovative and elegant solution to the problem discovered by the Vieths should have been discovered years, if not decades earlier. Yet the state of the art was nowhere near their solution. At the time Ddrops introduced its product, the market leaders were products with different compositions, different methods of administration and different doses. None of them instructed users to place one drop on an object such as a mother's nipple or pacifier. The only such product identified by Petitioner in 2016-2017 was Ddrops' product. If Petitioner's obviousness arguments were valid, surely massive companies such as Mead-Johnson, the maker of Enfamil® D-Vi-Sol® or Merck, the manufacturer of Vigantol®, would have introduced it years before tiny Canadian company Ddrops entered the market. But no one else did. A long-felt but unmet need existed that the '958 Patent uniquely solved.

D. Industry Praise and Recognition

“Evidence that the industry praised a claimed invention or a product that embodies the patent claims weighs against an assertion that the same claimed invention would have been obvious.” *Apple*, 839 F.3d at 1053. Competitors are not likely to praise an obvious invention. *Id. See Institut Pasteur*, 738 F.3d at 1347 (“Industry praise ... provides probative and cogent evidence that one of ordinary skill in the art would not have reasonably expected” the claimed invention);

Power-One, Inc. v. Artesyn Techs., Inc., 599 F.3d 1343, 1352 (Fed. Cir. 2010) (industry praise, and specifically praise from a competitor, indicates the invention would not have been obvious). Evidence of awards received is probative evidence of non-obviousness. See *Lectrosonics*, Paper 33 at 68-70.

From the beginning, Ddrops has received industry praise and recognition for its vitamin D product that embodies the patented features of the ‘958 Patent. At a trade show in 2008, a representative from Enfamil, the then-industry leader, told Dr. Vieth, “You have a nice new technology here. It’s really good.” Another competitor’s sales representative told co-inventor Mrs. Vieth, that they wanted to figure out how to do a product like Ddrops. Ex. 2068, ¶s 54-55. Customers and physicians have lauded the patented features of Ddrops’ product. Ex. 2071, ¶s 55-57, Exs. G, T. See also *id.*, ¶68, Ex. Q (Ddrops products used on *The Price is Right* television show).

Ddrops product quickly became the go-to product for research studies. Its product has been provided to universities, medical professionals and researchers around the world for clinical studies. Ex. 2071, ¶s 56-61; Exs. H-K. One clinical study concluded,

Interestingly 80% of care-givers reported giving their infants D-Drops® versus only 16% who supplemented with D-Vi-Sol. The

reason for the popularity of D-Drops® may be their ease of administration requiring only a single drop that can be placed on the mother's breast prior to nursing, versus the need to use a dropper to administer D-Vi-Sol®.

Ex. 2071, ¶69, Ex. R. This is high praise tied directly to the patented features of the '958 Patent.

Furthermore, Ddrops' product that embodies the patented invention has received numerous prestigious awards from around the world. From 2012 to 2016, Ddrops' baby vitamin D drops product has received awards such as the Mom's Choice Gold Award, the Cribbie Awards New Arrival Award, the Bounty Mums Love "Commended" Award, the Well.ca Green Choice Award, and the National Parenting Product Award. Ex. 2071, ¶s 62-66, Exs. L-P. These awards were all given because of the innovative features of Ddrops' product, specifically the one-drop method of administration to deliver a therapeutic dose of vitamin D. *Id.*, ¶67. All this industry praise and recognition supports the non-obviousness of claims 1 and 3-5 of the '958 Patent.

E. Commercial Success

"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.” *J.T. Eaton & Co. v. Atl. Paste & Glue Co.*, 106 F.3d 1563, 1571 (Fed. Cir. 1997). Here, Ddrops and Petitioner have achieved commercial success – the latter at the expense of Ddrops.

1. Ddrops’ Commercial Success

Ddrops’ product has been a commercial success due to its patented features. Since introduction in Canada in 2008, Ddrops has gone from zero percent sales to [REDACTED]. See *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”); Ex. 2071, ¶s 70-74, Ex. S. Reviews and comments by customers show that this success has been due to the patented features. *Id.*, ¶s 83-85, Exs. G, S.

Since introducing the Patented Product in the U.S., Ddrops has achieved similar commercial success. In less than [REDACTED] [REDACTED] Ddrops has grown its sales and market share to [REDACTED]% in the U.S. Again, this success, based on customer reviews, was due to the patented features of the product and the instructions covering the patented method. Ex. 2071, ¶s 75-78, 81; Ex. S.

2. Petitioner's Commercial Success

When Petitioner completed its two-step copying of Ddrops' product, it explicitly targeted Ddrops. Its plan was to [REDACTED]
[REDACTED]
[REDACTED] Ex. 2067 at 1 (emphasis added). Petitioner's CEO remarkably testified [REDACTED] Ex. 2026, 113:19-117:5 (emphasis added); *See, e.g.*, Ex. 2051 at 13 [REDACTED]
[REDACTED]; Ex. 2056 at 15 [REDACTED]; Ex. 2058 at 31
[REDACTED]

Petitioner's plan to steal market share from Ddrops with its copy-cat product has succeeded. Petitioner's copy-cat product has been well-received in the market. Simply by copying what Ddrops was doing Petitioner was able to achieve [REDACTED] with its reformulated product. Ex. 2026, 121:9-122:9; Ex. 2053. At the fourth quarter of 2020, [REDACTED]
[REDACTED]
[REDACTED] Ex. 2051 at 13. Thereafter, after introducing its knock-off product, Petitioner's total baby vitamin D market share [REDACTED]
[REDACTED]. This amounted to [REDACTED] during the first year of selling its copied product, after only changing its composition to meet all the

features claimed in the ‘958 Patent. Ex. 2026, 123:22-125:17; Ex. 2054 at 9.

Petitioner’s copied product was the fastest-growing brand in the brick and mortar and omni channels in 2021. Ex. 2026, 125:14-126:16; Ex. 2054 at 12.

Ddrops’ market share, [REDACTED]

[REDACTED]

[REDACTED]%. Ex. 2058 at 31. See Ex. 2071, ¶s 79-80, Ex. S.

Thus, both Ddrops’ commercial embodiment of the claims of the ‘958 Patent and Petitioner’s copycat product have experienced commercial success. In both cases, that success has been due to the patented features claimed in the ‘958 Patent and not for any other reason. This commercial success further shows that the inventions disclosed and claimed in the ‘958 Patent were not obvious.

IX. CONCLUSION

For the foregoing reasons, Petitioner has not satisfied its burden to establish that claims 1 and 3-5 of the ‘958 Patent are invalid as obvious. Patent Owners accordingly request that the Board reject the Petitioner’s arguments and affirm the validity of claims 1 and 3-5 of the ‘958 Patent.

HIGHLY CONFIDENTIAL – ATTORNEYS EYES ONLY

IPR 2023-00726
U.S. Patent No. 9,066,958

Dated: February 9, 2024.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

The undersigned hereby certifies that the foregoing Patent Owners’
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 February 9, 2024, 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:

David B. Conrad
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