UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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MOM Enterprises, LLC,

Petitioner

v.

ELAINE AND REINHOLD VIETH,

Patent Owners

_____

Case IPR 2023-00726

Patent 9,066,958

_____

DECLARATION OF STEVEN M. REID

MOM 1051
MOM Enterprises v. Vieth, Elaine
IPR2023-00726

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I, Steven M. Reid, declare and state as follows under penalty of perjury:

I. Introduction

1. I am over the age of twenty-one (21) and otherwise competent to make this declaration.
2. I have been retained by counsel as an expert witness on behalf of Elaine and Reinhold W. Vieth, owners of U.S. Patent No. 9,066,958 ("the '958 patent") in the captioned *inter partes* review concerning claims 1, 3, 4, and 5 that are challenged by MOM Enterprises, LLC ("Petitioner").
3. In connection with the *inter partes* review, I am being compensated for my time at my standard rate of $485 per hour and for expenses that I incur. Neither my work on the review, the outcome of the review, nor the content of my opinion herein affects my compensation. Further, I do not have any financial interest in the outcome of the review or any other proceeding between Patent Owners and Petitioner.

II. Background and Qualifications

4. I am currently a principal (partner) at Schwegman, Lundberg & Woessner, P.A. I earned a B.S. in chemistry at University of California, Davis (1993), where for three years I conducted graduate level research in the synthesis and characterization of novel biologically-relevant compounds useful in the

study of heme catabolism. I published my work in several leading chemical journals.

5. I also earned a Ph.D. in chemistry at Massachusetts Institute of Technology in 1998, and where my advisor, Richard R. Schrock, was thereafter awarded the Nobel Prize in Chemistry. Specializing in inorganic chemistry, I engaged in the synthesis of many new organometallic compounds variously useful as olefin polymerization catalysts, models in the study dinitrogen fixation, and metal complexes enabling exploration of steric and electronic constraints in metal-ligand bonding. My work reached international audiences through publication in leading journals.
6. After I completed my Ph.D., I accepted an appointment as a postdoctoral research associate at Texas A&M University in College Station, TX, where I engaged in organic and inorganic syntheses of new compounds. Concluding my appointment at Texas A&M in 1999, I accepted a second appointment as a postdoctoral research associate at Tulane University in New Orleans, LA. At Tulane, where I was sponsored by Dow Corning, my research focused heavily on the design, synthesis, and structural characterization of new organopalladium compounds useful in understanding metal-metal bonding and to achieve facile activation of chloroaromatic compounds. I published my research in leading chemistry journals.

7. In 2000, I joined the U.S. Patent and Trademark Office in Arlington, VA as a patent examiner in Technology Center 1600. In view of my academic credentials, I was housed specifically in Art Unit 1624 for examining patent applications directed primarily to chemical compounds with nitrogen-containing heterocycles, a principal structural feature of most biologically active small molecules. While at the U.S. PTO, I examined and passed to issuance many patent applications arising primarily in the pharmaceutical industry, including applications directed to new chemical entities, their formulations, and their methods of medical uses.
8. In 2001, I joined Foley & Lardner LLP as a technical specialist in the intellectual property law department, became a registered patent agent in 2005, earned my J.D. from The George Washington University Law School in Washington, D.C. in 2006, and was promoted to associate attorney also in 2006. I drafted and prosecuted patent applications, and I provided related counseling services, primarily to clients in the pharmaceutical industry. I was promoted to senior counsel in 2011.
9. In 2014, I resigned from Foley & Lardner LLP to continue my legal practice as a senior attorney, now principal, with my current employer, Schwegman, Lundberg & Woessner, P.A., where I am engaged in patent prosecution and related counseling for clients in the pharmaceutical and chemical industries.

10. I am the author or co-author of 11 scientific publications in peer-reviewed journals in the areas of synthetic organometallic chemistry and compound characterization. My *curriculum vitae* attached as Exhibit A provides additional details on my education and experience.

11. In view of my academic and professional experience outlined above, I am an expert in the field of chemistry. Throughout my career spanning more than 20 years, I have examined, drafted, and prosecuted hundreds of patent applications in the fields of medicinal chemistry, pharmaceuticals, formulations, drug delivery, and medical uses. In addition, I have counseled clients and prepared patentability and validity opinions in the same fields. Consequently, I have preserved my chemistry knowledge and experience, including the field of the '958 patent. While I am an expert in patent law and practice, I cabin my opinion detailed herein to technical considerations that are premised upon my formal education, experience in chemistry, and my interactions with innovators in the fields enumerated above.

III. Documents Considered in Formulating My Opinions

12. In formulating my opinion, I considered all documents that I cite throughout this declaration, including those listed in the following table:

Exhibit No.	Document
1001	U.S. Patent No. 9,066,958
1002	Prosecution History of U.S. Patent No. 9,066,958
1004	Declaration and Curriculum Vitae of Dr. Robert O. Williams III
1006	Chapter section 15.9 of "Wochenbettbetreuung in der Klinik und zu Hause", Hippokrates Verlag by Ulrike Harder (2003) ("Harder")
1007	Declaration of Accuracy of Translation by Joshua Sherman on, and including, altered translation of chapter section 15.9 of "Wochenbettbetreuung in der Klinik und zu Hause" performed by Rebecca Amy Tinworth ("Sherman")

Exhibit No.	Document
1008	H. Wolf, Aktuelle Therapie: Rachitisprophylaxe beim Saugling, *Deutsche Medizinische Wochenschrift* 95(9) (1970) 1530 ("Wolf")
1009	Translation of Wolf by Simon Chun Hsieh ("Wolf Tr.")
1010	European Pharmacopoeia Supplement 4.3 (2003) pp. 3148-3150 ("European Pharmacopoeia Supplement 4.3")
1011	E. M. Blass *et al.*, Suckling- and Sucrose-Induced Analgesia in Human Newborns, *Pain* 83 (1999) 611 ("Blass")
1012	L. M. Gartner *et al.*, Prevention of Rickets and Vitamin D Deficiency: New Guideline for Vitamin D Intake, *Pediatrics* 111(4) (2003) 908 ("Gartner")

Exhibit No.	Document
1023	Declaration of Accuracy of Translation by Stephen Benyunes on, and including, translation of chapter section 15.9 of "Wochenbettbetreuung in der Klinik und zu Hause" ("Benyunes")
1021	Translation of Harder by Rebecca Amy Tinworth ("Harder Tr."), Case 0:16-cv-04278-JNE-TNL, *Ddrops Company et al v. iHerb, Inc. et al*, Joan N. Erickson, presiding, D.I. 67-1, Filed 04/28/17 ("Tinworth")
1022	Supplemental Declaration of David Sherman, dated 11/06/23, filed 11/20/2023
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

Exhibit No.	Document
	Decision Granting Institution of *Inter Partes* Review, *MOM Enterprises, LLC, v. Elain and Reinhold W. Vieth*, IPR2023-00726, Paper No. 10, entered 09/15/23 ("Paper 10")
	Deposition of Stephen Benyunes, 12/05/23 and exhibits
	Deposition of David J. Sherman, 12/05/23 and exhibits
	Deposition of Dr. Robert O. Williams III, 12/07/23 and exhibits
	Deposition of Yasmin Kaderali, January 30, 2024 and exhibits
	Deposition of Stephanie Medina, February 1, 2024 and exhibits
	Declaration of Dr. Reinhold Vieth, February 3, 2024, and exhibits
	Declaration of Dr. Paul Horowitz, February 5, 2024, and exhibits

Exhibit No.	Document
	Declaration of Carey MacKenzie, February 7, 2024, and exhibits
	Declaration of Chris Temovsky, February 8, 2024, and exhibits

IV. The '958 Patent

13. The '958 patent recognizes various health benefits of vitamin D supplementation in infants and vigorous government encouragement therefor (*see* Ex. 1001, 1:6 – 2:8). Despite the need for supplementation, practical problems abound in reliably administering effective doses of vitamin D; these include unhealthy or unreliable sun exposure (*see id*. at 1:35-39), parental frustration in babies rejecting vitamin D formulations (*see id*. at 2:45-48), infant aspiration of vitamin D formulations administered directly into the mouth (*see id*. at 2:50-52), additives, short shelf life, bad taste, and high liquid volumes of vitamin D formulations (*see id*. at 2:53-60), and rancidity of some oil carriers of vitamin D (*see id*. at 3:1-5). The '958 patent inventors solved all these problems in a method that delivers to a human a nutritional or therapeutic effective amount of vitamin D (*see id*. at 5:8-11) in a single drop of medium chain triglycerides oil from an object's surface whereby the human sucks or licks the surface (*see id*. at 5:11-13). The

interaction between drop and surface is such that the drop does not drip or roll away, and it does not coat or adhere to the surface to prevent its efficient removal (*see id*. at 6:34-40).

V. Legal Standards

14. In formulating my opinion, in evaluating claims against the cited prior art, and in weighing the Petitioner's remarks thereon, I adhered to controlling legal precedents. Although I confine my opinion to technical matters, I am nevertheless fluent in such precedents because I am a practicing patent attorney. For the avoidance of doubt, I outline the relevant precedents below.

15. A requirement for patentability prescribes that an invention must not have been obvious to a person of ordinary skill in the art before the effective filing date of the patent. Thus, a patent claim could be invalid if it is proved that the claimed invention would have been obvious to the person.

16. An obviousness analysis must consider the following factors: (1) the level of ordinary skill in the art possessed by someone at the time the patent application was filed, (2) the scope and content of the prior art, (3) any differences between the prior art and the claimed invention, and, (4) if present, objective evidence or secondary indicia of non-obviousness. The analysis must not contemplate or otherwise use hindsight knowledge of the

invention; rather, the only permissible information is what was known at the time of the patent's effective filing date.

17. A prior art reference may be considered if it teaches a solution to any problem or need that is addressed by the patent. A prior art reference may also be considered if it discloses information that has obvious uses beyond its main purpose and if a person of ordinary skill in the art would reasonably consult that reference when trying to solve any problem or need addressed by the patent.

18. For obviousness purposes, it is not necessary for the prior art to disclose an exact teaching of the claimed invention. Thus, the obviousness analysis considers inferences and creative steps that a person of ordinary skill in the art would have taken in reviewing the prior art. A claimed invention is more likely to be obvious if it combined elements known from the prior art and the resulting combination yielded results that were predictable to a person of ordinary skill in the art. In contrast, a claimed invention is more likely to not be obvious if the combination of known elements yielded unexpected or unpredictable results, or if the prior art teaches away from combining the known elements.

19. That each and every element of the claimed invention might exist in the prior art, whether a single piece of prior art or several pieces of prior art,

does not necessarily rise to the level of obviousness. Thus, an obviousness analysis must additionally consider whether, at the time of the patent's effective filing date, there existed a reason that would have prompted a person of ordinary skill in the art to combine the elements known from the prior art in a way that the claimed invention arranges the elements. The following factors are probative in determining whether such a reason existed:

(1) whether the claimed invention was merely the predictable result of using prior art elements according to their known function(s);

(2) whether the claimed invention provides an obvious solution to a known problem in the art;

(3) whether the prior art teaches or suggests the desirability of combining elements claimed in the invention;

(4) whether the prior art teaches away from combining elements of the claimed invention, *i.e.*, the prior art would have discouraged a person of ordinary skill in the art from practicing the claimed invention, or would have led such a person in a different direction than practicing the claimed invention; and

(5) whether it would have been obvious to a person of ordinary skill in the art to try the combinations of elements, such as might exist in a

design incentive or market pressure to solve a problem and wherein only a finite number of identified, predictable solutions exist.

20. In addition, for an obviousness analysis to prove obviousness, it must be determined that the prior art provided a reasonable expectation of success. It is not enough in unpredictable technologies, such as life sciences inventions, to terminate the analysis at an obvious-to-try endpoint.

21. The obviousness analysis also must consider and evaluate any available objective evidence, or secondary indicia, that could inform a conclusion on whether the claimed invention is obvious. The indicia include the following:

(1) commercial success that resulted from the merits of the claimed invention rather than a product of design needs, market-pressure, advertising, or similar activities;

(2) whether the claimed invention satisfied a long-felt but unmet need;

(3) whether others had tried and failed to make the claimed invention;

(4) whether others invented the claimed invention at about the same time;

(5) whether others copied the claimed invention;

(6) whether there occurred changes or related technologies or market needs that were contemporaneous with the claimed invention;

(7) whether the claimed invention achieved unexpected results;

(8) whether others in the art praised the claimed invention;

(9) whether persons having ordinary skill in the art of the invention expressed surprise or disbelief regarding the claimed invention;

(10) whether others sought or obtained rights to the patent from the patentee holder; and

(11) whether the inventor proceeded contrary to accepted wisdom in the field.

VI. Claim Construction

22. I appreciate that for purposes of the present proceeding, claim terms are construed according to their ordinary and customary meanings as they are understood by a person of ordinary skill in the art and in light of the prosecution history of the '958 patent.

23. My opinion in this report contemplates that such a person would understand the '958 patent claim terms generally to have their ordinary and customary meanings. The following specific terms have such meanings:

a. In claims 1 and 3 – 5 of the '958 patent, the term "one drop of a composition consisting of . . . " would be understood by the person to mean "one drop of C_6-C_{12} liquid fatty esters of glycerol sufficient to administer a nutritional or therapeutically effective dose of vitamin D." *See* Ex. 1001 at 5:8-11.

b. In claims 1 and 3 – 5 of the ‘958 patent, the term “a nutritional or therapeutic effective amount . . . ” would be understood by the person to mean “the amount of vitamin D in the composition of use in the practice of the invention may be readily selected to be that amount which provides suitable effects on the circulating concentration of 25-hydroxyvitamin D.” *See id.* at 4:63-66.

c. In claims 1, 3, and 4 of the ‘958 patent, the term “liquid triglyceride of 6 to 12 carbon chain length . . . ” would be understood by the person to mean “C_6-C_{12} liquid fatty acid esters of glycerol including medium chain triglycerides which can be a mixture of 2-4 (C_6-C_{12}) fatty acids/glycerol esters” *See id.* at 5:21-27.

d. In claim 5 of the ‘958 patent, the term “liquid triglyceride of 6 to 12 carbon chain length . . . ” would be understood by the person to mean “C_6-C_{12} liquid fatty acid esters of glycerol including medium chain triglycerides which can be a mixture of 2-4 (C_6-C_{12}) fatty acids/glycerol esters, where not less than 95% of the fatty acids have 8 to 10 carbon atoms.” *See id.*

e. In claims 1 and 3-5 of the ‘958 patent, the term “wherein said drop adheres to the surface of said object” would be understood by the person to mean “the drop is sufficiently viscous so that one drop does not

> immediately drip or roll away from the object that enters the mouth, so that no portion would drip off the object and surface. The drop does not coat or adhere to the object so as to prevent efficient removal of the drop from the object." *See id.* at 6:35-3.

24. I understand that the claim construction above accords with the district court claim construction order in the parallel litigation. Ex. 2005, 2.

25. I also understand that, for purposes of granting the petition for instituting this proceeding, the Board adopted the district court's claim construction. Paper 10, 15-16. In particular, the Board explicitly recapitulated the court's construction of the term "wherein said drop adheres to the surface of said object" to mean:

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

Paper 10, 15 (quoting Ex. 2005, 2; emphasis added). I understand the Board to amplify the expression "efficient removal" as removal "of the drop through sucking." *Id.* at 16 (quoting Ex. 1001, 6:34-54).

26. 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 as I discuss below. 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.

VII. Summary of Opinions

27. None of Petitioner's three grounds for alleged invalidity of claims 1 and 3 – 5 of the '958 is supported by the cited prior art. Fatal to each ground is Harder because its singular focus on midwifery ejects the reference from the scope of material that would have concerned or even attracted the attention of a person of ordinary skill in the art faced with the challenges of delivering a nutritional or therapeutic effective dose of vitamin D in a single drop to a human, such as an infant.

28. Further, Petitioner's counsel prompted the genesis of multiple translations of Harder, and drafted the translator's declarations therefor, that altered the only full and untainted translation by adding to Harder words for an infant to lick off a drop of vitamin D oil from a spoon. Absent this element in Harder, as Petitioner's expert witness admitted, Harder simply does not teach an infant licking off a spoon.

29. Inasmuch as the alteration might warrant attention, against good judgment, it is flatly contradicted by my experiments, in agreement with additional declaration evidence, demonstrating that a drop of vitamin D_3 in MCT oil immediately coats a spoon, whereupon an infant would not be able to remove the drop from the spoon to receive a nutritional or therapeutic effective dose of vitamin D.

30. Because Wolf teaches administration of vitamin D drops *with* another liquid, Wolf teaches away from the single drop method of claims 1 and 3 – 5 of the '958 patent, and Wolf teaches away from Harder. Wolf is not combinable with Harder, therefore.

31. Blass discloses the use of sucrose solution-dipped pacifiers to achieve a synergism between orogustatory and orotactile mechanisms of non-pharmacological analgesia in infants. Blass has nothing whatsoever to say about delivery of medications, and a person of ordinary skill in the art would therefore not consider Blass's pacifier-dipping methodology as relevant in the least to delivering an efficacious one drop dose of vitamin D to an infant.

32. Because European Pharmacopoeia is a monograph on MCT oil, and Gartner reports on guidelines for lower vitamin D doses, neither reference rescues Harder and its combinations with Wolf and Blass, respectively.

VIII. Cited Prior Art

A. Harder

33. I have viewed Harder (Ex. 1006), but because it is written in German, a language that I do not read, I considered Petitioner's initial proffered English translation by David Joshua Sherman (Ex. 1007). I understand, however, that Sherman is not a fresh translation of Harder, it does not even purport to be a translation, but instead it is the admitted alteration of one sentence from

an earlier and full translation of Harder by Rebecca Amy Tinworth. *See* Ex. 1007 at ¶ 1; *see also* Ex. 1022 at ¶ 3. Sherman twice affirmed the competency of Tinworth to perform the translation of Harder. *See* Ex. 1007 at ¶ 1; *see also* Ex. 1022 at ¶ 2.

34. I also reviewed the translation of Harder by Rebecca Amy Tinworth (Ex. 1021). Tinworth asserted that her education in German established her competency to perform a "true, full and accurate translation of [Harder]." *Id*. at ¶ 3.

35. I reviewed still another translation of Harder proffered by Petitioner, this time by Stephen Benyunes (Ex. 1023).

36. I performed side-by-side comparisons of Sherman and Benyunes to Tinworth. I concluded that, excepting one altered sentence, Sherman is identical to Tinworth, as I discuss below. I also concluded that Benyunes largely accords with Tinworth except for various and minor word choices and phraseologies: however, Benyunes, as with Sherman, alters the same sentence from Tinworth.

37. Excepting the alteration, Harder is a chapter excerpt that provides guidance on neonatal prophylaxis of bleeding, rickets, and tooth decay by administration of vitamin K, vitamin D, and fluoride, respectively. *See* Ex. 1007, 3. Harder discloses four methodologies ("options") by which vitamin

D is administered to babies in order to prevent rickets: Option 1 is the "most reliable method" by which vitamin D tablets are "dispers[ed] quickly in a spoonful of water and [are] drunk easily from the spoon." *See id.* at 5-6. Option 2 contemplates attenuation or outright halt of Option 1 when a baby can spend time exposed to daylight. *See id.* at 6. Harder characterizes as "problematic" an Option 4 whereby a baby is administered synthetically produced vitamin D. *See id.* at 6.

38. Harder discloses an Option 3 to which one resorts when a child is susceptible to allergies or where Option 2 (tablets) produces increased bloating. *Id*. In Option 3, a baby is administered one drop daily of the prescription-only "Vigantol® oil". *Id.* Harder does not define Vigantol® oil.

39. According to Tinworth, under Option 3 the 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.

40. According to Sherman, however, under Option 3 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).

41. According to Benyunes, under Option 3 "[o]nce 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).

42. By its stated terms, the Sherman translation of Harder changed nothing in the Tinworth translation of Harder except to add to one sentence the words "to be licked off." Ex. 1007 at 1. Sherman moreover testified that Petitioner's counsel asked him to change just this single sentence of Tinworth (*see* Sherman deposition at 72:2-5) for a reason that Petitioner's counsel worded for Sherman, not a reason that he wrote himself ("They're not my words"; Sherman deposition at 73:2).

43. Concerning his translation of Harder, Benyunes testified that he "didn't create the document [declaration], no" (Benyunes deposition at 53:22), even though Benyunes was given the opportunity to amend the declaration "prepared for me and presented for me to . . . sign." *Id.* at 53:15-16; *see id.* at 93:12-15.

44. Contrary to his standard sentence-by-sentence process of translation from an original text in German, Benyunes instead copied the Tinworth translation of Harder to the extent that "the words chosen [by Tinworth] were essentially as I would have chosen myself . . ." Benyunes deposition, 60:14-15; *see also id*. at 81:4-11, 98:13-14. According to Benyunes, the Tinworth

translation of Harder is "[t]he only version that I've seen" (*see id.* at 65:3-11), and he never saw the Sherman alteration of Harder. *See id*. at 69:2-7. Benyunes moreover testified that he was asked by a product manager, and she by Petitioner's counsel, initially to translate just a single sentence or more likely a single paragraph of Harder in the "Option 3" paragraph, concerning administration of Vigantol ® oil to a baby. *See id.* at 72:5 – 73:4; 75:12-13). Benyunes clarified that he "translated [Harder section 15.9] . . . basing sections of my translation on an earlier one." *Id.* at 98:13-14.

45. From the preceding considerations, it is abundantly clear to me that the only unadulterated translation of Harder is Tinworth. Sherman is an exact copy of Tinworth and altered only at the specific direction of Petitioner's counsel to motivate addition of the four words "to be licked off." Benyunes, according to Benyunes himself, is patterned directly upon Tinworth. Benyunes, as with Sherman, moreover bears the mark of intervention by Petitioner's counsel to produce a translation also rendered with the four words. For these reasons and because the Sherman and Benyunes translations are admittedly derivative of Tinworth, not translations *de novo*, my opinion places heavy weight on Tinworth. For reasons that I discuss below, reliance upon Sherman or Benyunes, however ill-advised, still would not alter my opinion on non-obviousness.

B. Wolf

46. Because Wolf (Ex. 1008) is a document in German, as with Harder, I reviewed its English translation proffered by Petitioner (Ex. 1009). Unlike Harder, however, Petitioner did not engage a translation service for repeated treatments of Wolf until a desirable translation was produced. Wolf discloses a prophylaxis of rickets in babies by a recommended daily administration of 500 I.U. of vitamin D_3. *See* Ex. 1009, 7. For this purpose, Wolf discloses numerous "pure vitamin D_3 preparations" that are tablets or liquids (*id.* at 8) and "vitamin preparations containing vitamin D_2 or D_3" that are also tablets or liquids. *Id*. According to Wolf, drops of the liquid preparations or tablets are administered with liquid on a spoon. *Id.* at 7. Wolf does not disclose administration of drops of any liquid vitamin D preparation, nor does Wolf specify a liquid with which vitamin D drops are administered. Wolf describes Vigantoletten® and Vigorsan® as the most suitable "pure vitamin D_3 preparations," (*id*. at 9), and Wolf lists one drop daily of Vigantol® among these and other vitamin D_3 preparations. *Id.* at 8. Wolf does not define the term "pure" in reference to vitamin D_3 preparations.

C. European Pharmacopoeia

47. European Pharmacopoeia (Ex. 1010) is an excerpt from supplement 4.3 to the full European Pharmacopoeia 4th Edition. The excerpt is a monograph on medium chain triglycerides (MCTs) providing, among other things, the acid origins and MCT composition of octanoic and decanoic acids (*see* Ex. 1010, 5), methods for identifying MCTs (*see id.* at 5-6), and maximum amounts of impurities and assays for determining the same. *See id.* at 6-7.

D. Blass

48. Blass (Ex. 1011) is a research article that examined the underpinnings of sucrose-induced analgesia in newborns subjected to heel lance blood collection. *See* Ex. 1011, 6. In comparative experiments, newborns (1) were administered 2 mL of 12% sucrose solution orally or (2) sucked on a pacifier that was dipped in a sucrose solution every 30s, where either (1) or (2) occurred during a 2-minute period preceding heel lance blood collection. *See id.* at 8.

49. Observing pronounced reduction in baby grimacing and crying in both groups (1) and (2), and especially in (2) (*see id.* at 9 [Figure 2]), Blass posited a theory of analgesia that resides in a synergy "between orogustatory and orotactile mechanisms." *Id*. at 14. Nowhere does Blass attribute or otherwise link antinociception to sucrose as a pharmaceutically active agent

or to any particular dose of sucrose. It is instead manifestly clear that exposure of babies to a sweet solution or sweetened pacifiers, not the identity or amount of sweetener, is the goal to be achieved, for Blass repeatedly emphasizes that "sweet taste [is] an analgesic agent." *Id.* at 15.

50. According to Blass, non-nutritive suckling of pacifiers is already a known behavioral analgesia (*see id.* at 15), where "[s]weetened pacifiers provide an even more potent . . . treatment against local pain." *Id*. at 16. Blass concluded that "[b]ehaviorally induced analgesias either through taste, flavor, suckling, or contact offer very promising, effective, and safe, noninvasive and nonpharmacological treatments." *Id.* at 16.

E. Gartner

51. Gartner (Ex. 1012) is a clinical report on new National Academy of Sciences recommendations that infants, children, and adolescents intake 200 I.U. daily 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.

IX. Level of Ordinary Skill in the Art

52. My opinion in this declaration is premised upon consideration of the cited prior art above and the construed claims as viewed and understood by a

person of ordinary skill in the art at the time of the '958 patent's effective filing date, *i.e.*, September 14, 2006. The field of the '958 patent resides in vitamin D formulations and methods of administering them to humans (*see* Ex. 1001, 1:10-12), the cited prior art generally concerns formulations of medicaments or nutritive supplements to babies, and so the sophistication of the person who addresses problems and risks involving such formulations militates in favor of a formal advanced degree in formulations and related practical experience. Based upon these factors, such a person would possess a "doctorate in Pharmaceutics or related field with several years of experience in formulating compositions of and delivering medicines and nutritional supplements." Paper 10, 13.

53. Accordingly, I reject the naked assertion by Petitioner's expert witness Dr. Williams that such a person includes a "nurse." Ex. 1004 at ¶ 20. Although a nurse is a trained and educated professional, and even though a nurse, in the practice of the profession, sometimes administers medicaments and formulations, the skillset of a nurse does not contemplate the development of medicaments, formulations, and the considerations incident to such development. For similar reasons, the person of ordinary skill in the art especially does not include a midwife or doula; their training and experience reside considerably farther than does a nurse from the advanced formal

education in pharmaceutics or related field and the experience in formulating and delivering medicaments.

X. Opinions

A. Claims 1 and 5 Would Not Have Been Obvious Over Harder, Wolf, and European Pharmacopoeia (Ground 1)

54. A person of ordinary skill in the art would not have considered claims 1 and 5 as construed to be obvious in view of Harder, Wolf, and European Pharmacopoeia. This is because, in the first instance, the only credible translation of Harder does not disclose or otherwise intimate anything about dispensing a drop of Vigantol® to be licked off by a baby. Because neither Wolf nor European Pharmacopoeia also do not discuss a baby licking off or sucking Vigantol® off a spoon, the combination of Harder, Wolf, and European Pharmacopoeia would not suggest the method of claims 1 and 5 to the person of ordinary skill in the art.

1. A Person of Ordinary Skill in the Art Would not Have Considered Harder

55. A threshold factor underpinning my opinion considers that the person of ordinary skill in the art, as I discussed above, would have possessed a doctorate in pharmaceutics with several years of practical experience in formulating compositions of and delivering medicines and nutritional supplements. That person, confronted with the challenges of delivering a

nutritional or therapeutic effective amount of vitamin D to a human being, such as an infant, would consult authorities in the areas of pharmaceutics and delivery of formulations; the authorities include individuals of like education and experience, such as medical doctors including those with research experience, pediatricians, and other individuals with doctorates and experience in pharmaceutics. The authorities also include materials written by these individuals, such as treatises, textbooks, review articles, and primary peer-reviewed journal articles. Thus, in general, the person of ordinary skill confronted with the challenges faced by the inventors of the '958 patent would have consulted the collective wisdom and experience of like-minded and like-educated authorities.

56. Accordingly, the person would not have consulted Harder because the chapter excerpt of Harder is a collection of "FAQs" (frequently asked questions) written and answered by a midwife (*see* MacKenzie declaration, Exhibit B thereto, Table of Contents (Ch. 15), 281), and is part of a reference book directed to midwives (*see id*. at back cover). A midwife is not person of ordinary skill in pharmaceutics or formulations of nutritional supplements, such as vitamin D. Harder does not possess a doctorate in pharmaceutics or similar field, nor does Harder possess a medical degree:

Harder is educated in, practices, and lectures only on midwifery (*see id.* at 281).

57. Harder explicitly distinguishes her reference work from "obstetric textbooks" (*see id.* at VI, Preface). In this context, the chapters of Harder could not more plainly define the problems for which a person would consult Harder:

> **Basics**
>
> 1. The importance of the postpartum period
> 2. Psychosocial changes during the postpartum period
>
> **Practical aspects**
>
> 3. Regression of general physical changes
> 4. Regression of the birth organs
> 5. Lactation and breastfeeding
> 6. Special breastfeeding situations and breastfeeding advice
> 7. Nutrition of the newborn and infant
> 8. Care after a cesarean section birth
> 9. Care after a premature birth and after the birth of a sick child
> 10. Care after the birth of twins/multiple births
> 11. Care after the loss of a child
> 12. Irregularities during the postpartum period

13. Postpartum care in the hospital
14. Postpartum care at home
15. Frequently asked questions from parents about newborns and infant care

See id., Table of Contents.

58. None of the topics above would have concerned a person of ordinary skill the art in the field of the '958 patent. The person would not have been interested in midwifery, would not have sought this reference text in a library, and would not have considered that the education and experience of a midwife impinges the least upon pharmaceutics and delivery of nutrient or supplement formulations to humans. In plain terms, none of Harder, including Chapter 15.9, addresses or solves the problem of delivering a nutritionally effective amount of vitamin D to a human being or infant.

59. Petitioner's expert witness Dr. Williams buttressed these points. When asked, Dr. Williams could not testify that Harder taught anything about delivering an efficacious dose of vitamin D from a spoon, but he did repeatedly testify that "I would have to ask a clinician . . ." (Williams deposition at 138:21-22 and 140:2), who he defined as "[a] medical doctor or a nurse practitioner or somebody that treats . . ." (*id*. at 140:8-9). Dr. Williams' testimony corroborates Harder because she plainly distinguishes

her reference work from obstetric textbooks (*see* MacKenzie declaration, Exhibit B thereto, VI, Preface). Therefore, I regard Dr. Williams' testimony as confirmatory evidence that Harder is not a person of ordinary skill in the art of the '958 patent and that Harder does not by her own terms, and never was intended to, address that person.

60. Harder does not contemplate the variables that impinge upon a solution to this problem. *See* R. Vieth declaration at ¶ 30. Harder is a practical reference text for the practice of midwifery. While Harder could be credited as a useful resource to other midwives, it bears none of the traits that I discuss above positioning the reference as pertinent to the person of ordinary skill in the art engaged in formulations and delivery of vitamin D to an infant. For these reasons, the person would not have turned to or considered Harder.

2. Only Tinworth is a Trustworthy Translation of Harder

61. A second threshold consideration in reaching my opinion resides in the fact that of the three "translations" of Harder on record, Tinworth stands above the others in several respects, as I discussed above: it is and remains the only document of record reflecting a *de novo* translation of Harder in its entirety. Further, Tinworth is the only neutral translation of Harder, free from the taint of interference by Petitioner's counsel fastening to both Sherman and

Benyunes Absent any element of an infant licking a drop of Vigantol® off a spoon, as shown by Tinworth (*see* Ex. 1021 at 5), Harder alone or in combination with Wolf and European Pharmacopoeia would have failed to suggest the method of claims 1 and 5 to the person of ordinary skill the art.

62. Petitioner's expert witness Dr. Williams underscores this absent element, for purposes of his analysis, by quoting directly from Tinworth, not Sherman, in his characterization of Harder. *See* Ex. 1004 at ¶ 59. That is to say, Dr. Williams quoted Harder's instructions to administer a single drop of Vigantol® from a spoon with no reference to the licking off of the drop. *Id.* Williams moreover stated as "significant" to his analysis the addition of the four words "to be licked off" to the Sherman alteration of Tinworth. *See* Williams deposition at 99:15-100:12. In fact, Dr. Williams testified that without those four words, he would be unable to reach his "specific opinion" (*see id*. at 100:13-21), emphasizing that absence of the words would be the undoing of his own reliance upon Harder to teach a drop of Vigantol® to be licked off a spoon. *See id.* at 120:10-15, 17-19.

63. Unmoored from the four words "to be licked off" in Sherman, the Petitioner's own expert obviousness analysis has no fate other than to founder. The same applies *mutatis mutandis* to any reliance upon Benyunes. Because I reject Sherman and Benyunes for their dubious genesis, as I

discussed above, Tinworth remains the only credible translation of Harder: *sans* the four words that were "significant" to Williams, Harder alone or with Wolf and European Pharmacopoeia does not disclose or suggest that a drop of Vigantol® is to be licked off a spoon.

64. In the second instance, even if Harder taught a drop of Vigantol® to be licked off a spoon by a baby, according to the tainted Sherman or Benyunes translation, Harder in combination with Wolf and European Pharmacopoeia still would not have suggested to the person of ordinary skill in the art the method of claims 1 and 5 of the '958 patent. Two reasons support my conclusion: first, a drop of MCT oil containing 400 IU vitamin D, when placed on the tip of a spoon, does in fact coat or adhere to the spoon so as to prevent efficient removal of the drop from the spoon, such as "through sucking" (*see* Paper 10 at 16), as I demonstrate below. Second, though Petitioner relied upon Wolf for teaching the composition and dosage of Vigantol®, Wolf in fact teaches away from claims 1 and 5 of the '958 patent and, in addition, Wolf would not have been combinable with Harder as viewed by the person of ordinary skill the art, as I further explain below.

3. A Spoon is Coated with a Running Film of Vitamin D in MCT Oil

65. I demonstrated that one drop of a 400 IU solution of Vitamin D in medium chain triglycerides (MCT) oil, when applied to the tip of a spoon, does not

remain at the tip but rather spreads and coats the bowl, i.e., the concave surface, of the spoon. Because Vigantol® is not readily available, I utilized "Baby Ddrops ®", a liquid vitamin D_3 formulation that is commercially available from Ddrops Company. Exhibit B, panels **1 - 2**. The formulation contains, in each drop, 400 IU of Vitamin D_3 in organic fractionated coconut oil. Exhibit B, panel **3**. Such oil is a colorless mixture of triglycerides of primarily caprylic (C_8) and capric (C_{10}) acids, together commonly denoted as medium chain triglycerides. *See* Ex. 1010 at 5, Ex. 1001 at 5:21-28.

a) Procedure

66. I carried out the following procedure for each of two experiments. Ambient air was at 70 F, and a steel (a ferrous alloy) spoon and vial of Baby Ddrops liquid vitamin D_3 were allowed to thermally equilibrate in the ambient air. On a countertop, the handle of the spoon was supported on a machinist's steel "1-2-3 block", whilst a magnetic digital angle finder was temporarily affixed across the rim of the spoon bowl to set the angle of the spoon, as illustrated in Exhibit B Panel **4**. I marked the spoon handle at its point of contact with the 1-2-3 block to create a reference point.

67. In a first experiment, the spoon was positioned to enforce parallelism between the spoon bowl rim and the countertop, *i.e.*, by setting the angle of the spoon to 0.0 . Exhibit B, panels **4-5**. The digital angle finder was

removed and the handle of the spoon positioned at its reference point on the 1-2-3 block to re-establish a spoon angle of 0.

68. In a second experiment, the angle of the spoon was set to 14.8. Exhibit B, Panel **6**. The angle was chosen to approximate the position in which a spoon is held and brought to a mouth, such as by an adult to an infant.

69. In each experiment, the vial of Baby Ddrops liquid vitamin D_3 was held vertical to dispense a single drop of the formulation to the front edge of the spoon bowl rim.

b) Results

70. In the first experiment (spoon angle = 0.0), the drop immediately rolled downward to rest at the bottommost area of the spoon bowl, leaving a film or coating of oil extending from the tip of the spoon to the drop's resting point. Exhibit B, Panel **7**.

71. In the second experiment (spoon angle = 14.8), the drop immediately rolled, though more slowly, downward to rest at the bottommost area of the angled spoon bowl, also leaving a film or coating of oil extending from the tip of the spoon to the drop's resting point. Exhibit B, Panel **7**.

c) Conclusions

72. As a threshold matter, the experiment design confined the single drop to the concave surface of the spoon and to that portion of the spoon bowl rim that I

describe above as the front tip of the spoon. Hence, it was not a consideration, and in fact it was impossible, for the drop to ever drip off the spoon.

73. From the experiments that I describe above, I draw several conclusions. First, at both spoon angles, the drop never remained at the tip of the spoon, but instead spread away from it. Thus, inasmuch as the drop merely adhered to the spoon bowl surface whilst spreading, it coated the spoon with a trailing film of oil.

74. Second, I conclude that the results refute the opinion of Petitioner's expert witness Dr. Williams 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) where, as with MCT in the experiments, the oil includes "liquid triglycerides that have a carbon chain length of 6-12." *Id*. Specifically, the drop in each experiment, though it did not physically separate in whole or in part from the spoon, did "roll away" from the drop's origin at the tip of the spoon.

75. Third, the results militate against "efficient removal of the drop from the [spoon]" in construed claim 1 (Paper 10 at 15) especially where, as the Board emphasized, such removal "of the drop [occurs] through sucking." *See id*. at 16. The person of ordinary skill in the art would have known, such

as through direct lived experience, that the curved shaped of a spoon does not facilitate, and it can even outright prevent, the formation of a seal between mouth and spoon to initiate sucking. The person moreover would have known that an infant of nursing age does not, or is simply unable to, suck a spoon because it is "not a natural surface for an infant," as admitted by Petitioner's expert witness Dr. Williams. Ex. 1004 at ¶ 87.

4. Harder Does not Provide for Efficient Removal of a Drop From a Spoon

76. Even if Harder provided a drop of Vigantol® "to be licked off" a spoon by an infant, *contra* to Tinworth, the person of ordinary skill the art would not appreciate, and in fact would disagree, that the drop could undergo "efficient removal" from the spoon such as "through sucking." Paper 10, 15. This is because the experiments detailed above established that a single drop of oil quickly rolled away from the tip of the spoon at both tested angles and because the drop moreover spread away from the tip to coat the spoon. A person of ordinary skill in the art would appreciate that an infant could not remove a drop from the spoon to receive a nutritional or therapeutic effective amount of vitamin D because a substantial portion of it would have rolled into the bowl of the spoon, away from a baby's mouth who has no ability to lick or suck the spoon, much less in a manner that reaches the oil

pooled in the bowl of the spoon. *See* Horowitz declaration at ¶ 7(a); *see also* Vieth declaration at ¶¶ 46-49, 64, 68, and 100.

77. Harder, in fact, nowhere and in no way suggests that an infant receives any such amount of vitamin D, despite Harder's remark that "[u]se of the oil is simple . . ." Tinworth, 6. This is because, first, a spoon does not facilitate infant sucking: the drop could not be efficiently removed from the spoon.

78. Second, fortifying these points, Dr. Reinhold Vieth, who is co-owner of the '958 patent, explained that (a) infants do not, nor do they possess the ability to, lick anything from surfaces, including spoons (*see* Vieth declaration at ¶¶ 46-52, 60-71, and 93), and (b) it is impossible for an infant to lick a dose of anything from a spoon because the tongue would be depressed *below* the spoon. *See id.* at ¶ 68.

79. A third line of evidence resides in testimony by Petitioner's expert witness Dr. Williams, who despite his reliance upon Harder for guidance on licking off a drop of Vigantol®, was unable to state how many licks an infant would need to perform to receive an efficacious dose (*see* Williams deposition at 138:21-22, 139:1 – 140:4), or "what licking would be understood with regards to efficacious dose[]" (*id*. at 22-24), nor did Williams even "consider the efficacious part." *Id.* at 138:8-9. From these remarks, I conclude that Harder does not speak to Dr. Williams, whose "level of skill in the art

exceeded that of a POSITA" (Ex. 1004, ¶ 21; *see also* Williams deposition. 67:18-22), or to even to Dr. Williams putting himself into "the hypothetical position of a person of ordinary skill in the art, because I teach this level of person and I work with this level of person." Williams deposition, 68:4-7. This level of person includes PharmD students, PhD students, postdoctoral fellows (*see id.* at 68:11-15), but not medical or nursing students. *See id*. at 70:4-8. Thus, I conclude that Harder does not speak to Dr. Williams, nor would have Dr. Williams spoken to Harder.

80. Even if the person of ordinary skill the art could credit Harder as disclosing a method of administering a drop of Vigantol® on a spoon to be licked off by an infant, against the considerations above, the demonstrable fact that the drop rolls away from the spoon tip and coats the spoon bowl militates against delivery of a "nutritional or therapeutic amount of vitamin D." Ex. 1001, 9:34-35 (claim 1). The person would have no expectation of success that a baby could lick or suck a spoon, essentially ensuring that the baby could not obtain the full dose of vitamin D because the drop rolls away from the spoon tip and subsequently forms a film.

81. For these reasons, even the tainted translation of Harder by Sherman or Benyunes, alone or if combined with Wolf and European Pharmacopoeia,

would not have suggested to the person of ordinary skill in the art the method of claims 1 and 5 with a reasonable expectation of success.

5. Wolf Does Not Remedy the Deficiency of Harder

82. Because Wolf discloses vitamin D_3 preparations such as Vigantol® for administration such as by a spoon for prevention of rickets in infants (*see* Ex. 1009, 7-8), Wolf does not extend beyond Harder in this regard. Wolf does not rescue Harder. This is because, again, the only credible translation of Harder is Tinworth: it does not contain the words "to be licked off" that were later added to create Sherman and Benyunes. Because Wolf also does not disclose a drop of Vigantol® "to be licked off" a spoon, the combination of Wolf and Harder would not have suggested to the person of ordinary skill in the art the method of claims 1 and 5 as construed.

83. Even if Harder was credited with disclosing a drop of Vigantol® "to be licked off" as asserted by Sherman or Benyunes, Wolf does not address and therefore fails to solve the problem of efficient removal of the drop, even by licking, because the drop rolls away from the tip of the spoon and forms a coating or film on the spoon away from the tip, as I demonstrated above. Wolf does not disclose sucking or licking a spoon. Hence, Harder and Wolf do not combine to suggest a drop of Vigantol® that adheres to a surface within the meaning of claims 1 and 5 as construed.

84. Wolf moreover teaches away from claims 1 and 5 of the '958 patent because Wolf teaches that "[d]rops . . . should [] be administered to the baby on a spoon *with some liquid*." Ex. 1009, 7 (emphasis added). A person of ordinary skill in the art reading Wolf would therefore understand that a single drop of Vigantol®, when provided to a baby for the prevention of rickets, is to be diluted *via* addition with a liquid prior to administration of the resultant Vigantol®/liquid combination to a baby. Nowhere does Wolf suggest that a single drop of Vigantol® or any other liquid that Wolf discloses should be or even can be administered to a baby.

85. Because Wolf teaches the administration of a drop formulated with another liquid, Wolf teaches away from the method of claims 1 and 5 of the '958 patent. Wolf moreover proceeds in a manner contrary to Harder to the extent that both references address drop formulations of vitamin D_3: Wolf advocates for administration of liquid compositions of vitamin D drops, whilst Harder, despite all its shortcomings that I discuss above, advocates for administration of single drops. Therefore, Wolf solves none of the problems that hobble Harder, and because these references are divergent in approaches to treating rickets, the person of ordinary skill in the art would not have combined, or even considered the combination of, Harder and Wolf to reach the method of claims 1 and 5.

6. European Pharmacopoeia Does Not Remedy the Deficiency of Harder

86. Because the monograph on MCT in European Pharmacopoeia does not address administration of MCT, European Pharmacopoeia also does not remedy the deficiency of Harder alone or in combination with Wolf.

B. Claim 3 Would Not Have Been Obvious Over Harder, Wolf, European Pharmacopoeia, and Blass (Ground 2)

87. The Petitioner's expert witness Dr. Williams relied upon Blass for the unremarkable proposition that a pacifier "would more likely trigger the sucking reflex" of an infant (Ex. 1004, ¶¶ 87, 106) and moreover for the erroneous notion that a person of ordinary skill in the art would have consulted Blass for "methods of delivering medication" (*id.* at ¶ 87) or, doing violence to Blass, to "improve the method of delivery of a liquid . . . *like that disclosed in Harder*." *Id*. at ¶ 106 (emphasis added). The problem with Williams' notions is Blass itself, for Blass would have suggested nothing of the sort to a person of ordinary skill in the art.

88. The corpus of Blass is a theory borne out by experiment that antinociception during heel lancing of infants is most pronounced in a synergy realized "between orogustatory and orotactile mechanisms." Ex. 1011, 14. In other words, as the person of ordinary skill the art would understand, mouth-taste and mouth-feel combine to "offer very promising, effective, and safe,

noninvasive and nonpharmacological treatments." *Id.* at 16. In practical terms, Blass engaged the orogustatory mechanism by providing infants a 12% sucrose solution, activated the orotactile mechanism by providing infants pacifiers, and realized synergy between the two mechanisms by repeated dipping of pacifiers into a 12% sucrose solution. *See id.* at 8.

89. The person of ordinary skill in the art knows that sucrose is not an active pharmaceutical ingredient. Blass does not describe sucrose as such an ingredient, as evidenced, for example, by the repeated emphasis throughout Blass on the sweet *taste* of sucrose and the role of taste and/or orotactility as "nonpharmacological treatments." *Id.* at 16.

90. Blass is moreover unconcerned with delivery of a sucrose solution of any amount to an infant in the sense that an infant might ingest sucrose. Rather, Blass demonstrated that maintenance of a sweet taste in an infant's mouth is the objective to be achieved, precisely by periodic dipping of a pacifier in a 12% sucrose solution over a 2-minute period. *See id.* at 8.

91. The person of ordinary skill in the art would not "consult Blass for methods of delivering medication" (*see* Ex. 1004, ¶ 85) because Blass has nothing whatsoever to say about delivery of medication. The person 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.

92. Buttressing the considerations above is that fact that Blass discloses the dipping of a pacifier in a 12% sucrose solution (*see* Ex. 1011 at 8): the person of ordinary skill the art would understand that dipping a pacifier is not a method to meter a dose of anything. Instead, the dipping of a pacifier in the 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 pacifier to infant mouth.

93. In contrast, Harder could not more emphatically stress the risk of a Vigantol® overdose when even "2 drops fall onto the spoon," advising the washing of the spoon and starting over with a single drop. *See* Ex. 1021 at 5; *see also* Ex. 1007 at 6. The care and attention that Harder fastens to administration of a single drop of Vigantol®, even if that was possible, put into sharp relief the comparatively haphazard pacifier-dipping methodology of Blass. Thus, the person of ordinary skill the art would not have looked to Blass for suggesting an alternative method of delivering a medicament, such as Vigantol®.

94. That any one of the Harder translations and Wolf both advise use of a spoon to administer a drop of Vigantol® to an infant for prevention of rickets militates against motivation that a person of ordinary skill in the art 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, 5; *see also* Ex. 1007, 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 an encumbrance to be lightened or a problem to be solved, but a simple use to be enacted by parents. Therefore, the person of ordinary skill in the art would have had no reason to combine Harder and Wolf with Blass.

C. Claim 4 Would Not Have Been Obvious Over Harder, Wolf, European Pharmacopoeia, and Gartner (Ground 3)

95. Claim 4 would not have been obvious to a person of ordinary skill in the art because Gartner, cited by Petitioner for teaching a diminution of vitamin D (200 IU daily; *see* Ex. 1012 at 3) relative to Wolf (500 IU daily; *see* Ex. 1009 at 7), does not rescue the combination of Harder, Wolf, and European

Pharmacopoeia from its flaws that I previously discussed. Section X(A), s*upra*.

96. I rely upon Tinworth as the most credible translation of Harder because it is the only full and neutral translation of record, in contrast to Sherman and Benyunes. The Tinworth translation of Harder, as with Wolf, fails to suggest that an infant suck or lick off a drop of Vigantol® from a spoon. Because European Pharmacopoeia is silent on anything about vitamin D or its administration, and because Gartner counsels for a lower dose of vitamin D relative to Wolf, the combination of Harder, Wolf, European Pharmacopoeia, and Gartner still would not have suggested the method of claim 4 to the person of ordinary skill in the art.

97. Even if Harder were to be read as suggesting that a drop of Vigantol® was "to be licked off" a spoon offered to an infant, as asserted by the alterations in Sherman and Benyunes, my experiments that I described above demonstrated that a single drop of MCT oil containing 400 IU vitamin D_3, when applied to the tip of a spoon as urged by Harder, immediately rolls away from the tip and leaves a coating of oil on the spoon bowl. The person of ordinary skill the art would understand that an infant could not efficiently remove the drop from the spoon such as through sucking or licking (*see* Vieth declaration at ¶¶ 66-69, 93 and 100; *see also* Horowitz declaration at

¶¶ 6(h) and 7(a)), and would have no assurance that the infant would thereby receive a nutritional or therapeutic amount of vitamin D. This is so even if the nutritional or therapeutic amount of vitamin D is 200 IU daily as taught by Gartner.

D. Secondary Considerations are Evidence of Non-Obviousness

98. My opinion also accounts for objective indicia of non-obviousness. Specifically, as I discuss below, I am aware of at least three such indicia that are established from other declarants and evidence of record.

99. **First**, the method of claims 1 and 3 – 5 of the '958 patent satisfies a long-felt but unmet need to deliver a therapeutically effective and correct amount of vitamin D in a formulation that is acceptable to infants. *See* Horowitz declaration at ¶ 6(l) and 6(m); *see also* Vieth declaration at ¶ 30-31, 34, and 53; Temovsky declaration at ¶ 35. Despite an infant's need for vitamin D, the endogenous source of vitamin D *via* exposure to sunlight and exogenous sources by injection or compounded in oils are problematic. *See* Horowitz declaration at ¶¶ 6(b)-(e); *see also* Temovsky declaration at ¶¶ 36-42.

100. An example of a problematic oil is sunflower oil, the carrier in Petitioner's vitamin D drop formulation until Petitioner changed the oil to MCT. *See* Medina deposition at 63:13 – 64:16.

101. The inventors of the '958 patent solved problems attendant to "then-available options such as cod liver oil, Vigantol® oil, and injectable vitamin D" (Horowitz declaration at ¶ 6(m)) by a formulation and method of delivery "to efficaciously administer just the right amount of vitamin D in a form that is acceptable to infants and caregivers." *Id*. at 6(l); *see also* Vieth declaration at ¶¶ 29, 30, and 37-45; Temovsky declaration at ¶ 52.

102. **Second**, I am aware of evidence detailed below that Petitioner's Mommy's Bliss vitamin D Organic Drops formulation copied Ddrops's Baby Ddrops vitamin D drop formulation.

103. I conclude that each formulation embodies the composition as defined in claims 1 and 3 – 5 of the '958 patent. [redacted]

Each of Petitioner's formulations is therefore a composition of 9 to 9000 mcg/mL vitamin D C_6-C_{12} liquid fatty acid esters of glycerol including medium chain triglycerides which can be a mixture of 2 – 4 (C_6-C_{12}) fatty

acids/glycerol esters in accordance with claim 1 of the '958 patent. Further, MCT oil is a mixture of triglycerides of at least 95% C_8 and C_{10} saturated fatty acids. *See* Ex. 1010 at 5; *see also* Ex. 1001 at 5:21-27.

104. Baby Ddrops liquid vitamin D_3 contains 400 IU vitamin D_3 per drop (Exhibit B, panels 1-2) in organic fractionated coconut oil (MCT), which computes to 303 mcg/mL vitamin D_3 in MCT. Therefore, the Baby Ddrops formulation, as with Petitioner's formulations above, is a composition of 9 to 9000 mcg/mL vitamin D C_6-C_{12} liquid fatty acid esters of glycerol including medium chain triglycerides which can be a mixture of 2 – 4 (C_6-C_{12}) fatty acids/glycerol esters in accordance with claim 1 of the '958 patent. *See* Temovsky declaration at ¶ 28.

105. From the evidence and calculations above, I conclude that Petitioner's Mommy's Bliss vitamin D Organic Drops formulation is superimposable upon Ddrops' Baby Ddrops liquid vitamin D_3, and that each formulation satisfies each element of the composition as recited in claims 1 and 3 – 5 of the '958 patent. In other words, the Patent Owner and Petitioner each markets a commercial product that shares identity with each other and are embodiments of the '958 patent claims at issue.

106. A chronology of product development at MOM lays bare the conclusion that Petitioner copied Ddrops' Baby Ddrops liquid vitamin D_3 to steal

market share. First, in 2010, MOM knew of Ddrops as a company (*see* Kaderali deposition 24:19-23), and that Ddrops sold Baby Ddrops liquid vitamin D_3 (*see id.* at 33:15-19, 149:3-9).

107. [redacted]

108. In 2016, Petitioner decided to launch a baby vitamin D product (*see* Kaderali deposition at 48: 2-11), and in 2016-17 Petitioner did launch the product (*see id*. at 47:2-3) that is Mommy's Bliss Organic D Drop, featuring vitamin D in sunflower oil. *See* Medina deposition at 35:2-7, Exhibit 28 thereto, Bates 1758. Mommy's Bliss Organic D Drop is a single drop serving. *Id*. Mommy's Bliss Organic D Drop contains 90 servings. *Id*. Petitioner's CEO testified that 90 servings and single drop servings are "key facts" about Mommy's Bliss Organic D Drop. *See id*. at 84:18 – 85:7; *see also* Medina deposition at 40:25 – 41:8.

109. By Q4 of 2020, Ddrops commanded the largest market share of liquid vitamin D on Amazon Baby [redacted], and [redacted] Petitioner's CEO testified that Petitioner "wanted to steal share from competition," which included Ddrops. *See* Kaderali deposition at 116:6 – 117:5.

110. In 2020, Petitioner decided to reformulate its baby vitamin D product from sunflower oil to MCT (*see* Medina deposition, 81:23 – 82:7). Petitioner was aware that Ddrops' product used MCT (*see id*. at 65:6 – 66:9), and then introduced the MCT oil-based product to market in 2020 or 2021. *See id*. at 82:12-16. [redacted]

111. The foregoing chronology shows that since 2010, Petitioner knew of Ddrops' Baby Ddrops liquid vitamin D_3, its 90 servings of single-drop servings of vitamin D in MCT, and Ddrops' market success. Even though Petitioner researched and knew of other commercial vitamin D formulations, and none of those were 90 servings of single drops, Petitioner chose to reformulate its Mommy's Bliss Organic D Drop that produced a replica of

Baby Ddrops liquid vitamin D_3 and thereafter witnessed a precipitous increase in market share.

112. **Third**, I am aware that Baby Ddrops liquid vitamin D_3 enjoyed considerable commercial success in Canada, as evidenced by its growth from 0% market share in 2008 to [redacted] in 2013, and its subsequent staying power as the "top infant vitamin D market leader in Canada." Temovsky declaration, ¶¶ 73-74; *see also* Exhibit S thereto.

113. From 2015, when Baby Ddrops liquid vitamin D_3 was launched in the U.S. it enjoyed market success along a similar trajectory to [redacted] in 2019 (*see id.* at ¶¶ 75-78), but in 2021, in contrast to the Canadian trajectory, market share in the U.S. had dropped to [redacted]. *See id.* at ¶ 79.

114. Commercial success of Baby Ddrops liquid vitamin D_3 in each country cannot be attributed to "print, television, or radio advertisements" or "flashy marketing and advertising bells and whistles" because Ddrops [redacted] Temovsky, ¶ 83. Further normalizing efforts between the two countries, Ddrops successfully enforced its Canadian patent against copyists in Canada (*see id*. at ¶¶ 87-93), and Ddrops similarly enforced the '958 patent against copyists in the U.S. (*see id*. at ¶¶ 94-101).

115. Commercial downturn of Baby Ddrops liquid vitamin D_3 in the U.S. in 2021 cannot be attributed to the COVID-19 pandemic because no similar downturn was evidenced in the Canadian market. *See id.* at ¶ 80.

116. The considerations above constitute compelling evidence that Baby Ddrops liquid vitamin D_3 thrived in Canadian and U.S. markets not from advertising or successful patent infringement action, but because of its "innovative composition and administration method that delivers an effective and therapeutic dose of the Patented Product." Temovsky, ¶ 82. The success is markedly underscored by the fact that market share of Baby Ddrops liquid vitamin D_3 in the U.S. [redacted] (*see* Medina deposition at 82:12-16).

117. The considerations above evidence a harvest of ripened fruit that grew from Petitioner's seed "to steal share from competition" (*see* Kaderali deposition at 116:6 – 117:5) by copying Baby Ddrops liquid vitamin D_3 in accordance with claims 1 and 3 – 5 of the '958 patent. Because Petitioner's Mommy's Bliss vitamin D Organic Drops Petitioner is a copy of Patent Owner's Baby Ddrops liquid vitamin D_3, Petitioner's enrichment by

"steal[ing] share from competition" (*id*.) further evidences the commercial success of Petitioner's Baby Ddrops liquid vitamin D_3 in the U.S. market.

XI. Conclusion

118. In conclusion, Harder is not a competent reference because a person of ordinary skill in the art would have never consulted it and, moreover, Harder's spoon-based administration of Vigantol® is crippled by impracticalities of serving medication to infants by spoon. Petitioner advanced two translations of Harder of dubious trustworthiness, leaving Tinworth as the only full and neutral translation that, importantly, discloses nothing about an infant licking Vigantol® off a spoon.

119. Further undermining Harder, my experiments demonstrate that a single drop of MCT oil containing 400 IU vitamin D_3 immediately rolls away from the tip of, and thereby coats the bowl of, a spoon. The results demonstrate that the drop does not adhere to the spoon such that an infant would have any chance of receiving a nutritional or therapeutic effect dose of vitamin D.

120. None of Petitioner's additional references rescues Harder. Because Wolf teaches administration of vitamin D drop preparations *with* another liquid, Wolf teaches away from claims 1 and 3 – 5 of the '958 and, for the same reason, diverges from the method of Harder. Blass is categorically focused on non-pharmacological analgesia *via* infant suckling of sweetened pacifiers,

and has nothing to suggest to the person of ordinary skill in the art concerned with administering one drop of a vitamin D formulation. Gartner's suggestion to decrease vitamin D dosing and European Pharmacopeia's monograph on MCT do not remedy the intractable difficulties with Harder alone or in combination with Wolf.

121. For all the reasons that I discuss herein, a person of ordinary skill in the art would not have considered any of claims 1 and 3 – 5 of the '958 patent to have been obvious at the effective filing date of the '958 patent based on any of Petitioner's asserted grounds.

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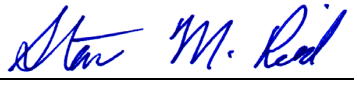
I, Steven M. Reid, declare and state that all statements made herein on my own knowledge are true and that all statements made on information and belief are believed to be true, and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

Dated: February 9, 2024 By: 

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sreid@slwip.com

EXHIBIT A

Steven M. Reid, Ph.D., J.D.

PROFESSIONAL COMPETENCIES

Twenty-three years of patent experience including advising in-house counsel, drafting and prosecution of patent applications, and writing legal opinions and summaries for executive officers, concerning small molecule therapeutics, radio-diagnostics, organic synthesis, solid forms of drugs, drug delivery, and dosage forms. Seasoned in formulating world-wide patent strategies, prosecuting complex patent portfolios, conducting IP due diligence investigations, and rendering legal opinions on patent validity and freedom-to-operate.

EDUCATION

J.D. | **The George Washington University Law School** | Washington | DC 2006

Ph.D. | Inorganic Chemistry | **Massachusetts Institute of Technology** | Cambridge | MA 1998
Dissertation*: Chelating Polyamido Complexes of Rhenium, Molybdenum, and Hafnium: Organometallic Chemistry to Ziegler-Natta Catalysis*

B.S. | Chemistry | **University of California** | Davis | CA 1993

LEGAL EXPERIENCE

Principal | Schwegman Lundberg & Woessner, P.A. **Mar. 2014 – present**
1600 TCF Tower | 121 S. Eighth St. | Minneapolis | MN

- Shepherded university pharmaceutical inventions from conception with principal investigators to letters patent, and advised university counsel and technology transfer offices on complex chemical patent matters.
- Obtained over 200 domestic and foreign patents for polymorph forms of renal failure drug in Phase 3 clinical trial, and represented client in related IP due diligence resulting in $350M strategic investment.
- Chief architect of new patent portfolio covering small molecule oncology therapeutics for small pharma company in collaboration with Fortune 500 biopharma company.
- Analyzed patent portfolio of global oncology biopharmaceutical company and advised in-house corporate and patent counsel on intersection of patent priority and chain of title.
- Authored clearance opinions in analyte detection for major biomedical device company.

Senior Counsel | Foley & Lardner LLP **Aug. 2001 – Mar. 2014**
3000 K Street NW | Washington, DC Feb. 2011 – Mar. 2014

- Prosecuted world-wide complex patent portfolio to obtain protection of FDA-approved Alzheimer's Disease imaging agents for university client and top Fortune 500 healthcare licensee.
- Provoked interference at U.S. PTO resulting in settlement in favor of Fortune 500 pharmaceutical company against generic competitor to protect blockbuster calcimimetic drug.
- Conducted IP due diligence investigations as central components of acquisition deals for start-up pharmaceutical company, resulting in successful partnership for commercializing therapeutics.
- Collaborated directly with research principals at Fortune 500 pharmaceutical companies to implement strategies providing patent protection for commercial forms of HCV anti-viral agents.
- Reviewed IP licensing, confidential disclosure, and material transfer agreements for IP due diligence.
- Mentored junior attorneys and presented to firm on decisions from Court of Appeals for the Federal Circuit.

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Associate | Foley & Lardner LLP Feb. 2006 – Jan. 2011
Law Clerk / Patent Agent Aug. 2001 – Jan. 2006

- Architect of world-wide patent strategy for third largest private company on small molecule therapeutics.
- Conducted eight IP due diligence investigations for Asia's largest pharmaceutical company.
- Drafted over 70 applications in organic synthesis, drug polymorphs, small molecule therapeutics, dosage forms, and drug formulations.
- Orally argued and won appeals before U.S. PTO Board of Patent Appeals and Interferences.
- Authored validity and freedom-to-operate opinions on small molecule therapeutics, crystal forms of drugs, and heat-sensitive inks.
- Presented Continuing Legal Education and marketing presentations on solid forms of pharmaceutical compounds and *KSR* Supreme Court decision on obviousness.
- Analyzed inventor notebooks to determine conception and diligence of anti-cancer drug in potential interference proceeding.

Patent Examiner | United States Patent and Trademark Office | Arlington | VA Sept. 2000 – July 2001

- Examined applications of small molecule pharmaceuticals, radio-diagnostics, and imaging agents (Art Unit 1624).
- Performed keyword and chemical structure-based prior art searches.

TECHNICAL EXPERIENCE

Post-doctoral Research Associate | Tulane University | New Orleans | LA April 1999 – July 2000
Field: Organopalladium chemistry and palladium-catalyzed organosilane synthesis
Advisor*:* Prof. Mark Fink

- Discovered synthetic routes to organopalladium complexes that catalyze silicon-carbon bond formation.
- Collaborated with chemists and chemical engineers on a cross-functional team at Dow Corning Corporation for the discovery and evaluation of potential organopalladium catalysts.

Post-doctoral Research Associate | Texas A&M University, College Station | TX July, 1998 – March, 1999
Field: Heterocyclic ligand synthesis and transition metal coordination chemistry
Advisor: Prof. F. A. Cotton

- Synthesized 2-pyridyl-2-pyrimidylamines, a class of tridentate ligands useful for constructing polynuclear transition metal complexes.
- Improved the synthesis of the fused heterocycle 1,9-diazaphenoxazine and demonstrated its utility as a multidentate ligand in a mixed $Cr(II)/Li^{+}$ complex.

Doctoral Research Associate | Massachusetts Institute of Technology Aug. 1993 – June 1998
Field: Synthetic organometallic and organic chemistry
Advisor: Prof. Richard R. Schrock

- Synthesized diamidoether complexes of hafnium(IV) alkyls and evaluated activated versions for their ability to polymerize olefins.
- Discovered a new class of proton-metal interactions in a series of rhenium(V) phosphine-hydrido complexes.

Undergraduate Research Associate | University of California | Davis | CA Sept. 1991 – June 1993
Field: Synthetic inorganic and bioinorganic chemistry
Advisor: Prof. Alan L. Balch

- Synthesized octaethyloxophlorin complexes of Ni(II), Mn(II), and In(III) as models of intermediates in heme catabolism.
- Elucidated the reversible carbon-carbon bond formation between two Ni(II) oxophlorin radicals.

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PUBLICATIONS AND SPEAKING

Santa Clara-Duke Quality Conference, September 9, 2016, panel speaker on U.S. PTO search and time, Santa Clara University School of Law.

"New Patent Office Examination Procedures: Bane or Boon?" *Patent, Trademark & Copyright Journal*, 79 PTCJ 173 (2009).

"A Dicoordinate Palladium(0) Complex with an Unusual Intramolecular η^1-Arene Coordination" *J. Am. Chem. Soc.* 2003, *125*, 7816.

"Reductive Routes to Dinuclear d^{10}-d^{10} Palladium(0) Complexes and Their Redistribution Equilibria in Solution" *Organometallics* 2001, *20*, 2959.

"Facile Reductive Elimination of Ethane from Strained Dimethylpalladium(II) Complexes" *J. Am. Chem. Soc.* 2001, *123*, 4081.

"Synthetic, Structural, and Dynamic NMR Studies of (Bisphosphine)Palladium(0) Complexes of Dibenzylideneacetone" *J. Organomet. Chem.* 2000, *616*, 10.

"Synthesis of Rhenium Complexes That Contain the $[(C_6F_5NCH_2CH_2)_3N]^{3-}$ Ligand" *Organometallics* 1998, *17*, 4077.

"Synthesis of Titanium, Zirconium, and Hafnium Complexes that Contain Diamido Donor Ligands of the Type $[(t\text{-BuN-}o\text{-}C_6H_4)_2N]^{2-}$, and an Evaluation of Activated Versions for the Polymerization of 1-Hexene" *Organometallics*, 1999, *18*, 3649.

"Synthesis of Titanium Complexes That Contain Triamido-Amine Ligands" *Organometallics* 1996, *15*, 1470.

"Carbon-Carbon Bond Formation in the Dimerization of (Octaethyloxophlorin radical)nickel(II)" *J. Am. Chem. Soc.* 1993, *115*, 2531.

"Coordination Patterns for Oxophlorin Ligands. Pyridine-Induced Cleavage of Dimeric Manganese(III) and Iron(III) Octaethyloxophlorin Complexes" *Inorg. Chem.* 1993, *32*, 2610.

"Nickel(II) Complexes of the Octaethyloxophlorin Dianion and Octaethyloxophlorin Radical Dianion" *Inorg. Chem.* 1993, *32*, 4730.

"A Cofacial, Dimeric, Metallaoxophlorin Complex: [Indium(III)(octaethyloxophlorin)]$_2$" *J. Chem. Soc., Chem. Commun.*, 1993, *13*, 1088.

BAR MEMBERSHIPS

District of Columbia | 2006
United States Patent and Trademark Office | 2003

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EXHIBIT B

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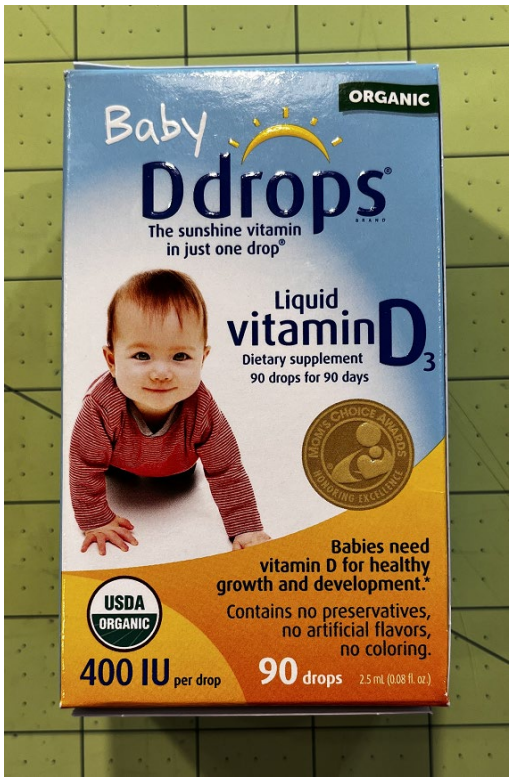
ORGANIC
Baby
Ddrops
The sunshine vitamin in just one drop®
Liquid vitamin D3
Dietary supplement
90 drops for 90 days
Babies need vitamin D for healthy growth and development.*
Contains no preservatives, no artificial flavors, no coloring.
USDA ORGANIC
400 IU per drop
90 drops
2.5 mL (0.08 fl. oz.)

2

Baby
Ddrops
ORGANIC
Liquid vitamin D3
400 IU per drop
Dietary supplement
90 drops 2.5 mL (0.08 fl. oz.)

3

Supplement Facts

Serving Size 1 Drop (0.028 mL or 0.001 fl. oz.)
Servings Per Container 90

Amount Per Serving	% DV[1]
Vitamin D3 (Cholecalciferol) **10 mcg (400 IU)**	100%

[1] Daily Value (DV) for infants less than 1 year old

Other ingredient:
Organic fractionated coconut oil.

Does not contain: Corn, casein, dairy, egg, fish, gluten, lactose, peanuts, sesame, shellfish, soy, starch, sugar, sulphites, wheat, yeast, preservatives, coloring or artificial flavors.

Directions: Infants less than 1 year old - Place 1 drop daily onto mother's nipple or on a clean surface, such as a washed finger, and allow baby to suck for at least 30 seconds. Or mix one drop daily with milk, juice or other food.

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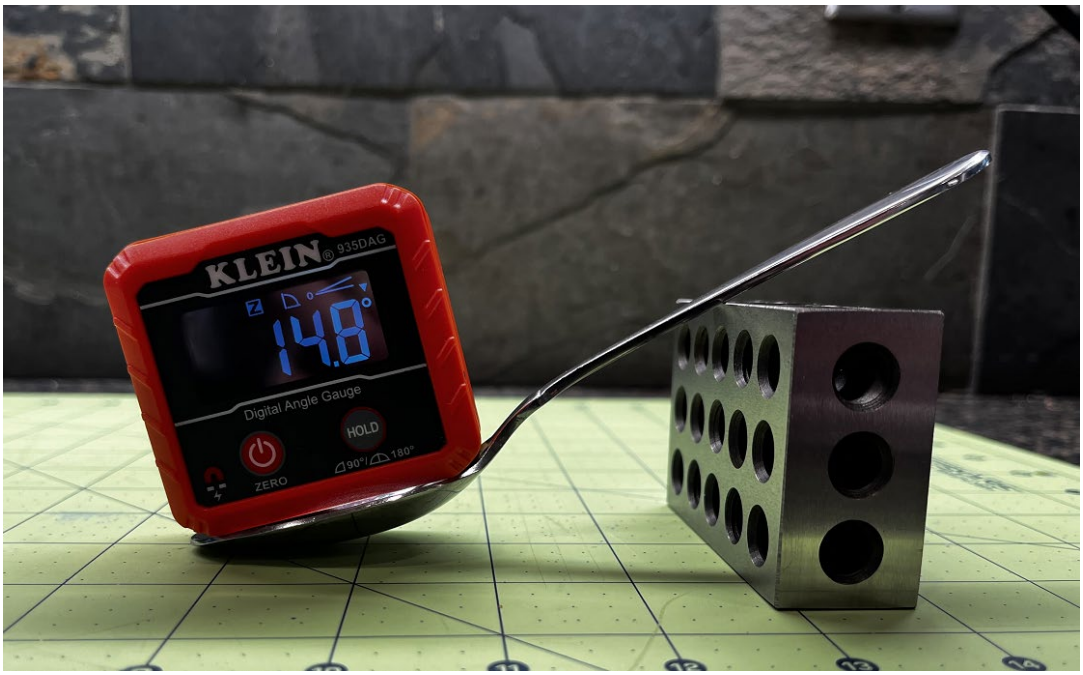

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