

MOM Enterprises, LLC v. Elaine and Reinhold W. Vieth

Petitioner's Demonstratives

IPR2023-00726

Patent No. 9,066,958

Before John G. New, Sheridan K. Snedden, and Cynthia M. Hardman

Administrative Patent Judges

FISH.

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DEMONSTRATIVE EXHIBIT - NOT EVIDENCE

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Instituted Grounds

* Independent claim noted in **red**

Ground	Claims	§ 103 Basis
1	1 , 5	Harder, Wolf, and European Pharmacopoeia Supplement 4.3
2	3	Harder, Wolf, European Pharmacopoeia Supplement 4.3, and Blass
3	4	Harder, Wolf, European Pharmacopoeia Supplement 4.3, and Gartner

Petition, 2

The '958 Patent

The '958 Patent

(12) **United States Patent**
Vieth et al.

(10) **Patent No.:** **US 9,066,958 B2**
(45) **Date of Patent:** **Jun. 30, 2015**

(54) **VITAMIN D COMPOSITIONS AND METHOD
OF ADMINISTRATION TO A HUMAN BEING**

(22) **Filed:** **Feb. 13, 2007**

(30) **Foreign Application Priority Data**
Sep. 14, 2006 (CA) 2558202

(57)

ABSTRACT

Composition of vitamin D in medium-chain triglycerides and use thereof in delivering a nutritional or therapeutic amount of vitamin D to a human being, particularly, an infant. The compositions are applied to an object, such as skin or in the case of an infant to a woman's nipple or pacifier from which the infant sucks off the composition. The method provides a more suitable, safer and efficient way of providing the human being with vitamin D. The compositions further comprise a free fatty acid and/or monoglyceride, oxidant preservative and, optionally, other vitamins.

The '958 Patent – Claim 1

1. A method of delivering a nutritional or therapeutic amount of vitamin D to a human being, said method comprising:
 - (i) applying one drop of a composition consisting of a nutritional or therapeutic effective amount of 9 to 9000 mcg/ml vitamin D in a liquid triglyceride of 6 to 12 carbon chain length, to an exterior surface of an object, wherein said drop adheres to the surface of said object; and
 - (ii) having said human being suck or lick said composition directly from said object.

EX. 1001, 9:34-44; Petition, 24-25

The '958 Patent – Claims 3, 4, and 5

3. A method as claimed in claim 1, wherein said human being is an infant and said object is a woman's nipple or the external surface of a pacifier.

4. A method according to claim 1, wherein the composition consists of from 150 to 450 mcg/ml vitamin D in a liquid triglyceride of 6 to 12 carbon chain length.

5. A method according to claim 1, wherein said triglyceride comprises at least 95% triglycerides having a carbon-chain length selected from 8 to 10.

Claim Construction

Claim Term	Board's Preliminary Construction
“wherein said drop adheres to the surface of said object . . .” (’958 Patent, claims 1, 3-5)	the drop is sufficiently viscous so that one drop does not immediately drip or roll away from the object that enters the mouth, so that no portion would drop 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
“vitamin D” (’958 Patent, claims 1, 3-5)	(5Z-7E)-(3S)-9,10-seco-5,7,10(19)-cholestatrien-3-ol also having the trivial names cholecalciferol or calcitriol (D3); and ergocalciferol (D2),” wherein “a person of ordinary skill in the art would understand this language to refer to either Vitamin D2 or Vitamin D3

Level of Ordinary Skill in the Art

Board's Preliminary Determination

A POSITA would have a doctorate degree in Pharmaceuticals or a related field with several years of experience in formulating compositions of and delivering medicines and nutritional supplements along with a bachelor's of science degree in biology, chemistry, biochemistry or a related field.

Prior Art

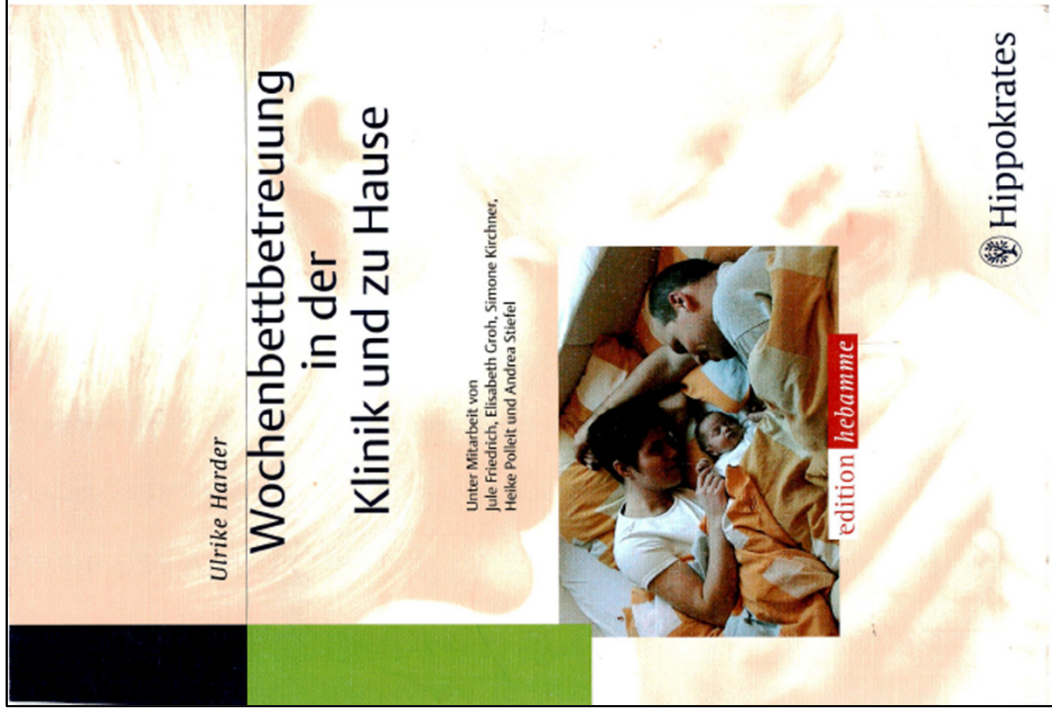
Prior Art

Reference	Referenced As	Pub. Date	Cls.
Wochenbettbetreuung in der Klinik und zu Hause, Hippokrates Verlag by Ulrike Harder	“Harder” (EX. 1006, translated at EX. 1007)	January 10, 2003	1, 5
Aktuelle Therapie: Rachitisprophylaxe beim Saugling by H. Wolf	“Wolf” (EX. 1008 translated at EX. 1009)	July 3, 1970	1, 5
Excerpts from European Pharmacopoeia Supplement 4.3	“European Pharmacopoeia Supplement 4.3” (EX. 1010)	January 2003	1, 5
Suckling- and Sucrose- Induced Analgesia in Human Newborns by Elliott M. Blass & Lisa B. Watt	“Blass” (EX. 1011)	December 1999	3
Prevention of Rickets and Vitamin D Deficiency: New Guideline for Vitamin D Intake by Lawrence M. Gartner	“Gartner” (EX. 1012)	April 11, 2003	4

Ground 1

Claims 1 and 5 are Obvious Over Harder,
Wolf, and European Pharmacopoeia
Supplement 4.3

Harder: Postpartum Care in the Hospital and at Home (2003)



Postpartum Care in the Hospital and at Home

Supporting women who have recently given birth and newborns has been one of my favorite midwife activities for many years, because good postpartum care is an important prerequisite for the development of a balanced mother-child relationship. During my professional work, I have repeatedly noticed that the postpartum period is scarcely covered in obstetric textbooks. To close this gap, I wrote “Wochenbettbetreuung in der Klinik und zu Hause” [Postpartum Care in the Hospital and at Home], which was originally planned as just a short guide, but grew into a comprehensive textbook during the editing period.

Harder was Publicly Available in the National Library of Medicine and Indexed by “Postnatal Care Methods”

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245	10\$aWochenbetreuung in der Klinik und zu Hause / \$cu. Harder.
260	##\$aStuttgart : \$bHippokrates, \$cc2003.
300	##\$axli, 282 p. : \$bill., ports.
336	##\$atext \$btxt \$2rdacontent
337	##\$aunmediated \$bn \$2rdamedia
338	##\$avolume \$bnc \$2rdacarrier
490	1#\$aEdition Hebamme
650	12\$aPostnatal Care \$xmethods
650	22\$aPostpartum Period
830	#0\$aEdition Hebamme.
935	##\$a(DNLM)1165932-nlmdb
947	##\$aSGZ
992	##\$pP6 \$eEL \$a20030130
993	##\$aSAN \$b20030522
994	##\$aCDN \$b20030610
995	##\$aAUTH \$b20030701 \$cREV \$d20180131
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- “The 650 fields included ... ‘Postnatal Care,’ ‘Postnatal Care methods,’ and ‘Postpartum Period.’”
- “[A]ny person of skill in the art of natal care, post-natal care and related fields in 2003 would have the ability to access this material via the library catalog.”

Harder teaches options for “rickets prophylaxis” with vitamin D

? Sind Vitamin-D-Tabletten für jedes Kind notwendig?

Die Vorstellung, einem gesunden Säugling jeden Tag eine Tablette zu geben, erzeugt bei vielen Eltern ein gewisses Unbehagen. Das ist verständlich, denn in der Regel werden ja Tabletten zur Behandlung von Krankheiten verordnet. Die tägliche Vitamin-D-Tablette hingegen behandelt keine Erkrankung, sondern soll eine

? Do all children need vitamin D tablets?

Many parents are uncomfortable with the idea of giving a healthy infant a tablet each day. This is understandable, given that tablets are usually prescribed to treat illnesses. The daily vitamin D tablet, by contrast, does not treat an illness, but is designed to prevent the possible occurrence of rickets. Parents need to be given accurate information on vitamin D and rickets by pediatricians, midwives and pediatric nurses so that they can make an informed decision with regard to a form of rickets prophylaxis (see below).

Harder discloses a “simple” use of Vigantol® oil

Option 3

In the case of children who are susceptible to allergies, or where increased bloating is experienced after taking the tablets, Vigantol® oil (1 drop contains 500 I.U.) can also be recommended instead of tablets in both of the options outlined above. The oil has proved to be successful over many years and contains only one excipient as a vehicle for the fat-soluble vitamin D, namely medium-chain triglycerides (vegetable oil). The customary Vigantolletten® contain eleven excipients, namely silicon dioxide, cornstarch, sodium carboxy methyl starch, talc, glycerol tristearate, cellulose, D-mannitol, gelatin, sucrose, partially-hydrated soybean oil and α -tocopherol. Unfortunately, there are no recommended tablets containing fewer excipients. Virgosan® 500 contains lactose (milk sugar), Vitamin D₃-Hevert® is only

Use of the oil is simple: 1 drop of Vigantol® oil is given to the baby to be licked off from the tip of a spoon once a day before a breastfeed or a meal. Under no circumstances should it be

Claim 1 and Harder: Method

A method of delivering a nutritional or therapeutic amount of vitamin D to a human being, comprising:

(i) applying one drop of a composition consisting of a nutritional or therapeutic effective amount of 9 to 9000 mcg/ml vitamin D in a liquid triglyceride of 6 to 12 carbon chain length, to an exterior surface of an object, wherein said drop adheres to the surface of an object; and

(ii) having said human being suck or lick said composition directly from said object

“1 drop of Vigantol® oil . . . to the baby from the tip of a spoon once a day....” (Tinsworth)

“1 drop of Vigantol® oil . . . to the baby to be licked off from the tip of a spoon once a day....” (Sherman)

“Once a day ... 1 drop of Vigantol® oil . . . on the tip of a spoon to lick off.” (Beyunes)

Claim 1 and Harder: Composition

A method of delivering a nutritional or therapeutic amount of vitamin D to a human being, comprising:

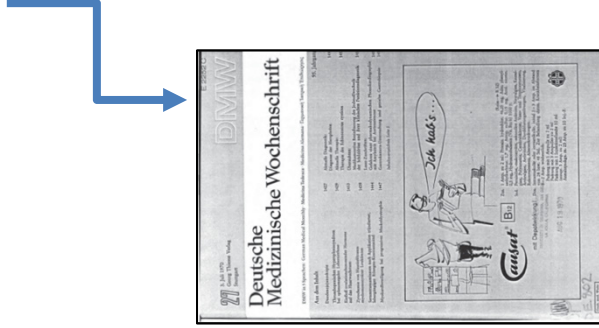
*(i) applying **one drop of a composition consisting of a** nutritional or therapeutic effective amount of **9 to 9000 mcg/ml vitamin D in a liquid triglyceride of 6 to 12 carbon chain length**, to an exterior surface of an object, wherein said drop adheres to the surface of an object; and*

(ii) having said human being suck or lick said composition directly from said object

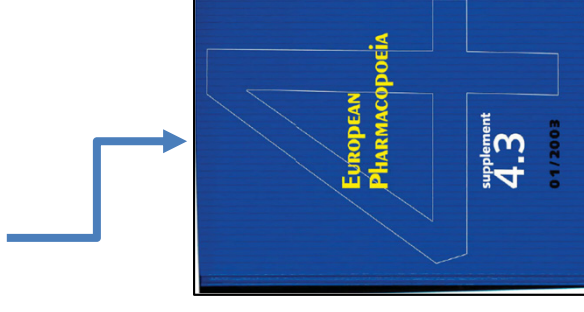
“Vigantol® oil (1 drop contains 500 I.U.) can also be recommended instead of tablets The oil has proved to be successful over many years and contains only one excipient as a vehicle for the fat-soluble vitamin D, namely medium-chain triglycerides.”

“Vigantol® oil (1 drop contains 500 I.U.)” in “medium-chain triglycerides”

“one drop of a composition consisting of a nutritional or therapeutic effective amount of 9 to 9000 mcg/ml vitamin D in a liquid triglyceride of 6 to 12 carbon chain length”

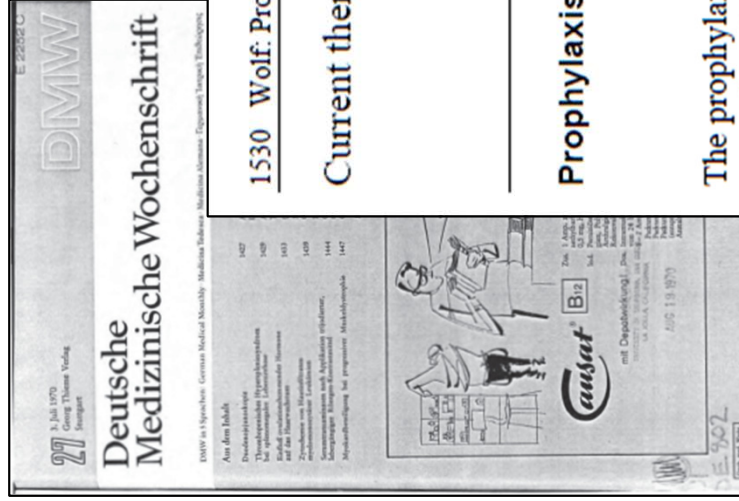


Wolf discloses the composition and dosage of “Vigantol® oil.”



European Pharmacopeia discloses a monograph for “medium chain triglycerides”

Wolf: Prophylaxis of Rickets in Babies (1970)



1530 Wolf: Prophylaxis of rickets in babies

Deutsche Medizinische Wochenschrift

Current therapy

Editorial team:

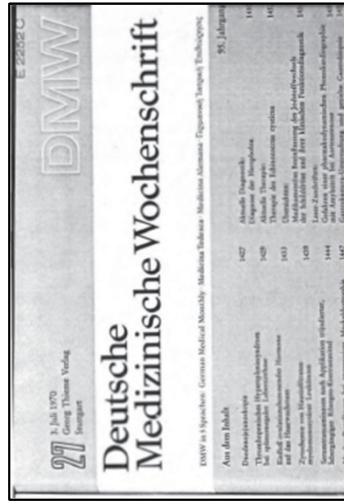
Prof. Dr. H. Hornbostel, Hamburg
Prof. Dr. W. Kaufmann, Tübingen
Prof. Dr. W. Siegenthaler, Bonn

Prophylaxis of rickets in babies

H. Wolf
University pediatric clinic of Göttingen
(Director: Prof. Dr. G. Joppich)

The prophylaxis of rickets, which is essential for young babies at our geographical latitude, is currently a topic of lively discussion, especially in Germany. Preventing rickets means that it is necessary to take vitamin D₃ (cholecalciferol), which counteracts rickets. Current approaches to the prophylaxis of rickets are unsatisfactory for the following reasons: (i) The high prophylactic stoss doses (5–10 mg of vitamin D₃ per stoss dose), as used in the public health service, can involve dangers. (ii) Despite stoss prophylaxis, it was not possible to achieve reliable prevention of rickets. (iii) Enrichment of baby food with vitamin D₃, which is in itself desirable, is managed inconsistently. There are gaps in this “silent” prophylaxis using milk.

Wolf discloses the composition and dosage of Vigantol oil



2. The daily administration of 500 I.U. of vitamin D₃, at least for the first year of life from the newborn phase, is desirable.

Table 1. Prophylaxis of rickets in babies and small children with pure vitamin D₃ preparations

Preparation name	Manufacturer	Vitamin D ₃ content	Daily dose
D-Mulsin®	Mucos	10 g of emulsion = 60 000 I.U. of D ₃	1 drop
D ₃ -Vicotrat®	Heyl	"Oleosum" 1 ml = 0.25 mg = 30 drops = 10 000 I.U. of D ₃	2 drops
Vigantol®	Bayer/Merck	1 ml = 0.5 mg = 30 drops = 20 000 I.U. of D ₃	1 drop
Vigantolekten®	Bayer/Merck	1 tablet = 0.025 mg = 1000 I.U. of D ₃ *	½ tablet
Vigorsan® D ₃	Albert-Roussel-Pharma	1 tablet = 0.025 mg = 1000 I.U. of D ₃ *	½ tablet

Wolf discloses the composition and dosage of Vigantol oil

“one drop of a composition consisting of a nutritional or therapeutic effective amount of 9 to 9000 mcg/ml vitamin D in a liquid triglyceride of 6 to 12 carbon chain length”

98. Based on a calculation of the number of international units per drop using the teaching of Wolf, Wolf teaches a composition of Vigantol oil that is 505.04 micrograms of vitamin D per milliliter, which is within the claimed range of 9 to 9000 micrograms per milliliter:

$$\frac{666.66 \text{ I.U.}}{\text{drop}} \times \frac{.025 \text{ mcg}}{1 \text{ I.U.}} \times \frac{1 \text{ drop}}{0.033 \text{ ml}} = 505.04 \text{ mcg/ml}$$

Wolf's description of Vigantol oil is identical to that disclosed by the '958 Patent

One prescription product contains vitamin D in an unspecified oil, (20,000 IU (500 mcg) per mL of oil). The method for

Table 1. Prophylaxis of rickets in babies and small children with pure vitamin D₃ preparations

Preparation name	Manufacturer	Vitamin D ₃ content	Daily dose
D-Mulsin®	Mucos	10 g of emulsion = 60 000 I.U. of D ₃	1 drop
D ₃ -Vicotrat®	Heyl	"Oleosome" 1 ml = 0.25 mg = 30 drops = 10 000 I.U. of D ₃	2 drops
Vigantol®	Bayer/Merck	1 ml = 0.5 mg = 30 drops = 20 000 I.U. of D ₃	1 drop
Vigantoleiten®	Bayer/Merck	1 tablet = 0.025 mg = 1000 I.U. of D ₃ *	½ tablet
Vigorsan® D ₃	Albert-Roussel-Pharma	1 tablet = 0.025 mg = 1000 I.U. of D ₃ *	½ tablet

European Pharmacopoeia Supplement 4.3



72. The official standards published within the European Pharmacopoeia provide a legal and scientific basis for quality control during the development, production, and marketing processes of medicines, including substances for pharmaceutical use. *See id.* The standards in the European Pharmacopoeia concern the qualitative and quantitative composition of and the tests to be carried out on medicines, on the raw materials used in production of medicines, and on the intermediates of synthesis. *See id.* All producers of medicines and/or substances for pharmaceutical use must therefore apply these quality standards to market their products in the signatory states of the Convention. *See id.*

European Pharmacopeia Supplement 4.3 discloses “medium chain triglycerides”

“one drop of a composition consisting of a nutritional or therapeutic effective amount of 9 to 9000 mcg/ml vitamin D in a liquid triglyceride of 6 to 12 carbon chain length”

TRIGLYCERIDES, MEDIUM-CHAIN

Triglycerida saturata media

DEFINITION

Mixture of triglycerides of saturated fatty acids, mainly of caprylic acid (octanoic acid, $C_8H_{16}O_2$) and of capric acid (decanoic acid, $C_{10}H_{20}O_2$). Medium-chain triglycerides are obtained from the oil extracted from the hard, dried fraction of the endosperm of *Cocos nucifera* L. or from the dried endosperm of *Elaeis guineensis* Jacq.

Content: minimum 95.0 per cent of saturated fatty acids with 8 and 10 carbon atoms.



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Claim 5 and European Pharmacopeia Supplement 4.3

“Claim 5. A method according to claim 1, wherein said triglyceride comprises at least 95% triglycerides having a carbon-chain length selected from 8 to 10.”

TRIGLYCERIDES, MEDIUM-CHAIN

Triglycerida saturata media

DEFINITION

Mixture of triglycerides of saturated fatty acids, mainly of caprylic acid (octanoic acid, $C_8H_{16}O_2$) and of capric acid (decanoic acid, $C_{10}H_{20}O_2$). Medium-chain triglycerides are obtained from the oil extracted from the hard, dried fraction of the endosperm of *Cocos nucifera* L. or from the dried endosperm of *Elaeis guineensis* Jacq.

Content: minimum 95.0 per cent of saturated fatty acids with 8 and 10 carbon atoms.



European Pharmacopeia's description of MCT compared to the '958 Patent description

Medium-chain triglycerides are obtained from the oil extracted from the hard, dried fraction of the endosperm of *Cocos nucifera* L. or from the dried endosperm of *Elaeis guineensis* Jacq. They consist of a mixture of triglycerides of saturated fatty acids, mainly of caprylic acid ($C_8H_{16}O_2$) and of capric acid ($C_{10}H_{20}O_2$). They contain not less than 95 percent of saturated fatty acids having 8 to 10 carbon atoms. The substance is a clear solution.

'958 Patent

Mixture of triglycerides of saturated fatty acids, mainly of caprylic acid ($C_8H_{16}O_2$) and of capric acid ($C_{10}H_{20}O_2$). Medium-chain triglycerides are obtained from the oil extracted from the hard, dried fraction of the endosperm of *Cocos nucifera* L. or from the dried endosperm of *Elaeis guineensis* Jacq.

Content: minimum 95.0 per cent of saturated fatty acids with 8 to 10 carbon atoms.

European Pharmacopeia
Supplement 4.3

Claim 1 and Harder: Properties of the Composition

A method of delivering a nutritional or therapeutic amount of vitamin D to a human being, comprising:

(i) applying one drop of a composition consisting of a nutritional or therapeutic effective amount of 9 to 9000 mcg/ml vitamin D in a liquid triglyceride of 6 to 12 carbon chain length, to an exterior surface of an object, wherein said drop adheres to the surface of an object; and

(ii) having said human being suck or lick said composition directly from said object

“[c]hildren need vitamin D to store calcium, which in turn is needed to strengthen bones.”

“an infant’s minimum daily requirement of vitamin D is 400 I.U. [international units], corresponding to 10 µg or 0.01 mg of crystalline vitamin D (one I.U. of vitamin D corresponds to 0.025 µg of pure crystalline vitamin D3).”

“1 drop of Vigantol® oil . . . to the baby from the tip of a spoon once a day.”

Adherence is a property of “medium chain triglycerides”

53. From Harder’s teachings, it would have already been apparent to a person of ordinary skill that medium chain triglycerides possessed the properties needed to adhere to the surface of an object. Unlike the ’958 Patent, which indicated that the composition was an “unspecified oil,” Harder discloses that Vigantol oil contained “medium chain triglycerides (vegetable oil),” which according to the ’958 Patent, would be sufficiently viscous to adhere to an object. *See id.* at 3–4; MOM-

Harder discloses a “nutritional or therapeutic amount” as property of the recommended dose of Vigantol

Four options for rickets prophylaxis:

In the case of children who are susceptible to allergies, or where increased bloating is experienced after taking the tablets, Vigantol® oil (1 drop contains 500 I.U.) can also be recommended instead of tablets in both of the options outlined above. The oil has proved to be successful over many years and contains only one excipient as a vehicle for the fat-soluble

97. In my opinion, Harder further discloses a daily nutritional or therapeutic amount of vitamin D to a human as a minimum daily requirement of vitamin D of 400 I.U. MOM-1007 at 3.

Wolf also teaches that the recommended dose of Vigantol is a “nutritional or therapeutic amount”

For the continuous (i.e. daily) prophylaxis of rickets, we recommend that, starting from the eighth day of life, 500 I.U. of vitamin D₃ be administered during the first year of life and during the following winter (October to April). This dose is also not toxic when the baby formula used contains 300 I.U. of vitamin D₃ per liter. Drops or tablets should not be added to the bottle, but administered to the baby on a spoon with some liquid.

Table 1. Prophylaxis of rickets in babies and small children with pure vitamin D₃ preparations

Preparation name	Manufacturer	Vitamin D ₃ content	Daily dose
D-Mulsin®	Mucos	10 g of emulsion = 60 000 I.U. of D ₃	1 drop
D ₃ -Vicotrat®	Heyl	“Oleosum” 1 ml = 0.25 mg = 30 drops = 10 000 I.U. of D ₃	2 drops
Vigantol®	Bayer/Merck	1 ml = 0.5 mg = 30 drops = 20 000 I.U. of D ₃	1 drop
Vigantolettlen®	Bayer/Merck	1 tablet = 0.025 mg = 1000 I.U. of D ₃ *	½ tablet
Vigorsan® D ₃	Albert-Roussel-Pharma	1 tablet = 0.025 mg = 1000 I.U. of D ₃ *	½ tablet

* According to the companies, it is currently not possible for pharmaceutical reasons to manufacture one tablet containing only 500 I.U. of vitamin D₃.

Ground 1

Rebuttals to Patent Owners' Arguments

Patent Owner's Arguments

Patent Owners contend:

- Harder is not prior art because it is directed at midwives
- Petitioner requested multiple translations to get the “desired” translation
- Infants cannot lick off a spoon
- Wolf teaches away because it suggests using “some liquid”
- Harder does not disclose adherence
- Harder does not disclose delivering “nutritionally or therapeutic dose”
- There are secondary considerations of non-obviousness

Petitioner's Rebuttal to Patent Owner

- Harder is not prior art because it is directed at midwives?
 - The Board correctly found otherwise:

See supra Section II.B. There is no requirement that a person of ordinary skill in the art would have looked to Harder specifically for the “formulation” of a vitamin D drop, as Patent Owner contends. *See* Prelim. Resp. 33. Rather, a person of ordinary skill in the art may have looked to Harder because they are experienced in delivering medicines and nutritional supplements, and Harder concerns the neonatal care of infants in the home and in the clinic—a topic that conceivably embraces delivering medicines and nutritional supplements to infants. Ex. 1007, 4. Indeed, guidelines recommended daily vitamin D supplementation to infants for the prevention of rickets. *See, e.g.*, Ex. 1009, 6; Ex. 1012, 3.

Petitioner's Rebuttal to Patent Owner

- Harder is not prior art because it is directed at midwives?
 - 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) (citations omitted).

Petitioner's Rebuttal to Patent Owners' Response

- Harder is not prior art because it is directed at midwives?
 - Harder was indexed in a library catalog as pertaining to “Postnatal Care methods”:

15. The 650 field of the MARC record in Appendix HARDER01 indicates *Wochenbettbetreuung in der Klinik und zu Hause* was indexed by subject for the purpose of discovery within a library catalog. The 650 fields included in Appendix HARDER01 indicate that the topic of *Wochenbettbetreuung in der Klinik und zu Hause* could be described as “Postnatal Care,” “Postnatal Care methods,” and “Postpartum Period.”. Library catalogers in the United

Petitioner's Rebuttal to Patent Owners' Response

- Harder is not prior art because it is directed at midwives?
 - Co-inventor Elaine Vieth was a nurse, not a researcher

Q. What is Ms. Vieth's occupation -- or was at the time?

A. Well, in the 1980s, at that time she was a -- at that time she was a part-time nurse.

Q. Was she a registered nurse?

A. Yes.

Q. And what hospital did she work at or hospitals?

A. She worked at the local medical clinic.

Q. How long did she work as a nurse?

A. Number of years? Until -- until around 2005, I guess. Like, in other words, from when she graduated, she was full-time for a few years. She

Petitioner's Rebuttal to Patent Owners' Response

- Petitioner requested multiple translations to get the “desired” translation?

Die **Anwendung** ist einfach: Einmal täglich vor dem Stillen bzw. der Mahlzeit wird 1 Tropfen Vigantol® Öl vorne auf einem Löffel dem Baby zum **Ablecken** gegeben. Es darf nie direkt in den Mund getropft werden! Fallen 2 Tropfen auf den Löffel, kann er abgewischt und neu betropft werden. Nach meiner Beobachtung wird die Tropfen-Einnahme von kritischen Eltern eher akzeptiert und täglich ausgeführt, als eine tägliche Tabletten-Einnahme. Mittlerweile konnte ich auch einige Kinderärzte von den Vorzügen des Öls überzeugen.

Use of the oil is simple: 1 drop of Vigantol® oil is given to the baby **to be licked off** from the tip of a spoon once a day before a breastfeed or a meal. Under no circumstances should it be put directly in the baby's mouth! Should 2 drops fall onto the spoon, the spoon should be washed and the process started again. In my experience, skeptical parents are more likely to be accepting of administering drops on a daily basis than a daily dose of tablets. I have also now been able to convince some pediatricians of the advantages of the oil.

Petitioner's Rebuttal to Patent Owners' Response

- Petitioner requested multiple translations to get the “desired” translation?
 - Mr. Sherman explains why “zum Ablecken” translates directly to “for licking.”

3. I have reviewed one sentence of the translation prepared by Rebecca Amy TINWORTH in 2017, which I understand was submitted during the lawsuit *Ddrops, Inc. v. iHerb, Inc.*, No. 0:16-cv-04278 (D. Minn.). Attached as Exhibit B are minor revisions to Ms. TINWORTH's translation. I confirm that the addition of “to be licked off” as a translation for the German phrase “zum Ablecken” on page 4 of the translation in the fifth line of the second paragraph under Option 3 provides a fuller and more accurate reflection of the German text (MOM-1006). See Ex. B. This is because “zum Ablecken,” which appears on page 21 of the German document (MOM-1006) translates directly to “for licking.” The German word “ablecken” means “to lick off” in English.¹

¹ CAMBRIDGE DICTIONARY, <https://dictionary.cambridge.org/dictionary/german-english/ablecken> (last visited Jul. 25, 2023) (webpage attached as Ex. C).

Petitioner's Rebuttal to Patent Owners' Response

- Petitioner requested multiple translations to get the “desired” translation?
 - Mr. Sherman explains why “zum Ablecken” translates directly to “for licking.”

Translation of **ablecken** – German–English dictionary

ablecken
verb
[infinitive] /'apleken/

[transitive] Löffel

seine Zunge über etw. gleiten lassen
to lick off

• *Sie leckte sich die Finger ab.*
She licked her fingers.

Add to word list

f t

Petitioner's Rebuttal to Patent Owners' Response

- Petitioner requested multiple translations to get the “desired” translation?
- Translators reaffirmed the accuracy of their translations in their depositions.

TRANSLATOR STEPHEN BENYUNES

Q. So sitting here today, do you still believe that your translation is true accurate and complete?

A. To the best of my knowledge, yes.

TRANSLATOR DAVID SHERMAN

Q. (By Ms. Patel) Sitting here today, do you believe that adding the language "to be licked off" where you added it to Ms. Tinworth's 2017 translation makes Ms. Tinworth's 2017 translation more accurate?

MR. ANDERSON: Object to the form of the question.

A. Yes, I do.

Q. (By Ms. Patel) And why is that?

A. It just reflects the German source more accurately. It's a better reflection of my interpreted meaning of the German source text.

Petitioner's Rebuttal to Patent Owners' Response

- Petitioner requested multiple translations to get the “desired” translation?
 - Patent Owner, Dr. Vieth, a German immigrant who speaks German, admitted that “zum Ablecken” means “to lick off.”

Q. Do you speak any German?

A. I was born in Germany and, yes, to some degree.

Q. You spoke it when you were -- did you speak it with your parents at all?

A. Household German, yes.

So you would agree that the key text in Harder that we've been discussing means something to the effect of "Here you go. Lick it off."

A. Yes.

EX. 1039 at 91:7-12, 109:4-7 (objection omitted); Pet. Reply, 10 42

Petitioner's Rebuttal to Patent Owners' Response

- Petitioner requested multiple translations to get the “desired” translation?
 - The translations are also corroborated by multiple German-to-English dictionaries.

Random House Webster's German-English Dictionary

ablecken *v.t.* to lick off.

EX. 1042, 3; Pet. Reply, 10

Collins German Dictionary

ablecken *vt sep* to lick; *Teller* to lick (clean).

EX. 1043, 3; Pet. Reply, 10

Langenscheidt German-English Dictionary

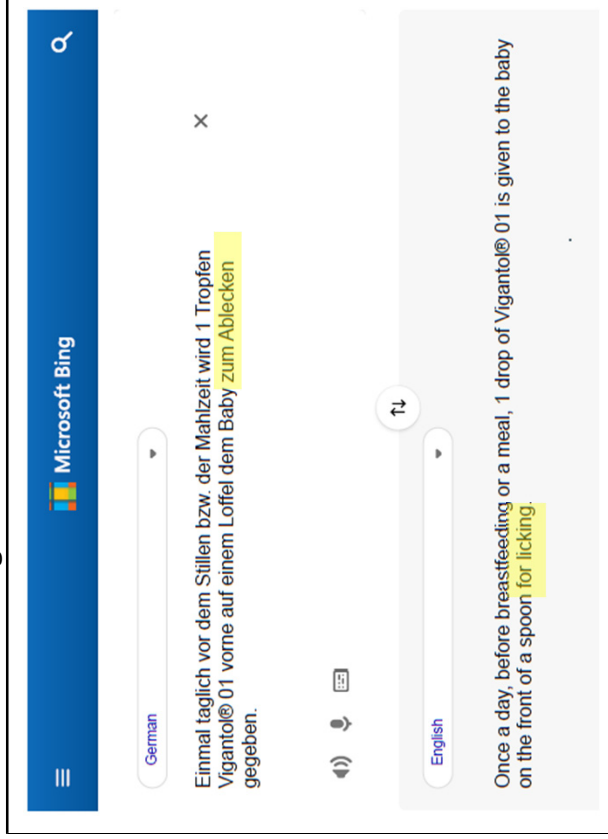
'ablecken *v/t (sep, -ge-, h)* lick (off)

EX. 1044, 3; Pet. Reply, 10

Petitioner's Rebuttal to Patent Owners' Response

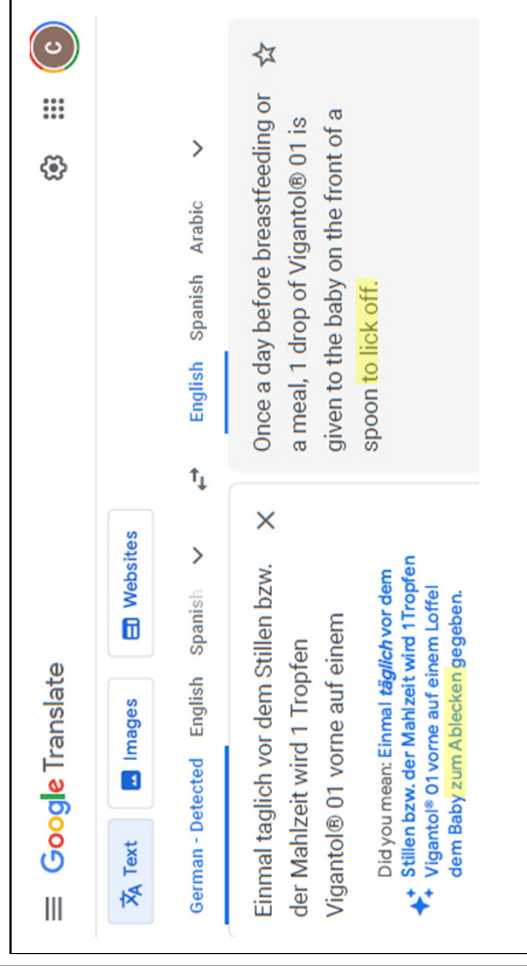
- Petitioner requested multiple translations to get the “desired” translation?
 - The translations are also corroborated by multiple German-to-English machine translations.

Microsoft Bing Translate



EX. 1046; Pet. Reply, 10

Google Translate



EX. 1045; Pet. Reply, 10

Petitioner's Rebuttal to Patent Owners' Response

- **Petitioner requested multiple translations to get the “desired” translation?**
 - Patent Owners did not depose Amy Tinsworth to determine whether she disagrees with corrections to her translation.

Patent Owners engaged their own translator but did not submit a competing translation of the offending sentence.

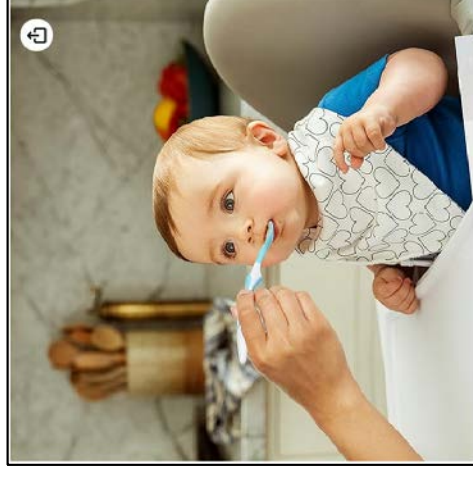
Petitioner's Rebuttal to Patent Owners' Response

- Infants cannot lick off a spoon?
 - Infants can be fed with spoons.

The human being may be an adult or an infant. The term “infant” in this specification includes babies and small children, and the term “adult” includes non-small children.

DR. USHA RAJ, PEDIATRICIAN

17. It is my opinion that the smaller plastic spoon, which has smooth edges, is very suitable for placing a drop of a Vitamin D oil, such as the Ddrops product I received, at its tip for presentation to a baby for the baby to lick the drop off. It is also my opinion that a baby can take the whole spoon into its mouth and suck and/or lick the drop off from this spoon.



Petitioner's Rebuttal to Patent Owners' Response

- Infants cannot lick off a spoon?

Simply Place One Drop.

Directly onto nipple

Into a drink

Onto a clean surface

Ddrops Organic Baby 400 IU 90 Drops - Daily Vitamin D Liquid for Infants.

Supports Teeth & Bone Health. No Preservatives, No Sugar, Non-GMO, Allergy-Friendly

Visit the [Ddrops Store](#)

★★★★★ 13,344

| Search this page

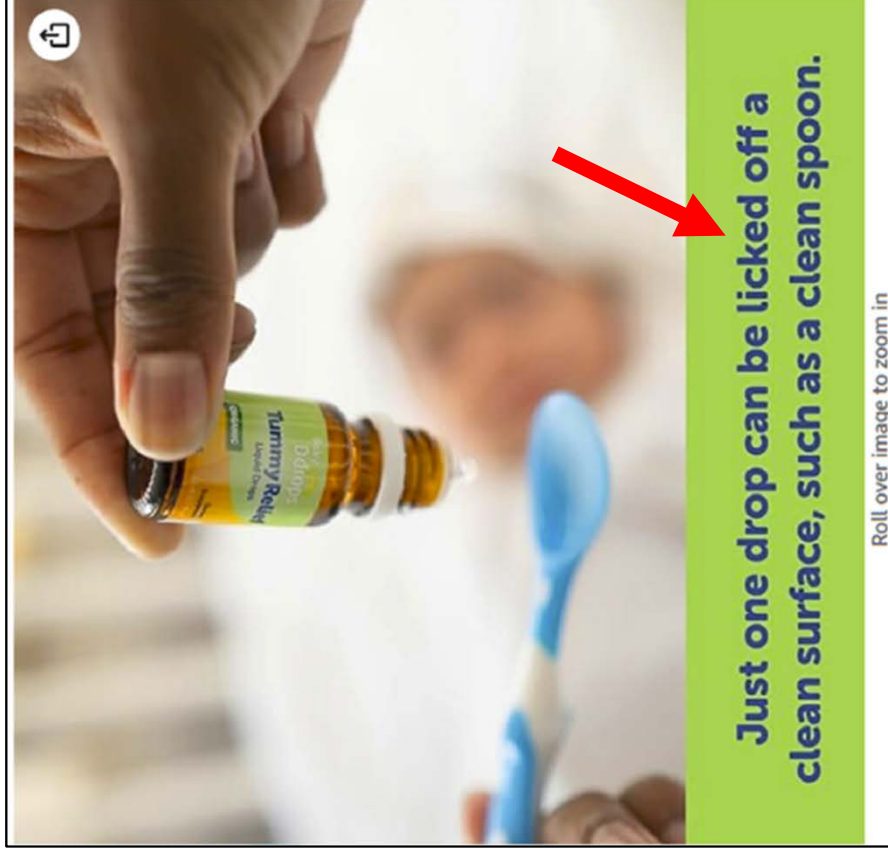
🌱 1 sustainability feature

10K+ bought in past month

Roll over image to zoom in

Petitioner's Rebuttal to Patent Owners' Response

- Infants cannot lick off a spoon?



Roll over image to zoom in

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

Visit the Ddrops Store

4.6 ★★★★★ 14 ratings | Search this page

Sustainably recognized

\$11⁹⁹ (\$99.92 / FL Oz)

prime One-Day

You could have earned \$850.87 in rewards on your Amazon purchases over the past year with 5% back with an Amazon Prime Store Card. Apply now and get a \$60 Amazon Gift Card upon approval. [Learn more](#)

Brand Ddrops

Special Feature Just one drop

Item Weight 0.13 Pounds

Item Dimensions LxWxH 2.68 x 1.57 x 4.41 inches

Product Benefits Gas Relief

Petitioner's Rebuttal to Patent Owners' Response

- **Wolf teaches away because it suggests using “some liquid”?**
 - A reference does not teach away if it “does not criticize, discredit, or otherwise discourage” the solution. In re Fulton, 391 F.3d 1195, 1201 (Fed. Cir. 2004).
 - Wolf does not discourage administering one drop without liquid.

Petitioner's Rebuttal to Patent Owners' Response

- Harder does not disclose adherence?
- The only criteria in the specification is “drips off” vs. “adhere[s] well enough”

TABLE 1

Experimental observation of potential liquids for suitability for nipple vitamin D

Vehicle for vitamin D	Experiment drop behavior on nipple ^a	Taste ^a	mouth-feel ^a	taste ^a	Stability of vitamin D in vehicle	Stability of solvent with storage ^a	present in breast milk
Water	drips off	None	none	none	Poor ^a	Stable	Yes
water-based emulsion (D-vi-sol)	drips off	Yes	no feel	strong taste	50-days on opening ^a	Stable	No
Ethanol	drips off	Yes	no feel	strong taste	Solvent concentration ^a	Evaporates	No
Canola oil	Adheres	Mild	Oily	mild	Stable	Oxidizes/rancidity	No
Olive oil	Adheres	Yes	Oily	mild	Stable	Oxidizes/rancidity	No
Sesame oil	Adheres	Yes	Oily	strong taste	Stable	Oxidizes/rancidity	no
Eitamin E acetate oil	Adheres	None	Oily	none	Uncertain	Stable	no
Medium-chain triglyceride	Adheres	None	slightly oily	none	stable >3 yr ^a	Stable	yes

^aDirect experimental observation.
^aMead-Johnson published stability statement for D-vi-sol.

Petitioner's Rebuttal to Patent Owners' Response

- Harder does not disclose adherence?
 - Patent Owner's expert admits the oil would not “drop off the object and surface.”

Board's Preliminary Construction

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 drop 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

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.

Petitioner's Rebuttal to Patent Owners' Response

- Harder does not disclose adherence?
 - Dr. Raj confirmed Harder's method was feasible as described.

23. After performing this test, I came to the following conclusions:

- a. The recommendation in Harder that one drop of Vitamin D oil be placed at the tip of a spoon and be given to a baby to be licked off if very feasible and easy to perform;
- b. The small plastic spoon is suitable for the method of administration described in Harder;
- c. If the drop rolls down to the center of the spoon, either the spoon should be washed, and the drop placed accurately at the tip of spoon so that the baby can lick it off. Alternately, the entire spoon could be placed in the baby's mouth for the baby to lick and/or suck the drop off.

Petitioner's Rebuttal to Patent Owners' Response

- Harder does not disclose adherence?
 - Viscosity (which impacts adherence) is an inherent property of MCT.

53. From Harder's teachings, it would have already been apparent to a person of ordinary skill that medium chain triglycerides possessed the properties needed to adhere to the surface of an object. Unlike the '958 Patent, which indicated that the composition was an "unspecified oil," Harder discloses that Vigantol oil contained "medium chain triglycerides (vegetable oil)," which according to the '958 Patent, would be sufficiently viscous to adhere to an object. *See id.* at 3–4; MOM-

Petitioner's Rebuttal to Patent Owners' Response

- Harder does not disclose adherence?
 - Harder need not appreciate the properties of Vigantol or explain its functioning when describing the method.



Inherency is not necessarily coterminous with the knowledge of those of ordinary skill in the art. See *Titanium Metals*, 778 F.2d at 780. Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art. See *id.* at 782. However, the 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. See *id.* at 782 (“Congress has not seen fit to permit the patenting of an old [composition], known to others ..., by one who has discovered its ... useful properties.”)

Petitioner's Rebuttal to Patent Owners' Response

- Harder does not disclose a “nutritionally or therapeutic dose”?
 - Harder discloses that using Vigantol oil is “successful” for “prophylaxis of rickets.”

Four options for the prophylaxis of rickets:

In the case of children who are susceptible to allergies, or where increased bloating is experienced after taking the tablets, Vigantol® oil (1 drop contains 500 I.U.) can also be recommended instead of tablets in both of the options outlined above. The oil has proved to be successful over many years and contains only one excipient as a vehicle for the fat-soluble vitamin D, namely medium-chain triglycerides (vegetable oil). The customary Vigantolletten®

Use of the oil is simple: 1 drop of Vigantol® oil is given to the baby to be licked off from the tip of a spoon once a day before a breastfeed or a meal. Under no circumstances should it be put directly in the baby's mouth! Should 2 drops fall onto the spoon, the spoon should be washed and the process started again. In my experience, skeptical parents are more likely to be accepting of administering drops on a daily basis than a daily dose of tablets. I have also now been able to convince some pediatricians of the advantages of the oil.

Ground 2

Claim 3 is Obvious Over Harder, Wolf,
European Pharmacopoeia Supplement
4.3, and Blass

Claim 3 is Obvious Over Harder, Wolf, European Pharmacopoeia Supplement 4.3, and Blass

3. A method as claimed in claim 1, wherein said human being is an infant and said object is a woman's nipple or the external surface of a pacifier.

Claim 3: Motivation to Combine

- The spoon disclosed in Harder is not a natural surface for an infant, in contrast with a nipple or nipple-like shape.

like that disclosed in Harder. It would have been obvious to improve the method of Harder by applying the drop to a pacifier instead of to the tip of the spoon, because a POSITA would recognize, as a matter of common sense and human experience, that the spoon disclosed in Harder is not a natural surface for an infant, in contrast with a nipple or nipple-like shape, and may sometimes inhibit an effective delivery if the infant refuses to suck. The '958 Patent recognizes that "infants often spit out at least some of the liquid" vitamin D supplement drops. MOM-1001 at 2:47-48. A POSITA would be motivated to use a surface, such as a pacifier, that would more likely trigger the sucking reflex to ensure delivery of the complete dose applied to the surface.

Claim 3: Motivation to Combine (cont'd)

- Dr. Vieth submitted prior art during prosecution showing that administering oral vitamin D on a nipple was a method already in use.

14. Furthermore, we disclosed to the examiner the Scanlon, “Vitamin D Expert Panel Meeting – Final Report,” which on its page 21 states without further discussion, “A solution in Germany is to put an oral vitamin D preparation on the mother’s nipple once a day before the baby breastfeeds”. There was no elaboration whether that preparation was aqueous, emulsion, or oil, liquid, powder or cream; there was no mention of how much was to be applied; and there was no mention of what percentage of the applied dose was actually swallowed by the infant.

Claim 3: Motivation to Combine (cont'd)

- Nipples are the way babies feed. Pacifiers are a “common” “alternative.”

14 Q. What gave you the idea of a pacifier?

15 A. Umm ...

16 Q. Was it your idea or was it your wife's
17 idea?

18 A. I didn't want to suck nipples on babies
19 and a pacifier is a reasonable parental alternative
20 for people to give to a baby, a common one.

21 Q. So why were nipples in the question?

22 A. Because that's how a baby is breast
23 feeding.

Claim 3: Motivation to Combine (cont'd)

- A POSITA would know that a pacifier would be more effective than a spoon.

1 Q In 2006, would a person of skill in the art
2 have understood or believed that a pacifier would be
3 a more effective method of administration than a
4 spoon for an infant?
5 MS. FLORENCE: Objection, form. Go ahead
6 and answer to the extent you can.

7 THE WITNESS: I think a person of ordinary
8 skill in the art would know that a baby is more
9 likely to suck on a pacifier than off of a spoon.

Blass: Suckling- and Sucrose-Induced Analgesia in Human Newborns (1999)

- Blass demonstrates that an infant could suck medicine or a supplement (like sucrose) off the surface of a pacifier.

“Forty full term infants newly born ... were randomly assigned to one of four experimental groups (n = 10 infants/group) representing the treatments of sucrose alone, water alone, a pacifier dipped in water or one dipped in sucrose.”

“The infant ... sucked a pacifier (Mam Mini Mam orthodontic pacifier) dipped in the assigned solution”



PAIN

www.elsevier.com/locate/pain

Pain 83 (1999) 611–623

Suckling- and sucrose-induced analgesia in human newborns

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Received 20 January 1999; received in revised form 17 May 1999; accepted 28 June 1999

Abstract

This experiment had three goals: 1. To identify the basis of suckling-induced analgesia in healthy, term, newborn humans undergoing the painful, routine procedure of heel lance and blood collection. 2. To evaluate how taste-induced and suckling-induced analgesias combine to combat pain. 3. To determine whether facial grimacing was an accurate index of diminished pain, or whether it was linked to tissue trauma. We report that: 1. Sucking an unlabeled pacifier was analgesic, when and only when suck rate exceeded 50 sucks/min. 2. The combination of suckling and sucrose was analgesic, when and only when suck rate exceeded 50 sucks/min. 3. Sucrose was analgesic, when and only when it was tasted. 4. Grimacing was reduced to almost nought by procedures that essentially eliminated crying and markedly reduced heart rate during the blood harvesting procedure. © 1999 International Association for the Study of Pain. Published by Elsevier Science B.V.

Keywords: Human newborns; Pain; Heel lance; Suckling; Sucrose; Pacifier; Crying; Grimacing; Heart rate

1. Introduction

Suckling-induced analgesia (SIA) is of current theoretical and applied interest in pediatrics and developmental neurobiology (Blass, 1996; Stevens et al., 1997; Barr et al., 1999; Blass et al., 1999a). Causal relationships have been established between suckling, a noninvasive and nonpharmacological treatment, and analgesia (Fried and Colquhoun, 1990; O'Connor, 1994; Blass, 1996; Barr et al., 1999). Campos, 1994; Blass and Shah, 1995; Barr et al., 1998) and some underlying mechanisms have been identified (Blass and Fitzgerald, 1988; Blass et al., 1987; Ren and Blass, 1997). The two identified components of SIA utilize separate detection systems and neural mechanisms to reach a final common analgesia pathway. The orostatory component has been engaged in both rat (Blass and Fitzgerald, 1988; Shide and Blass, 1989) and full term (Blass and Hoffmeyer, 1991; Blass and Caramanico, 1994; Blass and Hoffmeyer, 1991; Blass et al., 1996; Ren and Blass, 1997a,b). Nonnutritive suckling of either a pacifier or a nonlactating nipple causes analgesia in both human and rat full term newborns through stimulation of oropharyngeal tactile- and mechanoreceptors (Smith et al., 1990; Blass et al., 1995). The analgesic qualities of nonnutritive suckling in premature infants have not yet been assessed (see Stevens et al., 1997 for meta-analysis). Taste-induced analgesia in both human (Blass et al., 1989; Smith et al., 1990) and rat (Blass and Fitzgerald, 1988; Shide and Blass, 1989) newborns endures well after ingestion has been completed. It is mediated by opioid mechanisms. It does not survive naloxone and therefore is not a taste-induced analgesia (Blass, 1989; Blass and Shide, 1994) and does not appear in infants born to women who were maintained on methadone during pregnancy (Blass and Caramanico, 1994). In contrast, orostatic induced calming and analgesia in rat and human infants terminates almost immediately upon sucking completion and is not opioid mediated (Blass and Caramanico, 1994). It is not blocked by high doses of naloxone in rats and sucking very effectively calmed infants with a prenatal methadone history who were not calmed by sweet tastes (Blass and Caramanico, 1994). In human infants, in 10–60 min after birth, the analgesic effect of the pacifier and unlabeled frunites (Blass, 1996). Combining nonnutritive suckling (NNS) with sweet taste is even more protective (Ren and Blass, 1997). Opioid influences on analgesia in human infants have been evaluated in only four studies, however. NNS reduces crying during circumcision by about 30% (Blass and Hoffmeyer, 1991; Gunnar et al., 1984) and sucking a sweet pacifier caused a

Blass: Suckling- and Sucrose-Induced Analgesia in Human Newborns (1999)

- Blass demonstrates that an infant could suck medicine or a supplement (like sucrose) off the surface of a pacifier.

“relative to the water-control and water-pacifier groups, sucrose in combination with a pacifier, drastically reduced crying and grimacing during the painful procedure of heel lance.”

“[s]weet solutions can be readily given to infants on a pacifier in advance of and during necessary treatments or evaluations that may be moderately painful.”



PAIN

www.elsevier.com/locate/pain

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Suckling- and sucrose-induced analgesia in human newborns

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Ground 2

Rebuttals to Patent Owner's Arguments

Petitioner's Rebuttal to Patent Owners' Response

- Blass has “nothing to say about delivering medication”?
 - A POSITA would have understood from Blass that a pacifier could deliver a “solution” (like sucrose) on its surface.
 - 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).

Petitioner's Rebuttal to Patent Owners' Response

- Examiner distinguished Blass based on the arguments presented by Patent Owners during prosecution?
 - The Examiner did not consider Blass in light of the missing one-drop vitamin D composition disclosed in Harder.

REASONS FOR ALLOWANCE

The following is an examiner's statement of reasons for allowance: The cited references in combination fail to teach, motivate or suggest a vitamin D composition consisting of vitamin D and a liquid triglyceride of 6 to 12 carbon chain length and a method of delivering the vitamin D composition wherein a single drop of a vitamin D composition consisting of vitamin D in a liquid triglyceride is applied to a surface so that the single drop would adhere to the object, until it is sucked or licked off of the surface, and thus effectively administer the desired level of vitamin D to the user. One skilled in the art would not be motivated to apply a single drop of the

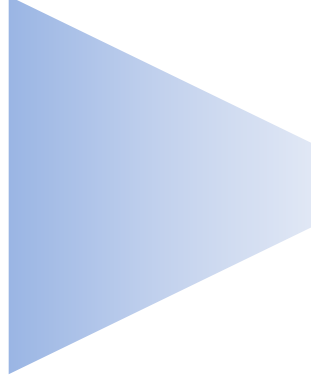
Ground 3

Claim 4 is Obvious Over Harder, Wolf,
European Pharmacopoeia Supplement
4.3, and Gartner

Claim 4 is Obvious Over Harder, Wolf, European Pharmacopoeia Supplement 4.3, and Gartner

4. A method according to claim 1, wherein the composition consists of from 150 to 450 mcg/ml vitamin D in a liquid triglyceride of 6 to 12 carbon chain length.

9 to 9000 mcg/ml vitamin D (Claim 1)



150 to 450 mcg/ml vitamin D (Claim 4)

Gartner: Prevention of Rickets and Vitamin D Deficiency: New Guideline for Vitamin D Intake

BACKGROUND

Cases of rickets in infants attributable to inadequate vitamin D intake and decreased exposure to sunlight continue to be reported in the United States.¹⁻³ Rickets is an example of extreme vitamin D deficiency. A state of deficiency occurs months before rickets is obvious on physical examination. The new recommended adequate intake of vitamin D by the National Academy of Sciences (NAS) to prevent vitamin D deficiency in normal infants, children, and adolescents is 200 IU per day.⁴ This differs from the 400 IU per day that has been recommended in previous editions of the *Pediatric Nutrition Handbook* of the American Academy of Pediatrics (AAP). The new NAS guidelines for infants are based on data primarily from the United States, Norway, and China, which show that an intake of at least 200 IU per day of vitamin D will prevent physical signs of vitamin D deficiency and maintain serum 25-hydroxy-vitamin D at or above 27.5 nmol/L (11 ng/mL). Although there are generally less data

Gartner teaches the new recommended vitamin D intake for all infants as 200 I.U. of vitamin D for the first two months of life.

Gartner: Motivation to Combine

- A POSITA would have been motivated to combine Harder, Wolf, and European Pharmacopoeia Supplement 4.3 with Gartner for an updated recommendation of dosage.

nation. The new recommended adequate intake of vitamin D by the National Academy of Sciences (NAS) to prevent vitamin D deficiency in normal infants, children, and adolescents is 200 IU per day.⁴ This differs from the 400 IU per day that has been recommended in previous editions of the *Pediatric Nutrition Handbook* of the American Academy of Pediatrics (AAP). The new NAS guidelines for infants are based on data primarily from the United States, Norway, and China, which show that an intake of at least 200 IU per day of vitamin D will prevent physical signs of vitamin D deficiency and maintain serum 25-hydroxy-vitamin D at or above 27.5 nmol/L (11 ng/mL). Although there are generally less data

EX. 1012 at 908; *Petition*, 36-37

93. Gartner would thus motivate a POSITA to manufacture a dosage of 200 I.U. of Vitamin D (which is lower than the 666.66 I.U. disclosed in Wolf and the 500 I.U. disclosed in Harder). A POSITA would then understand, based on this recommendation, to reduce the concentration of one drop of Vigantol oil to align with the updated teachings of a respected source like the American Academy of Pediatrics in 2003.

EX. 1004, ¶93; *Petition*, 36-37

Gartner: Motivation to Combine (cont'd)

- Gartner was published in *Pediatrics*—the journal referenced in Wolf.

BASED ON WOLF

90. As demonstrated by Wolf, ongoing studies can result in changes in the recommended dosages of vitamin D supplements. See *id.* In my opinion, like the authors of Wolf, a POSITA would consult peer reviewed journals like *Pediatrics* to determine the current state of art for the appropriate daily dosage to deliver a nutritional and therapeutic amount of vitamin D in supplements like Vigantol oil.

WOLF Citing *Pediatrics*

Literature

(1) American Pediatric Society, Committee on Nutrition: The prophylactic requirement and the toxicity of Vitamin D, *Pediatrics* 31 (1963), 512.

Gartner: Motivation to Combine (cont'd)

to 200 I.U. (5 mcg) per day. MOM-1012 at 908. A POSITA would therefore be motivated to reduce the dosage of vitamin D resulting from teachings in Wolf (666.66 I.U. in one drop, or 505.04 mcg/ml) to meet the daily recommended dosage of vitamin D intake taught by Gartner.

Claim 4 is Obvious Over Harder, Wolf, European Pharmacopoeia Supplement 4.3, and Gartner

109. Based on a calculation applying the updated recommended dosage of 200 I.U. per day taught by Gartner to the teachings of Wolf, a daily administration of vitamin D would result in an infant or child receiving 151.51 mcg/ml from one drop of Vigantol oil—which is within the range of 150 to 450 mcg/ml in Claim 4:

$$\frac{200 \text{ I.U.}}{\text{drop}} \times \frac{.025 \text{ mcg}}{1 \text{ I.U.}} \times \frac{1 \text{ drop}}{0.033 \text{ ml}} = 151.51 \text{ mcg/ml}$$

Id. Gartner further confirms that a POSITA would reduce the daily intake of vitamin D taught by Wolf. Gartner teaches that at the time of its publication, the dosage of vitamin D of 400 I.U. per day, which was recommended in previous editions of the *Pediatric Nutrition Handbook*, would have resulted in one drop of Vigantol oil containing 303.03 mcg/ml of vitamin D, which also is within the claimed range.

Claim 4 is Obvious Over Harder, Wolf, European Pharmacopoeia Supplement 4.3, and Gartner

110. Harder also teaches that a POSITA would reduce the daily intake of vitamin D taught by Wolf. Based on a calculation applying the recommended dosage of 500 I.U. per day taught by Harder to the teachings of Wolf, the lower recommended dosage of vitamin D disclosed in Harder would also result in an infant receiving a drop of Vigantol oil within the 150 to 450 mcg/ml range limitation in

Claim 4:

$$\frac{500 \text{ I.U.}}{\text{drop}} \times \frac{.025 \text{ mcg}}{1 \text{ I.U.}} \times \frac{1 \text{ drop}}{0.033 \text{ ml}} = 378.79 \text{ mcg/ml}$$

Secondary Considerations of Non-Obviousness

Patent Owners Cannot Establish a Nexus to the Claimed Invention



“In order to accord substantial weight to secondary considerations in an obviousness analysis, the evidence of secondary considerations must have a nexus to the claims, *i.e.*, **there must be a legally and factually sufficient connection between the evidence and the patented invention.** The patentee bears the burden of showing that a nexus exists. To determine whether the patentee has met that burden, we consider the correspondence between the objective evidence and the claim scope.”

Patent Owners Cannot Establish a Nexus to the Claimed Invention (cont'd)

- The '958 Patent is directed to a *method* of administration—not a *product*.
- The Ddrops product has unclaimed properties and non-infringing methods of administration.



Patent Owners Cannot Identify Any Feature in Drops’ Product That Was Not Already Known



“In evaluating whether the requisite nexus exists, the identified objective indicia must be directed to what was not known in the prior art — including patents and publications — which may well be the novel combination or arrangement of known individual elements.”

Patent Owners' Evidence Praises Unclaimed Properties and Methods of Administration

- At most, praise for Ddrops is tied to other products in the Americas lacking the “one drop” feature of Vigantol.

6 **Q** At that time in 2006, there was no one drop

7 vitamin D delivery system on the market in Canada,

8 correct?

9 **A** 2006, no, there wasn't because I had a

10 two-year-old at that time and the only vitamin D

11 that we could give her was the D-vi-sol.

12 **Q** And D-vi-sol was a liquid medication that

13 provided via dropper, is that right?

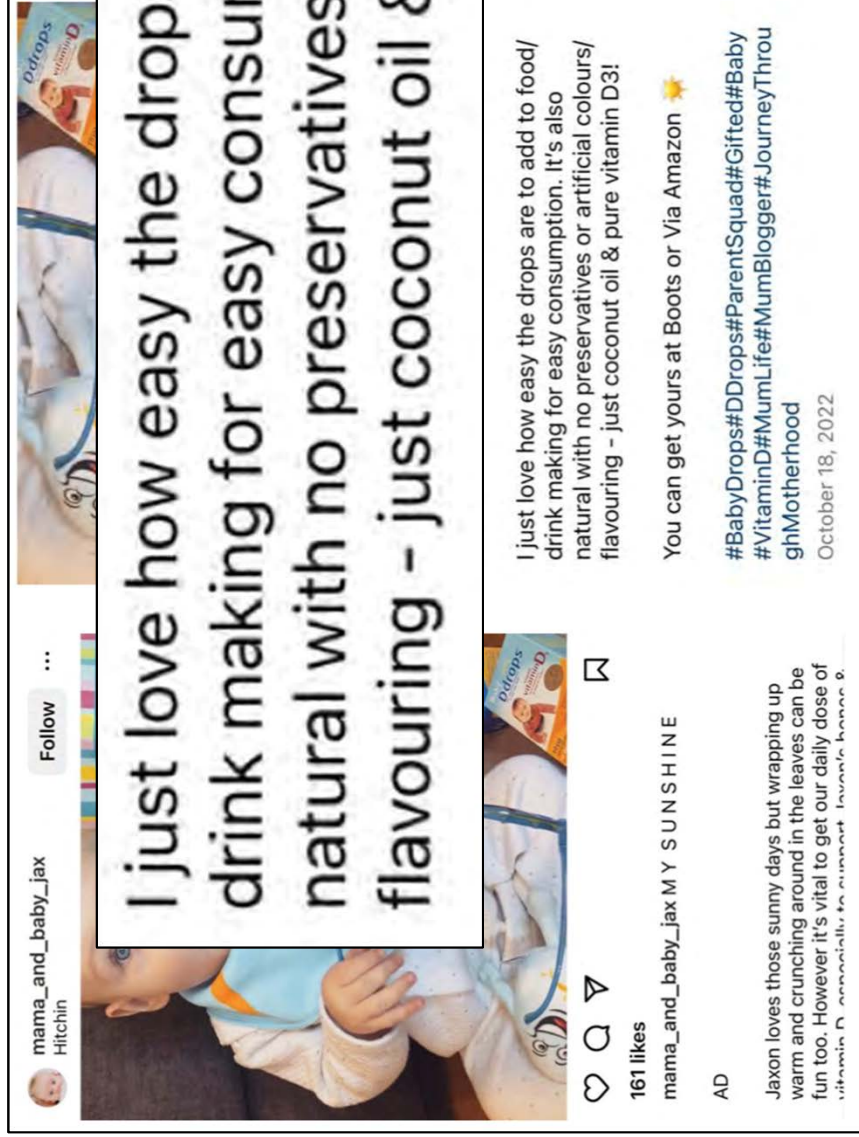
14 **A** Yes, it's a liquid emulsified medication and

15 you need one milliliter to dispense one dose with a

16 bulb dropper at the time.

Patent Owners' Evidence Praises Unclaimed Properties and Methods of Administration

- Patent Owner's hearsay evidence demonstrates that success is not tied to the claimed limitation of placing a drop *on a surface*.



Patent Owners' Evidence Praises Unclaimed Properties and Methods of Administration (cont'd)

- Patent Owner's hearsay evidence demonstrates that success is not tied to the claimed limitation of placing a drop *on a surface*.

Reviewed in the United States on June 8, 2023
Size: 0.08 Fl Oz (Pack of 1) **Verified Purchase**

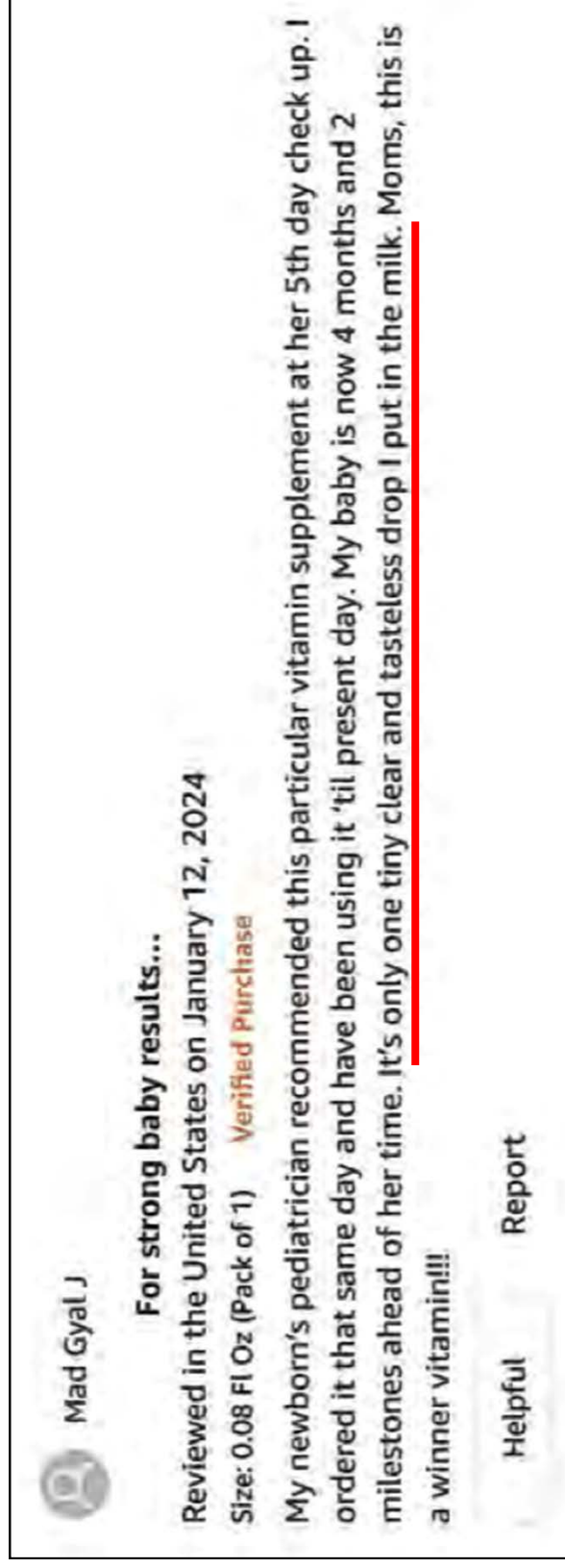
Way better than the prescription vitamin d that is overly sweet and is "butterscotch" flavor that the pediatrician prescribed. My newborn hated it, I tried it and it the amount of sweetness made my mouth feel disgusting. Found these drops and they have a buttery unflavored sweetness to them. The drop coats the mouth and cant be spit out, baby didn't hate it and didn't gag or spit it out due to the taste unlike the prescription. Super easy to administer, not sure why people are complaining, definitely a "user error" situation. I sometimes miss because my baby moves but it's rare to miss since the drop is slow and can calculate when it will drop and that's when I open my baby's mouth.

3 people found this helpful

Helpful Report

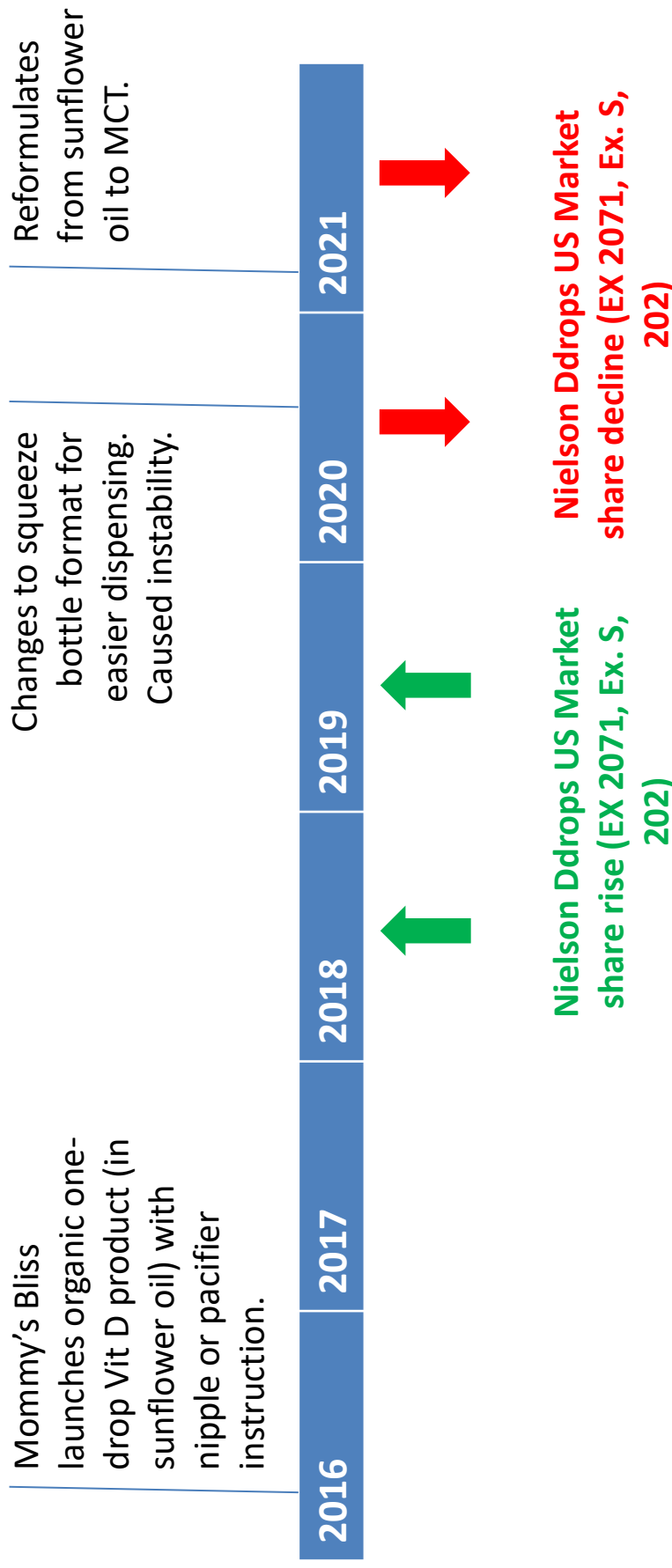
Patent Owners' Evidence Praises Unclaimed Properties and Methods of Administration (cont'd)

- Patent Owner's hearsay evidence demonstrates that success is not tied to the claimed limitation of placing a drop *on a surface*.



Petitioner’s Alleged Copying Does Not Support Non-obviousness

- Patent Owners’ “two-step” copying argument leading to Ddrops’ decline is temporally impossible.



Other Reasons Explain Why Petitioner's Product Was Successful

- Petitioner launched “organic” Vitamin D product in baby care aisle with many other baby-oriented products.
- Ddrops has tried to regain market share by reformulating as “organic” and introduce new baby products to expand beyond the vitamin aisle.



Questions?