

**UNITED STATES PATENT AND TRADEMARK
OFFICE
BEFORE THE PATENT TRIAL AND APPEAL BOARD**

**MOM ENTERPRISES, LLC,
PETITIONER,
v.
ELAINE AND REINHOLD W. VIETH,
PATENT OWNERS.**

**IPR2023-00726
PATENT NO. 9,066,958 B2**

Patent Owners' Demonstrative Exhibits

June 18, 2024

ARGUMENT OUTLINE

1. Petitioner cannot establish that Claims 1 and 3-5 of the '958 Patent are invalid as obvious.
2. Petitioner engages in hindsight reconstruction and improperly uses the '958 Patent as a “roadmap”.
 - a. No evidence why a POSITA would be motivated to combine the references.
3. No reference teaches or suggests a method for delivering a “nutritional or therapeutic effective amount of vitamin D”.
4. No reference teaches or suggests a method “wherein said drop adheres to the surface of said object”.
5. There is no admissible evidence of the actual composition of Vigantol oil.

ARGUMENT OUTLINE

6. Tinworth is the only untainted translation of Harder
7. A POSITA would not rely on Harder
8. Deficiencies exist with the 3 main references (Harder, Wolf, Blass) on which Petitioner relies
 - a. Wolf teaches away from the claimed inventions
 - b. Harder teaches away from the claimed inventions
 - c. Blass is from an entirely different field of research
9. Secondary indicia strongly support non-obviousness

THE PROBLEM TO BE SOLVED

- *How do you reliably deliver vitamin D to a human being or an infant, in a form and method that is reliably safe and nutritionally effective, amenable and acceptable to the recipient?*
- This is a complex problem, involving 5 inter-related variables:
 - A single drop
 - The correct concentration
 - The proper carrier
 - The delivery means
 - The method of administration

Ex. 1001, 2:53 – 3:17; Ex. 2068, ¶s 29-46.

THE PROBLEM TO BE SOLVED

- 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 a hand because it may drip off or get contaminated. Thus the claimed invention is novel and non-obvious over the prior art.

Ex. 1002, p. 28.

NO EVIDENCE ON MOTIVATION TO COMBINE

- To establish obviousness, Petitioner must identify a motivation to combine because “inventions in most, if not all, instances rely on building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known.” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 418-19 (2007).
- “[O]bviousness concerns whether a skilled artisan not only *could have made* but would have been motivated to make the combinations or modifications of prior art to arrive at the claimed inventions.” *Belden Inc. v. Berk-Tek LLC*, 805 F.3d 1064, 1073 (Fed. Cir. 2015) (emphasis in original).

NO EVIDENCE ON MOTIVATION TO COMBINE

- “The mere fact that these possible arrangements existed in the prior art does not provide a reason that the skilled artisan would have” combined them to create the claimed invention. *Vitek Vision Int’l ULC v. Assembly Guidance Sys., Inc.*, 94 F4th 882, 887 (Fed. Cir. 2024).
- Conclusory assertions that a POSITA could combine references with no specific evidence regarding motivation are legally insufficient to establish obviousness. *TQ Delta, LLC v. Cisco Sys.*, 942 F.3d 1352, 1358-61 (Fed. Cir. 2019).

NO EVIDENCE ON MOTIVATION TO COMBINE

- Petitioner offers no evidence on motivation to combine; just conclusory statements of opinion.
 - Williams was “informed by Counsel ... that a motivation to combine references may be supplied by the direction of the marketplace.” Ex. 1004, ¶32. But he did not state or describe what the motivation was. He was instructed not to answer questions about information relating to the alleged motivation to combine. Ex. 2025, 77:16 – 79:11.
 - Williams repeatedly states only a conclusion, with no rationale provided. See Ex. 1004, ¶s 77, 85, 88.
 - Williams’ conclusory opinions are legally insufficient to meet Petitioner’s burden of proof and it would be reversible error to find a motivation to combine prior art at issue in this action. See *TQ Delta*, 942 F.3d at 1358-61.

NO PRIOR ART TEACHES OR SUGGESTS A METHOD FOR DELIVERING A “NUTRITIONAL OR THERAPEUTIC EFFECTIVE AMOUNT OF VITAMIN D”

- Claims 1 and 3-5 require delivery of “a nutritional or therapeutic amount of vitamin D” to a human. Ex. 1001, 9:37-38.
- Petitioner makes straw-man arguments regarding Patent Owners’ position.
- Petitioner claims this limitation is inherent in the spoon method disclosed in Option 3 of Harder. But, “the use of inherency, a doctrine originally rooted in anticipation, must be carefully circumscribed in the context of obviousness.” *PAR Pharm., Inc. v. TWI Pharms., Inc.*, 773 F.3d 1186, 1194-95 (Fed. Cir. 2014).

NO PRIOR ART TEACHES OR SUGGESTS A METHOD FOR DELIVERING A “NUTRITIONAL OR THERAPEUTIC EFFECTIVE AMOUNT OF VITAMIN D”

- Inherency “is present only when the limitation at issue is the ‘natural’ result of the combination of prior art elements.” *PAR Pharm.*, 773 F.3d at 1194-95 (emphasis added).
- While it may be true that a nutritional or therapeutic amount of vitamin D can be delivered using the Harder spoon method, no evidence exists that delivery of a nutritional or therapeutic amount of vitamin D is the “natural result” of that method.
- Petitioner’s expert declaration does not contain the words “inherency” or “inherent”. See Ex. 1004.
- Neither Harder nor Wolf nor Blass teaches or suggests any way to deliver a nutritional or therapeutic amount of vitamin D.

NO PRIOR ART TEACHES OR SUGGESTS A METHOD “WHEREIN SAID DROP ADHERES TO THE SURFACE OF SAID OBJECT”

- Petitioner concedes none of the prior art explicitly discloses that Vigantol oil “does not coat or adhere” to a spoon. It again resorts to inherency.
 - Petitioner again relies on the ambiguous and inadmissible hearsay statement in Harder that “medium-chain triglycerides (vegetable oil)” is allegedly the carrier oil in Vigantol.
 - But there is no admissible evidence of the actual chemical composition of Vigantol.
 - Testing by Dr. Reid shows that a drop of MCT oil in a metal spoon does not adhere because it “spreads and coats the bowl, i.e., the concave surface, of the spoon.” Ex. 2072, ¶65.

NO PRIOR ART TEACHES OR SUGGESTS A METHOD “WHEREIN SAID DROP ADHERES TO THE SURFACE OF SAID OBJECT”

- Petitioner argues, “Viscosity (which impacts adherence) is an inherent property of Vigantol,” but it provides no basis or authority to support this alleged relationship. See Paper 74, p. 6.
- Viscosity may impact adherence, but Petitioner does not establish that adherence is the “natural result” of Vigantol oil.
- Petitioner’s assumption regarding the adherence characteristics of Vigantol does not satisfy the “necessarily so” high standard required for inherency. See *Persion Pharms. LLC v. Alvogen Malta Operations Ltd.*, 945 F.3d 1184, 1191 (Fed. Cir. 2019).

NO ADMISSIBLE EVIDENCE OF THE COMPOSITION OF VIGANTOL OIL

- Petitioner does not rely on Vigantol oil as a prior art reference.
- Harder does not establish the composition of Vigantol oil.
- Harder's statement, that Vigantol "contains only one excipient as a vehicle for the fat-soluble vitamin D, namely medium-chain triglycerides (vegetable oil)" (Ex. 1021, p. 5), is inadmissible hearsay.
 - While prior art is not hearsay when presented to show only that the claimed subject matter was in the public's possession, Petitioner relies on Harder to prove the actual composition of Vigantol.

NO ADMISSIBLE EVIDENCE OF THE COMPOSITION OF VIGANTOL OIL

- Harder's statement is inaccurate and ambiguous.
 - Vegetable oils typically are long-chain triglycerides. Ex. 2068, ¶s 33, 75-76.
 - Harder is a mid-wife with no skills or training in chemistry or chemical analysis and cites no authority for her statement, which is likely double hearsay.

NO ADMISSIBLE EVIDENCE OF THE COMPOSITION OF VIGANTOL OIL

- Dr. Vieth never knew the composition of Vigantol oil.
 - In the early 2000s, he received 3 generic amber glass vials in his lab from another researcher of what was allegedly Vigantol oil. The vials were simply labeled 1, 2, 3. He was asked how much vitamin D was in each vial. He tasked a lab assistant to assay each vial. He had no personal involvement in testing the vials. He doesn't know who prepared the vials. All he "knew was it was an oil and it had vitamin D in it." His efforts to obtain a genuine bottle of Vigantol oil for testing were unsuccessful. Ex. 1039, 38:18 – 39:23; 40:11-23; 41:6-15. Like Petitioner, Dr. Vieth can only speculate about the carrier oil used in Vigantol.

TINWORTH (EX. 1021) IS THE ONLY UNTAINTED TRANSLATION OF HARDER

- This is a key issue.
- Petitioner created the issue by filing inconsistent and ambiguous translations.
- Petitioner's expert admits that if the only translation is Tinworth, he cannot provide his obviousness opinions. Ex. 2025, 99:5 – 100:21; 120:10-19.

TINWORTH (EX. 1021) IS THE ONLY UNTAINTED TRANSLATION OF HARDER

- Tinworth is a peer-reviewed, “true, full and accurate translation” by a qualified translator. Ex. 1021, ¶s 2-3. Ex. 2024, 22:9-24; 26:20-22; 27:9-19.
 - No one has ever stated that Tinworth’s translation was wrong, erroneous or incomplete.
- Petitioner’s counsel obtained multiple, different translations after realizing Tinworth did not support its arguments; it wanted words to be added. Ex. 2024, 29:1 – 30:1; 30:25 – 31:8; Exs. 2032, 2033. Sherman reviewed a single sentence as requested, added 4 words, and signed a declaration drafted by Petitioner’s counsel. Ex. 2024, 24:7-28:12; 33:1-9; 35:2-7; 71:23-72:2; 73:23-74:3.

A POSITA WOULD NOT RELY ON HARDER

- Harder is a collection of “how-to” chapters written by midwives for midwives. Harder distinguishes her co-edited book from “obstetrics textbooks.” Ex. 2070, Ex. B; Ex. 2072, ¶53.
- A POSITA working in the field of the ‘958 Patent would not be interested in Harder and would not look to Harder as a reference. Ex. 2072, ¶s 55-57; Ex. 1036, 55:6-14. Harder is from a different field than the ‘958 Patent.
- Nothing in Harder discloses or suggest the “adheres” limitation. Ex. 2025, 130:10-15.
- Harder teaches away from the claimed invention.
 - Option 1 – the preferred case – is to dissolve a tablet in a spoonful of water. Ex. 1021, p. 4.
 - Option 3 is a special-case option that is described as dangerous. Ex. 1021, p. 5.

WOLF (EX. 1009) TEACHES AWAY FROM THE CLAIMED INVENTION

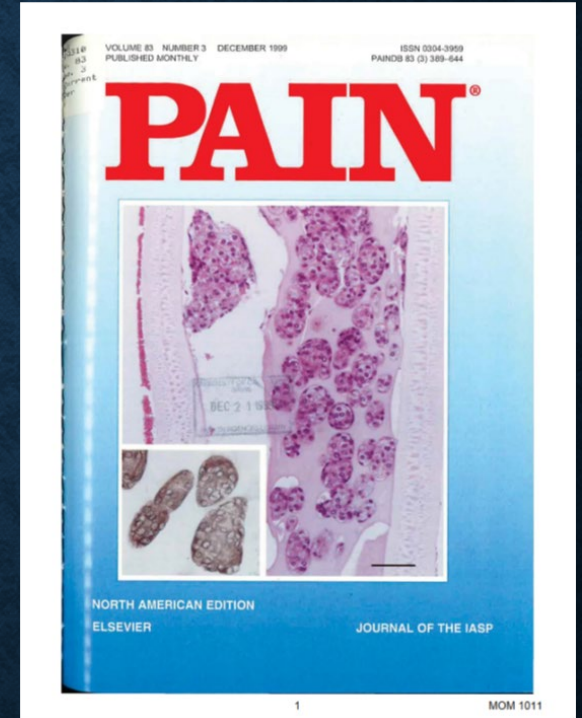
- Wolf teaches adding a liquid to crushed tablets or drops, contrary to the '958 Patent:
 - “Drops or tablets should not be added to the bottle, but administered to the baby on a spoon with some liquid.” Ex. 1009, p. 7 (emphasis added).
- A POSITA would understand Wolf as teaching adding a tablet or drop to a liquid such as milk, which is then administered to a baby with a spoon, rather than a drop consisting of the ingredients according to claim 1. Ex. 2025, 132:5-22.
- Wolf says nothing about the adhere limitation or nutritional or therapeutic amount limitation. Ex. 2025, 130:16 – 131:2.

BLASS (EX. 1011) IS FROM A DIFFERENT FIELD (PAIN MANAGEMENT)

- Blass is from “the official publication of the International Association for the Study of Pain (IASP) and it publishes original research on the nature, mechanisms and treatment of pain.”

Ex. 1011, p. 3.

- Blass had “three goals: 1. To identify the basis of sucking-induced analgesia in healthy, term, newborn humans undergoing the painful, routine, procedure of heel lance and blood collection. 2. To evaluate how taste-induced and sucking-induced analgesias combine to combat pain. 3. To determine whether facial grimacing was an accurate index of diminished pain, or whether it was linked to tissue trauma.” Ex. 1011, p. 6.



BLASS (EX. 1011) IS FROM A DIFFERENT FIELD (PAIN MANAGEMENT)

- Blass was testing whether an infant sucking would distract it from the pain it was otherwise feeling.
- Blass discloses nothing about administration of a medicament.
- Blass discloses nothing about nutritional or therapeutic effective amount.
- Blass discloses nothing about adhere.
- Petitioner's expert, Williams, agrees. Ex. 2025, 136:2 – 138:24.

EUROPEAN PHARMACOPOEIA (EX. 1010) AND GARTNER (EX. 1012) ADD NOTHING

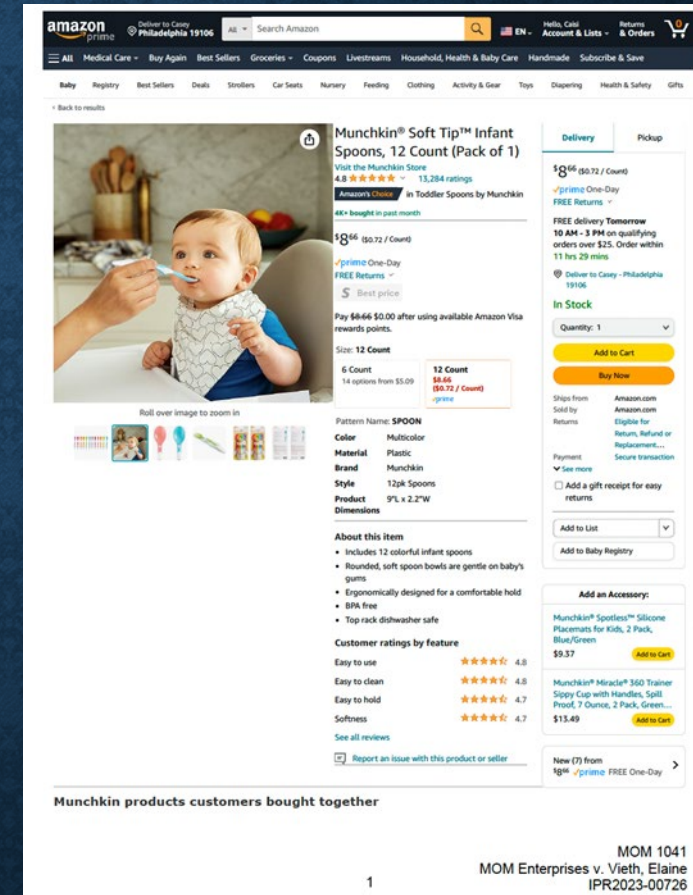
- *European Pharmacopoeia*, Supplement 4.3 at best describes the acid origins and MCT composition of octoanic and decanoic acids, methods for identifying MCT and maximum levels, and assays for determining impurities. Ex. 1010, pp. 5-6. Ex. 2068, ¶s 87-88; Ex. 2072, ¶47.
- Gartner is a clinical report that merely describes a then-recommended daily supplement amount for vitamin D, with no indication of how such an amount could be delivered reliably to provide a “nutritional or therapeutic effective amount”. Ex 1012, pp. 3-4; Ex. 2068, ¶97.

RAJ IS NOT QUALIFIED TO GIVE HER OPINIONS

- Raj is a professional witness who was asked to “opine on how a pediatrician would have understood Harder as it relates to the claims of the ‘958 Patent.” Ex. 1040, ¶1.
- Raj is a neonatologist specializing in the circulation in the lung; does not speak or read German; has no training or expertise as a linguist; and never previously testified how a pediatrician might read a foreign language document or given an opinion on competing translations. Ex. 2081, 16:4-25.
- Raj never read the ‘958 Patent and does not know its priority date. Raj simply selected one of the multiple Harder translations provided by Petitioner because it was what she considered the most recent. Ex. 2081, 44:7-13, 51:24-52:23.

RAJ'S MUNCHKIN SPOONS "TEST" IS NOT RELEVANT

- RAJ RECEIVED AN UNSOLICITED PACKAGE FROM PETITIONER'S COUNSEL CONTAINING A BOTTLE OF BABY DDROPS AND "12 MUNCHKIN SOFT TIP INFANT SPOONS." Ex. 1040, ¶s15-16.
- RAJ CONDUCTED AN EXPERIMENT USING THE BABY DDROPS PRODUCT AND THE MUNCHKIN SPOONS. Ex. 2081, 110: 18-21.



Ex. 1041

MOM 1041
MOM Enterprises v. Vieth, Elaine
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RAJ'S MUNCHKIN SPOONS TEST IS NOT RELEVANT

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Munchkin® Soft Tip™ Infant Spoons, 12 Count (Pack of 1)

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4.8 out of 5 stars (13,284 ratings)

Amazon's Choice in Toddler Spoons by Munchkin

NEW! Bought in just 1 month

12 Count (Pack of 1)

FREE delivery Tomorrow 10 AM - 3 PM on qualifying orders over \$25. Order within 11 hrs 29 mins

FREE Returns

Pay \$6.66 after 5% off

Color: 12 Count

14 options from \$2.09

Roll over image to zoom in

Pattern Name: SPOOI

Color: Multicolor

Material: Plastic

Brand: Munchkin

Style: 12pk 1st

Product Dimensions: 9" x 2.1"

About this item

- Includes 12 colorful
- Rounded, soft spoon
- grip
- Ergonomically designed
- BPA free
- Top track dishwasher
- Customer ratings
- Easy to use
- Easy to clean
- Model
- Amazon.com

Munchkin products customers bought together

2012

Compare with similar items

Item	Price	Price Per Unit	Delivery	Customer Ratings	Easy To Clean	Easy To Hold	Easy To Use	Softness	Durability	Sold By	Number Of Pieces	Dishwasher Safe	Weight	Style
Munchkin® Soft Tip™ Infant Spoons, 12 Count (Pack of 1)	\$66	\$0.72 / Count	FREE One-Day	4.8 ★★★★★ 13,284	4.8 ★★★★★	4.7 ★★★★★	4.8 ★★★★★	4.7 ★★★★★	4.6 ★★★★★	Amazon.com	12	✓	59 grams	12pk Spoons
Munchkin® Gentle Dip™ Multistage First Spoon Set for Baby Led Weaning, Self Feeding...	\$59	—	FREE Delivery	4.8 ★★★★★ 8,508	4.8 ★★★★★	4.7 ★★★★★	4.7 ★★★★★	4.7 ★★★★★	4.7 ★★★★★	Amazon.com	4	✓	0.05 grams	Child
Dr. Brown's TempCheck Temperature Color-Changing Spoons for Babies and Toddlers...	\$59	—	FREE One-Day	4.8 ★★★★★ 1,505	4.6 ★★★★★	4.6 ★★★★★	5.0 ★★★★★	—	4.5 ★★★★★	Amazon.com	4	✓	—	TempCheck Spoons
PandaEar Baby Silicone Soft Spoons Training Feeding for Kids Toddlers Children and Infants...	\$795	\$2.48 / oz	FREE Delivery	4.8 ★★★★★ 6,802	4.7 ★★★★★	4.9 ★★★★★	—	4.9 ★★★★★	4.7 ★★★★★	PandaEar	6	✓	3.2 ounces	Child

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prime ★★★★★ Up Price: <\$25 Number of Items Included: 1 to 3 Brand: Munchkin Item Length Longer Edge: 9 in & above More filters

1

2

- The Munchkin spoon used in Raj's "test" was first available on January 9, 2012, approximately six years after the priority date of the '958 Patent. Ex. 1041, p. 3; Ex. 2081, 89:16-90:3.
- Raj's "test" and opinions based thereon are not relevant. See *Genetics Inst., LLC v. Novartis Vaccines & Diagnostics, Inc.*, 655 F.3d 1291, 1307 (Fed. Cir. 2011) (the §103 analysis remains properly focused "at the time the invention was made").

Ex. 1041

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

SECONDARY INDICIA SUPPORT NON-OBVIOUSNESS

- Petitioner did not consider secondary indicia in its analysis. Ex. 1004, ¶31; Ex. 2025, 75:20 – 76:4.
- Secondary indicia are often the most probative evidence of non-obviousness and must be considered whenever such evidence is presented. *E.g., Liqwd, Inc. v. L'Oreal USA, Inc.*, 941 F.3d 1133, 1136-39 (Fed. Cir. 2019).
- Nexus exists between the '958 Patent claims and the commercial embodiments sold by Ddrops and Petitioner.
- Commercial success, long-felt need, industry praise and praise by researchers and consumers support non-obviousness.
- Petitioner's copying is strong evidence of non-obviousness.

PETITIONER COPIED THE PATENTED PRODUCT AND METHOD

- Exhibit 2046, p. 8.



Vitamin D Drop- Competition

Enfamil D.Vi.Sol

Supplement Facts
Serving Size 1 mL Daily
Servings Per Container: 50

Amount Per 1 mL	Infants	% Daily Value Children Under Age 4 Years
Vitamin D 400 IU	100%	100%

INGREDIENTS: GLYCERIN, WATER, POLYSORBATE 80, ARTIFICIAL FLAVOR, CARAMEL COLOR, CITRIC ACID (ANTIOXIDANT FOR VITAMIN D), VITAMIN D₃, SODIUM CITRATE.

Marketing Points

Delivers 100% of the Daily Value of vitamin D as recommended by the AAP
Vitamin D is an essential vitamin that helps your baby's body absorb calcium for strong bones and teeth
Complements your breast milk to help provide optimal nutrition for a healthy baby
Easy to use drops that are gluten-free

Wellbaby by Upspring

Supplement Facts
Serving Size: 4 drops or 0.2 mL
Servings Per Bottle: 90

Amount Per Serving	% DV**
Vitamin D3 (Cholecalciferol)	400 IU 100%

**Percent Daily Values (DV) for infants.

Other Ingredients: Fractionated Coconut Oil.
Free of: Flavor, sugar, dye, stain and preservatives.



D drop
1 drop per
serving

Zarbee's

3 drops a day
56 servings
Age: 2 months+



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nurturing the blissful bond between you and your baby from day one

MOM_0001757

PETITIONER COPIED THE PATENTED PRODUCT AND METHOD

- Exhibit 2046, p. 9.

**mommy's
BLISS**

CONCEPT: Mommy's Bliss Organic D Drop

Age: Newborn:+

Ingredients: Organic Vitamin D
Organic sunflower oil

Price: .15 per serving (retail) (\$4.5 or \$5 for 30 days, \$9 for 60 days, 90 days for \$13.5)

Shelf life: 2 years (conducting stability test using industry standard)

Key Pods

Servings: **90**

Dosage: 1 drop per day by attached dropper

No refrigeration required after opening

Price: 10.99 for 90 days

Competition:

Emfamil D.Vi.Sol = \$10.28 50 servings (77% share of category)

D Drops = \$13.62 90 days

Zbees = \$10.68 for 60 servings of .25 ML or 3 drops (room temp)

Zbees multi with D = \$7 for 19 days (fridge after opening)

PL \$11.64,

Carlson: 1 drop 365 serving \$7.99

Org. Child Life, 200 serving 11.99- 12.99 1 drop serving



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nurturing the blissful bond between you and your baby from day one

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COMMERCIAL SUCCESS

- Ddrops' market share grew from 0 to 27% in the U.S. due to the patented features and instructions. Ex. 2071, ¶s 75-78, 81, 83-85, Exs. G, S.
- Ddrops' market share declined substantially in 2021 after Petitioner introduced its knock-off product. Ex. 2071, Ex. S
- Petitioner's market share on Amazon grew substantially in 2021, while Ddrops' market share declined sharply. Ex. 2051, p. 13.
- Petitioner promoted its "new" vitamin D product in its post-copying marketing and sales materials. Ex. 2026, 144:23-145:12; Ex. 2027, 81:9-12; Ex. 2048, p. 1.
- Petitioner's infringing product was the fastest-growing brand in the brick and mortar and omni channels in 2021. Ex. 2026, 125:14-126:16; Ex. 2054, p. 12.

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