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 IPR2023-00726
Patent 9,066,958 B2

PETITIONER'S REPLY TO PATENT OWNERS' RESPONSE

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Updated Redactions to Petitioner's Reply to Patent Owners' Response - Filed by Patent Owner by order of the Board

TABLE OF CONTENTS

I. INTRODUCTION 1

II. CLAIMS 1 AND 3-5 ARE UNPATENTABLE 3

A. Harder Anticipates the Claims 3

1. Harder Discloses All Express Limitations 3

2. Allegedly Missing Properties are Inherent in Harder 5

B. Harder Is Prior Art a POSITA Is Presumed to Know 7

C. Harder Teaches That Vigantol Oil Is Delivered by Licking a Spoon 10

1. "zum Ablecken" Means "To Lick" 10

2. Harder's Oil "Adheres to the Surface" of an Object 11

3. Harder Discloses Infants Licking an Object 13

4. Marketing Materials Show Using Spoons With Infants 16

III. SUPPORTING REFERENCES AND EXPERT TESTIMONY FURTHER CONFIRM OBVIOUSNESS 19

A. Wolf, Blass, European Pharmacopiea, and Gartner Further Support Obviousness Finding 19

B. Patent Owners' Declarants Lack Sufficient Knowledge, Independence, and Credibility 21

1. Dr. Reid 21

2. Dr. Horowitz 21

3. Dr. Vieth 22

C. Dr. Williams' Testimony is Credible 23

IV. SECONDARY CONSIDERATIONS DO NOT RENDER OTHERWISE UNPATENTABLE CLAIMS PATENTABLE 24

A. Patent Owners Cannot Establish Nexus 25

B. Alleged Copying 27

C. Other Secondary Considerations 27

V. CONCLUSION 28

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PETITIONER'S EXHIBIT LIST

Exhibit	Description
MOM-1001	U.S. Patent No. 9,066,958 (the "'958 patent")
MOM-1002	U.S. Patent No. 9,066,958 File History
MOM-1003	Complaint, Ddrops Company, Reinhold Vieth, and Elaine Vieth v. MOM Enterprises, LLC, d/b/a Mommy's Bliss, 1:22-cv-00332-GBW, District of Delaware
MOM-1004	Declaration and Curriculum Vitae of Dr. Robert Williams
MOM-1005	Declaration and Curriculum Vitae of Librarian June Munford
MOM-1006	Section 15.9 of Wochenbettbetreuung in der Klinik und zu Hause, Hippokrates Verlag by Ulrike Harder (2003) ("Harder")
MOM-1007	Translation of Harder by Amy Tinworth ("Harder Tr.")
MOM-1008	Aktuelle Therapie: Rachitisprophylaxe beim Saugling by H. Wolf, Volume 95/no.9 Deutsche Medizinische Wochenschrift at 1530 (1970) ("Wolf")
MOM-1009	Translation of Wolf by Simon Chun Hsieh ("Wolf Tr.")
MOM-1010	Excerpts from European Pharmacopoeia Supplement 4.3 (2003) ("European Pharmacopoeia Supplement 4.3")
MOM-1011	Suckling- and Sucrose-Induced Analgesia in Human Newborns by Elliott M. Blass & Lisa B. Watt, 83 Pain 611, (1999) ("Blass")
MOM-1012	Prevention of Rickets and Vitamin D Deficiency: New Guideline for Vitamin D Intake by Lawrence M. Gartner, Volume 111/no. 4 of Pediatrics at 908 (2003) ("Gartner")
MOM-1013	Introduction of Oral Vitamin D Supplementation and the Rise of the Allergy Pandemic by Matthias Wjst, Volume 5/no. 8 of Allergy, Asthma & Clinical Immunology (2009) ("Wjst")
MOM-1014	The Case Against Ergocalciferol (Vitamin D2) as a Vitamin Supplement" by Reinhold Vieth, Volume 84/no.4 of The American Journal of Clinical Nutrition (2006) ("Vieth")
MOM-1015	Effect of Vitamin D Replacement on Musculoskeletal Parameters in School Children: A Randomized Controlled Trial by Vieth, Volume 91/no. 2 of the Journal of Clinical Endocrinology & Metabolism (2006) ("Vieth II")

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MOM-1016	Public Health Practices in Germany by W. W. Bauer, Volume 40/no. 9 of American Journal of Public Health and The Nation's Health ("Bauer")
MOM-1017	Canadian Patent Application No. 2,558,202
MOM-1018	Stipulation Letter by Petitioner
MOM-1019	Declaration of Sarika Patel
MOM-1020	Declaration of Dr. Casey M. Kraning
MOM-1021	Declaration of Amy Tinworth
MOM-1022	Supplemental Declaration of David Sherman
MOM-1023	Declaration of Dr. Stephen Benyunes
MOM-1024	Supplemental Declaration of Simon Liu
MOM-1025	Supplemental Declaration of June Munford
MOM-1026	MOM_0006559 (AEO-CONFIDENTIAL)
MOM-1027	MOM_0000011 (AEO-CONFIDENTIAL)
MOM-1028	Excerpts from The Complete and Authoritative Guide Caring For Your Baby and Young Child Birth to Age 5, American Academy of Pediatrics, Bantam Books, Eds. Steven P. Shelov and Robert E. Hannemann, Fourth Edition, (2005)
MOM-1029	MeSH Browser, MeSH Descriptor Data, "Postnatal Care" and "Therapeutics"
MOM-1030	Amazon.com_ Ddrops Organic Baby 400 IU 90 Drops - Daily Vitamin D Liquid for Infants
MOM-1031	2021-09-20 Archived Baby Ddrops® - Ddrops US EN
MOM-1032	Amazon.com_ Ddrops Baby Tummy Relief Liquid Drops, Organic Gripe Water for Newborns, Relief from Gas, Colic, Fussiness and Hiccups, Just One Drop, Herbal Ingredients, 120 Drops
MOM-1033	RESERVED
MOM-1034	Target.com_ Mommy's Bliss Baby Organic Vitamin D Drops - 0.11oz (100 Servings)
MOM-1035	Target.com_ Mommy's Bliss Organic Vitamin D Drops Carton Label
MOM-1036	Deposition Transcript of Dr. Paul Horowitz (AEO-CONFIDENTIAL)
MOM-1037	Deposition Transcript of Dr. Steven Reid (AEO-CONFIDENTIAL)
MOM-1038	Deposition Transcript of Chris Temovsky (AEO-CONFIDENTIAL)

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MOM-1039	Deposition Transcript of Dr. Reinhold Vieth (AEO-CONFIDENTIAL)
MOM-1040	Declaration of Dr. J. Usha Raj
MOM-1041	Amazon.com_Munchkin® Soft Tip™ Infant Spoons, 12 Count (Pack of 1) Baby
MOM-1042	Excerpt from Random House Webster's German-English, English-German Dictionary (1998)
MOM-1043	Excerpt from Collins German Dictionary Third Edition (1998)
MOM-1044	Excerpt from Langenscheidt German-English, English-German Dictionary (2003)
MOM-1045	Google Translate webpage printout
MOM-1046	Microsoft Bing Translate webpage printout
MOM-1047	12/11/2023 Em fr Anderson to Fish re: Ddrops v. MOM - IPR
MOM-1048	A History of Infant Feeding by Emily Stevens et al., Volume 18/no. 2 of The Journal of Perinatal Education (2009)

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I. INTRODUCTION

The prior art plainly discloses the claimed invention of the ’958 patent. Administering vitamin D to infants as claimed was a problem the prior art had solved years before. As such, Patent Owners’ Response is most notable for what it omits: substantive evidence rebutting what Harder expressly discloses. Patent Owners admit Harder discloses delivering a single drop of Vigantol oil—a composition that undisputedly meets both the dose and oil composition limitations—to an infant using a spoon. Dr. Vieth, a German immigrant who spoke household German, admits Harder instructs to “lick it off.” Thus, Harder effectively anticipates the claimed invention. Patent Owners manufacture disputes to distract from Harder’s plain disclosure. But none rebut the Petition’s showing of unpatentability.

First, Patent Owners contend that a POSITA would not have considered Harder. But prior art is not so limited. Harder, a textbook published in the National Library of Medicine, solves the very problem facing Patent Owners: how to safely administer vitamin D to infants.

Second, Patent Owners invent a dispute about the meaning of “zum Ablecken.” Two translators, three dictionaries, Dr. Vieth, and two computerized translations all agree: “zum Ablecken” means “to lick off.” Patent Owners offer

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no translation of their own, but instead rely on a translation that everyone else agrees is incomplete.

Third, Patent Owners argue that a POSITA would have known that a spoon could not be used to administer one drop of Vigantol oil. Harder expressly contradicts this argument. It is also undercut by both common sense and Patent Owners' own marketing documents.

Fourth, Patent Owners contend that the claims require a certain level of "adherence" and receiving "a therapeutically-effective dose." But these characteristics are not expressly claimed, and to the extent required, are inherent in the prior art. Discovery of the inherent properties of the prior art is not an invention.

Finally, Patent Owners fall back onto secondary considerations to try to avoid obviousness. But they cannot establish nexus to any novel part of the claims, because each limitation is found in the prior art. Setting nexus aside, secondary considerations cannot overcome the Petition's compelling obviousness case.

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II. CLAIMS 1 AND 3-5 ARE UNPATENTABLE

A. Harder Anticipates the Claims

1. Harder Discloses All Express Limitations

Harder discloses claims 1, 4 and 5. Patent Owners allege that the problem addressed by the invention involved "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." Paper No. 61, (Patent Owner Response, "POR"), 4-5. Harder discloses each variable. Harder discloses a single drop. Pet., 28-29 (citing EX1007, 6 ("1 drop of Vigantol® oil")).[1] By disclosing Vigantol oil, Harder discloses the claimed concentration and carrier. Pet., 25-28 (citing EX1007, 6 ("(1 drop contains 500 I.U.)" and "contains only one excipient…medium-chain triglycerides")). Harder also describes the delivery and method of administration (licking off a spoon). Pet. 28-31 (citing EX1007, 6 ("given to the baby to be licked off from the tip of a spoon")). No hindsight is needed; Harder itself disclosed the claimed method and composition.[2] "Anticipation is the epitome of obviousness."

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[1] Citations herein to Harder are to stamped pages.

[2] Wolf further supports the composition and dosing of the Vigantol oil. EX1009, 7-8. Additionally, "medium-chain triglycerides" ("MCT") have chain lengths of 8-10 carbons. EX1010, 5. Harder's oil undisputedly meets the claimed chain length.

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Realtime Data, LLC v. Iancu, 912 F.3d 1368, 1373 (Fed. Cir. 2019) (cleaned up) (upholding anticipation finding despite petition raising obviousness); *see also Wasica Fin. GmbH v. Cont'l Auto. Sys., Inc.*, 853 F.3d 1272, 1278 n.3 (Fed. Cir. 2017).

Patent Owners' analysis depends on an alternate reality in which Vigantol and Harder were not known. Patent Owners allege they "engaged in years of experimentation, research and analysis before achieving the innovative single-drop solution." POR, 5. In other words, they started from scratch. But the inquiry for obviousness does not assume a POSITA starts from scratch; a POSITA knows all relevant prior art. *In re Carlson*, 983 F.2d 1032, 1038 (Fed. Cir. 1992). The prior art undisputedly included Vigantol. In fact, Patent Owners tried to recreate Vigantol oil for years after learning about it in 2000 and receiving samples. EX1039, 28:7-9, 31:14-41:4, 90:4-102:9. Dr. Vieth tried to obtain a sample from a German pharmacy. *Id.*, 41:19-43: 3. He tested and compared his solutions against Vigantol. *Id.*, 64:20-72:22. Dr. Vieth recorded in his lab notebook that [redacted][3]. *See* EX2068, 78. Yet Dr. Vieth never disclosed Vigantol oil during prosecution. *See* EX1002, 28, 64.

[3] [redacted]

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Dr. Vieth's path to the invention has no bearing on patentability. *Life Techs., Inc. v. Clontech Labs., Inc.*, 224 F.3d 1320, 1325 (Fed. Cir. 2000). What matters is the state of the prior art before the invention. *Otsuka Pharm. Co., Ltd. v. Sandoz, Inc.*, 678 F.3d 1280, 1296. Vigantol oil and its properties were known and had "proved to be successful over many years,"[4] (EX1007, 6), solving the ***same problem*** Patent Owners set out to solve: administering vitamin D to infants to prevent rickets. Harder disclosed the very method of administering Vigantol that Patent Owners claimed in the '958 patent.

2. Allegedly Missing Properties are Inherent in Harder

Patent Owners' complaints about Harder's alleged failure to teach the adherence and therapeutic effectiveness of its oil are directed to unclaimed, yet inherent features of the invention. Where the prior art does not expressly disclose a claim limitation, "inherency may supply a missing claim limitation in an obviousness analysis." *PAR Pharm., Inc. v. TWI Pharms., Inc.*, 773 F.3d 1186, 1194-95 (Fed. Cir. 2014).

While neither a specific level of adherence nor efficacy are claim limitations, they nevertheless are necessarily present in Vigantol oil, as the Board

[4] Wolf confirms Vigantol's success. EX1009, 8 (teaching "[p]rophylaxis of rickets in babies and small children" with 1 drop of Vigantol® oil).

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found at institution. *See* I.D., 36-40. Regarding adherence, as described above, Harder discloses the claimed formulation. EX1007, 6; *see also* EX1004, ¶¶96-104. Harder further discloses that it is administered when it is "licked off from the tip of a spoon." EX1007, 6. Viscosity (which impacts adherence) is an inherent property, and a POSITA would have understood from Harder that the oil had sufficient viscosity in one drop (and therefore adherence) to be administered using a spoon. EX1004, ¶¶50-54. Even Patent Owners' pediatrician, when testing an MCT oil, found that "it was impossible[] for the drop to ever drip off the spoon," and it "did not physically separate in whole or in part from the spoon." EX2072, ¶¶72, 74.

Regarding efficacy, Harder disclosed the claimed dosage, since 500 I.U. equals 378.8 mcg/mL, falling within the claimed range of 9-9000 mcg/mL. EX1007, 6; *see also* EX1004, ¶98; EX1037, 53:13-54:25, 59:15-24. Harder discloses that this "has proved to be successful over many years" in treating children. EX1007, 6. By delivering a dosage squarely within the range of the claims, Harder necessarily discloses delivering the claimed efficacious dose. *See Par Pharm.*, 773 F.3d at 1195-96. Additionally, "proof of efficacy is not required for a prior art reference to be enabling for purposes of anticipation." *Impax Laby's. Inc. v. Aventis Pharm. Inc.*, 468 F.3d 1366, 1383 (Fed. Cir. 2006).

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Claim 1 only requires placing one drop on an object for delivery; it does not require ensuring that the entire dose is delivered. While the specification of the '958 patent states that 30 seconds on a pacifier is required to achieve 96% effectiveness, (EX1001, 4:50-57, 9:11-12), it would be inappropriate to import this minimum time from the specification into the claims.

Further, Harder was not required to have recognized these inherent properties. *Schering Corp. v. Geneva Pharm., Inc.*, 339 F.3d 1373, 1377 (Fed. Cir. 2003). Dr. Vieth's "discovery" of these properties of Vigantol does not rise to the level of invention. "[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. IRECO Inc.*, 190 F.3d 1342, 1347 (Fed. Cir. 1999).

B. Harder Is Prior Art a POSITA Is Presumed to Know

Because Harder's disclosures are irrefutable, Patent Owners argue that a POSITA "would not consult a document such as Harder," because a POSITA would have instead consulted "authorities in the fields of pharmaceutics and the delivery of medicants," as opposed to a book targeting mid-wives. POR, 30-31; *see also* EX1037, 38:10-39:19; EX1036, 55:6-56:9. But as the Board correctly

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found at institution[5], a POSITA "may have looked to Harder because they are experienced in delivering medicines and nutritional supplements, and Harder concerns the neonatal care of infants in the home and in the clinic—a topic that conceivably embraces delivering medicines and nutritional supplements to infants." I.D., 34; *see also* EX1037, 32:2-18.

Additionally, prior art is not limited as Patent Owners suggest. "Prior art is analogous and can be applied…if it either (1) is from the same field of endeavor, regardless of the problem addressed or (2) is reasonably pertinent to the particular problem with which the inventor is involved." *Unwired Planet, LLC v. Google Inc.*, 841 F.3d 995, 1000-01 (Fed. Cir. 2016) (citation omitted). Harder meets each one of these tests. It is from the same field—i.e., ensuring proper infant nutrition.

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[5] The Board made this finding regardless of the fact that it first determined that the definition of a POSITA should not include nurses. *See* I.D., 12-13. Notably, co-inventor Elaine Vieth ***was a practicing nurse*** at the time of the invention, suggesting a nurse could be a POSITA. EX1039, 45:13-47:12. *See Daiichi Sankyo Co. v. Apotex, Inc.*, 501 F.3d 1254, 1257 (Fed. Cir. 2007) (reversing district court's finding of non-obviousness, as error in level of skill in the art did not reflect inventors' level of skill or problem being solved, tainting its obviousness analysis).

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Harder addresses the same problem—how to deliver the correct dose of vitamin D to an infant, recognizing the challenges inherent in giving babies medicine and ensuring they are not exposed to toxic levels of vitamin D. And Harder is "reasonably pertinent to the particular problem with which the inventor is involved," given that it ***solved*** the inventors' very problem. *Unwired Planet*, 841 F.3d at 1000.

A POSITA seeking to improve vitamin D delivery to an infant would surely have sought to understand current known delivery methods, and Harder details four options that were in use before the priority date. EX1007, 5-7. Harder was identifiable in a library catalog under the topics "Postnatal Care," "Postnatal Care methods," and "Postpartum Period." EX1025, ¶15; EX1037, 33:10-34:14; EX1029.

It is of no moment that Harder teaches three additional options, so long as the fourth option is a "*suitable* option from which the prior art did not teach away." *See PAR Pharm.*, 773 F.3d at 1197-98. "Teaching away" is to "criticize, discredit, or otherwise discourage" the solution. *In re Fulton*, 391 F.3d 1195, 1201 (Fed. Cir. 2004). Harder does not. Further, "whether a reference 'teaches away' from the invention is inapplicable" to anticipation. *Celeritas Techs. v. Rockwell Int'l Corp.*, 150 F.3d 1354, 1361 (Fed. Cir. 1998). Harder anticipates claim 1, so "teaching away" is irrelevant.

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Because Harder and the ’958 patent share a common purpose and common solution, Harder is plainly prior art that a POSITA “is presumed to know.” *In re Carlson*, 983 F.2d at 1038. Patent Owners bid to disqualify Harder fails.

C. Harder Teaches That Vigantol Oil Is Delivered by Licking a Spoon

1. “zum Ablecken” Means “To Lick”

Patent Owners resort to inflammatory accusations against Petitioner and counsel. *See, e.g.*, POR, 11, 12, 29. But these unsubstantiated attacks do not change the facts. Ms. Tinsworth’s initial translation was nothing more than an unfortunate oversight regarding the phrase “dem Baby zum Ablecken gegeben” that was caught in prior litigation by Fish attorneys and corrected, as her boss, David Sherman, attested, when he reviewed and modified Ms. Tinsworth’s translation. *See* EX1007, ¶3. Mr. Sherman explained why: “zum Ablecken” translates directly to “for licking.” EX1022, ¶3. There was no nefarious intent.

The undisputed evidence is that “zum Ablecken” in Harder means “to lick off.” Even Dr. Vieth, a German immigrant who speaks German, admits this. EX1039, 91:7-12, 108:2-109:23. The translators reaffirmed the accuracy of their translations in their depositions. EX2023, 97:13-100:4; EX2024, 74:22-76:14. Their translations are corroborated by multiple German-to-English dictionaries and machine translations. *See* EX1042, 3; EX1043, 3; EX1044, 3; EX1045; EX1046.

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Tellingly, Patent Owners never deposed Ms. Tinsworth to ask if she disagreed. They cancelled her scheduled deposition. EX1047.

Nor did Patent Owners offer a competing translation or evidence to show that "zum Ablecken" means anything other than "to lick off." In fact, they engaged and paid their own translator to translate the ***table of contents*** of Harder, yet declined to have that translator translate the offending sentence. EX2070. "Zum Ableckan" means "to lick off."

2. Harder's Oil "Adheres to the Surface" of an Object

The Board adopted the parties' agreed construction of "wherein said drop adheres to the surface of said object":

> [T]he 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.

I.D., 15-16.

Patent Owners' "expert," Dr. Reid applied a narrower construction that the Board did not—and should not—adopt. Citing nothing, Dr. Reid contends that the single drop must be fashioned so that it "does not spread out, coat, or form a film on the surface[.]" EX2072, ¶26.

As an initial matter, Dr. Reid is not a POSITA, and is therefore not qualified to interpret the claims. *Kyocera Senco Indus. Tools Inc. v. Int'l Trade Comm'n*, 22

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F.4th 1369, 1376-77 (Fed. Cir. 2022). Regardless, neither the claims nor the specification support Dr. Reid's construction. In the specification, the only test was whether the drop "drips off" versus "[a]dheres." EX1001, Table 1; *id*., 6:49-54. The "oil vehicles ***all adhered*** to the nipple ***well enough*** to make them suitable for handling during breastfeeding or for use of a pacifier," as opposed to the water and alcohol-based solutions, which dripped off. *Id*., 7:22-24 (emphasis added). The patent says nothing about a drop "adher[ing] so as to remain localized." EX2072, ¶26.

Dr. Reid's contrived experiments demonstrate that the "Baby Ddrops®" product "adheres" within the meaning of the claims.[6] He admitted that "it was impossible, for the drop to ever drip off the spoon." *Id*., ¶72; *see also, id.*, ¶74; EX1037, 47:10-49:13. Petitioner's pediatrician, Dr. Raj, confirmed Harder's method was feasible. *See* EX1040, ¶¶18-23. Therefore, unlike the water and alcohol carriers that "drip[] off" a surface, the oil drop "adhere[s]," just as the tested oils did in the '958 patent. EX1001, 6:49-54, Table 1. Nothing more is required by the claims under the construction agreed to by the parties and adopted by the Board. Indeed, the Board properly rejected evidence of similar experiments

[6] Patent Owners admit that the Baby Ddrops product meets the claims. *See* POR, 47.

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in its institution decision. *See* I.D., 38-39; *compare* EX2072, 70-71 (Dr. Reid's experiments) *with* EX2009, 98, 106 (Michael Mischnick's experiments).

Likewise, neither of Patent Owners' declarants provide evidence showing that vitamin D oil cannot be removed from a spoon or object. Dr. Horowitz, like Dr. Reid, imports another limitation into claims by requiring that the "supplement must stick to the surface…without running off, ***yet leave less than or equal to 10% of the provided supplement behind***." EX2069, 12 (¶6(j)) (emphasis added). Dr. Horowitz (who is not a POSITA) cites nothing in the patent that supports narrowing the claim this way, and even if it did, including it would improperly import a limitation from the specification. The Board should disregard this narrowed construction.

3. Harder Discloses Infants Licking an Object

As an initial matter, the claims of the '958 patent are drafted broadly. Claims 1, 4, and 5 do not require a specific object, but simply require the vitamin D drop be placed on its "exterior surface." EX1001, cl. 1. A spoon is an object. To prove that a claim covering multiple alternative embodiments is invalid, a challenger need only prove that one of the embodiments is invalid. *See, e.g., In re Cuozzo Speed Techs., LLC*, 793 F.3d 1268, 1281 (Fed. Cir. 2015). Nothing more is required to anticipate these claims.

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Further, claim 1 states "having said human being suck or lick" the vitamin D drop, and does ***not*** require administration to a newborn, as Patent Owners imply. *See* EX1001, cl. 1. Even claim 3, which recites an "infant," does not require administration to a newborn. *Id*., cl. 3. The '958 patent defines "infant" to include "babies and small children." *Id*., 4:1-3. Thus, Patent Owners' focus on administering vitamin D to newborns, as opposed to more developed infants, is misdirection. *See, e.g.*, EX2069, 11 (¶6(h)); *id.*, 12-13 (¶6(k)); EX1036, 83:14-84:1; EX1039, 116:12-13 (referring to "six-week old baby").

Nor is Harder limited to infants. For example, Harder speaks of children generally as requiring vitamin D. *See, e.g.*, EX1007, 4 ("Children need **vitamin D** to store calcium") (emphasis in original); *id*., 6 ("Children are given a daily dose of 500 I.U. of vitamin D in the winter only[.]").

It is undisputed that a one-year-old baby can be fed with a spoon. Patent Owners' pediatrician, Dr. Horowitz, admits that the "protective reflex" "typically fades" after "4 to 6 months of age." EX2069, 11 (¶6(h)); *see also* EX2068, ¶46; EX1036, 81:14-22, 83:6-12. Petitioner's pediatrician, Dr. Raj, confirms that a baby can "suck and/or lick the drop off from" a small spoon. EX1040, ¶17. Thus, at minimum, a POSITA would understand that a baby six months or older could be treated as Harder teaches.

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Even if the claims required a showing that all babies, including newborns, can lick or suck oil off a spoon—they do not—Petitioner has still met its burden through Harder. A baby is able to "lick" in the sense that its tongue sticks out and a caregiver can cause it to make contact with the drop on the spoon to retrieve some of the composition. EX1036, 79:3-10, 80:13-81:9; EX1028, 11 (book Dr. Horowitz contributed to confirming newborn "may first lick" at first breastfeed); EX1036, 126:10-128:4. Indeed, Patent Owners' pediatrician expert Dr. Horowitz admits that "[i]nfants naturally thrust their tongue when hard objects like the tip of a spoon or other feeding utensils are inserted into their mouths[.]" EX2069, 11 (¶6(h)).

The claims do not require removal of any particular amount of the drop. They simply state "having said human being suck or lick said composition directly from said object." EX1001, cl.1. Patent Owners argue that "government regulations" require it, (*see* EX1037, 45:10-14; EX1036, 76:23-77:1, 121:16-123:6), but that would violate the basic tenets of claim construction.

To the extent Patent Owners resort to the preamble to require actual receipt of an effective dose, that fails too. The preamble is not limiting, and Patent Owners have not alleged otherwise. A preamble "generally is not limiting when the claim body describes a structurally complete invention such that deletion of the preamble phrase does not affect the structure or steps of the claimed invention."

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Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc., 289 F.3d 801, 809 (Fed. Cir. 2002). Here, the body of the claim describes a structurally complete invention by reciting each complete step. Even if considered limiting, however, the preamble is silent as to the efficacy of the dose actually received; it states only that "a nutritional or therapeutic amount of vitamin D" is "***deliver[ed]***" to a human. EX1001, cl.1. The claim does not recite, for example "wherein the human being receives an effective dose by sucking for at least 30 seconds" and such requirement should not be read in. EX1037, 25:6-26:3. Further, a POSITA "would have had a reasonable expectation that performing the recited method would bring about the recited result," for all of the reasons discussed herein. *See Eli Lilly and Co. v. Teva Pharms. Int'l GmbH*, 8 F.4th 1331, 1345 (Fed. Cir. 2021).

4. Marketing Materials Show Using Spoons With Infants

In fact, Patent Owners ***intend*** to administer to newborns with a spoon. EX1032, 1; EX1030, 1. Patent Owner's exclusive licensee, Ddrops Company, markets baby supplements for "newborns"—including its vitamin D product—where "[j]ust one drop can be licked off a clean surface, such as a clean spoon":

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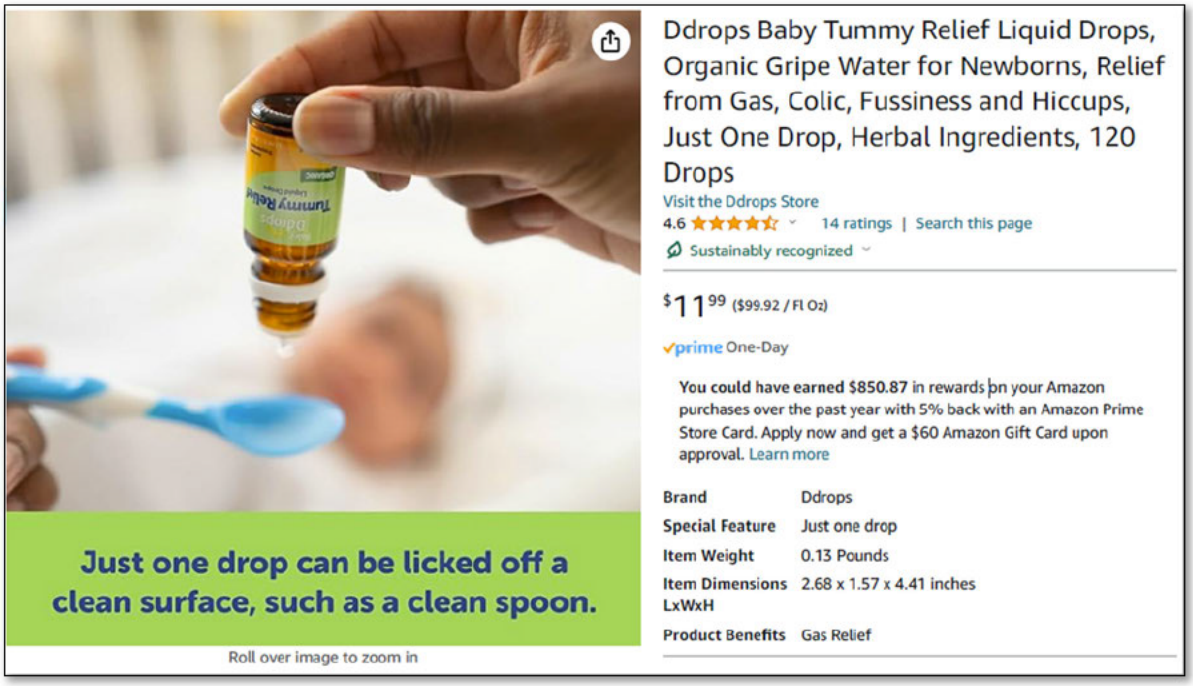
EX1030 (annotated).



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EX1032. Patent Owners' declarant confirmed this. EX1038, 41:14-43:18, 86:11-87:6. Common sense tells us that spoons can be used with infants:

EX1041, 1. Spoon-feeding infants dates back more than 150 years. EX1048, 4.

This evidence undermines Dr. Vieth's testimony that "[u]se of a spoon would be stupid. You cannot place a spoon into an infant's mouth. They will gag." EX2068, ¶46; *see also* POR, 17, 35; EX2069, 10 (¶h). These opinions are simply not credible in light of Patent Owners' own marketing materials and basic common sense. These materials confirm the reliability of Harder's instruction.

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III. SUPPORTING REFERENCES AND EXPERT TESTIMONY FURTHER CONFIRM OBVIOUSNESS

A. Wolf, Blass, European Pharmacopiea, and Gartner Further Support Obviousness Finding

Wolf further confirms that by 1970 a POSITA knew that a daily one drop dose of Vigantol oil could be "administered to the baby on a spoon." *See* EX1009, 7-8; EX1037, 70:21-71:5. Patent Owners' argument that Wolf teaches away because it suggests using "some liquid" fails. *See* POR, 37-38; *see also id.*, 19-20. A reference does not teach away if it "does not criticize, discredit, or otherwise discourage" the solution. *In re Fulton*, 391 F.3d at 1201. Wolf does not discourage administering one drop without liquid. It also pre-dates Harder by several decades. Thus, it does not teach away from the claims.

For claim 3, Patent Owners read Blass too narrowly. *See* POR, 39-42. Blass discloses an experiment where sucrose was administered to infants using the surface of a pacifier. *See* EX1011, 7-8. A POSITA would combine that feature with Harder. The test for obviousness "is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference[.]" *Allied Erecting and Dismantling Co. v. Genesis Attachments, LLC*, 825 F.3d 1373, 1381 (Fed. Cir. 2016). But rather, whether "a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention[.]" *Id*. A POSITA would have understood from Blass that a

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pacifier could replace the spoon as a surface for delivery of a substance such as Vigantol oil. *See* Pet., 33-35; EX1036, 113:1-9 (Dr. Horowitz stating that in 2006 "a [POSITA] would know that a baby is more likely to suck on a pacifier than off a spoon.")); *see also id.*, 14:12-23. Dr. Horowitz even testified that a POSITA would have "explore[d] other options to using a spoon[.]" *Id.*, 111:16-23. A nipple is a natural alternative. EX1039, 83:14-23. Dr. Vieth disclosed such a prior art teaching during prosecution. *Id.*, 89:2-8; EX2008, 3, 6 ("A solution in Germany is to put an oral vitamin D preparation on the mother's nipple once a day before the baby breastfeeds"). A pacifier is also a natural alternative to a nipple. EX1039, 83:14-23.

Regarding the European Pharmacopeia, Patent Owners characterize it as "a highly selected excerpt[]," but otherwise drop their admissibility and completeness objections. *See* POPR, 20-23. Patent Owners offer no other substantive rebuttal to the European Pharmacopeia or Gartner. They admit that Gartner's dosing disclosures were already in the prior art. POR, 44. Thus, these references support a finding of obviousness. *See* Pet., 35-39.

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B. Patent Owners' Declarants Lack Sufficient Knowledge, Independence, and Credibility

1. Dr. Reid

Patent Owners' first declarant, Dr. Reid, is a patent attorney, not a POSITA. EX1037, 15:8-11; *compare* EX2072, ¶¶4-9, 52 *with* I.D., 13 *see also* EX2072, ¶ 52. His opinions on the claims should be given no weight. "Allowing a patent law expert without any technical expertise to testify on the issues of infringement and validity amounts to nothing more than advocacy from the witness stand." *Sundance, Inc. v. DeMonte Fabricating Ltd.*, 550 F.3d 1356, 1364-65 (Fed. Cir. 2008); *see also Kyocera*, 22 F.4th at 1377.

2. Dr. Horowitz

The testimony of Patent Owners' pediatrician declarant, Dr. Horowitz, is also unreliable. Dr. Horowitz is not disinterested; he has an established relationship with the Ddrops company. Dr. Horowitz discovered Ddrops products and wanted to sell them to his patients at a significant markup. *See* EX1036, 46:6-50:5; EX1038, 116:17-119:17. He has made "a couple thousand dollars a year" this way. EX1036, 51:3-9. These products are the only supplement he sells. *Id.*, 46:24-47:15. Dr. Horowitz took steps to "get a seller's permit" and reached out to Ddrops affirmatively to arrange to sell the products. *Id.*, 47:16-48:3. It is unsurprising, then, that when Patent Owners needed a pediatrician who would defend the novelty of the Ddrops product, they turned to a familiar advocate.

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EX1036, 6-16; EX1038, 116:17-117:13, 119:5-17. The strength of his advocacy impaired his credibility. When asked, "you can't say whether an adult could lick a drop of oil off of a surface," Dr. Horowitz replied, "I can say that that's beyond the scope of my area of expertise." EX1036, 37:5-25.

Even if Dr. Horowitz was credible, his opinions on claim scope are irrelevant because he is not a POSITA. His opinions, at least as to patentability and claim construction, should be given no weight. *Sundance*, 550 F.3d at 1364-65; *Kyocera*, 22 F.4th at 1377.

3. Dr. Vieth

Dr. Vieth and his wife are co-inventors on and co-owners of the '958 patent. They are financially interested in the success of their exclusive licensee Ddrops. Dr. Vieth is not disinterested. Further, his testimony revealed a lack of credibility. While Dr. Vieth alleged that he "never used 'Vigantol' oil in connection with the research or preparation of the inventions claimed in the '958 Patent," (EX2008, ¶10)[7], his testimony and lab notebook showed that he effectively sought to recreate the properties of Vigantol oil, as described above in §II(A)(1). *See, e.g.*, EX1039, 28:7-19, 31:14-37:11, 39:19-42:9, 48:11-55:10, 64:20-72:22.

[7] This statement is noticeably absent from Dr. Vieth's POR declaration. *See* EX2068.

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C. Dr. Williams' Testimony is Credible

To distract from the Petition's merits, Patent Owners repeatedly mischaracterize Dr. Williams' testimony. For example, they argue that "Petitioner's counsel wrote the first draft and subsequent drafts of Williams' report," (POR, 24), but ignore that Dr. Williams testified that these drafts were based on his conversations, his opinions, and his thoughts on the prior art, and that he made revisions. *See*, *e.g.*, EX2025, 30:3-31:8, 33:10-13, 34:18-36:9. Indeed, Dr. Williams testified that the declaration accurately reflects his opinions, and that he would not have signed it otherwise. *See id.*, 31:1-8, 167:20-168:25.

Patent Owners further criticize Petitioner's counsel, but many questions objected to clearly sought protected attorney work product:

- "whether the description of a POSITA contained in his declaration was provided by counsel";
- "asked if he had been asked to consider the points raised by the Board in its Decision";
- "what he was told about the significance of the Wolf reference when it was provided to him by Petitioner's counsel";
- "whether he was told there were secondary considerations but he should not consider them."

POR, 8, 20, 45 (citing EX2025, 64:8-22, 67:8-17, 129:18-22, 76:6-77:11).

Far from being "bogus claims of privilege," as Patent Owners contend (POR, 24), these questions plainly implicated "drafting, editing, and collaboration between the expert and attorney" that is not discoverable. *See Adobe Inc. v. Rah*

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Color Techs. LLC, IPR2019-00627, Paper 59 at 7-8 (Dec. 12, 2019); 37 C.F.R. §42.51(b)(1)(iii). These were not sincere efforts to discover the substantive bases for Dr. Williams's opinions. Many were framed to invade the work product privilege or unfairly smear Dr. Williams if that effort was blocked. Notably, Patent Owner did not consult the Board or raise any other form of complaint prior to presenting it in the Response.

Patent Owners also misrepresent that Dr. Williams "was instructed not to answer questions regarding the inconsistencies between his opinions expressed in his declaration…signed in 2017, and those given in his declaration here." POR, 24. While Petitioner's counsel initially so instructed, (EX2025, 50:15-51:22), during a break she withdrew the objection, and counsel, when properly asking "why," was able to investigate these alleged "inconsistencies" with Dr. Williams, (*see, e.g., id*., 80:4-81:8, 81:20-82:9, 82:22-83:6). Again, Patent Owners' complaints lack substance.

IV. SECONDARY CONSIDERATIONS DO NOT RENDER OTHERWISE UNPATENTABLE CLAIMS PATENTABLE

As established above, every element of claim 1 is in Harder,[8] and secondary

[8] Harder's disclosure also anticipates claims 4 and 5, as other references show that the MCT excipient in Harder meets those limitations. *See* EX1010, 5.

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considerations are irrelevant to an anticipation analysis. *Cohesive Techs., Inc. v. Waters Corp.*, 543 F.3d 1351, 1364 (Fed. Cir. 2008) ("secondary considerations are not an element of a claim of anticipation"). Therefore, the Board need not consider Patent Owners' secondary considerations evidence and arguments. Nevertheless, these arguments also fail and can be given no weight.

A. Patent Owners Cannot Establish Nexus

Patent Owners must show that the relevant commercial products are coextensive with the claimed invention to establish a presumption of nexus. *Fox Factory, Inc. v. SRAM, LLC*, 944 F.3d 1366, 1373 (Fed. Cir. 2019). Patent Owners fail here on multiple fronts. First, both the Ddrops product and Petitioner's vitamin D formulations instruct the customer on how to use the products with methods that are non-infringing, such as mixing one drop with milk or other foods. *See* EX2071, 50-52; EX2061, 1-4.

Second, nexus cannot be tied to any feature that distinguishes the invention from the prior art. "In evaluating whether the requisite nexus exists, the identified objective indicia must be directed to what was not known in the prior art[.]" *Novartis AG v. Torrent Pharms. Ltd.*, 853 F.3d 1316, 1331 (Fed. Cir. 2017). Patent Owners do not dispute that Harder's Vigantol oil provides the claimed dosage of vitamin D in just one drop of an MCT oil. Harder also taught a method of administration that did not require placing Vigantol oil directly into the mouth.

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Because Patent Owners cannot identify any feature in Ddrops' product that was not already known, nexus cannot be established, and the Board should disregard the secondary considerations evidence.

Third, regarding commercial success, Patent Owners cannot tie ***any*** success to the claimed invention. Patent Owners allege that Petitioner's copying caused Ddrops product's lost market share in 2021. *See* POR, 63-64. But Ddrops' market share declined in ***2020***, not 2021. EX2071, Ex. S. Petitioner did not introduce its MCT formula until 2021, as Patent Owners admit. POR, 52. Thus Patent Owners' argument is ***temporally impossible***. Moreover, in 2020, Petitioner did change the ***bottle format*** to make it easier to dispense one drop. EX1038, 79:15-80:2; EX2026, 140:21-142:4. Thus, if anything, the market share change was due to the bottle format, not the claimed invention.

Moreover, additional reasons existed explaining why Petitioner's product was more successful than Ddrops. For example, Petitioner's product is organic. EX1038, 78:20-79:13. Petitioner also has a long history in baby care, with many baby-oriented products, and its product was placed in the baby aisle. *Id*., 81:1-5, 82:19-83:19. In contrast, this was Ddrops' first baby care product, and it was placed in the vitamin aisle, with less exposure to its key demographic. *Id*., 80:13-25. In fact, Ddrops has tried to regain market share by ***copying Petitioner***—Ddrops is now marketed as organic, and Ddrops has introduced new baby products

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to expand beyond the vitamin aisle. *Id*., 83:20-86:2. Patent Owners' argument that the "success has been due to the patented features claimed in the '958 patent and not for any other reason," (POR, 64), is demonstrably false.

Patent Owners' declarant on secondary considerations, Dr. Reid, failed to consider the impact of these unpatented properties in his analysis. *See* EX1037, 71:6-73:9. Because the products can be used in non-infringing ways (i.e., mixed with food) and have significant unpatented and unaccounted for properties, no nexus exists. Patent Owners have not met their burden. *Fox Factory*, 944 F.3d at 1373.

B. Alleged Copying

Patent Owners' reliance on copying by others also fails. While Patent Owners accuse a slew of alleged copyists, they provide no details about whether the copied products meet the claims or whether they can be used in non-infringing methods. No nexus was established, and this evidence should be disregarded. *Id*.

C. Other Secondary Considerations

Nor does long-felt unmet need or industry praise win the day. Regarding long-felt unmet need, as shown in Section II(A), the solution to Patent Owners' "problem," (POR, 57), was known for decades. *See* EX1007, 6 (Vigantol oil "has proved to be successful over many years"); EX1009, 8. Vigantol oil could deliver the claimed dose in a single drop. *Id*. Regarding industry praise, tellingly, Patent

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Owners lead off with evidence that constitutes inadmissible hearsay, and should be disregarded. POR, 60 (citing in part EX2068, ¶¶ 54-55; EX2071, ¶ 55). Regardless, Patent Owners fail to tie the industry praise to any novel limitation. At most, the praise is tied to other products in the Americas lacking the "one drop" feature of Vigantol disclosed in the published prior art. *See* POR, 60-61; EX1039, 26:1-27:2, 46:25-47:12; EX2027, 40:4-41:3, 56:1-10, 61:16-25; EX1038, 14:6-20.

Even if the Board considers Patent Owners' secondary considerations, they cannot overcome the Petition's strong obviousness case. *See Leapfrog Enters. Inc. v. Fisher-Price Inc.*, 485 F.3d 1157, 1162 (Fed. Cir. 2007).

V. CONCLUSION

Therefore, Petitioner respectfully requests the Board find the Challenged Claims unpatentable.

Date: April 12, 2024

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CERTIFICATION UNDER 37 CFR § 42.24

Under the provisions of 37 CFR § 42.24(d), the undersigned hereby certifies that the word count for the foregoing Petitioner Reply to Patent Owner Response totals 5,597 words, which is less than the 5,600 allowed under 37 CFR § 42.24(c)(1).

Date: April 12, 2024

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CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. §§42.6(e), the undersigned certifies that on 10/17/2024, a complete and entire copy of the Updated Redactions to Petitioner's Reply to Patent Owners' Response is being served filing this document trough the Patent Trial and Appeal Case Tracking System (P-TACTS) and by electronic mail as directed by Petitioner upon the following counsel of record for Petitioners:

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