

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MOM Enterprises, LLC,
Petitioner,

v.

ELAINE AND REINHOLD VIETH,
Patent Owners,

Case IPR 2023-00726
Patent 9,066,958

DECLARATION OF WARREN D. WOESSNER

VIETH EXHIBIT - 2009
MOM Enterprises, LLC, v. ELAINE AND REINHOLD W. VIETH
IPR2023-00726

I, Warren D. Woessner, declare and state as follows under penalty of perjury:

I. BACKGROUND

1. I have been retained by Ddrops Company, Reinhold Vieth, and Elaine Vieth.

2. I have reviewed and considered:

Petition and Exhibits (MOM-1001 to MOM-1018) filed by the petitioner in IPR2023-00726.

All documents referred to herein.

Declarations and Reports submitted in Civil Action No. 16-4278, Ddrops Company, *et al.* v. iHERB, INC., *et al.*, including Preliminary Expert Report of Warren D. Woessner and materials referred to therein; Declaration of Robert O. (Bill) Williams III, Ph.D. In support of Defendants' Opposition to Plaintiffs' Renewed Motion for Preliminary Injunction; Declaration of David R. Conrad In Support of Defendants' Opposition to Plaintiffs' Renewed Motion for Preliminary Injunction; and Rebuttal Expert Report of Warren D. Woessner support of Plaintiffs' Renewed Motion for Preliminary Injunction and materials identified, referred to, and cited therein.

3. A true and correct copy of the Declaration of Warren D. Woessner and The Preliminary Expert Report of Warren D. Woessner in Civil Action No. 16-4278 Ddrops Company, *et al.* v. iHERB, INC., *et al.*, both dated December 22, 2016, are attached as Exhibit WW-A.

4. A true and correct copy of the Second Declaration of Warren D. Woessner and The Rebuttal Expert Report of Warren D. Woessner in Support of Plaintiffs' Renewed Motion for Preliminary Injunction in Civil Action No. 16-4278, Ddrops Company, *et al.* v. iHERB, INC., *et al.*, both dated May 23, 2017, are attached as Exhibit WW-B.

5. I am educated and knowledgeable in the area of chemistry, including medical and pharmaceutical chemistry and have written and prosecuted patent applications in those areas throughout my career. I am also an expert in the field of patent law and practice, but have constrained this declaration to technical matters. I consider myself to be a person of greater than ordinary skill in the field of US Patent 9,066,958 (the “'958 Patent”). I have over 30 years of experience in intellectual property law, including, but not limited to, preparing and prosecuting United States patent applications, counseling, transactions, and the preparation of patentability opinions, infringement opinions, and validity opinions, much of this work has been in the chemical and biological arts and thus have maintained my technical knowledge and expertise in the field of the '958 Patent. A copy of my

resume, which outlines my educational background, work experience, and presentations/publications is attached hereto as Exhibit WW-C. My resume identifies the articles I have published within the last ten years.

6. I received a Bachelor of Arts degree in chemistry in 1966 from Cornell University and earned a Ph.D. in chemistry at the University of Wisconsin – Madison in 1971.

7. Following a post-doctoral fellowship in the Department of Medical Chemistry, School of Pharmacy, at the University of Wisconsin in 1971-72, I joined Miles Laboratories as a Research Scientist in their Natural Products Laboratory. There I worked on the synthesis of new drug candidates from 1972-1978. I have authored or co-authored a number of scientific publications in the area of synthetic organic chemistry, and hold more than 15 U.S. patents.

8. I entered the Law School of the University of Wisconsin in 1978 and earned my J.D. degree *cum laude* in 1981.

9. I have extensive experience with patents, including applying my technical knowledge to evaluating the patentability of inventions and evaluating the validity, enforceability, and infringement of patents in the pharmaceutical and biotechnology areas. Moreover, I have drafted and successfully prosecuted hundreds of patent applications before the United States Patent and Trademark Office (“PTO”).

10. I have participated in or supervised the prosecution of hundreds of United States patent applications before the PTO concerning mechanical, chemical, biotechnology, medical device, and pharmaceutical inventions, including methods of medical treatment and the administration of bioactive agents. I have argued several appeals successfully before the PTO Board of Patent Appeals and Interferences. I have been a member of the American Intellectual Property Law Association since 1984; have been chair of the Chemical Practice Committee and the Biotechnology Committee; a member of the Amicus Committee; and am currently a Fellow of the Association.

11. I am being compensated for my services at a rate of \$500 per hour. No part of my compensation is contingent on the outcome of this proceeding or the concurrent litigation.

US PATENT 9,066,958

12. US Patent No. 9,066,958 (the “958 Patent”) issued on June 30, 2015, from U.S. patent application Serial No. 11/674,234 (“the ‘234 Application”). The Application claimed priority from Canadian patent application 258,202, filed on September 14, 2006.

13. The goal of the inventors of the ‘958 Patent was to meet the need for a simple method to administer a precise amount of vitamin D in a small, controlled amount of solvent. Such a method is medically important since the minimal daily

requirement can be met by very small quantities of vitamin D, i.e., 10 µg of vitamin D₃ per day for an infant. *Id.*, 3:53-6:5. While low doses of vitamin D can prevent the onset of rickets in infants, higher doses can cause hypercalcemia and related toxic effects. MOM-1008/MOM-1009. The method must be simple and reproducible by the consumer, such as the care provider of an infant. MOM-1001 7:60-8:23.

14. The inventors' claimed method provides the daily requirement of vitamin D (400 IU) in a single drop that adheres to a surface such as a pacifier or skin, such as the mother's nipple. The baby, older child, or adult can ingest the appropriate amount of vitamin D by licking or sucking the composition from the surface. The inventors obtained the '958 Patent on this method.

15. The recitation of "wherein said [applied] drop adheres to the surface of said object" in the '958 Patent, claim 1 is important. The Petition and MOM-1004 read this language out of the claim by ignoring the role that the "object" plays in adhering (or in the case of Harder, not adhering).

16. The Examiner of the '958 Patent included in his Reasons for Allowance: "One skilled in the art would not be motivated to apply a single drop of the vitamin D composition to the exterior surface of an object including an arm or a hand because it may drip off or get contaminated. Thus, the claimed method are [sic] novel and non-obvious over the prior art." MOM-1002, page 28. The

significance of this statement is that the examiner found the “may drip off,” i.e., not adhere, is what the prior art showed and “adhered” is what the prior art did not suggest. The collection of references, even taken as a whole, show only delivery of compositions by procedures that would have the substance drip off the delivery object. Harder shows a substance that would drip off the spoon and Blass shows a substance that drips off the pacifier. The other references asserted do not show any delivery step at all.

17. Petitioner’s arguments that the “adherence” requirement is inherently present in prior art vitamin D compositions fails because: (a) the Harder reference is silent on adhering to the spoon, (b) I have confirmed that one drop of a composition consisting of Vitamin D and medium-chain triglycerides (Baby Ddrops) does not adhere to all surfaces to which the drop is applied, and (c) Petitioner has not shown the composition of the Vigantol oil at the time of Harder or at the effective filing date of the ‘958 Patent.

18. Apart from the fact that MOM-1004 does not establish the composition of the Vigantol oil discussed in the primary Harder reference, MOM-1006 and MOM-1007, the secondary references do not remedy the deficiencies in the primary reference.

19. The *European Pharmacopoeia* 4th Ed., Supplement 4.3, MOM-1010, relates to aspects of certain medium-chain triglycerides and not to any composition

that includes an active ingredient or administration and dosing of an active ingredient.

20. Wolf, MOM-1008 (and MOM-1009), relates to composition and dose, but has no teachings regarding a method of administration according to claim 1. Wolf does not disclose a drop and an object wherein the drop adheres to the object.

21. Bass, MOM-1011, reports the analgesic effects resulting from babies licking sugar water from the surface of a pacifier that has been dipped multiple times into the sugar solution.

22. Gartner, MOM-1012, relates only to concentration and dose, but has no teachings regarding a method of administration according to claim 1.

23. For the purpose of this report, I rely on the Claim Construction Order in the concurrent litigation. Ex. 2005. I rely on the ordinary meaning of claim terms not addressed in the order.

a. Claims 1 and 5 of the ‘958 Patent are not Obvious under Asserted Ground 1.

24. Harder, MOM-1006, is silent about whether or not one drop of Vigantol oil adheres to the spoon as required by the limitation of claim 1, “wherein said drop adheres to the surface of said object.”

25. As noted above, the vitamin D/medium chain triglycerides (MCT) composition recited in claim 1 is applied to the exterior surface of an object and adheres thereto so that a human, such as an adult or an infant can lick or suck the

composition directly from the surface, so as to ingest an effective dose of vitamin

D. The patent does not say that any C₆-C₁₂ or C₈-C₁₀ triglyceride mixtures will adhere to all surfaces. Patent claim 1 requires that whatever exact composition within the recited range and whatever object is used in the method must have, in combination, characteristics that will adhere to each other. The petition does not cite any prior art that satisfies this limitation or anything in the prior art that suggests this limitation.

26. The recitation of claim 5, in this respect, is the same as claim 1 except that the range of compositions recited in claim 5 is narrower than claim 1.

b. The Profile of the MCT Present in Vigantol Oil is Unknown.

27. The record contains no reliable evidence regarding the composition(s) of the MCT solvent in Vigantol oil available prior to 2006. The primary Harder reference only discloses that the solvent contains “medium chain triglycerides (vegetable oil).” MOM-1007, page 6.

28. Wolf only gives the concentration of vitamin D in an unspecified carrier. MOM-1008/MOM-1009.

29. The Petition falls far short of demonstrating that any MCT mixture would necessarily and inevitably adhere to the surface of a spoon (made of what?) as stated in Harder, much less to the surface of any object.

c. MCT is not Universally Adherent to all Surfaces

30. According to the MOM-1004, ¶50, because the ‘958 Patent “recognizes the importance of viscosity of the liquids in adherence to an object ... if an oil has a carbon chain length of 6-12 and is a [MCT], it will have a sufficient viscosity to adhere to an object each and every time.”

31. The Petition presents the conclusory and circular argument that because Plaintiffs’ claim 1 recites the claim limitation “wherein the drop [of the composition] adheres to the surface of said object,” that the disclosure in Harder that “[one] drop of Vigantol[®] oil is given to the baby from the tip of a spoon,” combined with the unsupported opinion in MOM-1004 that all MCTs are universally adherent to all surfaces, renders the selection of C₆-C₁₂ MCTs that will adhere to a given surface as an inherent property of the composition recited in claim 1. MOM-1004 ¶54, Petition, page 29.

32. This conclusion is without foundation. In connection with the prior related litigation (2017), I provided a bottle of Baby Ddrops[®] to Michael R. Mischnick, an attorney at Schwegman Lundberg & Woessner, P.A., who is a registered patent attorney and holds a degree in chemical engineering. I asked him to evaluate the ability of one drop of Baby Ddrops[®], to adhere to a stainless-steel spoon. As described by Mr. Mischnick, one drop of Baby Ddrops[®] product did not adhere to a stainless steel spoon. Mischnick Decl., Ex. WW-B, page 36 of 45 (page numbers refer to numbers at the top of the page). The drop of liquid was

contained by the lip of the spoon when the spoon was tipped forward slightly, but immediately flowed down the bowl of the spoon when the spoon was held level or tipped back slightly.

33. The composition of Baby Ddrops is organic fractionated coconut oil and Vitamin D3 (cholecalciferol). Ex. 2004, pg. 21, which is within the scope specifically recited in claim 1.

34. I do not agree with the presumption advanced by the Petition based on Harder that because one drop of Vigantol oil can be given to the baby from the tip of a spoon -or-, as the petition asserts “one drop of Vigantol oil can be given to the baby to be licked off from the tip of a spoon”, leads to the conclusion that (a) Vigantol oil adheres to the spoon, (b) any C₆-C₁₂ MCT mixture would adhere to any surface, or (c) anyone would understand this to require that the drop is placed on the concave surface of the spoon and would adhere to it.

35. As discussed above, I have proven that Baby Ddrops, one drop of which is 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” as recited in claim 1, does not adhere to a spoon. Mischnick, Ex. WW-B, page 36 of 45 (page numbers refer to numbers at the top of the page).

36. The secondary references do not remedy the absence of the necessary “adherence” element in Harder. Also absent from the cited prior art is the

composition of the MCT in Vigantol oil(s) that would impart this property to the recited composition and the recited object.

d. Claim 3 is Not Obvious

37. The disclosure in MOM-1011 (“Blass”) that an analgesic dose of a sucrose-water solution can be administered to a baby by dipping a pacifier into the free-flowing composition and presenting the wetted pacifier to the baby is remote from the ‘958 Patent. In Blass, the baby receives 0.5 ml of the sucrose solution in each of 4 doses. This amounts to administering 15 drops of the “medicine” in each of the doses. The person of ordinary skill in the art would not be motivated to apply and administer one drop of a viscous vitamin D/MCT composition in this fashion.

38. The disclosure in MOM-1011 (Blass) does not make the delivery in claim 1 (or 3) obvious to one of ordinary skill in the art. Blass involves a study on the administration of sucrose-water solutions to alleviate pain in infants undergoing routine hospital procedures. Babies were administered four doses of 12% sucrose dissolved in water by dipping a pacifier into the sucrose solution and having the baby lick a total of 2 ml of the solution from the pacifier. Blass compared the analgesic effects of sucking the sucrose solution from the pacifier vs. sucking water from the pacifier, and the sucrose solution was found to be more effective in the suppression of pain. Blass at 615; MOM-1011, page 10.

39. As summarized in the '958 Patent, Table 1, one drop of water applied to a human nipple "dripped off," undoubtedly due to its low viscosity. Since the viscosity of water is only 0.7972 mPa-s at 30°C, adding 12 wt-% sucrose as taught by Blass would not cause the solution to approach the viscosity of MCTs. Therefore, the person of ordinary skill in the art, given the positive results attained by Blass in controlling pain, would not be motivated to replace the effective sugar-water solutions with a much more viscous composition.

e. Claim 4 is Not Obvious.

40. Even conceding that the person of ordinary skill in the art would find it obvious to reduce the recited dose of vitamin D "to meet recommended dosages," it would still not be obvious to administer a one-drop dose so that it adheres to a surface from which the baby or adult can ingest it by licking or sucking the surface, as recited in claim 1, from which claim 4 depends.

f. Claim 5 is Not Obvious.

41. Claim 5 depends on claim 1 and is not obvious for the same reasons that claim 1 is not obvious. Also, while claim 5 recites that the MCT contains at least 95% C₆-C₁₂ triglycerides, there is no evidence that Vigantol oil, at the time, had this composition and no evidence to one of ordinary skill in the art at the time would have been led to this composition. I do not agree that the MCT content of Vigantol oil was known to the art in 2006.

III. COPYING

42. Exhibit WW-A, attached hereto, was submitted and filed in the prior related proceeding: Ddrops Company, *et al.* v. iHerb, Inc., *et al.*, Civil Action No. 0:16-cv-04278, before the US District Court for the District of Minnesota (the “prior related proceeding”). Exhibit WW-A, page 31 of 42 (page number refers to numbers at the top of the page), describes certain evidence that demonstrated that the defendant iHERB, Inc. practiced Claims 1-5 of the ‘958 Patent and did so by copying Ddrops patented product. The declaration and exhibits in Exhibits WW-A and WW-B were filed without a confidentiality designation and are available for the public to download from PACER. I am also aware that David B. Conrad of Fish and Richardson P.C. was designated Lead Attorney in the prior related proceeding and is identified as Lead Counsel in the current IPR Petition.

IV. CONCLUSION

43. Petitioner cannot demonstrate that the “adherence” property is present in the prior art. The Petition only argues obviousness in view of prior art that does not disclose or suggest the makeup of the composition recited in claims 1 and 3-5. The references asserted in the Petition fail the “all elements” requirement by their failure to show inherency and so cannot support the prima facie obviousness of the claims. Furthermore, the references are not logically combinable, absent the

impermissible use of hindsight, to assemble the claimed method from isolated disclosures of claim elements in the prior art.

44. In addition, the primary reference, a general infant care book discloses that Vigantol oil contains vitamin D and “medium-chain triglycerides (vegetable oil)” and nothing more. MOM-1007, page 6. One of ordinary skill in the art of the ‘958 Patent would not look to such a book for the formulation of a vitamin D product, particularly apparent from the fact that the composition of Vigantol oil is not described by any evidence cited in the Petition. Furthermore, one of ordinary skill in the art pertinent to the ‘958 Patent would know that vegetable oil referred to in MOM-1006, page 6, does not exclude the presence of long-chain triglycerides. One of ordinary skill in the art pertinent to the ‘958 patent would not be looking to a general book on post-natal child care for the formulation of a composition of vitamin D. Absent hindsight reconstruction there is no guidance to this claim limitation in any of the cited documents. Claims 1 and 3-5 therefore would not have been obvious to one of ordinary skill in the art as of the critical date.

I, Warren D. Woessner, 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: June 29, 2023

By: Warren D. Woessner

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WOESSNER
Exhibt WW-A

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MINNESOTA

DDROPS COMPANY, REINHOLD VIETH,
and ELAINE VIETH

Plaintiffs,

v.

iHERB, INC., and MADRE LABS, INC.,
d/b/a CALIFORNIA GOLD NUTRITION,

Defendants.

Civil No. 16-4278-JNE-TNL

**DECLARATION OF
WARREN D. WOESSNER**

I, Warren D. Woessner, declare and state as follows under penalty of perjury:

1. I have been retained as an expert witness in the above captioned litigation on behalf of Plaintiffs Ddrops Company, Reinhold Vieth, and Elaine Vieth.

2. If called to testify at trial or any hearing in this action, I would offer testimony consistent with the facts and opinions expressed in my expert report entitled, “The Preliminary Expert Report of Warren D. Woessner” dated December 22, 2016, a true and correct of which is attached as Exhibit A.

Signed under penalty of perjury pursuant to 28 U.S.C. §1746.

Dated: December 22, 2016.

s/Warren D. Woessner
Warren D. Woessner

Exhibit A

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MINNESOTA

DDROPS COMPANY, REINHOLD VIETH,
and ELAINE VIETH

Plaintiffs,

v.

iHERB, INC., and MADRE LABS, INC.,
d/b/a CALIFORNIA GOLD NUTRITION,

Defendants.

Civil Action No. 16-4278-JNE-
TNL

**PRELIMINARY EXPERT
REPORT OF WARREN
WOESSNER**

PRELIMINARY EXPERT REPORT OF WARREN WOESSNER

I. INTRODUCTION

I have been retained by Plaintiffs Ddrops Company (“Ddrops”), Reinhold Vieth, and Elaine Vieth (collectively, “the Plaintiffs”), to provide a preliminary written Report of my opinions and if necessary, to testify at a preliminary injunction hearing and, if necessary, at trial in the present action. This Report will discuss the prosecution history of U.S. Patent Application Serial No. 11/674,234, filed February 13, 2007, that issued as U.S. Patent No. 9,066,958 (“the ‘958 patent”), and the prevailing case law regarding claim construction and infringement. In this Report, I will compare the composition and labeling of the California Gold Nutrition® Baby D₃ Liquid Vitamin D₃ for Babies (“D₃ product”), that is marketed and sold by iHerb, Inc.(“iHerb”) and Madre Labs, Inc. d/b/a California Gold Nutrition (“CGN”) (collectively, the “Defendants”) to certain of the claims of the ‘958 patent.¹ I will also demonstrate how the labeling of the CGN D₃ product and Defendants’ comparison of their product to the Plaintiffs’ product evidences their willful blindness to the ‘958 patent. I will discuss how Defendants’ labeling instructs users to perform the steps of the claimed method, thus literally infringing certain of the claims of the ‘958 patent thereby rendering the Defendants liable for inducing direct infringement of certain of the claims of the ‘958 patent under 35 U.S.C. § 271(b).

This preliminary report is prepared to supplement Plaintiffs’ Motion for a preliminary injunction to prevent Defendants’ continued infringement of the ‘958 patent.

¹ CGN manufactures the D₃ product. CGN and iHerb advertise and iHerb sells the D₃ product on their websites, and the “product details” and “ingredients” are taken from the packaging and bottle labeling of the CGN D₃ product.

II. EXPERT QUALIFICATIONS

A. Area of Expertise

I am knowledgeable in and an expert in the fields of patent law and practice. I am also educated and knowledgeable in the area of chemistry, including medical and pharmaceutical chemistry and have written and prosecuted patent applications in those areas throughout my career. With regard to the particular patent in issue in this matter, I consider myself to be a person of greater than ordinary skill in the applicable art. I have over 30 years of experience in intellectual property law, including, but not limited to, preparing and prosecuting United States patent applications, counseling, transactions, and the preparation of patentability opinions, infringement opinions and validity opinions. A copy of my resume, which outlines my educational background, work experience, and presentations/publications is attached hereto as Exhibit 1. My resume identifies the articles I have published within the last ten years.

B. Educational Background

I received a Bachelor of Arts degree in chemistry in 1966 from Cornell University, and received my Ph.D. in chemistry at the University of Wisconsin – Madison in 1971. Following a post-doctoral fellowship in the Department of Medical Chemistry, School of Pharmacy, at the University of Wisconsin in 1971-72, I joined Miles Laboratories as a Research Scientist in their Natural Products Laboratory. There I worked on the synthesis of new drug candidates from 1972-1978. I have authored or co-authored a number of

scientific publications in the area of synthetic organic chemistry, and hold more than 15 U.S. patents.

I entered the Law School of the University of Wisconsin in 1978 and received my J.D. degree *cum laude* in 1981.

C. Relevant Professional Experience

I have extensive experience with patents, including evaluating the patentability of inventions, and evaluating the validity, enforceability and infringement of patents in the pharmaceutical and biotechnology areas. Moreover, I have drafted and successfully prosecuted hundreds of patent applications before the United States Patent and Trademark Office (“PTO”). From 1981-1984, I was an associate attorney at Kenyon & Kenyon in New York City. In this position, I was responsible for preparing and prosecuting patents before the PTO, preparing opinions relating to intellectual property and assisting in litigation. From 1984-1993, I was an attorney at Merchant & Gould in Minneapolis, Minnesota. From 1984-1988, I was an associate attorney and from 1989-1993, I was a shareholder. While at Merchant & Gould, I continued to prepare and prosecute patent applications, chiefly in the pharmaceutical, biotechnology and specialty chemical areas, and to prepare opinions and assist in litigation. In 1993, I co-founded Schwegman, Lundberg & Woessner, P.A., an intellectual property law firm of more than 100 patent attorneys that specializes in patent preparation and prosecution, client counseling and opinion work. The firm was ranked fifth in the U.S. for the number

(1051) of “natively-filed utility patents” in 2010. In 2014, the firm received an overall patent quality ranking of #1 by the Ocean Tomo Ratings patent score methodology.

I have participated in, or supervised the prosecution of hundreds of United States patent applications before the PTO concerning mechanical, chemical, biotechnology, medical device and pharmaceutical inventions, including methods of medical treatment and the administration of bioactive agents. I have argued a number of appeals successfully before the PTO Board of Patent Appeals and Interferences. I have been a member of the American Intellectual Property Law Association since 1984, have been chair of the Chemical Practice Committee and the Biotechnology Committee, a member of the Amicus Committee and am currently a Fellow of the Association.

D. Compensation

I am being compensated for my services as an expert consultant at a rate of \$500 per hour. I will be compensated as a testifying expert at a rate of \$750/hr. No part of my compensation is contingent on the outcome of this litigation, nor on the opinions provided by my report(s).

E. Testimonial Experience

Within the last four years, I was accepted as an Expert witness and provided testimony at trial in Energy Heating, LLC. v. Heat On-The-Fly, LLC in 2015 (D. N.D.). I was also deposed as an expert witness in Energy Heating.

F. Documents

The documents that I reviewed or considered to prepare this opinion are listed in Exhibit 2 (attached). I reserve the right to supplement or revise this list, as well as this opinion, in light of additional documents or evidence that may become available.

III. APPLICABLE LEGAL STANDARDS

1. Claim Interpretation

In order to determine whether or not a product or process infringes any of a patent's claims, the claim limitations must be interpreted and their meaning ascertained, as of the date of invention, e.g., the effective filing date of the application. Schering Corp. v. Amgen, Inc., 222 F.3d 1347 (Fed. Cir. 2000). In determining the meaning of a claim to one of ordinary skill in the art, a court will refer to the claims, the specification, and the prosecution history of the patent. This is referred to as "intrinsic" evidence. Markman v. Westview Instruments, Inc., 52 F.3d 967, 979 (Fed. Cir. 1995) (*en banc*), *aff'd*, 517 U.S. 370, 116 S. Ct. 1384 (1996); Vitronics Corp v. Conceptiontronic, Inc., 90 F.3d 1576, 1581-1582 (Fed. Cir. 1996). A court can use "extrinsic evidence" including expert and inventor testimony, dictionaries and learned treatises to assist it to ascertain the ordinary and customary meaning of claim terms, but the specification of the patent "is the single best guide to the meaning of a disputed term." Markman, 52 F.3d at 980; Vitronics, 90 F.3d at 1582; Phillips v. AWH Corp., 415 F.3d 1303 (Fed. Cir. 2005) (extrinsic sources must not be used to contradict claim meaning that is unambiguous in light of intrinsic evidence).

For example, the Court of Appeals for the Federal Circuit has repeatedly stated that both statements in the specification and attorney argument during prosecution are appropriate evidence by which to interpret the scope of the claims. Markman v. Westview Instruments, cited above; Unique Concepts, Inc. v. Brown, 939 F.2d 1558 (Fed. Cir. 1991); North Am. Vaccine v. American Cyanamid Co., 7 F.3d 1571 (Fed. Cir. 1993) (“As explained above, the examples are consistent with monofunctionality, not difunctionality. A patent applicant cannot disclose and claim an invention narrowly and then, in the course of an infringement suit, argue effectively that the claims should be construed to cover that which is neither described nor enabled in the patent.”); see also Jonsson v. Stanley Works, 903 F.2d 812 (Fed. Cir. 1990) (arguments made during prosecution history are relevant in determining meaning of patent’s claim language); CVI/Beta Ventures v. Tura LP, 112 F.3d 1146 (Fed. Cir. 1997) (“[T]hrough statements made during prosecution . . . an applicant for a patent . . . may commit to a particular meaning for a patent term, which meaning is then binding in litigation”).

2. Infringement

The properly interpreted claims are then compared to the accused product or process to see if it infringes any of the patent claims.

The legal standards for infringement are set forth in 35 U.S.C. § 271 “Infringement of patent.” Section (a) direct infringement, (b) inducing infringement, and (c) contributory infringement relevant to the claimed method are set forth below:

(a) Except as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States, or imports into the United States any patented invention during the term of the patent therefor, infringes the patent.

(b) Whoever actively induces infringement of a patent shall be liable as an infringer.

(c) Whoever offers to sell or sells within the United States or imports into the United States a component of a patented machine, manufacture, combination, or composition, or a material or apparatus for use in practicing a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use, shall be liable as a contributory infringer.

Before one can be held liable for indirect infringement under sections (b) and (c), one must knowingly have done some sort of act without which direct infringement under section (a) would not have occurred. At least, either the actor must intend that the composition it sells will be used in the patented method or must know that the composition is adapted for no other use. See, e.g., Water Technologies, Corp. v. Calco, Ltd., 850 F.2d 660 (Fed. Cir. 1988); Hewlett-Packard Co. v. Bausch & Lomb, Inc., 909 F.2d 1464 (Fed. Cir. 1990) (intent to cause direct infringement required for liability under 271(b)), Dawson Chem. Co. v. Rohm and Haas Co., 448 U.S. 176 (1980); Carbice Corp. of Amer. v. Amer. Patents Dev. Corp., 283 U.S. 27 (1931) (defining staple/nonstaple articles).

In Global-Tech Appliances, Inc. v. SEB S.A., 563 U.S. 754, 131 S. Ct. 2060 (2011), a case involving the legal standard for inducing infringement of a patent under 35 U.S.C. § 271(b), the Supreme Court held that liability under § 271(b) requires specific

intent, i.e., that the accused inducer have knowledge that the induced acts constitute patent infringement. The Court further held, however, that this “knowledge” requirement can be met by showing “willful blindness” by the defendant, i.e., that the defendant (1) “subjectively believe(s) that there is a high probability” that a patent exists and that the defendant’s acts infringe that patent; and (2) “take(s) deliberate actions to avoid learning” about those facts.

In Limelight Networks, Inc. v. Akamai Technologies, Inc. 134 S. Ct. 2111 (2014), the Supreme Court held that a finding of inducement requires a single entity to be responsible for the underlying direct infringement, either by performing all steps of the claimed method itself or by exercising control or direction over any steps performed by someone else.

Also, the presence of “substantial non-infringing use” will not preclude a finding of induced infringement under § 271(b). For example, a label listing both infringing and non-infringing uses for a composition will be found to induce infringement. AstraZeneca LP v. Apotex, Inc., 633 F.3d 1042 (Fed. Cir. 2010); see also Toshiba Corp. v. Imation Corp., 681 F.2d 1398 (Fed. Cir. 2012).

Infringement is a question of fact and a claim may be infringed either literally or under the doctrine of equivalents. Literal infringement exists when every limitation recited in the claim is found in the accused device (i.e., when the properly construed claim “encompasses or reads on” the accused device exactly). SmithKline Diagnostics, Inc. v. Helena Laboratories Corp., 859 F.2d 878 (Fed. Cir. 1988); Monsanto Co. v. Syngenta Seeds, Inc., 503 F.3d 1352 (Fed. Cir. 2007). Thus, one who simply copies a

patented composition or adopts a patented method would literally infringe the claim covering that composition or method.

If there is no literal infringement, infringement under the doctrine of equivalents can be found where the accused product has, at least, an equivalent of every limitation of the claim. Ethicon Endo-Surgery v. U.S. Surgical Corp., 149 F.3d 1309 (Fed. Cir. 1998); Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 117 S. Ct. 1040 (1997) (“Hilton Davis”). As acknowledged by the Supreme Court in Hilton Davis, there are a variety of linguistic formulations of the test for equivalents, none of which is always dispositive. 117 S. Ct. at 1054. The basic three-way test was laid down in 1950: an equivalent element is an element that “performs substantially the same function in substantially the same way to obtain substantially the same result” as a claim element. Graver Tank & Mfg Co. v. Linde Air Prod. Co., 339 U.S. 605, 70 S. Ct. 854 (1950). Another factor is whether one of skill in the art would have considered the elements to be interchangeable at the time of the infringement. Id. Although this test is not dispositive, equivalence ultimately “rests on the substantiality of the differences between the claims and the accused product or processes, assessed according to an objective standard.” Hilton Davis Chem. Co. v. Warner-Jenkinson Co., 62 F.3d 1512 (Fed. Cir. 1995).

However, it is well settled that the doctrine of equivalents also cannot be employed by a patent holder to recapture subject matter given up during prosecution to avoid prior art, whether by amendment of the claims or by arguments presented to the Patent Office. Pharmacia & Upjohn Co. v. Mylan Pharms., Inc., 170 F.3d 1373 (Fed. Cir. 1999); AstraZeneca AB v. Mut. Pharm. Co., 384 F.3d 1333 (Fed. Cir. 2004). This

prohibition is referred to as “prosecution history estoppel.” However, in some cases, a patentee can employ the doctrine of equivalents to encompass elements of the invention that were disclosed in the application but not claimed. See, e.g., YBM Magnex Inc. v. ITC, 145 F.3d 1317 (Fed. Cir. 1998) (numerical range entitled to cover equivalents in absence of language expressing an imperative).

In Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 535 U.S. 72, 122 S.Ct. 1831 (2002), the Supreme Court clarified both the acts during prosecution that would give rise to prosecution history estoppel, and the extent of the estoppel. The Court first held that a narrowing amendment made to satisfy any requirement of the Patent Act gives rise to estoppel: “A patentee who narrows a claim as a condition for obtaining a patent disavows his claim to the broader subject matter.” Id. at 1840. The Court then considered whether “the estoppel bar[s] the inventor from asserting infringement against any equivalent to the narrowed element or might some equivalents still infringe?” Id. The Court rejected an absolute bar to application of the doctrine of equivalents to such a narrowed claim, but established a rebuttable presumption that the patentee had generally disclaimed all the territory between the original claim and the amended claim. It ruled that the patentee can rebut the presumption by explaining why the amendment did not “surrender the particular equivalent in question.” Id. at 1842. For example, the patentee might establish that the equivalent was unforeseeable when the application was filed, so it could not later have been claimed, or provide some other reason that the equivalent could not reasonably have been expected to have been described in the patent. The patentee

can also meet the burden by showing that the rationale underlying the amendment may have “no more than a tangential relation to the equivalent.” Id.

However, prosecution history estoppel cannot be avoided by canceling broad claims and replacing them by narrower ones, or by filing a continuing application with narrowed claims rather than responding directly to an outstanding rejection. Desper Prods. v. QSound Lab., 157 F.3d 1325, 1338 (Fed. Cir. 1998); Mark I Mktg. Corp. v. R. R. Donnelley & Sons Co., 66 F.3d 285, 292, (Fed. Cir. 1995); Haynes Int’l v. Jessop Steel Co., 8 F.3d 1573, 1578-79 (Fed. Cir. 1993). Also, rewriting a dependent claim into independent form, while canceling the original independent claim, creates a presumption of prosecution history estoppel under Festo. Honeywell Int’l v. Hamilton Sundstrand Corp., 370 F.3d 1131 (Fed. Cir. 2004).

IV. VIETH, ET AL. (U.S. PATENT NO. 9,066,958)

1. Prosecution History

Vieth, et al. (U.S. Patent No. 9,066,958) issued on June 30, 2015 from U.S. patent application Serial No. 11/674,234 (“the ‘234 application”). This application claimed priority from Canadian patent application 258,202, filed September 14, 2006.

The patent issued with 12 claims:

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.

2. A method as claimed in claim 1, wherein said human being is an adult and said object is the skin of an arm or hand of said adult.

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.

6. 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, and a compound selected from the group consisting of a free fatty acid, a monoglyceride and an anti-oxidant preservative, in a liquid triglyceride of 6 to 12 carbon chain lengths, 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.

7. A method according to claim 6, wherein said compound is selected from the group consisting of caprylic acid, caprylic monoglyceride and monocaprylin.

8. A method according to claim 6, wherein said compound is at a concentration selected from 0.1% to 20% w/w of total weight of the composition.

9. A method according to claim 6, wherein said compound is at a concentration selected from 1% to 10% w/w of total weight of the composition.

10. 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, and a

nutritionally effective amount of a fat-soluble vitamin, in a liquid triglyceride of 6 to 12 carbon chain lengths, 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.

11. A method as claimed in claim 10 wherein said fat-soluble vitamin is selected from the group consisting of alpha-tocophenol (vitamin E), vitamin A, vitamin K and β -carotene.

12. A method according to claim 1, wherein the composition consists of 300 mcg/ml vitamin D in a liquid triglyceride of 6 to 12 carbon chain length.

Claims 6-11 recite components of the “composition” that do not appear to be indicated by the labeling to be present in the CGN product. However, this has not been confirmed by chemical analysis and accordingly, I express no opinion regarding claims 6-11 at this time. Claim 1 is the independent claim under consideration.

The ‘234 application was filed on February 13, 2007 with 15 claims. The two independent claims are reproduced below:

1. A composition comprising vitamin D in a liquid, triglycerides of 6 to 12 carbon chain lengths medium for use in delivering a nutritional or therapeutic amount of said vitamin D to a human being from the surface of an object having said composition on said surface to be sucked from said surface by said human being.

* * *

13. A method of delivering a nutritional or therapeutic amount of vitamin D to a human being, said method comprising
 (i) applying a composition comprising a nutritional or therapeutic effective amount of vitamin D in a liquid, triglyceride of 6 to 12 carbon chain lengths medium to a surface of an object; and
 (ii) said human being sucking or licking said composition directly from said object. [emphasis supplied].

The word “comprising” in patent law is an open-ended word and one of enlargement and not restriction, whereas the word “consisting” is one of restriction and exclusion. Manual of Patent Examination Procedure (“MPEP”) 2111.03. Parmelee Pharmaceutical Co. et al. v. Zink, 285 F.2d 465, 128 USPQ 271 (CA 8 1961). An applicant can leave a claim open with respect to the presence of additional elements and closed with respect to a particular element. Mannessman Demag Corp. v. Engineered Metal Products Co., Inc., 793 F.2d 1279, 230 USPQ 45 (Fed. Cir.1986); Berenter v. Quigg, 737 F. Supp. 5, 14 USPQ2d 1175 (DCDC 1988). The word “comprising” is synonymous with “including.” Ex parte Davis et al., 80 USPQ 448 (POBA 1948); In re Bertsch, 132 F.2d 1014, 56 USPQ 379 (CCPA 1942). It reads on additional steps or procedures and does not exclude materials or processes not recited in the claim, as does the “closed term,” “consisting of.” Gould v. Mossinghoff, Comr. Pats., 215 USPQ 310 (DCDC 1982). The term “consisting of” excludes from the claimed subject matter materials other than those recited in the claims and impurities ordinarily associated therewith. Sakano v. Rutemillar, 158 USPQ 47 (Bd. App. 1968).

Therefore, term “said method comprising” in then-pending claim 13 (and in issued claim 1) would be construed to encompass a method that would require, for example, an additional ingestion step of vitamin D or of other vitamins. The use of the term “a composition comprising” would be interpreted to permit the inclusion of other ingredients in the composition that is applied, such as other vitamins, solvents or antioxidants.

In the first Office Action, mailed March 2, 2010, the Examiner required the applicants to prosecute either the method claims or the composition claims. The Examiner rejected claim 13 under § 112(2) as indefinite due to the comma between “liquid” and “triglyceride” and for putting “medium” after “triglyceride.”

Claims 13 and 15 were rejected as obvious over published PCT application WO/00/54838 (9/21/2000) (“Piene”) in view of U.S. Patent No. 5,601,605 (“Crowe”). The Examiner argued that the Piene application disclosed “a liquid emulsion containing vitamin D and edible triglyceride ... which [triglyceride] had a high abundance of C₆-C₁₂ fatty acid residues,” that can be ingested by a human.

Crowe was cited for its disclosure of the use of an infant pacifier for administering medicine to infants. According to the Crowe patent, the medicine could be squeezed from a reservoir through a hole in the pacifier that the infant would suck or lick.

In response, the prosecuting attorney cancelled claims 1-12 and amended claim 13 to delete the offending comma and the word “medium,” to remove the § 112 rejection. The attorney also added claims 16, 17 and 18:

16. (New) A method according to claim 13 wherein the composition comprising 9 to 9000 mcg/ml vitamin D.

17. (New) A method according to claim 13 wherein the composition comprising from 150 to 450 mcg/ml vitamin D.

18. (New) A method according to claim 13, wherein said triglyceride comprises at least 95% triglycerides having a carbon-chain length selected from 8 to 10.

The attorney argued that Piene did not disclose “single-phase liquid oil” and that the Crowe patent requires loading a reservoir with more than a drop of the fluid that the

infant sucks out through the hole, like “a miniature baby bottle.” The attorney also argued that Crowe “clearly leads away from applying a liquid composition to the outside surface of a body.”

In an Office Action mailed August 25, 2000, the Examiner maintained the rejection of claims 13 and 15-24 as obvious over Piene in view of Crowe in further view of Fliszar et al., J. Pharm. Biomed. Anal., 40, 896 (2006) and U.S. Patent No. 6,638,978 (“Kabara”). Claims 13-24 were rejected as obvious over U.S. Patent No. 4,258,867 (Ikushima) in view of Crowe, Piene, Fliszar, Kabara, U.S. Patent No. 3,149,037 and a Vieth 2006 website.

Claims 16-17, directed to compositions having 9-9000 mcg/ml or 150-450 mcg/ml vitamin D, were rejected over the disclosure in Piene of recommended minimum daily doses. Claim 18, directed to triglyceride having 95% C₈-C₁₀ triglycerides was rejected on the basis that Fliszar discloses increased absorption of the active pharmaceutical ingredient by using medium chain triglycerides. Claims 19-22 directed to compositions also containing monoglycerides and free fatty acids were rejected on the basis that Kabara would motivate their use as preservatives. Since these rejections were directed to a number of later-canceled claims, they will not be discussed in detail.

On November 24, 2010, the attorney filed an amendment to claim 13 that recited that the method consisted of steps (i) and (ii) and that the vitamin D in the applied composition was “in a single phase triglyceride.” Claim 15 was amended to recite that the human being of claim 13 is an infant and the object to which the composition is

surface-applied is a nipple or the external surface of a pacifier. These amendments are shown below.

13. (Currently Amended) A method of delivering a nutritional or therapeutic amount of vitamin D to a human being, said method consisting of comprising:

(i) applying a composition comprising a nutritional or therapeutic effective amount of vitamin D in a single phase liquid triglyceride of 6 to 12 carbon chain lengths to a surface of an object; and

(ii) said human being sucking or licking said composition directly from said object.

14. (Original) A method as claimed in claim 13 wherein said human being is an adult and said object is the skin of an arm or hand of said adult.

15. (Currently Amended) A method as claimed in claim 13 wherein said human being is an infant and said object is a women's nipple or the external surface of a pacifier.

* * *

25. (New) A method of delivering a nutritional or therapeutic amount of vitamin D to a human being, said method consisting essentially of:

(i) applying a composition comprising a nutritional or therapeutic effective amount of vitamin D in a single phase liquid triglyceride of 6 to 12 carbon chain lengths to a surface of an object; and

(ii) said human being sucking or licking said composition directly from said object. [emphasis supplied].

With respect to claim 25, the attorney incorrectly argued as follows:

The “consisting essentially of” language in new claim 25 “limits the scope of a claim to the specified materials or steps” ‘and those that do not materially affect the basic and novel characteristic(s)’ of the claimed invention.” See MPEP 2111.03. Thus, the consisting essentially language excludes additional components required by the combination of references that materially affect the basic and novel characteristics of claim 25.

The attorney erred in his analysis because the composition of step (i) is still open ended with respect to other ingredients in the applied composition. The “consisting essentially of” language only limits the steps of the process to exclude additional steps that would materially affect the basic and novel characteristics of the claimed method. However, the attorney failed to explain what those additional steps might be. Nevertheless, further amendments mooted this attempt to distinguish the cited art by using this term.

In a final rejection mailed February 16, 2011, the Examiner rejected claims 13-25 under § 112(1) on the basis that “single phase” was not adequately disclosed in the specification. Claims 13-25 were rejected for using both “consisting of” and “comprising” or “consisting essentially of” and “comprising.” Since the issued claims use “comprising” and “consisting of,” this rejection will not be specifically discussed.

Claims 13 and 16-25 were again rejected over Piene, taken with Crowe, Fliszar and Kabara. Claims 13 and 15 were rejected over Piene and Blass et al., Pain, 83, 611 (1999). Blass et al. discloses administering sucrose to an infant by dipping a pacifier into sucrose solution. Claim 14, which is similar to issued claim 2, was not rejected as obvious.

On August 16, 2011, the attorney filed a request for continued examination and an amendment. Claims 13-18 were amended and claim 26 was added as follows:

13. (Currently Amended) A method of delivering a nutritional or therapeutic amount of vitamin D to a human being, said method ~~consisting of~~ comprising:

(i) applying one drop of a composition comprising a nutritional or therapeutic effective amount of vitamin D ~~in a single phase liquid~~

~~triglyceride of 6 to 12 carbon chain lengths to a~~ in a biologically-acceptable liquid oil, to an exterior surface of an object; and

(ii) said human being sucking or licking said composition directly from said object.

14. (Currently Amended) A method as claimed in claim 13, wherein said human being is an adult and said object is the skin of an arm or hand of said adult.

15. (Currently Amended) A method as claimed in claim 13, wherein said human being is an infant and said object is a woman's nipple or the external surface of a pacifier.

16. (Currently Amended) A method according to claim 13, wherein the composition ~~comprising~~ comprises 9 to 9000 mcg/ml vitamin D.

17. (Currently Amended) A method according to claim 13, wherein the composition ~~comprising~~ comprises from 150 to 450 mcg/ml vitamin D.

18. (Currently Amended) A method according to claim ~~[[13]]~~ 26, wherein said triglyceride comprises at least 95% triglycerides having a carbon-chain length selected from 8 to 10.

* * *

26. (New) A method according to claim 13 wherein said liquid oil is a liquid triglyceride of 6 to 12 carbon chain length.

The closed term, "consisting of," was replaced by the open term "comprising," in claim 13. The new element, "one drop" was added, but the triglyceride ingredient was replaced by "liquid oil" that is applied to the "exterior" surface of an object.

In response, an Office Action was mailed February 25, 2014, rejecting claims 13-17 and 25-26 as obvious over Piene in view of Blass, Crowe, U.S. Patent No. 5,620,462 ("Valenti") and the Vieth 2006 website.

Claim 18 was rejected over Piene in view of Blass, Crowe and Valenti in further view of Fliszar. The rejection of claims 19-22 and 24 is not relevant to the claims that eventually issued.

The Examiner noted that the phrase “said method comprising” did not exclude the application of more than a single drop, and that the drop was not required to adhere to the surface.

In response, the attorney amended claims 13 and 17 as follows:

13. (Currently Amended) 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 comprising consisting essentially 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 in a biologically acceptable liquid oil, to an exterior surface of an object, wherein said drop adheres to the surface of said object; and

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

* * *

17. (Currently Amended) A method according to claim 13, wherein the composition consists of comprises from 150 to 450 mcg/ml vitamin D in a liquid triglyceride of 6 to 12 carbon chain length.

New claim 30 was added that the composition consists of 300 mcg/ml vitamin D in a liquid (C₆-C₁₂) triglyceride.

While the attorney retained the open term, “comprising” for the method step, he used the partly-closed term “consisting essentially of” to describe the composition of the drop in claim 13. In claim 17, the attorney used the closed term, “consists of” to describe

the composition of the drop. Claim 25 was amended to add all the elements of claim 13 and to recite that the drop “consists of” vitamin D and the triglyceride.

In the next Office Action, mailed October 9, 2014, the Examiner rejected claims 13-15, 18 and 25, as indefinite for using “consisting essentially of,” but indicated that “consisting of” claims 17 and 30 would be allowable if placed in an independent form. No prior art rejections were made.

On January 8, 2015, the attorney filed an amendment to claim 13 to replace “a composition consisting essentially of” with “a composition consisting of.” Claims 23-26 were cancelled. The Examiner then allowed all of the pending claims and recorded the following “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 vitamin D composition to the exterior surface of an object including an arm or hand because it may drip off or get contaminated. Thus, the claimed method[s] are novel and non-obvious over the prior art.

2. Prosecution History Estoppel

Although the prosecution history is lengthy, relatively few amendments narrowed the issued claims so as to bar application of the doctrine of equivalents during claim construction. Furthermore, even if every claim element was not entitled to any range of equivalents, the CGN product would still literally infringe.

The cancellation of original claim 1 and the prosecution of independent claim 13 as the sole independent claim did not significantly narrow any claim elements. In fact, the scope of the triglycerides element was broadened during prosecution by the absence of the term “medium” in claim 13.

The original transitional phrase, “comprising” [the steps that follow] was retained, as was the term “liquid triglyceride of 6 to 12 carbon chain length.” The first step (i) of claim 13 was amended to recite that “one drop” of the vitamin D composition was applied, as was the concentration of the vitamin D (9-9000 mcg/ml from claim 16) and the phrase “wherein the drop adheres to the surface of the object.” Step (ii) was amended to recite an action step: “having” said human being suck or lick the composition directly from the object.

The range of 150-450 mcg/ml in claim 17 was not amended and claim 18 was not amended but issued as claims 4-5. Claim 30 (vitamin D at 300 mcg/ml) was not amended but was added during prosecution. It issued as claim 12.

It is my opinion that use of the open term “comprising” in the claim 1 preamble would permit the claim to encompass additional steps, such as the application of a second drop to the surface after claim 2. While prosecution history estoppel may apply to the concentration of vitamin D in the “composition” of claim 1, the range is very broad. Also, estoppel does not apply to the claim 4 range of 150-450 mcg/ml.

Prosecution history estoppel also does not apply to claim 18 (now claim 5) which recites that the triglyceride of claim 13 (now claim 1), comprises “at least 95%

triglycerides having a carbon chain length selected from 8-10.” This claim is open to “triglycerides” of longer or shorter carbon chain lengths.

3. Claim Construction

Because the claims at issue are directed to a method for the administration of a pharmaceutical composition comprising a vitamin in a triglyceride carrier, it is my opinion that the claim terms should be given their common and ordinary meaning, and that meaning would be at least reasonably certain to those of ordinary skill in the art at the time of the invention. It is my opinion that one of ordinary skill in the art is one of ordinary skill in the art of chemistry, e.g., one that holds a bachelor’s degree in chemistry or the pharmaceutical sciences. See Nautilus, Inc. v. BioSig Instruments, Inc., 134 S. Ct. 220 (2014). To the extent any claim terms need to be construed, Table 1 addresses the proper construction, which is based on the intrinsic evidence.

Table 1 –Preliminary Claim Construction

<u>Element (Claims 1-4)</u>	<u>Construction</u>
Vitamin D	The term means Vitamin D, Vitamin D ₃ and/or Cholecalciferol, which are used interchangeably in the patent specification. See ‘958 patent Col. 3, lines 52-56.
Nutritional and Therapeutic Amount	This term means, “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.” Col. 4, lines 63-66.

<u>Element (Claims 1-4)</u>	<u>Construction</u>
One Drop of Composition Consisting of 9 to 9000 mcg/ml* Vitamin D in a...	The element, “one drop” is defined as “the quantity of a liquid that coalesces into a single globule”; sizes vary according to physical conditions and the properties of the fluid itself.*** This construction is supported by the specification that discloses a one-drop volume of “about 33 microliter of medium chain triglyceride oil.” Col. 4, lines 15-20. See Col. 7, lines 40-41 (“one drop of an approximate volume of 33 microliters”). Examples 2- 4 of the ‘958 patent also disclose drops of 0.033 ml (30 drops/ml). The composition consists of 9 to 9000 mcg/ml vitamin D in liquid triglycerides. See Col. 5, lines 8-17.
Liquid Triglyceride of C ₆ -C ₁₂ Carbon Chain Length**	These are “medium chain triglycerides” which can be a mixture of 2 or 3 (C₆-C₁₂) fatty acids/glycerol molecule. See ‘958 patent, Col. 4, lines 33-48.

*Claim 4 contains a range of vitamin D concentration (“from 150-450 mcg/ml”) that is not subject to prosecution history estoppel.

**Claim 5 contains a triglyceride definition that is not subject to prosecution history estoppel (“at least 95% triglycerides [of C₈-C₁₀].”)

***McGraw-Hill Dictionary of Scientific and Technical Terms, McGraw-Hill Book Co. (1974).

V. THE DEFENDANTS’ “BABY VITAMIN D₃ DROPS”

Defendant CGN is currently manufacturing and marketing the D₃ product.

Defendant iHerb is selling the D₃ product via its website, iHerb.com, as a Madre Labs product, pursuant to an exclusive agreement with CGN ("californiagoldnutrition.com").

for a more complete account of Defendants’ online marketing strategy of their D₃ product. See the Declaration of L. Reagan Florence (December 21, 2016).

The bottle contains 10 ml of the fluid, and is packaged in a cardboard box. The ingredients are listed as “Fractionated Coconut Oil (Medium Chain Triglycerides from coconut)” and “Vitamin D₃ as Cholecalciferol” on the labeling and in the “Supplemental Facts” printed on the box. The product is sold in an amber bottle with an open orifice under the screw cap that is sized so as to deliver one drop at a time of a clear fluid containing “Liquid Vitamin D₃ for Babies, 400 IU” when the bottle is tipped by the user. The terms “vitamin D, vitamin D₃ and cholecalciferol” are used interchangeably on the CGN’s product labeling.

The package labeling is essentially identical to the bottle labeling. The portions of both labels most relevant to infringement of the claims of the ‘958 patent are as follows:

“Liquid Vitamin D₃ drops for Babies, 400 IU”

“Dietary Supplement 0.34 FL OZ (10 mL)”

“Manufactured for & Distributed by: California Gold Nutrition”

“Supplemental Facts”

“Vitamin D₃ (as cholecalciferol)”

“Serving Size 1 Drop (0.033 mL)”

“Amount per serving 400 IU”

“% Daily Value 100%”

“Other Ingredients: Fractionated Coconut Oil Medium Chain Triglycerides from coconut”

“Vitamin D supplementation for infants is recommended because breastfed infants generally do not obtain adequate vitamin D from other sources.”

SUGGESTED USE: For babies under 3 Yrs: 1 drop daily placed on mother’s nipple, clean finger or pacifier, and allow baby to suckle for at least 30 seconds.”

To determine whether or not the clear fluid “consists” of vitamin D and (C₆-C₁₂) medium chain triglycerides, and no other active ingredients or adjuvants, the fluid was analyzed by Chemi Pharmaceutical Inc., Mississauga, Ontario, Canada (“Chemi”).

As set forth in the declarations executed by Mr. Vahid Raoufi, the Quality Assurance Manager and Ms. Mariana Stavrikov, the Preseident of Chemi, the analyses found that a single 0.033 ml drop of the CGN D₃ product contained 527 IU of vitamin D₃. This is close to the package labeling, which states that an “Approx. 0.033 ml” drop contains 400 IU of vitamin D₃.

As set forth in the declarations, the Chemi analysis reports that the CGN D₃ product contains 417 mcg/ml of vitamin D₃, or 13.8 mcg per “serving size” which is a 0.033 ml drop. A 0.028 ml drop would contain 447 IU of vitamin D₃ and a 0.05 ml drop would contain 798 IU of vitamin D₃.

The Chemi analysis reports that, in addition to vitamin D₃, the CGN D₃ product contains 57.9 wt-% C₈-fatty acids, 41.5 wt-% C₁₀-fatty acids and 0.1 wt-% C₁₂ fatty acids following hydrolysis. See USP 39 (401). These results conform to the CGN’s D₃ product labeling that states that the only ingredients are vitamin D (“Cholecalciferol”) and “Medium chain triglycerides.”

VI. INFRINGEMENT OF THE ‘958 PATENT

Table 2 compares the elements of claims 1-5 of the ‘958 patent to the CGN product.

Table 2 - Preliminary Infringement Analysis.

'958 Claim	Element	CGN's Product: "Baby Vitamin D ₃ Drops"
1)	A method of delivering a nutritional or therapeutic amount of vitamin D to a human being, said method comprising:	CGN's packaging: "Vitamin D supplementation for infants is recommended because breast fed infants do not obtain adequate Vitamin D from other sources" (PL). The packaging and label identifies the Baby D₃ product as a "dietary supplement."* Label and packaging state that serving size is one drop that provides 400 IU vitamin D₃ "(% Daily value 100%)."
	i)Applying one drop...to an exterior surface of an object, wherein said drop adheres to the surface of said object	Label and packaging instructs purchasers: "suggested use for babies under 3 yrs: One (1) drop daily placed on mother's nipple, clean finger or pacifier, and allow baby to suckle for at least 30 seconds." (PL)(BL).
	a composition consisting of a nutritional or therapeutic effective amount [of vitamin D]	One drop (0.033 ml) provides 100% of Daily Value of Vitamin D ₃ (400 IU) (BL, PL). Chemi assay: 527 IU.
	of 9 to 9000 mcg/ml vitamin D	Chemi Analysis: one 0.033 ml (PL, BL) drop provides 417 mcg/ml vitamin D ₃ or 13.8 mcg/drop.
	in a liquid triglyceride of 6 to 12 carbon chain length; and	The product label discloses that the composition contains: "Medium Chain Triglycerides" (PL, BL).** Independent chemical analysis by Chemi demonstrates that the Defendants' product consists of only C₈, C₁₀ and C₁₂ fatty acids (total = 99.5 wt-%).

'958 Claim	Element	CGN's Product: "Baby Vitamin D₃ Drops"
	ii) having said human being lick or suck said composition directly from said object	Label and packaging instruct purchasers to "Allow baby to suckle [composition from mother's nipple, a clean finger or surface of pacifier] for at least 30 seconds." (PL, BL).
2)	A method as claimed in claim 1, wherein said human being is an adult and said object is the skin of an arm or hand of said adult.	Label instructs purchasers: "1 drop daily placed on mother's nipple, a clean finger or pacifier" (PL, BL).
3)	A method as claimed in claim 1, wherein the human being is an infant and said object is woman's nipple or the external surface of a pacifier.	Label instructs purchasers to "1 drop on mother's nipple, clean finger or pacifier, and allow baby to suckle for at least 30 seconds."
4)	A method according to claim 1, wherein the composition consists of from 150-450 mcg/ml vitamin D.	Chemi analysis found 418 mcg/ml vitamin D.
5)	A method according to claim 1, wherein the triglyceride comprises at least 95% triglycerides having a carbon-chain length selected from 8 to 10	Independent chemical analysis by Chemi demonstrates that the Defendants' product consists of triglycerides that are 99.4% C ₈ and C ₁₀ carbon chain length.

*BL = Bottle Labeling; PL = Package (box) labeling. The portions of the labels quoted on Table 2 are identical.

**Medium chain triglycerides (MCTs) are triglycerides whose fatty acids have an aliphatic tail of 6-12 carbon atoms. In the case of MCTs, 2 or 3 of the fatty acid chain attached to the glycerol are medium chain length (wikipedia.org/wiki/Medium_chain_triglyceride (visited Oct. 8, 2016)).

The labeling and contents of the CGN D₃ product renders the Defendants liable for inducing infringement of at least claims 1, 2, 3, 4 and 5 of the ‘958 patent. Because the Defendants instruct the user/purchaser to administer one drop of a liquid consisting of vitamin D₃ in C₆-C₁₂ triglycerides to a baby or an infant, the users directly infringe the patent claims when they administer the CGN D₃ product in accord with the labeling, since both the CGN composition and its vitamin D₃ concentration fall within the scope of claims of the ‘958 patent. According to the Declaration of Chris Temosky, dated December 14, 2016, Plaintiffs’ product was marked with the ‘958 patent number at least as of October 15, 2015, thus making the Defendants aware that Plaintiff’s product was protected by an unexpired U.S. patent. According to the Declaration of Susan Jankus, Ddrops Director of Sales and Marketing, dated December 21, 2016, she sent a copy of a press release and notice, on January 18, 2016 to representatives at iHerb. The press release and notice would have informed iHerb that the ‘958 patent had issued and that it covered the delivery system for Plaintiffs’ D₃ composition.

If the Defendants were unaware that the Plaintiffs’ Product was in fact patented, they nonetheless met and meet the requirement for “willful blindness” as set forth in Global-Tech, supra. This conclusion is supported by the declaration of L. Reagan Florence, dated December 21, 2016 and her Exhibit B, taken from the iHerb website, which contains a side-by-side comparison of the compositions of the Patented Product and Defendants’ D₃ Product that informs buyers/users that the Products are essentially identical. This copying of the Patented Product compels the conclusion that Defendants

were subjectively aware that Plaintiffs' Product were likely to be infringing patent(s) held by Plaintiffs, but Defendants took no further action.

VII. CONCLUSION

Therefore, an end user who administers the Defendants' D₃ product to themselves or to an infant in accordance with the instructions on the labeling literally infringes at least claims 1-5 of the '958 patent. CGN and iHerb are each intentionally inducing literal infringement of claims 1-5 in violation of § 271(b) by making and/or selling the CGN D₃ product. Defendants' intent to cause this infringement is evidenced directly by their knowledge that Plaintiffs' composition was patented --by marking or from the press release-- or can be inferred by Defendants copying Plaintiffs' Product to generate marketing materials comparing their product to Plaintiffs' product, along with directions to use it in the method recited by claims 1-5 of the '958 patent.

Date: 12/22/16


 Warren D. Woessner

Exhibit 1.

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LEGAL EXPERIENCE

Schwegman Lundberg & Woessner, P.A., Minneapolis, MN, 1993 - Present,
Founding Principal. Emphasis in chemical, pharmaceutical and biotechnological
patent prosecution, opinion work, licensing and client counseling.

Merchant & Gould, P.A., Minneapolis, MN, 1984-1993, Partner.

Kenyon & Kenyon, New York, NY, Associate attorney from 1981-1984.

BAR ADMISSIONS

State: Wisconsin-1981; New York-1982; Minnesota-1984. Federal Appellate:
U.S. Supreme Court; Federal Circuit; Patent Bar.

EDUCATION

Legal

University of Wisconsin, Madison Law School, Madison, Wisconsin, J.D.,
cum laude, 1981.

Research and Writing Editor, Wis. Law Review, 1980-1981.

Scientific

University of Wisconsin Department of Chemistry, Ph.D., Organic
Chemistry, 1971. Thesis: Hexatriene-Iron Tricarbonyl Isomerizations.
Synthesis of new organometallic compounds.

Cornell University, Ithaca, New York, B.A., Chemistry, 1962-1966.

SCIENTIFIC EXPERIENCE

University of Wisconsin School of Pharmacy. Postdoctoral Research Associate, 1971-1972. Developed new methods and reagents for the synthesis of natural products.

Miles Laboratories, Inc., Natural Products Laboratory, Madison, Wisconsin. Senior Research Scientist, 1972-1978. Synthesis and evaluation of new drugs.

PROFESSIONAL ACTIVITIES

American Intellectual Property Law Association, Chair, Chemical Practice Committee, 1993-1995; Chair, Professional Programs Subcommittee of Biotechnology Committee, 1999-2001; Vice-Chair, Biotechnology Committee, 2001-2003, Chair, 2003-2005; Amicus Committee, 1999-2002; 2008-2011; Fellow, 2005-present.

Minnesota Intellectual Property Law Association, Member 1984-present, Chair, Biotechnology Law Committee, 1986-1987.

IPO, Member, Patent Law (U.S.) Committee, 2010-present.

MNBIO (Minnesota Biotechnology Association), Board of Directors, 1999-2001.

Patent Strategy & Management, Board of Advisers, American Lawyer Media, 2000-2009.

Fund for the Legal Aid Society, Minneapolis, Board of Directors, 2001- present; Executive Committee, 2003-2012.

Licensing Executive's Society International. Certified Licensing Professional. 2008 - present.

Chem/Pharma IP Law Blog: "Patents4Life.com," March 2009-present.

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American Intellectual Property Law Assoc., 2015 Mid-Winter Meeting, Orlando, FL, “Mayo Meet Alice Meet Myriad: Abstract Idea or Inventive Concept” (Feb. 2015).

USPTO – Partnering in Patents, Alexandria, VA, “2014 Supreme Court Update,” (Oct. 2014).

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Association of University Technology Managers 2014 Annual Meeting, San Francisco, CA, “Optimizing Your Patent Budget” (Feb. 2014).

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American Intellectual Property Law Association, Live Online Seminar, “KSR and the Ripple Effect” (March 2, 2011).

Association of University Technology Managers (AUTM), 2011 Annual Meeting, Las Vegas, NV, “The Ever-Changing Kaleidoscope of U.S. Patent Law” (March 2011).

American Conference Institute, 12th Advanced Forum on Biotech Patents, Boston, MA, “Are Genes Patentable? Examining the Potential Ramifications of Myriad and Developing Practical Strategies to Protect Your IP” (December 2010).

American Intellectual Property Law Association 2010 Annual Meeting, Washington, DC, “KSR and the Ripple Effect: Examining the Broad and Increasing Impact of KSR on Patent Litigation and Practice” (October 2010).

Q1, Pharmaceutical Patent Protection and Enforcement Conference (Baltimore, MD), “Myriad: The District Court’s Opinion and the Road Ahead” (September 2010).

LES 2010 Spring Meeting, Boston, MA, “A Shot Across the Bow: The Process Behind Making and Responding to Demands to License Patented Technology” (May 2010).

Q1 Productions, 2nd Annual Partnerships in Personalized Medicine, San Mateo, CA, Speaker, “Legal Considerations in IP/Patent Protection for Partnerships Supporting Personalized Medicine,” (April 2010).

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“Biologics & Devices“ (March 2009).

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Orlando, FL, Speaker, “You Can’t Patent That! Can You“ and Judge, “A New
and Exciting Game Show: Analyze that Contract“ (February 2009).

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2006).

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“Assessing the Impact of the Doctrine of Equivalents on Claim Interpretation and
Non-Infringement Opinions,“ (September 2006).

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45. Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 535 U.S. 72, 122 S.Ct. 1831 (2002).
46. Desper Prods. v. QSound Lab., 157 F.3d 1325, 1338 (Fed. Cir. 1998).
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56. Declaration of L. Reagan Florence dated December 21, 2016, and Exhibits.
57. Declaration of Mariana Stavrikov, Chemi President, dated December 17, 2016, and Exhibit.
58. Declaration of Vahid Roufi, Chemi QA, dated December 17, 2016, and Exhibits (including laboratory analysis and lab results).
59. Declaration of Chris Temovsky, dated December 14, 2016, and Exhibits.
60. Declaration of Susan Jankus, dated December 21, 2016, and Exhibits.
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blog.vitaminddrops.com/?_ga=1.236193025.1081717007.1481665873 (visited Nov. 5, 2016).
62. Website and pages for iHerb: www.iherb.com; www.iherb.com/CGN-Infant-Vitamin-D3; www.iherb.com/California-Gold-Nutrition-Baby-Vitamin-D3-Drops-400-IU-34-fl-oz-10-ml/65958 (visited Nov. 5, 2016).
63. Website and pages for CGN: www.californiagoldnutrition.com;
www.californiagoldnutrition.com/product/vitamins/baby-d3/.
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65. Packaging, bottle, labeling, dropper, and contents of California Gold Nutrition® Baby D₃ Liquid Vitamin D₃ for Babies ("D₃ product").

WOESSNER
Exhibt WW-B

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MINNESOTA

DDROPS COMPANY, REINHOLD VIETH,
and ELAINE VIETH

Plaintiffs,

v.

iHERB, INC., and MADRE LABS, INC.,
d/b/a CALIFORNIA GOLD NUTRITION,

Defendants.

Civil No. 16-4278-JNE-TNL

**SECOND DECLARATION
OF WARREN D. WOESSNER**

I, Warren D. Woessner, declare and state as follows under penalty of perjury:

1. I have been retained as an expert witness in the above captioned litigation on behalf of Plaintiffs Ddrops Company, Reinhold Vieth, and Elaine Vieth.

2. If called to testify at trial or any hearing in this action, I would offer testimony consistent with the facts and opinions expressed in my initial expert report entitled, "The Preliminary Expert Report of Warren D. Woessner" dated December 22, 2016, and my second expert report entitled, "Rebuttal Expert Report of Warren D. Woessner in Support of Plaintiffs' Renewed Motion for Preliminary Injunction", dated May 23, 2017, a true and correct of which is attached as Exhibit A.

Signed under penalty of perjury pursuant to 28 U.S.C. §1746.

Dated: May 23, 2017.

s/Warren D. Woessner
Warren D. Woessner

EXHIBIT A

IN THE UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

Ddrops Company, Reinhold Vieth, and
Elaine Vieth,

Plaintiffs,

v.

iHerb, Inc. and Madre Labs, Inc.
d/b/a California Gold Nutrition,

Defendants.

Civil Action No. 0:16-cv-04278 (JNE-TNL)

**REBUTTAL EXPERT REPORT OF WARREN D. WOESSNER IN SUPPORT OF
PLAINTIFFS' RENEWED MOTION FOR PRELIMINARY INJUNCTION**

Table of Contents

I. BACKGROUND.....	1
II. SUMMARY OF MY SUPPLEMENTAL REPORT	1
III. THE CLAIMS OF THE '958 PATENT ARE NOVEL AND UNOBVIOUS	2
IV. SUMMARY	
(A) Claim Construction.....	2
(B) Claims 1-5 of the '958 Patent are not Anticipated by or Obvious in View of the Art Cited by Defendants	3
(i) Legal Standards of Anticipation.....	3
(ii) Claims 1 and 5 of the '958 Patent are not Anticipated.	4
(a) Weight is to be given to the "wherein" clause in claim 1.....	4
(b) The requirement in claim 1 that the present composition adheres to the exterior surface of an object so that it can be sucked or licked therefrom is not explicit or inherent in the prior art.	4
(1) The medium chain triglycerides (MCTs) recited in claimed method.....	4
(2) The profile of the MCTs present in Vigantol oil is unknown.....	5
(3) MCTs are not universally adherent to all surfaces	6
(4) The Prior Art cited by the Defendants Fails the "Strict Identity" Rule.	7
(iii) Legal Standards of Obviousness.....	7
(iv) Claims 1-5 of the '958 Patent are not Obvious.....	11
(a) Claims 1 and 5 are not obvious in view of Harder considered alone, or in combination with the secondary references.	11
(b) Claim 2 is not obvious.	13
(c) Claim 3 is not obvious.....	14
(d) Claim 4 is not obvious.....	14
(e) Claim 5 is not obvious.....	14
V. CONCLUSION.....	14

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Other Materials

Preliminary Expert Report of Warren D. Woessner

Declaration of Robert O. (Bill) Williams III, Ph.D. In support of Defendant's Opposition to Plaintiffs' Renewed Motion for Preliminary Injunction ("Defendants' Opp".)

Declaration of Michael R. Mischnick In Support of Plaintiffs' Renewed Motion for Preliminary Injunction

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I. BACKGROUND

The goal of the inventors was to meet the need for a simple method to administer a precise amount of vitamin D in a small controlled amount of solvent. Such a method is medically important since the minimal daily requirement can be met by very small quantities of vitamin D, i.e., 10 µg of vitamin D₃ per day for an infant. While low doses of vitamin D can prevent the onset of rickets in infants, higher doses can cause hypercalcemia and related toxic effects. (Conrad Decl., Ex. K.) The method must be simple and reproducible by the consumer, such as the care provider of an infant.

The inventors' claimed method provides the daily requirement of vitamin D (400 IU) in a single drop of solvent that adheres to a surface such as a pacifier or skin, such as the mother's nipple. The baby, older child or adult can ingest the appropriate amount of vitamin D by licking or sucking the composition from the surface. The inventors obtained U.S. Patent No. 9,066,958 on this method that has a priority date of their previous Canadian application, filed September 14, 2006. Conrad Decl., Ex. E ("958 patent").

II. SUMMARY OF MY SUPPLEMENTAL REPORT

In accord with the case law and the prosecution history of the '958 patent, the claim 1 clause, "wherein said [applied] drop adheres to the surface of said object" should be given weight as a claim limitation. If the "wherein" clause is given patentable weight, Defendants cannot meet the "strict identity test" for anticipation or the "all elements" requirement for obviousness.

Defendants arguments that the "adherence" requirement is inherently present in prior art vitamin D compositions fails because: (a) the inherent presence of a missing claim element in the prior art must be necessary and inevitable, (b) Baby Ddrops does not adhere to all surfaces to which one drop is applied, and (c) Defendants cannot establish the composition of the single vitamin D composition (Vigantol oil) that was available prior to the effective filing date of the '958 patent. Defendants must employ impermissible hindsight to reconstruct Plaintiffs' invention from isolated pieces of the prior art.

Apart from the fact that Defendants cannot establish the composition of the Vigantol oil discussed in the primary Harder reference, the secondary references do not remedy the deficiencies in the primary reference.

Stoppard discloses administration of an undefined amount of an unspecified liquid medicine by dipping a finger into a dose of the medicine and having the baby suck it off. One drop of the composition recited in claim 1 containing, e.g., the minimum daily requirement of vitamin D cannot be administered in this fashion.

Gibbins and/or Bass report the analgesic effects resulting from babies licking sugar water from the surface of a pacifier that has been dipped multiple times into the sugar solution.

Piene discloses a surfactant-stabilized oil-in-water emulsion containing vitamin D in the oil phase and calcium in the water phase. Calcium, water and the surfactant are excluded from the vitamin D composition recited in the '958 patent by use of the closed claim phrase "consisting of".

III. THE CLAIMS OF THE '958 PATENT ARE NOVEL AND UNOBVIOUS

(A) Claim Construction

In view of the fact that Defendants have argued that the "wherein" clause of claim 1 is not a claim limitation, and should be given no weight in resolving the anticipation or obviousness questions, I have supplemented the initial constructions of the claim elements, to assist in addressing this issue. Reproduced below are the constructions that Plaintiffs currently propose:

<u>Claim Term</u>	<u>Plaintiffs' Proposed Construction</u>	<u>Citation</u>
" <i>vitamin D</i> "	"Vitamin D, Vitamin D ₃ and/or Cholecalciferol"	Opening Br. 19-20
" <i>nutritional and therapeutic amount</i> "	"that amount which provides suitable effects on the circulating concentration of 25-hydroxy vitamin D"	Opening Br. 20
" <i>one drop of a composition consisting of 9 to 9000 mcg/ml Vitamin D in a ...</i> "	"the quantity of a liquid that coalesces into a single globule, whose size varies according to physical conditions and the properties of the fluid itself, which	Opening Br. 20-21

<u>Claim Term</u>	<u>Plaintiffs' Proposed Construction</u>	<u>Citation</u>
	consists of 9 to 9000 mcg/ml vitamin D in a liquid triglyceride"	
" <i>Liquid Triglyceride of C₆-C₁₂ Carbon Chain Length</i> "	"medium chain triglycerides [MCTs] which can be a mixture of 2 or 3 (C ₆ -C ₁₂) fatty acid/esters of glycerol molecules"	Opening Br. 21-22
" <i>applying one drop of the composition, to the exterior surface of an object, wherein said drop adheres to the surface of said object</i> "	Object and surface are selected so that one drop will not drip or run off within 10 seconds.	Conrad Decl. Ex. E ('958 Patent at Example 1.)

(B) Claims 1-5 of the '958 Patent are not Anticipated by or Obvious in View of the Art Cited by Defendants

(i) Legal Standards of Anticipation

A patent is invalid if "the invention was...described in a printed publication in this or a foreign country" more than one year before the effective filing date of the patent application. 35 U.S.C. § 102 (b), pre-AIA. A patent is invalid for anticipation under 35 U.S.C. § 102(b) if a single prior art reference discloses each and every limitation of the claimed invention, arranged as in the claim. This requirement has been referred to as the "strict identity rule." The absence of a claim element in the prior art renders the art non-anticipatory under this rule. See, J.M. Mueller, Patent Law, Wolters-Kluwer (5th ed. 2016) at 230.

A reference's disclosure of individual elements of the claim in question is usually explicit, but case law makes it clear that the disclosure can be inherent. Schering Corp. v. Geneva Pharms., 339 F.3d 1373, 1379 (Fed. Cir. 2003). The inherent presence of the element can be established by extrinsic evidence that establishes that the missing element was, in fact, necessarily and inevitably present in the prior art. In re Oelrich, 666 F.2d 578 (C.C.P.A. 1981). Mueller at 233-235.

For example, in the present case, the prior art is silent about whether or not administration of one drop of Vigantol oil by placing it on the end of a spoon inherently discloses the claim element "wherein said drop adheres to the surface of said object."

(ii) Claims 1 and 5 of the '958 Patent are not Anticipated.

(a) Weight is to be given to the "wherein" clause in claim 1.

Claim 1 of the '958 patent recites that an applied drop of the vitamin D composition adheres to the surface to which it is applied. Defendants have attempted to avoid the task of establishing the inherency of this claim element in the prior art by erroneously arguing that the "wherein" clause in claim 1 of the '958 patent should be given no weight as a claim limitation. The case law cited by Defendant is irrelevant to this issue.

Neither Hofer v. Microsoft Corp., 405 F.3d 1326 (Fed. Cir. 2005) or Syntex (USA) LLC v. Apotex, Inc., 407 F.3d 1371 (Fed. Cir. 2005) addresses the weight to be given to a "wherein" clause. Hofer involves the weight to be given to a "whereby" clause, which is distinct from a "wherein" clause. Syntex did not involve the interpretation of a "wherein" clause, or even the elements of a method claim. The phrase "in a stabilizing amount" was held not to be limiting because it described the effect of an ingredient that was also described in terms of a wt/vol range in the drug composition.

Much more to the point, in Griffin v. Bertina, 285 F.3d 1029, 1034 (Fed. Cir. 2002), the court held that a "wherein" clause limits a process claim when the clause gives "meaning or purpose" to the manipulative steps. See also, Manual of Patent Examination Procedure ("MPEP") (8th ed. 2006) at § 2103(c) and 2111.04. The Examiner of the U.S. application that issued as the '958 patent also properly gave weight to the "wherein" clause in his "Reasons for Allowance." Woessner Report, at page 22. See Desenberg v. Google, Inc., 392 Fed. App. 868, 876 (Fed. Cir. 2010).

(b) The requirement in claim 1 that the present composition adheres to the exterior surface of an object so that it can be sucked or licked therefrom is not explicit or inherent in the prior art.

(1) The medium chain triglycerides (MCTs) recited in claimed method.

As noted above, the vitamin D/MCT composition recited in claim 1 is applied to the exterior surface of an object and adheres thereto so that a human, such as an adult or an infant can lick or suck the composition directly from the surface, so as to ingest an effective dose of vitamin D. The patent does not disclose that any C₆-C₁₂ or C₈-C₁₀ triglyceride mixtures will adhere to all surfaces.

As recited by claim 1 of the '958 patent, 9 to 9,000 mcg/ml of vitamin D are dissolved in a liquid triglyceride of 6 to 12 carbon chain lengths. As recited by claim 5, the triglyceride component includes at least 95% triglycerides of 8 to 10 carbon chain length. As disclosed in Example 5, of the '958 patent, the medium chain triglycerides are United States Pharmacopeia (USP) Grade. According to the USP, the fatty acid fraction of the medium chain triglycerides contain 50-80% C₈ fatty acids and 20-50% C₁₀ fatty acids. The viscosity is between 25-33 centipoises determined at 20° ± 1 [C]. The triglycerides are obtained by processing the oil derived from the endosperms of palm or coconut species as described below. USP, Medium Chain Triglycerides, USP-29-NF24, page 3452 (Jan. 1, 2007), Ex. A. This composition is reflected in the table at Col. 5, lines 40-47 of the '958 patent.

It is clear that the USP specifications for MCT permit a considerable amount of variation in both the amounts of C₆ to C₁₂ triglycerides and the viscosity of the recited composition.

(2) The profile of the MCTs present in Vigantol oil is unknown.

On the other hand, the record is incomplete and/or uncertain regarding the composition(s) of the MCT solvent in Vigantol oil available prior to 2006. The primary Harder reference only discloses that the solvent contains “medium chain triglycerides (vegetable oil).” Conrad Decl., Ex. I.

The most complete description of Vigantol oil is in Medicines Q&A table taken from the NHS Evidence website, www.evidence.nhs.uk (March 2012) Conrad Decl., Ex. L. The description of the Vigantol oil excipients is given as “Medium Chain Triglycerides, nitrogen, carbon dioxide, migliol (coconut and palm oil)”.¹ Baby Ddrops do not contain “coconut oil” or “palm oil”, as assumed by Dr. Williams. Williams Decl., para. 20, and his comments about their viscosity or adherence are irrelevant to this analysis. Furthermore, Medicines Q&A was published about six years after the effective filing date of the '958 patent.

¹ Although Defendants suggest that Dr. R. Vieth was familiar with the formula of Vigantol oil before Vieth et al. filed the application for the '958 patent, the paper in J. Clin. Endocrin. and Metabolism published in November 2005 does not disclose that Vieth analyzed the “oil” or solvent composition of Vigantol oil. Hoskins Decl., Ex. J at 4-6. Furthermore, the Houghton et al. paper, Am. J. Clinical Nutr., 84, 695 (2006) also does not provide the composition of Vigantol oil. Hoskins Decl., Ex. I.

The 1970 Wolf chapter only gives the concentration of vitamin D in an unspecified carrier. Conrad Decl. Ex. K.

"Migliol" is apparently a reference to one or both of the Miglyol[®] medium chain triglyceride products available from CREMER OLEO GmbH & Co. K.G., Hamburg, Germany, "Miglyol[®] 810 and 812." Conrad Decl., Exhibit N. The specification sheet employed as Ex. N is undated, and was obtained from the CREMER website in 2017. It discloses that Miglyol[®] 810 contains 65-80% caprylic acid (C₈ fatty acid) and 20-35.0% capric acid (C₁₀ fatty acid). Miglyol[®] 812 contains 50-65% caprylic acid and 30-45% capric acid. The viscosity of each triglyceride mixture is given as 27-33 mPa-s.

The triglycerides are semi-synthetic. They are synthesized using both coconut oil and palm oil, that are hydrolyzed and fractionated to yield medium chain fatty acids. The medium chain fatty acids are used to esterify glycerol to yield MCT mixtures. See, V.K. Bakken, "Medium Chain Triglycerides -- Their Composition Preparation and Application," J. Amer. Oil Chem. Soc., 45, 23 (1968). Ex. B.

It is clear from the above information that the composition and viscosity of MCT's can vary over a wide range. Defendants have also provided no evidence as to the composition of the MCTs used in Vigantol[®] sold prior to September 2006 beyond the vague disclosure in the 2003 Harder book ("medium chain triglycerides (vegetable oils)") and Plaintiffs do not concede that the Vigantol[®] sold at that time contained "Migliol(s)" or Miglyol(s). The A to Z table, Conrad Decl., Ex. L, was published in 2013. Defendants have fallen far short of demonstrating that any MCT mixture would necessarily and inevitably adhere to the surface of a spoon (made of what?), much less to the surface of any object.

(3) MCTs are not universally adherent to all surfaces

According to the Williams Declaration, because the '958 patent "recognizes the importance of viscosity of the liquids in adherence to an object ...if an oil has a carbon chain length of 6-12 and is a [MCT], it will have a sufficient viscosity to adhere to an object each and every time." Williams Decl. at page 6.

The "Argument" section of "Defendants' Opposition to Plaintiffs' Renewed Motion for Preliminary Injunction" ("Def. Opp.") does not assert that the MCT make-up of Vigantol oil that was available to the public prior to September 2006 is/was the same

as the MCT used in Baby Ddrops. Instead, Defendant presents the conclusory and circular argument that because Plaintiffs' claim 1 recites that the claim limitation "wherein the drop [of the composition] adheres to the surface of said object," that the disclosure in Harder that "[one] drop of Vigantol[®] oil is given to the baby from the tip of a spoon," combined with the unsupported opinion in the Williams Declaration that all MCTs are universally adherent to all surfaces, renders the selection of C₆-C₁₂ MCTs that will adhere to a given surface an inherent property of the composition recited in claim 1. Def. Opp. at page 18, Conrad Decl., Ex. I at page 4.

This conclusion is without foundation. I provided a bottle of Baby Ddrops[®] to Michael R. Mischnick, an attorney at Schwegman Lundberg & Woessner, P.A., who is a registered patent attorney and holds a degree in chemical engineering. I asked him to evaluate ability of one Michael drop of Baby Ddrops[®] to adhere to a stainless steel spoon. As described by Mr. Mischnick, one drop of Plaintiffs' Baby Ddrops[®] product did not adhere to a stainless steel spoon. Mischnick Decl. Ex. C. The drop of liquid was contained by the lip of the spoon when the spoon was tipped forward slightly, but immediately flowed down the bowl of the spoon when the spoon was held level or tipped back slightly.

(4) The Prior Art cited by the Defendants Fails the "Strict Identity" Rule.

In accord with Plaintiffs' proposed claim construction of the "wherein" clause, any presumption advanced by Defendants that the one sentence in Harder (Conrad Decl., Ex. 1) that because one drop of Vigantol oil can be administered by applying it to the tip of a spoon, leads to the conclusion that (a) Vigantol oil must adhere to the spoon and (b) any C₆-C₁₂ MCT mixture would adhere to any surface, has been rebutted. Therefore, the references cited by the Examiner as anticipatory of claims 1 and 5 fail the "strict identity test" and cannot anticipate any of the claims of the '958 patent.

(iii) Legal Standards of Obviousness.

A patent is also invalid if "the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains." 35 U.S.C. § 103, pre-AIA. However, to establish a prima facie obviousness of a claimed invention, all the claim features must be taught or suggested by the prior art, apart from the obviousness of

their combination. In re Royka, 490 F.2d 986 (CCPA 1974). This has been termed the "All Elements Test." See, Mueller at 419, fn. 269.

The Supreme Court's decision in KSR International v. Teleflex Inc., 550 U.S. 398 (2007), which addressed the obviousness of a simple combination of mechanical elements, provides guidelines for resolving the obviousness question. While Defendants selectively quote from sections of KSR that generally discuss factors that would suggest that a combination of known elements would be obvious to a person of ordinary skill in the art, KSR also warns against the impermissible use of hindsight or ex post reasoning to address the obviousness question. As summarized by the Supreme Court in KSR:

A factfinder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant upon ex post reasoning. See Graham, 383 U.S., at 36, 86 S. Ct. 684, 16 L. Ed. 2d 545 (warning against a "temptation to read into the prior art the teachings of the invention in issue" and instructing courts to "guard against slipping into the use of hindsight" (quoting Monroe Auto Equipment Co. v. Heckethorn Mfg. & Supply Co., 332 F.2d 406, 412 (CA6 1964))).²

As stated by the court In re Katz, 687 F.2d 450, 454 (C.C.P.A. 1982): "Disclosure to the public of one's own work constitutes a bar to the grant of a patent claiming the subject matter so disclosed (or subject matter obvious therefrom) only when such disclosure occurred more than one year prior to the date of the application." More succinctly stated in Katz: "[O]ne's own invention, whatever the form of disclosure to the public, may not be "prior art" against oneself, absent a statutory time bar."³

While it would appear that such firm holdings by the courts would make it both a simple matter for the practitioner, the Examiner, or the courts to identify obviousness rejections or appellate decisions based on hindsight, unfortunately this is far from the case. Hindsight bias is insidious, as it can become a part of the resolution of the

² For the purposes of this report "Impermissible Hindsight," "Hindsight Reconstruction" or simply "Hindsight" will be defined as the use of non-prior art generated by the inventor as prior art under § 102. Although this non-prior art is usually referred to as "knowledge of the claimed invention," it can include other information about the invention disclosed by the inventors prior to filing the application or in the specification.

³ Id. [Emphasis in Original], citing In re Facius, 161 U.S.P.Q. 294 (C.C.P.A. 1969). As conceded by the Defendants, the relevant portions of at least one of the publications, Fuleighan et al., Hoskins Decl. Ex. J, contain R. Vieth's work, and so are not prior art under § 102(a). The Wjest paper, Hoskins, Ex. H and the Houghton et al. paper, Hoskins, Ex. I are not prior art under any section of § 102. The Fliszar et al. paper was published in October 2005, and so is only prior art to the '958 patent under § 102(a). Hoskins Decl. Ex. P.

obviousness question very early in the process. As set forth in Graham v. John Deere Co. of Kansas City, 383 U.S. 1 (1996):

Under § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented.

As stated In re Carroll:

In deciding obviousness, one must look at the prior art from the vantage point in time *prior* to when the invention was made; hindsight obviousness after the invention was made is not the test.⁴

Of course it can be extremely difficult to re-construct the Examiner's reasoning ex post facto, but in KSR the Supreme Court at least held that there must be some foundation under an obviousness rejection apart from the fact that the elements of the invention were available to the art:

Rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness (emphasis supplied).⁵

In a decision holding a jet engine feature unobvious, the Federal Circuit emphasized that the use of the "new" TSM test to block hindsight reconstruction:

To preclude hindsight in this [103] analysis, this court flexibly seeks evidence from before the time of the invention in the form of some teaching, suggestion, or even mere motivation (conceivably found within the knowledge of an ordinary skill artisan) to make the variation or combination.⁶

This language is remarkably similar in tone to that used by Chief Judge Markey in W. L. Gore and Associates v. Garlock, Inc. thirty four years ago:

It is difficult but necessary that the decision maker forgot what he or she has been taught at trial about the claimed invention and cast the mind back

⁴ 601 F.2d 1184 (C.C.P.A. 1979).

⁵ 121 S. Ct. at 1741.

⁶ Rolls-Royce, PLC. v. United Technologies Corp., 603 F.3d 1325 (Fed. Cir. 2010).

to the time the invention was made (often as here many years), to occupy the mind of one skilled in the art who is presented with the references, and who is normally guided by the then-accepted wisdom in the art.⁷

In contrast to the simple mechanical device considered by the KSR court, Judges Markey, Davis and Miller reviewed a sophisticated new polymeric fabric (Gore-Tex®), gaps and negative teachings in the art and secondary considerations supporting patentability. Still both the Gore panel and the KSR Court cited In re Bergel, 292 F.2d 955 (C.C.P.A. 1961) as requiring some suggestion of the invention in the prior art, and at least as far as the need to disregard "siren hindsight" is concerned, the opinions are not inconsistent, with each other, or with the nearly century-old language of the Supreme Court in Diamond Rubber Co. v. Consolidated Rubber Tire Co.⁸

Knowledge after the event is always easy, and problems once solved present no difficulties, indeed, may be represented as never having had any, and expert witnesses may be brought forward to show that the new thing which seemed to have eluded the search of the world was always ready at hand and easy to be seen by a merely skillful attention. But the law has other tests of the invention than subtle conjectures of what might have been seen and yet was not.

Where the prior art gives no indication of which parameters are critical or the direction as to which of many possible choices is likely to be successful, the fact that the claimed combination falls within the scope of possible combinations taught therein does not render it obvious.⁹

In other words, the need to "pick and choose" from the available prior art to arrive at the elements of the claimed invention should set off a warning light that hindsight reconstruction is in use. As an early embodiment of the Fed. Cir. clearly stated in W.L. Gore and Associates v. Garlock, Inc.:

To imbue one of ordinary skill in the art with knowledge of the invention in suit when no prior art reference[s]...of record convey or suggest that knowledge, is to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher.¹⁰

⁷ 721 F.2d at 1553. Judge Markey also wrote that "objective evidence of nonobviousness...can often serve as insurance against the insidious attraction of the siren hindsight when [the decision maker] is confronted with the difficult task of evaluating the prior art." Id. The Supreme Court found no such "insurance" in KSR.

⁸ 220 U.S. 428, 435 (1911).

⁹ In re O'Farrell, 853 F.2d 894 (Fed. Cir. 1988).

¹⁰ 721 F.2d 1550, 1553 (Fed. Cir. 1983).

Even though KSR made it clear that the teaching, motivation or suggestion (the "TSM test") to make the invention need not reside solely in the prior art, the Court did not disturb decades of jurisprudence holding that the claim cannot provide the rationale to combine elements from the prior art to recreate it. As stated in Gore, the Examiner is not entitled to use the claim as a "frame" and to employ "individual naked parts of separate prior art references...as a mosaic to recreate a facsimile of the claimed invention."¹¹

Even after KSR, the TSM test not only remains available to test obviousness rejections, but most litigants and Examiners still use the test as the framework for obviousness rejections. This allows litigants and practitioners to argue that the Defendants or the Examiner is using Applicant's invention as either the "motivation" to make the invention or as evidence of a "reasonable expectation of success."

(iv) Claims 1-5 of the '958 Patent are not Obvious.

(a) Claims 1 and 5 are not obvious in view of Harder considered alone, or in combination with the secondary references.

As discussed above, the Harder book excerpt relied upon by Defendants as anticipatory, does not disclose or suggest that a single drop of Vigantol oil would adhere to the exterior surface of an object, as that term is defined in the specification. In fact, the vitamin D/MCT composition marketed by Plaintiffs as Baby Ddrops does not adhere to a spoon, so that a baby, or anyone else, can obtain a dose of vitamin D by licking or sucking the composition from the tip of a spoon. Mischnick, Ex. C. Conrad, Ex. I.

The secondary references do not remedy the absence of the necessary "adherence" element in Harder. Also absent from the cited prior art is the composition of the MCT or MCTs in Vigantol oil(s) that would impart this property to the recited composition. The fact that the cited references do not teach or suggest every claim element moots the obviousness question per se, In re Ochiai, 76 F.3d 1565 (Fed. Cir. 1995); In re Royka, 400 F.2d 986 (CCPA 1974) (to establish prima facie obviousness of a claimed invention, all the claim features must be taught or suggested by the prior art.)

¹¹ Id. at 1552. See also In re Warner, 379 F.2d 1011 (C.C.P.A. 1967) cert. den'd. 389 U.S. 1057 (1968). ("[W]e note that it is impermissible to use the claimed invention as an instruction manual or 'template' to piece together isolated disclosures and teachings of the prior art so that the claimed invention may be rendered obvious.")

Defendants rely on the general teaching in Stoppard, Hoskins Decl., Ex. F, that if "your baby will not take his medicine from a spoon or a dropper, measure the required dose into a container. Dip your little finger into it, then let your baby suck it off your finger." These directions simply cannot be carried out with the recited dose of 1 drop of the recited vitamin D/MCT composition. The dose is simply too small to "dip" a finger into it. Rather, the recited dose is first applied to, e.g., a finger tip where it adheres until the baby licks or sucks it off. This mode of delivery of a small unit dose of the "medicine" does not suggest administering it by first applying a single dose to a finger from which the baby can ingest it. The only disclosure of the use of a dropper is at panel 2 of "A to Z," where the dropper tip is placed into the baby's mouth and the required dosage is "released" directly into the baby's mouth. Hoskins Decl., Ex. F at page 32.

The disclosures in Gibbins and/or Blass do not render Plaintiffs' mode of delivery obvious. Hoskins Decl., Ex. K (Blass et al., Pain, 611 (1999)). Hoskins Decl., Ex. L (Gibbins et al., Pain Research and Management, 6, 21 (2001)). As the titles would suggest, both papers involve studies on the administration of sucrose-water solutions to alleviate pain in infants undergoing routine hospital procedures. In Blass et al., babies were administered four doses of 12% sucrose dissolved in water by dipping a pacifier into the sucrose solution and having the baby lick a total of 2 ml of the solution from the pacifier. The goal of the study was to compare the analgesic effects of sucking the sucrose solution from the pacifier vs. sucking water from the pacifier, and the sucrose solution was found to be more effective in reducing pain. Blass at 615. Gibbins at page 22 apparently summarizes the Blass study.

As summarized in the '958 patent, Table 1, and described at para. 19 of the Williams Decl., one drop of water applied to a human nipple "dripped off," undoubtedly due to its low viscosity. Williams Decl. at para. 19. Since the viscosity of water is only 0.7972 mPa-s at 30°C, adding 12 wt-% sucrose, as taught by Blass or Gibbins would not cause the solution to approach the viscosity of MCTs. Therefore, the person of ordinary skill in the art, given the positive results attained by Blass and Gibbins in controlling pain, would not be motivated to replace the effective sugar-water solutions with a much more viscous composition. This conclusion is supported by the disclosure in Gibbins at

page 22, Col. 1, that increasing the sucrose dose to greater than 0.5 wt-% did not improve the analgesic effect.

(b) Claim 2 is not obvious.

Dependent claim 2 recites that "said human being is an adult and said object is the skin of an arm or hand of said adult." This claim is intended to encompass self-administration of the recited vitamin D/MCT composition, as disclosed in the '958 patent at Example 6.

In support of their obviousness conclusion, Defendants cite Piene, PCT/GB00/00986 (March 16, 2000) which discloses that there "is a need for alternative dosage forms for vitamin D to accommodate the different preferences of 'different age groups.'" Conrad Decl., Ex. P. While this need may be manifest, Piene meets the need by administering vitamin D and calcium in a two-phase composition comprising a continuous aqueous phase containing a viscosity modifier and a dissolved calcium compound, and a discontinuous phase comprising vitamin D and an edible triglyceride, further containing an emulsifying agent that is an edible phospholipid or a fatty acid ester. Peine at Abstract and page 1.

These compositions are remote from the compositions of the claims of the '958 patent. They are oil-in-water emulsions that are intended for oral administration, i.e., to be ingested by drinking them. Id. at pages 8 and 12. Such compositions are excluded from the vitamin D/MCT compositions recited by the claims of the '958 patent by the use of the phrase "consisting of," which limits the composition to its two named components. In re Gray, 53 F.2d 520 (CCPA 1931); MPEP 2111.03.

To further support their obviousness conclusion, Defendants cite Stoppard. As discussed above, Stoppard instructs the caregiver to dip his/her finger into an unspecified "medicine" and then present it to the baby. There is no suggestion in any of these documents that the vitamin D/MCT oil, a sucrose solution or an oil-in-water emulsion, should be self-administered to an adult by the adult's or a third party's applying one drop of the composition to the finger of the adult. The adult then sucks or licks it off to deliver a therapeutic or nutritional amount of vitamin D.

Peine is also not logically combinable with Harder, Gibbins or Blass. Harder delivers one drop of a vitamin D/MCT composition to a baby directly from a spoon.

Blass and Gibbins deliver low viscosity aqueous sucrose solutions to babies from the surface of a pacifier.

(c) Claim 3 is not obvious.

While Defendants argue that they only need to show the prior art teaches applying "a medicine to either a woman's nipple or a pacifier," as discussed above, Stoppard's administration of "a medicine" by dipping a finger into a premeasured amount of the liquid medicine or medicinal composition would not motivate the art worker to administer a single drop of the composition of claim 1 of the '958 patent to a baby in this manner.

The disclosures in Blass and Gibbins that an analgesic dose of a sucrose-water solution can be administered to a baby by dipping a pacifier into the free-flowing composition and presenting the wetted pacifier to the baby is remote from Plaintiffs' claimed invention. In Blass and Gibbins, the baby is receiving 0.5 ml of the sucrose solution in each of 4 dosings. This amounts to administering 15 drops of the "medicine" in each of the doses. The person of ordinary skill in the art would not be motivated to apply and administer one drop of a viscous vitamin D/MCT composition in this fashion.

(d) Claim 4 is not obvious.

Even conceding that the person of ordinary skill in the art would find it obvious to reduce the recited dose of vitamin D "to meet recommended dosages," it would still not be obvious to administer a one drop dose so that it adheres to a surface from which the baby or adult can ingest it by licking or sucking the surface, as recited in claim 1.

(e) Claim 5 is not obvious.

Claim 5 is not obvious for the same reason that claim 1 is not obvious. Also, while claim 5 discloses that the MCTs contain at least 95% C₆-C₁₂ triglycerides, only Miglyol[®] 812 is analyzed in Fliszar. Miglyol 810 was not analyzed. Hoskins Decl., Ex. P at Tables 3 and 4. While 812 contained greater than 95% total triglycerides, two other commercially available MCT products were analyzed that contained very little triglyceride content. Also, the GC method referenced in Fliszar indicated that only 91.1% triglycerides are present in Miglyol 812. As noted above, Plaintiffs do not concede that the MCT content of Vigantol oil was known to the art in 2006.

IV. CONCLUSION

Defendants cannot demonstrate that the "adherence" property is either explicit or inherent in the prior art. Therefore it fails the "strict identity" test for anticipation. Defendants are left to argue obviousness in view of prior art that does not disclose or suggest the makeup of the composition recited in the claims-in-suit. The references cited by Defendants also fail the "all elements" requirement and so cannot support the prima facie obviousness of the claims. Furthermore, the references are not logically combinable, absent the impermissible use of hindsight to assemble Plaintiffs' method from isolated disclosures of claim elements in the prior art.

For example, the primary reference discloses that Vigantol oil contains vitamin D and "medium- chain triglycerides (vegetable oil)" and nothing more. Conrad Decl., Ex. L. The undated CREMER specification sheets for Miglyol 810 and 812 (Conrad Decl., Ex. N) disclose MCT compositions that would meet the adherence limitation recited in the claims if judicious selections from the broad ranges of C₆- and C₁₂-triglycerides were made, so that the vitamin D/MCT composition would adhere to the surfaces of some "objects," but not to others. Absent hindsight reconstruction there is no guidance to this claim limitation in any of the cited documents, and claims 1-5 are therefore not obvious.

SCHWEGMAN, LUNDBERG & WOESSNER, P.A.

Dated: May 23 2017

By: Warren D. Woessner

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EXHIBIT A

U.S. PHARMACOPEIA

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Medium-Chain Triglycerides

Glycerides, mixed decanoyl and octanoyl.

Caprylic and capric triglycerides.

Change to read:

» Medium-Chain Triglycerides [▲]consist of a mixture of triglycerides of saturated fatty acids, mainly of caprylic acid (C₈H₁₆O₂) and capric acid (C₁₀H₂₀O₂). The fatty acids are derived 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. ^{▲NF24} They contain not less than 95 percent of saturated fatty acids with 8 and 10 carbon atoms.

Packaging and storage— Preserve in tight containers, protected from light. Store at temperatures not exceeding 25°.

Labeling— Where it is intended for use in parenteral nutrition, it is so labeled.

Appearance— The substance is clear and not more intensely colored than a solution prepared immediately before use by mixing 2.4 mL of ferric chloride CS and 0.6 mL of cobaltous chloride CS with *Diluent*, prepared as directed below, to make 10.0 mL, and diluting 5.0 mL of the solution so obtained with *Diluent* to make 10.0 mL. Make the comparison by viewing the substance and the solution downward in matched color-comparison tubes against a white surface (see *Color and Achromicity* { 631 }).

Diluent— Transfer 27.5 mL of hydrochloric acid to a 1000-mL volumetric flask, and dilute with water to volume.

Identification—

A: It meets the requirements of the test for *Saponification value*.

B: It meets the requirements of the test for *Fatty acid composition*.

Specific gravity { 841 } : between 0.93 and 0.96, at 20°.

Acid value { 401 } : not more than 0.2.

Hydroxyl value { 401 } : not more than 10.

Iodine value { 401 } : not more than 1.0.

Peroxide value { 401 } : not more than 1.0.

Saponification value { 401 } : between 310 and 360, determined on 1.0 g.

Unsaponifiable matter { 401 } : not more than 0.5%, determined on 5.0 g.

Fatty acid composition { 401 } — The fatty acid fraction of Medium-Chain Triglycerides exhibits the following composition, as determined in the section *Fatty Acid Composition*. Disregard any peak with an area less than 0.05% of the total area:

Carbon-Chain Length	Number of Double Bonds	Percentage (%)
6	0	≤2.0
8	0	50.0–80.0
10	0	20.0–50.0
12	0	≤3.0
14	0	≤1.0

Viscosity { 911 } : between 25 and 33 centipoises determined at $20 \pm 0.1^{\circ}$ with a capillary viscosimeter.

Refractive index { 831 } : between 1.440 and 1.452, at 20° .

Alkaline impurities— Dissolve 2.0 g of Medium-Chain Triglycerides in a mixture of 1.5 mL of alcohol and 3.0 mL of ethyl ether. Add 0.05 mL of *bromophenol blue TS*, and titrate with 0.01 N hydrochloric acid to a yellow endpoint: not more than 0.15 mL of 0.01 N hydrochloric acid is required.

Water, Method I { 921 } : not more than 0.2%.

Total ash { 561 } : not more than 0.1%, determined on 2.0 g.

Heavy metals, Method II { 231 } — [NOTE—Use this test for Medium-Chain Triglycerides intended for use other than in parenteral nutrition.]

Test solution— Transfer 2.0 g of Medium-Chain Triglycerides to a quartz crucible, add 0.5 g of magnesium oxide, and mix. Ignite the crucible to dull redness until a homogeneous white or grayish-white mass is obtained. Ignite at 800° for 1 hour, cool, and dissolve the residue by adding two 5-mL portions of diluted hydrochloric acid. Add 0.1 mL of phenolphthalein TS and then ammonium hydroxide until a pink color is obtained. Cool, add glacial acetic acid until the solution is decolorized, then add 0.5 mL in excess, and dilute with water to 20.0 mL.

Standard solution— To 0.5 g of magnesium oxide add 2.0 mL of *Standard Lead Solution*, and evaporate to dryness at 105° for 1 hour. Using the same conditions as prescribed for the *Test solution*, ignite, dissolve in diluted hydrochloric acid, add ammonia and then acetic acid, and dilute with water to 20.0 mL.

Procedure— To 12 mL of the *Test solution*, add 2.0 mL of *pH 3.5 Acetate Buffer*, mix, add to 1.2 mL of thioacetamide-glycerin base TS, and mix immediately. To 10 mL of the *Standard solution*, add 2.0 mL of the *Test solution*, add 2.0 mL of *pH 3.5 Acetate Buffer*, mix, add to 1.2 mL of thioacetamide-glycerin base TS, and mix immediately. Prepare a blank, using a mixture of 10 mL of water and 2.0 mL of the *Test solution*. Compared to the blank, the *Standard solution* shows a light brown color. Dilute both the *Test solution* and the *Standard solution* with water to 50 mL, allow to stand for 2 minutes, and view downward over a white surface: any brown color from the *Test solution* is not darker than that of the solution from the *Standard solution* (not more than 10 µg per g).

Limit of chromium— [NOTE—Use this test for Medium-Chain Triglycerides intended for use in parenteral nutrition.]

Test stock solution— Transfer about 50 g of Medium-Chain Triglycerides to a 100-mL volumetric flask, dissolve in and dilute with diisobutyl ketone to volume.

Test solution— Transfer 4.0 mL of *Test stock solution* to a 10-mL volumetric flask, and dilute with diisobutyl ketone to volume.

Chromium standard solution— Transfer about 0.283 g of potassium dichromate, previously dried at 105° for 4 hours and accurately weighed, to a 1000-mL volumetric flask, and dilute with water to volume. Immediately before use, dilute this

solution with water to 1000 times its volume. This solution contains the equivalent of 0.1 µg of chromium per mL.

Standard solutions— Into each of three 10-mL volumetric flasks, transfer 4.0 mL of *Test stock solution*, add 0.5, 1.0, and 2.0 mL, respectively, of *Chromium standard solution*, and dilute with diisobutyl ketone to volume. These solutions contain 0.005 µg, 0.01 µg, and 0.02 µg of chromium per mL, respectively.

Procedure— Concomitantly determine the absorbances of the *Standard solutions* and the *Test solution* at least three times each, at the wavelength of maximum absorbance at 357.8 nm, with a suitable atomic absorption spectrophotometer (see *Spectrophotometry and Light-Scattering* (851)) equipped with a graphite furnace and a chromium hollow-cathode lamp, using argon as the carrier gas. Record the average of the steady readings for each of the *Standard solutions* and the *Test solution*. Plot the absorbances of the *Standard solutions* and the *Test solution* versus the concentration of added chromium. Draw the straight line best fitting the points, and extrapolate the line until it meets the concentration axis. The distance between this point and the intersection of the axes represents the concentration of chromium in the *Test solution*. Not more than 0.05 µg per g is found.

Limit of copper— [NOTE—Use this test for Medium-Chain Triglycerides intended for use in parenteral nutrition.]

Test stock solution and Test solution— Proceed as directed in the test for *Limit of chromium*.

Copper standard solution— Transfer about 0.393 g of cupric sulfate, accurately weighed, to a 1000-mL volumetric flask, and dilute with water to volume. Immediately before use, dilute this solution with water to 1000 times its volume. This solution contains the equivalent of 0.1 µg of copper per mL.

Standard solutions— Into each of three 10-mL volumetric flasks, transfer 4.0 mL of *Test stock solution*, add 1.0, 2.0, and 4.0 mL, respectively, of *Copper standard solution*, and dilute with diisobutyl ketone to volume. These solutions contain 0.01 µg, 0.02 µg, and 0.04 µg of copper per mL, respectively.

Procedure— Concomitantly determine the absorbances of the *Standard solutions* and the *Test solution* at least three times each, at the wavelength of maximum absorbance at 324.7 nm, with a suitable atomic absorption spectrophotometer (see *Spectrophotometry and Light-Scattering* (851)) equipped with a graphite furnace and a copper hollow-cathode lamp, using argon as the carrier gas. Record the average of the steady readings for each of the *Standard solutions* and the *Test solution*. Plot the absorbances of the *Standard solutions* and the *Test solution* versus the concentration of added copper. Draw the straight line best fitting the points, and extrapolate the line until it meets the concentration axis. The distance between this point and the intersection of the axes represents the concentration of copper in the *Test solution*. Not more than 0.1 µg per g is found.

Limit of lead— [NOTE—Use this test for Medium-Chain Triglycerides intended for use in parenteral nutrition.]

Test stock solution and Test solution— Proceed as directed in the test for *Limit of chromium*.

Lead standard solution— Dissolve 160 mg of lead nitrate in 100 mL of water that contains 1 mL of lead-free nitric acid, and dilute with water to 1000 mL. Pipet 10 mL of this solution into a 100-mL volumetric flask, dilute with water to volume, and mix. Immediately before use, dilute this solution with water to 100 times its volume. This solution contains the equivalent of 0.1 µg of lead per mL.

Standard solutions— Into each of three 10-mL volumetric flasks, transfer 4.0 mL of *Test stock solution*, add 1.0, 2.0, and 4.0 mL, respectively, of *Lead standard solution*, and dilute with diisobutyl ketone to volume. These solutions contain 0.01 µg, 0.02 µg, and 0.04 µg of lead per mL, respectively.

Procedure— Concomitantly determine the absorbances of the *Standard solutions* and the *Test solution* at least three times each, at the wavelength of maximum absorbance at 283.3 nm, with a suitable atomic absorption spectrophotometer (see *Spectrophotometry and Light-Scattering* (851)) equipped with a graphite furnace coated inside with palladium carbide and a lead hollow-cathode lamp, using argon as the carrier gas. Calcination is carried out in the presence of oxygen at a temperature below 800°. Record the average of the steady readings for each of the *Standard solutions* and the *Test solution*. Plot the absorbances of the *Standard solutions* and the *Test solution* versus the concentration of added lead. Draw the straight line best fitting the points, and extrapolate the line until it meets the concentration axis. The distance between this point and the intersection of the axes represents the concentration of lead in the *Test solution*. Not more than 0.1 µg per g is

found.

Limit of nickel— [NOTE—Use this test for Medium-Chain Triglycerides intended for use in parenteral nutrition.]

Test stock solution and *Test solution*— Proceed as directed in the test for *Limit of chromium*.

Nickel standard solution— Immediately before use, dilute 10 mL of nickel standard solution TS with water to 1000 mL. This solution contains the equivalent of 0.1 µg of nickel per g.

Standard solutions— Into each of three 10-mL volumetric flasks, transfer 4.0 mL of *Test stock solution*, add 1.0, 2.0, and 4.0 mL, respectively, of *Nickel standard solution*, and dilute with diisobutyl ketone to volume. These solutions contain 0.01 µg, 0.02 µg, and 0.04 µg of nickel per mL, respectively.

Procedure— Concomitantly determine the absorbances of the *Standard solutions* and the *Test solution* at least three times each, at the wavelength of maximum absorbance at 232 nm, with a suitable atomic absorption spectrophotometer (see *Spectrophotometry and Light-Scattering* { 851 }) equipped with a graphite furnace and a nickel hollow-cathode lamp, using argon as the carrier gas. Record the average of the steady readings for each of the *Standard solutions* and the *Test solution*. Plot the absorbances of the *Standard solutions* and the *Test solution* versus the concentration of added nickel. Draw the straight line best fitting the points, and extrapolate the line until it meets the concentration axis. The distance between this point and the intersection of the axes represents the concentration of nickel in the *Test solution*. Not more than 0.1 µg per g is found.

Limit of tin— [NOTE—Use this test for Medium-Chain Triglycerides intended for use in parenteral nutrition.]

Test stock solution and *Test solution*— Proceed as directed in the test for *Limit of chromium*.

Tin standard solution— Dissolve 500 mg of metallic tin (Sn), accurately weighed, in a mixture of 5 mL of water and 25 mL of hydrochloric acid, and dilute with water to 1000 mL. Immediately before use, dilute 10 mL of this solution with dilute hydrochloric acid (2.5 in 100) to 1000 mL, and then dilute 10 mL of the solution so obtained with water to 500 mL. This solution contains the equivalent of 0.1 µg of tin per g.

Standard solutions— Into each of three 10-mL volumetric flasks, transfer 4.0 mL of *Test stock solution*, add 1.0, 2.0, and 4.0 mL, respectively, of *Tin standard solution*, and dilute with diisobutyl ketone to volume. These solutions contain 0.01 µg, 0.02 µg, and 0.04 µg of tin per mL, respectively.

Procedure— Concomitantly determine the absorbances of the *Standard solutions* and the *Test solution* at least three times each, at the wavelength of maximum absorbance at 286.3 nm, with a suitable atomic absorption spectrophotometer (see *Spectrophotometry and Light-Scattering* { 851 }) equipped with a graphite furnace coated inside with palladium carbide and a tin hollow-cathode lamp, using argon as the carrier gas. Record the average of the steady readings for each of the *Standard solutions* and the *Test solution*. Plot the absorbances of the *Standard solutions* and the *Test solution* versus the concentration of added tin. Draw the straight line best fitting the points, and extrapolate the line until it meets the concentration axis. The distance between this point and the intersection of the axes represents the concentration of tin in the *Test solution*. Not more than 0.1 µg per g is found.

Residual solvents { 467 } : meets the requirements.
(Official January 1, 2007)

Auxiliary Information— *Staff Liaison* : Catherine Sheehan, B.Sc., Scientist
Expert Committee : (EM105) Excipient Monographs 1
USP29–NF24 Page 3452
Pharmacopeial Forum : Volume No. 31(1) Page 98
Phone Number : 1-301-816-8262

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Medium-Chain Triglycerides

Glycerides, mixed decanoyl and octanoyl.
Caprylic and capric triglycerides.

Change to read:

» Medium-Chain Triglycerides [▲]consist of a mixture of triglycerides of saturated fatty acids, mainly of caprylic acid (C₈H₁₆O₂) and capric acid (C₁₀H₂₀O₂). The fatty acids are derived 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. ^{▲NF24} They contain not less than 95 percent of saturated fatty acids with 8 and 10 carbon atoms.

Packaging and storage— Preserve in tight containers, protected from light. Store at temperatures not exceeding 25°.

Labeling— Where it is intended for use in parenteral nutrition, it is so labeled.

Appearance— The substance is clear and not more intensely colored than a solution prepared immediately before use by mixing 2.4 mL of ferric chloride CS and 0.6 mL of cobaltous chloride CS with *Diluent*, prepared as directed below, to make 10.0 mL, and diluting 5.0 mL of the solution so obtained with *Diluent* to make 10.0 mL. Make the comparison by viewing the substance and the solution downward in matched color-comparison tubes against a white surface (see *Color and Achromicity* ^{< 631 >}).

Diluent— Transfer 27.5 mL of hydrochloric acid to a 1000-mL volumetric flask, and dilute with water to volume.

Identification—

A: It meets the requirements of the test for *Saponification value*.

B: It meets the requirements of the test for *Fatty acid composition*.

Specific gravity ^{< 841 >}: between 0.93 and 0.96, at 20°.

Acid value ^{< 401 >}: not more than 0.2.

Hydroxyl value ^{< 401 >}: not more than 10.

Iodine value ^{< 401 >}: not more than 1.0.

Peroxide value ^{< 401 >}: not more than 1.0.

Saponification value ^{< 401 >}: between 310 and 360, determined on 1.0 g.

Unsaponifiable matter $\langle 401 \rangle$: not more than 0.5%, determined on 5.0 g.

Fatty acid composition $\langle 401 \rangle$ — The fatty acid fraction of Medium-Chain Triglycerides exhibits the following composition, as determined in the section *Fatty Acid Composition*. Disregard any peak with an area less than 0.05% of the total area:

Carbon-Chain Length	Number of Double Bonds	Percentage (%)
6	0	≤ 2.0
8	0	50.0–80.0
10	0	20.0–50.0
12	0	≤ 3.0
14	0	≤ 1.0

Viscosity $\langle 911 \rangle$: between 25 and 33 centipoises determined at $20 \pm 0.1^\circ$ with a capillary viscosimeter.

Refractive index $\langle 831 \rangle$: between 1.440 and 1.452, at 20° .

Alkaline impurities— Dissolve 2.0 g of Medium-Chain Triglycerides in a mixture of 1.5 mL of alcohol and 3.0 mL of ethyl ether. Add 0.05 mL of bromophenol blue TS, and titrate with 0.01 N hydrochloric acid to a yellow endpoint: not more than 0.15 mL of 0.01 N hydrochloric acid is required.

Water, Method I $\langle 921 \rangle$: not more than 0.2%.

Total ash $\langle 561 \rangle$: not more than 0.1%, determined on 2.0 g.

Heavy metals, Method II $\langle 231 \rangle$ — [NOTE—Use this test for Medium-Chain Triglycerides intended for use other than in parenteral nutrition.]

Test solution— Transfer 2.0 g of Medium-Chain Triglycerides to a quartz crucible, add 0.5 g of magnesium oxide, and mix. Ignite the crucible to dull redness until a homogeneous white or grayish-white mass is obtained. Ignite at 800° for 1 hour, cool, and dissolve the residue by adding two 5-mL portions of diluted hydrochloric acid. Add 0.1 mL of phenolphthalein TS and then ammonium hydroxide until a pink color is obtained. Cool, add glacial acetic acid until the solution is decolorized, then add 0.5 mL in excess, and dilute with water to 20.0 mL.

Standard solution— To 0.5 g of magnesium oxide add 2.0 mL of *Standard Lead Solution*, and evaporate to dryness at 105° for 1 hour. Using the same conditions as prescribed for the *Test solution*, ignite, dissolve in diluted hydrochloric acid, add ammonia and then acetic acid, and dilute with water to 20.0 mL.

Procedure— To 12 mL of the *Test solution*, add 2.0 mL of pH 3.5 *Acetate Buffer*, mix, add to 1.2 mL of thioacetamide-glycerin base TS, and mix immediately. To 10 mL of the *Standard solution*, add 2.0 mL of the *Test solution*, add 2.0 mL of pH 3.5 *Acetate Buffer*, mix, add to 1.2 mL of thioacetamide-glycerin base TS, and mix immediately. Prepare a blank, using a mixture of 10 mL of water and 2.0 mL of the *Test solution*. Compared to the blank, the *Standard solution* shows a light brown color. Dilute both the *Test solution* and the *Standard solution* with water to 50 mL, allow to stand for 2 minutes, and view downward over a white surface: any brown color from the *Test solution* is not darker than that of the solution from the *Standard solution* (not more than 10 μg per g).

Limit of chromium— [NOTE—Use this test for Medium-Chain Triglycerides intended for use in parenteral nutrition.]

Test stock solution— Transfer about 50 g of Medium-Chain Triglycerides to a 100-mL volumetric flask, dissolve in and dilute with diisobutyl ketone to volume.

Test solution— Transfer 4.0 mL of *Test stock solution* to a 10-mL volumetric flask, and dilute with diisobutyl ketone to volume.

Chromium standard solution— Transfer about 0.283 g of potassium dichromate, previously dried at 105° for 4 hours and accurately weighed, to a 1000-mL volumetric flask, and dilute with water to volume. Immediately before use, dilute this

solution with water to 1000 times its volume. This solution contains the equivalent of 0.1 µg of chromium per mL.

Standard solutions— Into each of three 10-mL volumetric flasks, transfer 4.0 mL of *Test stock solution*, add 0.5, 1.0, and 2.0 mL, respectively, of *Chromium standard solution*, and dilute with diisobutyl ketone to volume. These solutions contain 0.005 µg, 0.01 µg, and 0.02 µg of chromium per mL, respectively.

Procedure— Concomitantly determine the absorbances of the *Standard solutions* and the *Test solution* at least three times each, at the wavelength of maximum absorbance at 357.8 nm, with a suitable atomic absorption spectrophotometer (see *Spectrophotometry and Light-Scattering* (851)) equipped with a graphite furnace and a chromium hollow-cathode lamp, using argon as the carrier gas. Record the average of the steady readings for each of the *Standard solutions* and the *Test solution*. Plot the absorbances of the *Standard solutions* and the *Test solution* versus the concentration of added chromium. Draw the straight line best fitting the points, and extrapolate the line until it meets the concentration axis. The distance between this point and the intersection of the axes represents the concentration of chromium in the *Test solution*. Not more than 0.05 µg per g is found.

Limit of copper— [NOTE—Use this test for Medium-Chain Triglycerides intended for use in parenteral nutrition.]

Test stock solution and Test solution— Proceed as directed in the test for *Limit of chromium*.

Copper standard solution— Transfer about 0.393 g of cupric sulfate, accurately weighed, to a 1000-mL volumetric flask, and dilute with water to volume. Immediately before use, dilute this solution with water to 1000 times its volume. This solution contains the equivalent of 0.1 µg of copper per mL.

Standard solutions— Into each of three 10-mL volumetric flasks, transfer 4.0 mL of *Test stock solution*, add 1.0, 2.0, and 4.0 mL, respectively, of *Copper standard solution*, and dilute with diisobutyl ketone to volume. These solutions contain 0.01 µg, 0.02 µg, and 0.04 µg of copper per mL, respectively.

Procedure— Concomitantly determine the absorbances of the *Standard solutions* and the *Test solution* at least three times each, at the wavelength of maximum absorbance at 324.7 nm, with a suitable atomic absorption spectrophotometer (see *Spectrophotometry and Light-Scattering* (851)) equipped with a graphite furnace and a copper hollow-cathode lamp, using argon as the carrier gas. Record the average of the steady readings for each of the *Standard solutions* and the *Test solution*. Plot the absorbances of the *Standard solutions* and the *Test solution* versus the concentration of added copper. Draw the straight line best fitting the points, and extrapolate the line until it meets the concentration axis. The distance between this point and the intersection of the axes represents the concentration of copper in the *Test solution*. Not more than 0.1 µg per g is found.

Limit of lead— [NOTE—Use this test for Medium-Chain Triglycerides intended for use in parenteral nutrition.]

Test stock solution and Test solution— Proceed as directed in the test for *Limit of chromium*.

Lead standard solution— Dissolve 160 mg of lead nitrate in 100 mL of water that contains 1 mL of lead-free nitric acid, and dilute with water to 1000 mL. Pipet 10 mL of this solution into a 100-mL volumetric flask, dilute with water to volume, and mix. Immediately before use, dilute this solution with water to 100 times its volume. This solution contains the equivalent of 0.1 µg of lead per mL.

Standard solutions— Into each of three 10-mL volumetric flasks, transfer 4.0 mL of *Test stock solution*, add 1.0, 2.0, and 4.0 mL, respectively, of *Lead standard solution*, and dilute with diisobutyl ketone to volume. These solutions contain 0.01 µg, 0.02 µg, and 0.04 µg of lead per mL, respectively.

Procedure— Concomitantly determine the absorbances of the *Standard solutions* and the *Test solution* at least three times each, at the wavelength of maximum absorbance at 283.3 nm, with a suitable atomic absorption spectrophotometer (see *Spectrophotometry and Light-Scattering* (851)) equipped with a graphite furnace coated inside with palladium carbide and a lead hollow-cathode lamp, using argon as the carrier gas. Calcination is carried out in the presence of oxygen at a temperature below 800°. Record the average of the steady readings for each of the *Standard solutions* and the *Test solution*. Plot the absorbances of the *Standard solutions* and the *Test solution* versus the concentration of added lead. Draw the straight line best fitting the points, and extrapolate the line until it meets the concentration axis. The distance between this point and the intersection of the axes represents the concentration of lead in the *Test solution*. Not more than 0.1 µg per g is

found.

Limit of nickel— [NOTE—Use this test for Medium-Chain Triglycerides intended for use in parenteral nutrition.]

Test stock solution and Test solution— Proceed as directed in the test for *Limit of chromium*.

Nickel standard solution— Immediately before use, dilute 10 mL of nickel standard solution TS with water to 1000 mL. This solution contains the equivalent of 0.1 µg of nickel per g.

Standard solutions— Into each of three 10-mL volumetric flasks, transfer 4.0 mL of *Test stock solution*, add 1.0, 2.0, and 4.0 mL, respectively, of *Nickel standard solution*, and dilute with diisobutyl ketone to volume. These solutions contain 0.01 µg, 0.02 µg, and 0.04 µg of nickel per mL, respectively.

Procedure— Concomitantly determine the absorbances of the *Standard solutions* and the *Test solution* at least three times each, at the wavelength of maximum absorbance at 232 nm, with a suitable atomic absorption spectrophotometer (see *Spectrophotometry and Light-Scattering* 〈 851 〉) equipped with a graphite furnace and a nickel hollow-cathode lamp, using argon as the carrier gas. Record the average of the steady readings for each of the *Standard solutions* and the *Test solution*. Plot the absorbances of the *Standard solutions* and the *Test solution* versus the concentration of added nickel. Draw the straight line best fitting the points, and extrapolate the line until it meets the concentration axis. The distance between this point and the intersection of the axes represents the concentration of nickel in the *Test solution*. Not more than 0.1 µg per g is found.

Limit of tin— [NOTE—Use this test for Medium-Chain Triglycerides intended for use in parenteral nutrition.]

Test stock solution and Test solution— Proceed as directed in the test for *Limit of chromium*.

Tin standard solution— Dissolve 500 mg of metallic tin (Sn), accurately weighed, in a mixture of 5 mL of water and 25 mL of hydrochloric acid, and dilute with water to 1000 mL. Immediately before use, dilute 10 mL of this solution with dilute hydrochloric acid (2.5 in 100) to 1000 mL, and then dilute 10 mL of the solution so obtained with water to 500 mL. This solution contains the equivalent of 0.1 µg of tin per g.

Standard solutions— Into each of three 10-mL volumetric flasks, transfer 4.0 mL of *Test stock solution*, add 1.0, 2.0, and 4.0 mL, respectively, of *Tin standard solution*, and dilute with diisobutyl ketone to volume. These solutions contain 0.01 µg, 0.02 µg, and 0.04 µg of tin per mL, respectively.

Procedure— Concomitantly determine the absorbances of the *Standard solutions* and the *Test solution* at least three times each, at the wavelength of maximum absorbance at 286.3 nm, with a suitable atomic absorption spectrophotometer (see *Spectrophotometry and Light-Scattering* 〈 851 〉) equipped with a graphite furnace coated inside with palladium carbide and a tin hollow-cathode lamp, using argon as the carrier gas. Record the average of the steady readings for each of the *Standard solutions* and the *Test solution*. Plot the absorbances of the *Standard solutions* and the *Test solution* versus the concentration of added tin. Draw the straight line best fitting the points, and extrapolate the line until it meets the concentration axis. The distance between this point and the intersection of the axes represents the concentration of tin in the *Test solution*. Not more than 0.1 µg per g is found.

Residual solvents 〈 467 〉 : meets the requirements.

(Official January 1, 2007)

Auxiliary Information— *Staff Liaison* : Catherine Sheehan, B.Sc., Scientist

Expert Committee : (EM105) Excipient Monographs 1

USP29–NF24 Page 3452

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EXHIBIT B

Medium-Chain Triglycerides—Their Composition, Preparation, and Application

V. K. BABAYAN, Stokely-Van Camp Inc., Indianapolis, Indiana

Abstract

Medium-chain triglycerides, prepared from fractionated fatty acids of vegetable oils ranging from caproic to lauric, have been prepared and used in the treatment of patients suffering from malabsorption syndromes. Commercial practices for processing of the kernel oils to obtain such fractionation of fatty acids are described, and the practical sources for such medium-chain fatty acids are given. Medium-chain esters of synthetic fatty acids and modifications of such esters for special medicinal and nutritional uses are suggested for future consideration and application.

Introduction

ALTHOUGH A WIDE VARIETY of fats and oils are available from animal, vegetable, and marine kingdoms, there is not any readily available ester solely consisting of such medium-chain fatty acids. By utilizing the kernel oils as a source for such fatty acids, with commercial processing techniques, esters have been synthesized which have specific compositions that are suitable for metabolism via the portal system. It is in order now to set up some standards for the raw material, specification of finished products, and the projection of some future modifications for broader investigation of the application of such medium-chain esters. This paper attempts to clarify the terminology used thus far in order to avoid misnomers concerning the term "medium-chain triglycerides."

Preparation and Specifications

From various sources (1-4) it is possible to ascertain that the kernel oils, such as coconut, palm kernel, babassu, etc., are the most common and available sources for the medium-chain fatty acids. Furthermore industry, having established large-scale usage for the various fractions of the fatty acids of these kernel oils, can supply medium-chain fatty acids at reasonable prices to serve as raw material for the preparation of such medium-chain triglycerides.

Since coconut oil is processed in large volume for industrial and edible uses, we shall follow the processing operation of that oil to illustrate how the C_6 - C_{12} fatty acids become available for our use. The crude coconut oil, as it is received from the Philippines and other Asian or African ports, is hydrolyzed (split under high pressure with steam) to recover glycerin and fatty acids. The fatty acids, in turn, are fractionally distilled into specific fractions for various specialty uses. In the fractionation of coconut oil fatty acids, usually three fractions are taken. Figure 1 is a schematic presentation of the fatty acids of coconut oil with the respective cuts or fractions taken in the fractionation of such acids. The approximate percentage of the composition of the original oil is given to illustrate the supply available for the fractionation. The fractionation points have been taken as practical considerations in commercial operations to dictate the most advantageous fractions for supplying the market needs and demands. Since fractionation is not an absolute, clear-cut separation in commercial

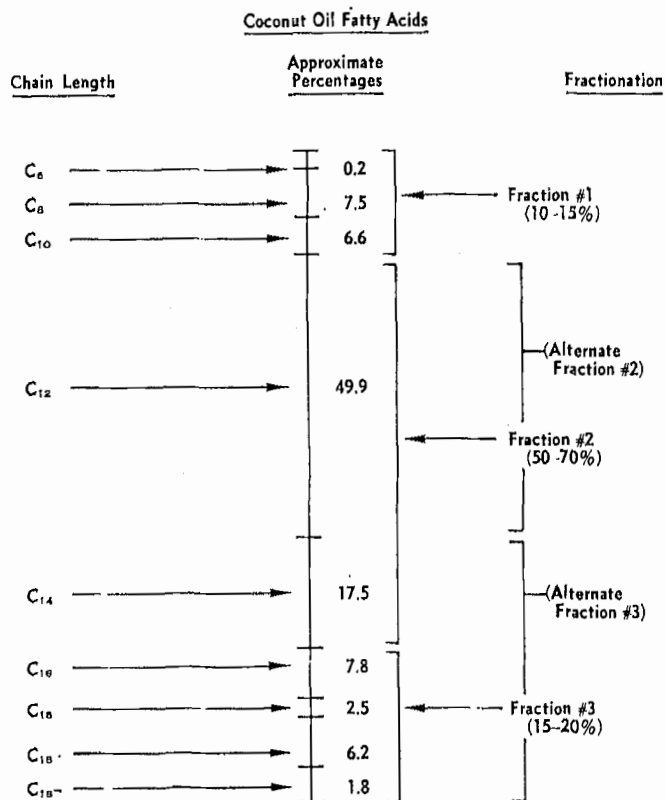


Fig. 1. Medium chain triglycerides—their composition, preparation and application.

practice, some contamination and overlap of fractions may occur. Double distillation is used to further purify the fractions and make specific fractions as needed.

Through the years the demand for lauric acid and/or lauric-myristic acid combinations has dominated the industry planning and operations. The synthetic detergents, such as amine condensates and amides with lauric acid or lauric-myristic acid compositions, have necessitated that fractional distillation cuts be Fraction 2 or Alternate Fraction 2 as the prime consideration of operation. Mono, di-, and polyhydric alcohol esters, as well as ethylene oxide adducts, have helped to create the market for more specific fatty acid compositions. Today one can purchase, for a price, relatively pure grades of individual fatty acids or blends of specific percentage ratios of two or more acids. It is sufficient to say that the initial fractional distillation of coconut oil fatty acids should give the medium-chain acids from C_6 - C_{10} as the first cut or fraction. Industry can divert Fractions 2 and 3 or its alternate fractions into other areas of operation and use. The commercial feasibility of fractionating coconut oil fatty acids and having uses for the fatty acids from C_{12} - C_{18} however make it possible to have a ready source of C_6 - C_{10} acids for the preparation of the MCT oils.

Initially the MCT oils, which were prepared and submitted to Hans Kaunitz (5-10) and his colleagues

at Columbia University for the animal feeding tests, essentially constituted the compositions and ratios of fatty acids made available from coconut oil fatty acid fractionation. The products in use today by the various investigators are quite similar to the original preparations investigated by Dr. Kaunitz. It is fortunate that the final selections have turned out this way, but it is not a coincidence. The selection was made after intensive investigation of the products resulting from the systematic isolation, preparation, and clinical testing of the pure esters of fatty acids from butyric acid to stearic acid. Ahrens (11,12) and his colleagues studied the metabolism of the pure triglycerides of C_4 - C_{18} saturated fatty acids to establish the range of portal vein transport. Hashim and Van Itallie (13-18) confirmed the findings of Ahrens in studies that involved both animals and human beings. They also extended the MCT clinical investigations to cover a wide range of MCT compositions where the fatty acids, their ratios, and their positions in the triglyceride were altered for the metabolic studies. Beveridge (19), Kritchevsky (20,21), Isselbacher (22,23), Furman (24), and many others (25-35) who were working with minor variations of the MCT preparations, investigated various aspects of the applications and uses of MCT. The culminations of the clinical studies carried out by all these investigators established the fact that MCT oils could have great flexibility in composition, providing that certain safeguards were maintained. There appeared to be little difference in the clinical acceptability of MCT whether the composition was at random distribution or a physical mixture of two or more glycerides. There could be variations in physical form and/or chemical constants and in the characteristics of the MCT preparations because of the fatty acid compositions and ratios. Such differences however resulted in very little, if any, difference in the metabolism of the preparations in both animals and human beings as long as the length of fatty acid chain was kept below lauric acid. With these accumulated data as a guide the final MCT specifications and compositions were established to conform with sensible, practical, and commercial operations while rigid quality control was maintained for uniformity and consistency.

The MCT available to clinical investigators at present is the product which, in the last analysis, has been found to be the best all-around composition for the unique applications and uses contemplated. The MCT preparation uses a double-distilled fraction of coconut oil fatty acids as its starting material, followed by esterification with glycerin and the use of a metallic or slightly acidic catalyst. The crude ester which is formed is subjected to refining, bleaching, and deodorizing operations. It should be kept in mind that the solubility and volatility characteristics of such a product are somewhat different from the conventional vegetable oils and animal fats.

The esterification step in the preparation of MCT requires the utmost care since it is essential that complete esterification take place and thus insure that

TABLE I
Raw Material Specifications Fatty Acids for MCT Oil

Free fatty acid (as oleic)	185% min.
Iodine value (Wijs)	1.0 max.
Color (Lovibond)	10 Y./1.0 R.
Unsaponifiables	0.5 % max.
Fatty acid composition	
C_8	1-2%
C_9	65-75%
C_{10}	25-35%
C_{12}	2 % max.

TABLE II
MCT Oil Specifications

Free fatty acids (as oleic)	0.05% max.
Saponification value	345-355
Iodine value (Wijs)	1.0 max.
Acetyl value	5.0 max.
Setting point	-5°C max.
Color (Lovibond)	10 Y./1.0 R.
Unsaponifiables	0.5 max.

the final product is a neutral oil with bland flavor and odor characteristics. A typical fatty acid feed stock for MCT is given in Table I. A typical MCT oil specification is given in Table II; the fatty acid composition falls in the range of that shown in Table I.

Under the conditions of esterification the resulting triglyceride will be pretty much at random distribution, and the ratios of the esters present will be predicated on the ratio of the fatty acids used in the feed. With the feed stock based upon a specification that is essentially composed of C_8 and C_{10} fatty acids, the predominant structures present in the MCT are shown in Figure 2. Figure 2 is essentially that of Eekey (36), where C_8 and C_{10} triglycerides have been substituted for the saturated and unsaturated fatty acids in his graph.

The results of the various clinical investigations will identify MCT oil as the investigators have received it. Sometimes the similarity of the analyses of two or more investigators will be noted, and at other times there will be definite differences. These are not variations in their analytical techniques but rather are the variations of the particular batch of MCT supplied. For the purpose of the clinical investigators, triglycerides were prepared from specific fatty acids and combinations thereof. In some cases 99% purity acids were used. Triglycerides of such purity were used to study the mechanism of the transport and to establish the specific pathways of assimilation. Triglycerides were also prepared where mixed acids were at random distribution in one case and physical mixtures of such pure triglycerides in other cases. For example, C_8 and C_{10} triglycerides which were prepared from 99% pure C_8 and C_{10} acids were in physical admixture of C_8 triglyceride and C_{10} triglyceride in one case and

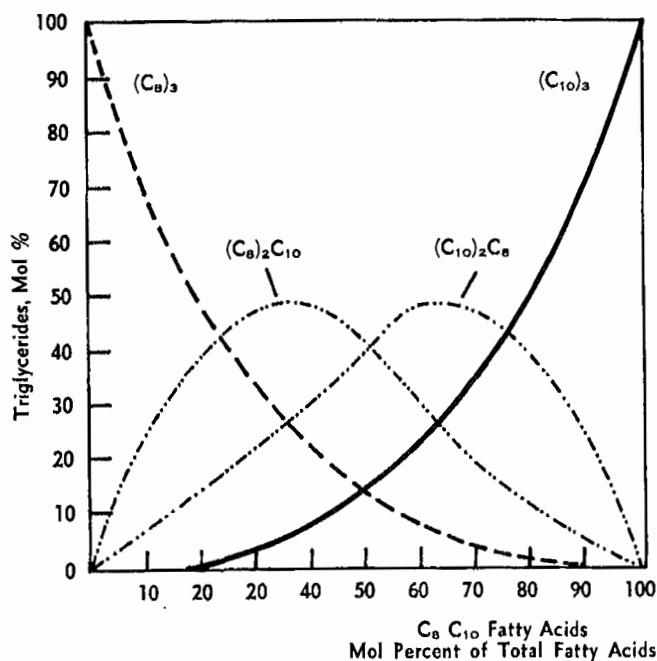


Fig. 2. Medium chain triglycerides—their composition, preparation and application.

were rearranged in the same ratios at random distribution. The metabolic studies did not show any differences in their acceptability or utilization.

Since such products from pure triglycerides did not show any differences in metabolism experiments when compared with triglycerides which were prepared from the mixed fatty acids, the preparation procedure adopted became that which uses the mixed fatty acids available from the fractionation of coconut oil. C_6 and C_{12} are essentially present in minor amounts and can be considered contaminants. Usually the C_8 and C_{10} acids constitute better than 95% of the fatty acid feed stock; the C_{12} acids are kept below 2%, and the C_6 acids are taken at the level found in the feed. The C_{12} acid limitation is placed to safeguard the fractionation of the fatty acids and to insure that the MCT oil prepared is completely metabolized from the gut via the portal system rather than the lymphatics. There is also some slight preference shown by the patients for MCT which is kept low in the C_{12} acid composition. Such MCT oil, low in C_{12} acid ratio, is completely alcohol-soluble and may lend itself more easily for formulations and applications.

In some experiments MCT with small and large amounts of the ethyl ester of linoleic acid, the glycerin ester of linoleic, linolenic, and arachidonic acids were prepared and used, along with safflower oil, soybean oil, and corn oil. Clinical investigators examined both the physical mixtures and the rearranged products. It was found quite feasible to prepare such variations of MCT oil with varying amounts of polyunsaturated fatty acid esters, either by the physical admixture of MCT or a pure C_8 triglyceride and a triglyceride high in polyunsaturates, such as safflower oil or the same composition after rearrangement. Swern (37) shows another way of illustrating the same type of system and the fatty acid compositions present in such esters. With mixed fatty acid esters, naturally the possibilities are increased and the picture is more complex. VanderWal (38,39) has reported on some of the more complex systems and the probabilities of the compositions available in such systems for saturated and unsaturated fatty acid triglycerides of the longer chain-length, but his projections would be equally valid for the medium-chain triglycerides.

Aside from the MCT oils derived from such vegetable oils as coconut oil and other kernel oils, a few words should be supplied about the possibilities in preparing further modifications of such medium-chain triglycerides which can be considered from synthesis and/or sources other than edible oils.

Since there are new processes for the synthesis of fatty acids via fermentation and even more immediate sources such as those from oxidation of paraffins, ozonolysis of oleic, linoleic, and tall oil acids, a host of synthetic fatty acids, both odd-carbon and even-carbon chain lengths, are at hand (40). Synthetic fatty acids of C_6 - C_{13} have been utilized to make similar esters for clinical investigation. By using the odd-carbon chain acids with glycerin, propylene glycol, etc., esters have been prepared and are being investigated clinically. Hashim and Van Itallie (41) have already reported on some of their initial results

in using such odd-carbon chain acids and esters. More will be forthcoming in the next few years since there are many new avenues to explore in the further extension of the medium-chain fatty esters. It is indeed a fertile field for the medical researcher.

ACKNOWLEDGMENT

Permission to publish Dr. Fefer's paper given by Enjay Chemical Company and the Enjay Chemical Laboratories. Some of the experimental details provided by R. F. Robey and M. Coopersmith. The help of Henry Lehman, Gerard Knight, and Haig Partizian of the Drew Chemical Corporation in the MCT investigation and preparation efforts is appreciated.

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[Received February 10, 1967]

EXHIBIT C

**IN THE UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA**

Ddrops Company, Reinhold Vieth, and
Elaine Vieth,

Plaintiffs,

v.

iHerb, Inc. and Madre Labs, Inc.
d/b/a California Gold Nutrition,

Defendants.

Civil Action No. 0:16-cv-42(JNE-TNL)

DECLARATION OF MICHAEL R. MISCHNICK

I, Michael R. Mischnick, hereby declare as follows:

1. I am a Senior Attorney at the law firm of Schwegman Lundberg & Woessner, P.A.

2. I am a registered patent attorney at Schwegman Lundberg & Woessner, P.A. My practice includes patent procurement, portfolio analysis, technical analysis, and strategic counseling, focusing on chemical engineering, chemical processing, materials science, medical devices, and biomedical technologies. I received a degree in Chemical Engineering from Iowa State University and a law degree from the University of Minnesota. A more complete description of my work experience is attached as Exhibit A.

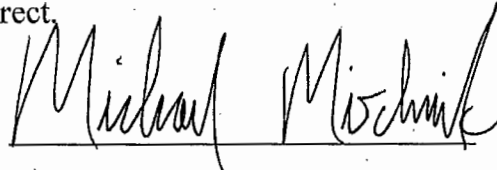
3. I have reviewed the Declaration of Robert O. Williams ("Williams Decl.") in Support of Defendant's Opposition to Plaintiff's Renewed Motion for Preliminary Injunction dated April 28, 2017. I have reviewed the portion of the Harden book discussed in sections C and D of the Williams Decl., (Conrad Decl., Ex. I) at para 17, Williams opines that the '958 Vieth patent discloses "if an oil has a carbon chain length of 6-12 and is a medium chain triglyceride [MCT], it will have sufficient viscosity to adhere to an object each and every time [it is applied thereto]."

4. That presumption is unwarranted. The viscosity of any MCT composition will vary depending on the composition of its components. See specification for Migliol 810 and 812. Conrad Decl., Ex. L at page 2, line 5: "Migliol 810 has a higher C₁₀ content, therefore its viscosity and cloud point is lower [than Migliol 812]."

5. At page 7, para. 24, Williams states: "The Harden book also teaches how to administer Vigantol oil: 1 drop of Vigantol oil is given to the baby from the tip of a spoon once a day." Harden at 4. At the direction and request of Dr. Woessner, to test the adherence of Baby Ddrops to a spoon, I applied one drop to the tip of a stainless steel spoon, tipped slightly downwards. The drop was contained by the lip of spoon. However, when the spoon was tipped slightly upward, the drop immediately ran down the bowl of the spoon in a thin sheet. Therefore, the MCT mixture in Baby Ddrops does not impart sufficient viscosity to the product so that it will adhere to "an object" each and every time. Therefore, the disclosure that one drop of Vigantol oil can be administered to a baby on the tip of a spoon does not anticipate the element in claim 1 of the '958 patent that one drop of the composition adheres to the exterior surface of an object. A photograph of the spoon is attached as Ex. B.

6. I declare under penalty of perjury under the laws of the United States of America that foregoing is true and correct.

Dated: May 23, 2017.

A handwritten signature in black ink, reading "Michael Mischnick", written over a horizontal line.

Michael R. Mischnick

EXHIBIT A

MICHAEL R. MISCHNICK

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Legal
Experience

Schwegman, Lundberg, & Woessner, P.A., Minneapolis, MN

Senior Attorney, April 2011-Present

Represented clients in patent preparation and prosecution of patent applications and freedom-to-operate investigations, including patent portfolio management, meeting with inventors, preparing patent applications, responding to office actions, and preparing appeal briefs and reply briefs for appeals to the Board of Appeals and Patent interferences. Technologies include medical devices including orthopedic devices; LED displays; 3D printing; membrane and film manufacturing; chemical processing, including solar-grade silicon and hydrogen cyanide production; geothermal energy recovery; and food production and processing.

Shumaker & Sieffert, P.A., Woodbury, MN

Associate, June 2009–April 2011

Represented clients in patent preparation and prosecution of patent applications, including meeting with inventors, preparing patent applications, responding to office actions, preparing appeal briefs and reply briefs for appeals to the Board of Appeals and Patent interferences. Technologies include medical devices (implantable stimulation devices, sensing devices, and fluid delivery devices); semiconductor electronics, security coatings; computer storage devices; and a video game accessory.

Fish & Richardson P.C., Minneapolis, MN

Intellectual Property Litigation Associate, September 2007–March 2009

Summer Associate/Law Clerk, May 2006–April 2007

Represented clients for intellectual property matters including: pre-suit investigation and complaint drafting; drafting and responding to written discovery requests; document review and production; researching procedural and substantive issues for motions on the pleadings, discovery motions, summary judgment motions, and post-trial motions; assisting in preparation for depositions; trademark enforcement through litigation and domain name dispute resolution; drafting patent reexamination requests; respond to office actions from the U.S.P.T.O.; and patent analysis for infringement opinions. Technologies included internet software, electronics, computer hardware, sports equipment, and medical devices.

**Hon. Patrick J. Schiltz, U.S. District Judge, United States District Court
for the District of Minnesota, St. Paul, MN**

Legal Extern August 2006–March 2007

Assisted Judge Schiltz with patent cases at various stages of litigation, including *Markman* hearings and drafting a *Markman* order for a mechanical clutch mechanism and a patent jury trial on electrical switches.

3M Innovative Properties Company, St. Paul, MN

Law Clerk, Office of Intellectual Property Counsel, May 2005–April 2006

Prepared patent applications on abrasive products for Industrial Business Division of 3M. Evaluated filtration and filter member patents of newly acquired company. Performed legal research for legal issues related to patents including patentability; antitrust; and licensing contracts.

Beem Patent Law Firm, Chicago, IL

Patent Agent, 2001 – 2004

Represented clients in patent preparation and prosecution, including meeting with inventors, preparing patent applications, responding to office actions from the U.S.P.T.O., and analyzing claims and prosecution histories for patentability, infringement, and validity opinions. Technologies include mechanical power tools; fasteners; experimental chemical equipment; internet software; and a horse racing sulky.

Education

University of Minnesota Law School, Minneapolis, MN

Juris Doctor 2007, *Magna Cum Laude*

GPA: 3.671/4.33 (Top Quartile: 3.549–4.151)

Minnesota Law Review, Research & Managing Editor

Student Intellectual Property Law Association, President 2005–06

Iowa State University, Ames, IA

B.S. Chemical Engineering 2001, *With Distinction, Engineering Honors Program*

GPA: 3.58/4.0

Admissions

- United States Patent and Trademark Office, Registration No. 52,036
- Admitted to the Bar, State of Minnesota
- Admitted to Practice Before the United States District Court for the District of Minnesota

Publication

Note, *Evaluating the Integrity of Biotechnology Research Tools: Merck v. Integra and the Scope of the 35 U.S.C. § 271(e)(1)*, 91 Minn. L. Rev. 484 (2006).

Activities

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Associate, June 2009–April 2011

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Patent Agent, 2001 – 2004

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Publication

Note, *Evaluating the Integrity of Biotechnology Research Tools: Merck v. Integra and the Scope of the 35 U.S.C. § 271(e)(1)*, 91 Minn. L. Rev. 484 (2006).

Activities

- American Intellectual Property Law Association
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EXHIBIT B



WOESSNER
Exhibt WW-C

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LEGAL EXPERIENCE

Schwegman, Lundberg & Woessner, P.A., Minneapolis, MN, 1993 - Present, Founding Partner. Emphasis in chemical, pharmaceutical and biotechnological patent prosecution, opinion work, licensing and client counseling.

Merchant & Gould, P.A., Minneapolis, MN, 1984-1993, Partner.

Kenyon & Kenyon, New York, NY, Associate attorney from 1981-1984.

BAR ADMISSIONS

State: Wisconsin-1981; New York-1982; Minnesota-1984. Federal Appellate: U.S. Supreme Court; Federal Circuit; Patent Bar.

EDUCATION

Legal

University of Wisconsin, Madison Law School, Madison, Wisconsin, J.D., cum laude, 1981.

Research and Writing Editor, Wis. Law Review, 1980-1981.

Scientific

University of Wisconsin Department of Chemistry, Ph.D., Organic Chemistry, 1971. Thesis: Hexatriene-Iron Tricarbonyl Isomerizations. Synthesis of new organometallic compounds.

Cornell University, Ithaca, New York, B.A., Chemistry, 1962-1966.

SCIENTIFIC EXPERIENCE

University of Wisconsin School of Pharmacy. Postdoctoral Research Associate, 1971-1972. Developed new methods and reagents for the synthesis of natural products.

Miles Laboratories, Inc., Natural Products Laboratory, Madison, Wisconsin. Senior Research Scientist, 1972-1978. Synthesis and evaluation of new drugs.

PROFESSIONAL ACTIVITIES

American Intellectual Property Law Association, Chair, Chemical Practice Committee, 1993-1995; Chair, Professional Programs Subcommittee of Biotechnology Committee, 1999-2001; Vice-Chair, Biotechnology Committee, 2001-2003, Chair, 2003-2005; Amicus Committee, 1999-2002; 2008-2011; Fellow, 2005-present.

Minnesota Intellectual Property Law Association, Member 1984-present, Chair, Biotechnology Law Committee, 1986-1987.

IPO, Member, Patent Law (U.S.) Committee, 2010-present.

MNBIO (Minnesota Biotechnology Association), Board of Directors, 1999-2001.

Patent Strategy & Management, Board of Advisers, American Lawyer Media, 2000-2009.

Fund for the Legal Aid Society, Minneapolis, Board of Directors, 2001- present; Executive Committee, 2003-2012.

Licensing Executive's Society International. Certified Licensing Professional. 2008.

Chem/Pharma IP Law Blog: "Patents4Life.com," March 2009-present.

PUBLICATIONS

Warren D Woessner et al., "Section 101 and Life Sciences—What's Left to Patent After Myriad, Mayo and Alice?" 101 J. Pat. & Trademark Society 121 (2019)

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"Technology Transfer: From Non-Profit Research to Profit - Outside Counsel's View," Abstracts, 196th ACS National Meeting, Los Angeles, CA (September 25-30, 1988).

"Selected Aspects of Patent Law Affecting the University Inventor," Abstracts, 194th ACS National Meeting, New Orleans, LA (August 30-September 4, 1987).

"Patent Law and the Professor," Chemtech, 536 (September 1986).

INVITED PRESENTATIONS

Minnesota Intellectual Law Association, (Minneapolis, MN) “Inequitable Conduct Lives -Refresher and Update”, (May 10, 2022)

Srafford Webinars, “Manufacturing Patents and Patent Eligibility; Recent Court Treatment, USPTO Guidance, Alternatives for Protection”(April 15, 2021).

Association of University Technology Managers, Eastern Regional Meeting, Raleigh, NC, “Inventions in the Life Sciences – Is There Anything Left to Patent?”(Oct. 2021)

ALPLA webinar “Inequitable Conduct Lives” (Nov. 3, 2021)

LES 2019 Annual Meeting, Phoenix AZ “Modern Medicine – Is there anything Left to Patent?”(Oct. 23, 2019)

Association of University Technology Managers 2014 Annual Meeting, San Francisco, CA, "Optimizing Your Patent Budget" (Feb. 2014).

American Intellectual Property Law Association, 2012 and 2013 Annual Meetings, Washington, DC "Therasense and its Aftermath" (October 2012 and 2013).

American Conference Institute, 13th Advanced Forum on Biotech Patents, Boston, MA, "Inequitable Conduct Following Therasense: Assessing Its Significance for Biotech Patent Litigation" (December 1, 2011).

American Conference Institute, Paragraph IV Disputes, "The Post-Therasense World" (December 7, 2011).

American Intellectual Property Law Association 2011 Annual Meeting, Washington, D.C., "Patent Wars – The Game Show – Prosecutors vs. Litigators" (Oct. 2011).

American Intellectual Property Law Association, Live Online Seminar, "KSR and the Ripple Effect" (March 2, 2011).

Association of University Technology Managers (AUTM), 2011 Annual Meeting, Las Vegas, NV, "The Ever-Changing Kaleidoscope of U.S. Patent Law" (March 2011).

American Conference Institute, 12th Advanced Forum on Biotech Patents, Boston, MA, "Are Genes Patentable? Examining the Potential Ramifications of Myriad and Developing Practical Strategies to Protect Your IP" (December 2010).

American Intellectual Property Law Association 2010 Annual Meeting, Washington, DC, "KSR and the Ripple Effect: Examining the Broad and Increasing Impact of KSR on Patent Litigation and Practice" (October 2010).

Q1, Pharmaceutical Patent Protection and Enforcement Conference (Baltimore, MD), "Myriad: The District Court's Opinion and the Road Ahead" (September 2010).

LES 2010 Spring Meeting, Boston, MA, "A Shot Across the Bow: The Process Behind Making and Responding to Demands to License Patented Technology" (May 2010).

Q1 Productions, 2nd Annual Partnerships in Personalized Medicine, San Mateo, CA, Speaker, "Legal Considerations in IP/Patent Protection for Partnerships Supporting Personalized Medicine," (April 2010).

Association of University Technology Managers, 2010 Annual Meeting, New Orleans, LA, "You Can't Patent That! Can You? (March 2010); 2010 Eastern Regional Meeting, San Juan, Puerto Rico (June 2009).

American Conference Institute, 11th Advanced Forum on Biotech Patents, New York, NY, Speaker: "What's Patentable? The Impact of Bilski and Related Precedents" (September 2009).

American Intellectual Property Law – Virtual Seminar, Washington, D.C., "Subject Matter Eligibility – The Changing Landscape" (September 2009).

The Collaborative Convergence Series – Medtech, Minneapolis, MN, Moderator, "Biologics & Devices" (March 2009).

Association of University Technology Managers (AUTM), Annual Meeting, Orlando, FL, Speaker, "You Can't Patent That! Can You" and Judge, "A New and Exciting Game Show: Analyze that Contract" (February 2009).

Licensing Executive Society, Annual Meeting, Kissimmee, FL, Moderator, "Managing the Gladiators – Surviving Patent Litigation" (October 2008).

Association of University Technology Managers, Eastern Regional Meeting, Boston, MA, Speaker, "Stem Cell Frontiers – Policy, Promise and Patents," (July 2008).

BIO 2007 International Biotechnology Convention, Boston, MA, Panelist, "Life After Merck KGaA v. Integra Life Science," (May 2007).

American Conference Institute, 8th Advanced Forum on Biotech Patents, Menlo Park, CA, Speaker, "Applying and Avoiding the Doctrine of Inherent Anticipation," (April 2007).

C5's 4th International FTO Forum, London, UK, Speaker, "Claim Interpretation and Risk Evaluation – Construing Claims," (March 2007).

American Conference Institute, 7th Advanced Forum on Biotech Patents, Boston, MA, Speaker, "Applying and Avoiding the Doctrine of Inherent Anticipation," (November 2006).

Practising Law Institute, Preparing Patent Legal Opinions, New York, NY, Speaker, "Patent Infringement and Freedom to Operate Opinions," (September 2006).

American Conference Institute, Freedom to Operate, New York, NY, Speaker, "Assessing the Impact of the Doctrine of Equivalents on Claim Interpretation and Non-Infringement Opinions," (September 2006).

Association of University Technology Managers, Central Regional Meeting, Minneapolis, MN, Speaker, "Patent Strategies for Stem Cell Technology," (July 2006).

C5, Tactical and Practical Guide to Freedom to Operate, London, UK, Speaker, "Risk Evaluation Key Tips In Construing Claims," (July 2006).

LES/AUTM 2006 Spring Meeting, Philadelphia, PA, Moderator, "Managing the Gladiators -- Surviving Patent Litigation," (May 2006).

American Conference Institute, 6th Advanced Forum on Biotech Patents, San Francisco, CA, Co-Chair, (February 2006).

American Conference Institute, A Tactical and Practical Guide to Freedom to Operate, New York, NY, "The Continuing Impact of *Festo* on Non-infringement Opinions," March 2005.

Practicing Law Institute, Preparing Patent Legal Opinions 2004, New York, NY, "Product Clearance and Non-infringement Opinions in a Post-*Festo* World," September 2004.

American Intellectual Property Law Association (AIPLA), Advanced Biotechnology & Chemical Patent Practice Seminars, "Research Tool Patents - Fight or Flight," Seattle, WA and Wilmington, DE, June 11 and 25, 2004.

BIO 2004 International Biotechnology Convention, Workshop moderator, "The Evolving Law of Research Tools," June 2004.

Association of University Technology Managers (AUTM), Annual Meeting, San Antonio, TX, "Managing the Gladiators - Surviving Patent Litigation," March 2004.

American Conference Institute, A Tactical and Practical Guide to Freedom to Operate, New York, NY, "Legal Standards for Non-infringement Opinions," April 2004, San Francisco, CA and November 2003, New York, NY.

American Intellectual Property Law Association, Annual Meeting, Washington, DC, "The Utility Requirement -- Beyond Credibility," October 2003.

Practising Law Institute, Preparing Legal Opinions 2003, New York, NY, "Patent Infringement and Freedom to Operate Opinions," September 2003.

Practising Law Institute, Preparing Patent Legal Opinions 2002, San Francisco, CA, "Patent Infringement and Freedom to Operate Opinions," October 2002.

BIO 2002 International Biotechnology Convention, Toronto, Canada, "Patenting Leading-Edge Biotechnology," June 2002.

Yale University Biotechnology Student Interest Group, Speakers Series, New Haven, CT, "Patenting Transgenic Animals -- From the Harvard Mouse to 'Hello Dolly!'," April 2002.

Association of University Technology Managers (AUTM), Annual Meeting, San Diego, CA, "Commercialization of Agricultural Biotechnology from Academia," March 2002.

American Intellectual Property Law Association, Mid-Winter Institute, Phoenix, AZ, "Litigation of Pharmaceutical Patents Under the Hatch-Waxman Act," January 2002.

American Conference Institute, Patenting Genomics, Proteomics and Complex Biotech, "Meeting the Requirements of the PTO's Utility and Written Description Requirements," November 2001.

Strategic Research Institute, Pharma and Biotech -- Intellectual Property and Business Development, San Francisco, CA, "Strategies for Successful Biotech Patent Prosecution," April 2001.

Cambridge Healthtech Institute, Human Proteomic Project Conference, McLean, VA, "Patenting Proteomics," April 2001.

American Intellectual Property Law Association, Spring Meeting, San Francisco, CA, "Practical Guide to Research Tool Patent Strategies: A Panel Discussion," May 2001.

AUTM, Annual Meeting, New Orleans, LA, "Managing the Gladiators -- Surviving Litigation," March 2001.

ATCC, Biotech Patent and Licensing Forum, Arlington, VA, "Prosecution in View of the Written Description and Utility Requirements," September 2000.

AUTM, Central Regional Meeting, Cincinnati, OH, Workshop, "Anatomy of a Home Run -- The Carbovir Story," August 2000.

American Intellectual Property Law Association, Advanced Biotechnology/Chemical Patent Practice Seminars, Program Coordinator and Speaker, "Patent Prosecution In View of the 1999 Revised Interim Utility and Written Description Requirement Guidelines," Washington, DC and San Francisco, CA, April and June 2000.

MNBIO, Symposium, "Genetically Modified Food -- Issues and Opportunities," Minneapolis, MN, "Protecting Innovation in Ag Biotech," April 2000.

AUTM, 2000 Annual Meeting, Atlanta, GA, Workshop, "Anatomy of a Home Run -- The Carbovir Story," February 2000.

American Intellectual Property Law Association, 2000 Mid-Winter Institute, LaQuinta, CA, "Strategies for Successful Biotech Prosecution in the PTO," January 2000.

BIO 1999 International Biotechnology Meeting, Seattle, WA, Session, "Patenting Early-Stage Biotechnology," June 1999.

American Intellectual Property Law Association, Spring Meeting, Chicago, IL, "UC v. Lilly and its Progeny -- Back to the Future?," April 1999.

AUTM, Central Regional Meeting, Minneapolis, MN, Workshop, "Patenting Early-Stage Technology," August 1998.

BIO '98 International Biotechnology Meeting, New York, NY, Session, "Patenting Transgenic Animals -- From the Harvard Mouse to 'Hello Dolly,'" May 1998.

American Intellectual Property Law Association, Advanced Biotechnology/Chemical Patent Practice Seminar, "Prosecuting Patent Applications To Meet the Enablement and Written Description Requirements of § 112," New York, NY (Spring 1998).

AUTM, Annual Meeting, San Antonio, TX, "Advanced Issues in Academic-Industry Relations," February 1998.

American Intellectual Property Law Association, Annual Meeting, Washington, DC, "How To: Patent Transgenic Animals," October 1997.

Suffolk University Law School/Boston Patent Law Association, Second Annual High Technology Law Conference, Boston, MA, "'Hello Dolly!' -- Transgenic Animal Patents from the Harvard Mouse to the Cloned Sheep," September 1997.

American Intellectual Property Law Association, Basic Biotechnology/Chemical Patent Practice Seminar, Speaker, "Drafting and Prosecuting Applications to Meet the Utility/How-To-Use Requirement of §§ 101/112," Arlington, VA, Chicago, IL, San Francisco, CA, Spring 1996.

AUTM, Annual Meeting, Charleston, SC, Workshop, "Patenting and Licensing Agricultural Biotechnology," February 1996.

AUTM, Central Regional Meeting, Ames, IA, Workshop, "Patenting and Licensing Plants and Animals," July 1995.

Wisconsin Intellectual Property Law Association and the University of Wisconsin Law School, Intellectual Property - Law and Practice, Speaker, "Methods of Medical Treatment - Suspects on Trial," May 1995.

American Chemical Society, 209th National Meeting, Anaheim, CA, Speaker, "Owning Life -- Patents on Transgenic Plants and Animals," April 1995.

American Intellectual Property Law Association, Basic Chemical and Biotechnology Patent Practice Seminar, Speaker, "Drafting and Prosecuting a Chemical Application to Meet Utility and Enablement Requirements," Boston, MA; Minneapolis, MN; Seattle, WA; Fall 1994.

AUTM, Annual Meeting, Phoenix, AZ, Workshop, "Advanced Patents," February 1994.

AUTM, Annual Meeting, Dallas, TX, Workshop, "How To Dig Out Prior Art," February 1993.

AUTM, Central Regional Meeting, Indianapolis, IN, Workshop, "Difficult License Negotiations," July 1993.

American Intellectual Property Law Association, Annual Meeting, Washington, DC, "How To: Patent Agricultural Biotechnology," October 1993.

AUTM, Annual Meeting, Orlando, FL, Workshop, "Optimizing Your Foreign Filing Program," February 1992.

American Type Culture Collection (ATCC), Biotechnology Patent Conference, Washington, DC, Speaker, "Plant and Animal Patenting Strategies," April 1992.

AUTM, Annual Meeting, San Francisco, CA, Workshop, "Maximizing The Value of Outside Counsel," February 1991.

AIPLA, Annual Meeting, Crystal City, VA, "How To: Infringement Opinions In View of Recent Federal Circuit Opinions on Estoppel," October 1991.

AIPLA, Midwinter Meeting, Palm Desert, CA, Presentation to Chemical Practice Committee: "The Application of the Doctrine of Equivalents to Chemical Practice," February 1990.

Hamline Law School, Conference on Agricultural Biotechnology, Minneapolis, MN, Speaker, "Protection of Agricultural Intellectual Property," April 1990.

Society of University Patent Administrators, Annual Meeting, New Orleans, LA, Plenary Session Speaker, "Intellectual Property Law -- Troubling Trends and What We Can Do About It," February 1989.

ATCC, Biotechnology Patent Conference, Bethesda, MD, Speaker, "Gene Transfer in Plants -- Technology and Patent Strategies," April 1989.

American Chemical Society, 196th National Meeting, Los Angeles, CA, Panelist, "Technology Transfer: From Non-Profit Research to Profit," September 1988.

American Chemical Society, 194th National Meeting, New Orleans, LA, Panelist, "Selected Aspects of Patent Law Affecting the University Inventor," September 1987.