

HIGHLY CONFIDENTIAL – ATTORNEYS EYES ONLY

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MOM Enterprises, LLC,
Petitioner,

v.

ELAINE AND REINHOLD W. VIETH,
Patent Owners,

Case IPR 2023-00726
Patent 9,066,958

PATENT OWNERS' SUR-REPLY

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2001	Docket Sheet: 1:22-cv-00332-GBW Ddrops Company. et al. v. MOM Enterprises, LLC, Gregory B. Williams, presiding, Date filed: 03/16/2022, Date of last filing: 06/22/2023. Accessed through PACER, June 23, 2023.
2002	CIVIL DOCKET FOR CASE #: 0:15-cv-03981-WMW-SER, U.S. District Court, U.S. District of Minnesota (DMN), Accessed through PACER, June 23, 2023.
2003	CIVIL DOCKET FOR CASE #: 0:16-cv-04278-JNE-TNL, U.S. District Court, U.S. District of Minnesota (DMN), Accessed through PACER, June 23, 2023.
2004	Declaration of Chris Temovsky, dated June 28, 2023, with attached Exhibits A-D
2005	Claim Construction Order, Case 1:22-cv-00332-GBW, Ddrops Company, et al. v. MOM Enterprises, LLC, Gregory B. Williams, presiding, D.I. 72, Filed 06/02/23
2006	MARC STANDARDS, Library of Congress Network Development and MARC Standards Office, MARC 21 Format for Bibliographic Data, https://www.loc.gov/marc/ last accessed June 23, 2023
2007	U.S. Bureau of Labor Statistics, Occupational Outlook Handbook, Interpreters and Translators, https://www.bls.gov/ooh/media-and-communication/interpreters-and-translators.htm , last accessed June 23, 2023.
2008	Declaration of Reinhold Vieth, dated June 28, 2023, with attached Exhibits A-B

Exhibit Number	Description
2009 WITHDRAWN	Declaration of Warren D. Woessner WITHDRAWN
2010	Transcript of Markman Hearing, June 1, 2023, Case No. 1:22-cv-00332-GBW Ddrops Company, et al. v. MOM Enterprises, LLC, Gregory B. Williams, presiding
2011	Oxford English Reference Dictionary, 2 nd Edition, the Oxford University Press, 1996 (Definitions of adhere and viscosity)
2012	DECLARATION IN SUPPORT OF PATENT OWNERS' MOTION FOR PRO HAC VICE ADMISSION OF ALAN M. ANDERSON
2013	DECLARATION IN SUPPORT OF PATENT OWNERS' MOTION FOR PRO HAC VICE ADMISSION OF L. REAGAN FLORENCE
2014	DECLARATION IN SUPPORT OF PATENT OWNERS' MOTION FOR PRO HAC VICE ADMISSION OF MATTEW PALEN
2015	Transcript of 27 Oct. 2023 Board Conference Call
2016	EXPUNGED
2017	EXPUNGED
2018	[Proposed] PROTECTIVE ORDER
2019	REDLINE OF [Proposed] PROTECTIVE ORDER AGAINST DEFAULT PROTECTIVE ORDER
2020	[REVISED PROPOSED STIPULATED] PROTECTIVE ORDER
2021	REDLINE OF [REVISED PROPOSED STIPULATED] PROTECTIVE ORDER AGAINST DEFAULT PROTECTIVE ORDER

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2022	Rule 30(b)(6) Deposition Transcript of Innovative Labs, taken September 6, 2023, and Exhibits 1-23
2023	Deposition Transcript of Stephen Benyunes, taken December 5, 2023
2024	Deposition Transcript of David J. Sherman, taken December 5, 2023
2025	Deposition Transcript of Robert O. Williams, III, taken December 7, 2023
2026	Deposition Transcript of Yasmin Kaderali, taken January 30, 2024
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2067	Email Chain, dated November 10 & 11, 2020
2068	Declaration of Reinhold Vieth, dated February 3, 2024, and Exhibits A-F
2069	Declaration of Paul Horowitz, dated February 5, 2024, and Exhibits A-M
2070	Declaration of Casey MacKenzie, dated February 7, 2024, and Exhibits A-B
2071	Declaration of Chris Temovsky, dated February 8, 2024, and Exhibits A-X
2072	Declaration of Steven M. Reid, dated February 9, 2024, and Exhibits A-B
2073	Exhibit 2073 to the Deposition of J. Usha Raj, MD, MHA
2074	Exhibit 2074 to the Deposition of J. Usha Raj, MD, MHA
2075	Exhibit 2075 to the Deposition of J. Usha Raj, MD, MHA
2076	Exhibit 2076 to the Deposition of J. Usha Raj, MD, MHA
2077	Exhibit 2077 to the Deposition of J. Usha Raj, MD, MHA
2078	Redacted Exhibit 2068 - Declaration of Ronald Vieth
2079	Redacted Exhibit 2079 - Declaration of Chris Temovsky
2080	Redacted Exhibit 2072 - Declaration of Steven M. Reid
2081	Deposition of Julia Usha Raj, M.D. taken May 1, 2024
2082	Errata Sheet – Deposition of Reinhold Vieth, Ph.D. taken April 2, 2024
2083	Errata Sheet – Highly Confidential – Deposition of Chris Temovsky taken March 27, 2024
2084	Errata Sheet – Deposition of Paul Horowitz, MD taken March 19, 2024

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2085	Errata Sheet – Deposition of Steven M. Reid taken March 21, 2024
2086	Corrected Exhibit 2051 - Kaderali Deposition Ex. 33
2087	Corrected Exhibit 2064 - Medina Deposition Ex. 46
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I. INTRODUCTION

Cognizant of the weakness of its obviousness arguments, Petitioner sought to add a new theory of invalidity. The Board, however, rejected that tactic. *See* Paper 89. Petitioner’s remaining arguments are factually deficient, inaccurate and misleading. Petitioner repeatedly engages in impermissible hindsight reconstruction, pointing to alleged snippets in the prior art to argue it would have been obvious to a POSITA to create the claimed inventions. Petitioner, however, ignores key claim elements that are lacking in the prior art. In Petitioner’s world, a POSITA (or an infringer’s counsel) may keep obtaining translations of foreign language documents until they get one they like. Moreover, Petitioner’s invalidity arguments rest on an inadmissible hearsay statement from a midwife regarding the purported chemical composition of Vigantol. Finally, Petitioner weakly responds to the significant evidence of secondary indicia, which establish that claims 1 and 3-5 of the ‘958 Patent are not invalid.

II. CLAIMS 1 AND 3-5 ARE VALID

A. The Board Should Only Consider the Tinworth Translation

Petitioner’s expert unequivocally testified that he can render no opinion on obviousness if he only has the Tinworth translation of Harder. Ex. 2025, 99:5-100:21; 120:10-19. Recognizing this fatal flaw, Petitioner now submits multiple

inadmissible excerpts allegedly from various dictionaries. It downplays this fatal flaw by claiming, without any evidence, that Petitioner’s counsel “caught in prior litigation” an “unfortunate oversight” that was then corrected by a new translator. Paper 74, 10.

Petitioner essentially asks the Board to adopt a new policy for foreign language prior art, which allows a party to obtain multiple translations until one supports their arguments. The concept that a prior art statement is not sufficiently clear for consistent translation but nonetheless sufficiently clear to invalidate patent claims is nonsensical. Such a policy would undermine the credibility of any invalidity determination. Parties should not be encouraged to shop around until they get a “winning” translation. Validity determinations surely are not subject to such manipulation. In the real world, researchers and POSITAs do not engage in such behavior. *See* Ex. 1039, 150:22-151:12; Ex. 2073, 49:20-50:5.

Petitioner’s attempt to pass-off its inconsistent translation quagmire as an “unfortunate oversight” rings hollow. Petitioner’s counsel relied on the Tinworth translation in prior litigation until it discovered it was inadequate for its invalidity arguments. Ex. 1021, ¶s2-3; Ex. 2024, 22:9-24. Counsel then requested the translation service to rewrite it, adding four words to Tinworth’s translation. *See*

Paper 61, 11-15. None of Petitioner’s numerous translators testified that Tinworth’s translation was wrong or inaccurate.

Contrary to Petitioner’s suggestion (Paper 74, 11), Patent Owners are not obligated to depose Tinworth or obtain another translation. Petitioner’s burden to establish invalidity never shifts to the patent owner. Paper 89, 4-5. Tinworth signed a declaration verifying the accuracy and completeness of her translation. Petitioner is obligated to obtain a sworn retraction from Tinworth, but it failed to obtain one.

Petitioner falsely contends that Dr. Vieth admitted to the translation of “zum Ablecken.” Paper 61, 10. First, his personal understanding of German is not relevant. Second, Dr. Vieth does not read German, and at most speaks “household German.” Ex. 1039, 91:7-14. He never heard those two words spoken at home. *Id.*, 149:24-150:14. Moreover, his testimony merely was his agreement as to the text being discussed – the Sherman translation. *Id.*, 109:4-7; Ex. 2082 at 3.

Petitioner submits multiple excerpts from a variety of dictionaries, but those new exhibits (Exs. 1042-1046) lack foundation and are inadmissible under Fed. R. Evid. 901. Additionally, they are hearsay for which no exception applies. *See* Fed. R. Evid. 801, 802. None of Petitioner’s experts relied on the newly-produced excerpts in preparing their opinions, thus failing Fed. R. Evid. 703. Given that

Patent Owners’ did not submit any new translations of Harder, Petitioner’s five additional exhibits are non-responsive, improperly submitted new evidence. *See* 37 C.F.R. §42.123(b).

B. Petitioner Has Not Produced Admissible Evidence of the Composition of Vigantol

Harder claims that Vigantol “contains only one excipient as a vehicle for the fat-soluble vitamin D, namely medium-chain triglycerides (vegetable oil).” Ex. 1021, 5. Petitioner argues that Harder therefore establishes that Vigantol “undisputedly meets the claimed chain length.” Paper 74, 3. This argument must be rejected for at least two reasons.

First, Harder’s statement regarding Vigantol is hearsay. It is “a statement, other than one made by the declarant while testifying at the trial or hearing, offered in evidence to prove the truth of the matter asserted.” Fed. R. Evid. 801(c). While prior art is not hearsay when presented to show only that the claimed subject matter was in the public’s possession, Petitioner is relying on Harder to prove the actual chemical composition of Vigantol.

Even if the Board overlooks hearsay, Harder’s statement is inaccurate and ambiguous. Harder states that Vigantol contains “medium-chain triglycerides (vegetable oil).” But vegetable oils are typically long-chain triacylglycerols (LCT).

Ex. 2068, ¶s33, 75-76. Fractionated coconut oil is typically referred to as MCT.

Ex. 2072, ¶104. Harder, a midwife with no alleged skills or training in chemistry or chemical analysis, cites no authority for her statement. Establishing that Vigantol consists of MCT and vitamin D is critical to Petitioner’s invalidity argument.

Petitioner failed to produce admissible evidence to prove this. The Board, therefore, should find that Petitioner has not proven the chemical composition of Vigantol by a preponderance of the evidence.

C. No Prior Art Teaches a Method for Delivering a “Nutritional or Therapeutic Effective Amount of Vitamin D”

Claims 1 and 3-5 of the ‘958 Patent require delivery of “a nutritional or therapeutic amount of vitamin D” to a human. Ex. 1001, 9:37-38. None of the cited prior art addresses this limitation. Petitioner, therefore, attempts to confuse the issue using a series of strawman arguments. It argues, “To the extent Patent Owners resort to the preamble to require actual receipt of an effective dose, that fails.” Paper 74, 15. Patent Owners have *not* made any arguments based on the preamble. Petitioner’s arguments regarding preambles are just noise.

Petitioner argues the Board should not read a requirement into the claims that “the human being receives an effective dose by sucking for at least 30 seconds.” *Id.* at 16. Again, Patent Owners have never asked the Board to read some

time interval into the claims. The specification discloses that the “nutritional or therapeutic amount” limitation relates to efficiency of the transfer of the Vitamin D from the surface to the human. *See* Ex. 1001, 4:50-57.

Petitioner argues that the limitation is inherent in the spoon method disclosed in Harder. *See* Paper 74, 5-7. However, “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). Inherency “is present only when the limitation at issue is the ‘natural’ result of the combination of prior art elements.” *Id.* “[T]he mere fact that a certain thing may result from a given set of circumstances is not sufficient” to find a limitation as inherent. *In re Oelrich*, 666 F.2d 578, 581 (C.C.P.A. 1981). Instead, the “limitation at issue necessarily must be present.” *PAR Pharm.*, 773 F.3d at 1195-96.

While it *may* be true that a nutritional or therapeutic amounts of vitamin D can be delivered using the Harder spoon method, no evidence exists that delivery of a nutritional or therapeutic amounts of vitamin D is the “natural result” of that method. Petitioner cannot establish inherency by probabilities or possibilities. *See id.* at 1196.

Petitioner argues that proof of efficacy is not required for anticipation. Paper 74, 6. But the Board struck its new anticipation arguments. Petitioner offers no argument or rationale why a POSITA would determine how to administer a “nutritional or therapeutic effective amount” of vitamin D using a method plucked from the field of pain management to solve the inter-related problems Patent Owners elegantly solved, much less to find the missing element of “adheres.” Its expert’s declaration does not even contain the words “inherency” or “inherent.” *See* Ex. 1004. Neither Harder, Blass nor Wolf teaches or suggests any way to deliver the necessary nutritional or therapeutic effective amount of vitamin D required. Petitioner’s inherency argument thus fails. *See, e.g., OSI Pharms., LLC v. Apotex Inc.*, 939 F.3d 1375, 1382-85 (Fed. Cir. 2019); *Janssen Pharms., Inc. v. Tolmar, Inc.*, 2024 U.S. Dist. LEXIS 34128 at *56-64 (D. Del. Feb. 26, 2024).

D. No Prior Art Discloses a Method “Wherein Said Drop Adheres to the Surface of Said Object”

The parties’ agreed construction of “wherein said drop adheres to the surface of said object” is:

the drop is sufficiently viscous so that one drop does not immediately drip or roll away from the object that enters the mouth, so that no portion would drip off the object and surface. The drop *does not coat*

or adhere to the object so as to prevent *efficient removal* of the drop from the object.”

Ex. 2005 (emphasis added). The construction makes clear that adhesion has two characteristics: (1) the drop must remain attached to the surface, and (2) the drop must remain localized to facilitate its removal from the surface. Ex. 2072, ¶s25-26.

Petitioner argues that the Board “found at institution” that the adherence limitation is necessarily present in Vigantol oil. Paper 74, 5-6. Of course, the Board made no such finding. “[T]here is a significant difference between a petitioner’s burden to establish a ‘reasonable likelihood of success’ at institution, and actually proving invalidity by a preponderance of the evidence at trial.” *TriVascular, Inc. v. Samuels*, 812 F.3d 1056, 1068 (Fed. Cir. 2016).

Petitioner acknowledges that none of the prior art explicitly discloses that Vigantol oil “does not coat or adhere” to a spoon. Therefore, it again resorts to inherency. Petitioner begins by relying on the ambiguous and inadmissible hearsay statement in Harder that MCT is allegedly the carrier oil in Vigantol. But there is no admissible evidence concerning the chemical composition of Vigantol. Even if Vigantol is formulated with MCT, scientific testing by Patent Owners’ expert 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.

Petitioner has not presented any evidence to contradict this finding. The spoon angles used by Dr. Reid made it impossible for the drop to drip off the spoon. *Id.*, ¶72. Shockingly, Petitioner quotes this innocuous explanation about the test design, mischaracterizes it as his test result, and then argues it demonstrates that “the ‘Baby Ddrops’ product ‘adheres’ within the meaning of the claims.” *See* Paper 74, 6, 12. Patent Owner’s expert never tested whether MCT can drip off a metal spoon at angles steeper than 14.8 degrees. Petitioner’s argument is blatantly disingenuous. It cannot change the actual test results showing that MCT does *not* adhere to a metal spoon simply by cherry-picking random quotes and misrepresenting them.

Petitioner next alleges that “[v]iscosity (which impacts adherence) is an inherent property” of Vigantol, but it provides no basis or authority to support this asserted relationship. *Id.* at 6. Viscosity *may* impact adherence, but Petitioner failed to show that adherence is the “natural result” of Vigantol oil. Even a highly viscous substance like honey does not adhere well, *e.g.*, to Teflon or wax paper.

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).

Finally, Petitioner argues that Patent Owners have failed to “provide evidence showing that vitamin D oil cannot be removed from a spoon or object.” Paper 74, 13. But Patent Owners do not have the burden of persuasion in an IPR. *In re Magnum Oil Tools Int’l, Ltd.*, 829 F.3d 1364, 1375 (Fed. Cir. 2016). It is nonsensical to require Patent Owners to prove a negative, i.e., non-operability. Dr. Reid’s experiments show that a drop of MCT oil rolls away from the tip of a metal spoon and coats the bowl of the spoon. This certainly makes “efficient removal” of the drop difficult if not impossible.

E. Petitioner Fails to Establish a Motivation to Combine

Petitioner argues that various prior art references inherently disclose various elements of the claims of the ‘958 Patent. Paper 74, 5-6, 19-20. Picking and choosing among the allegedly disclosed elements, Petitioner exclaims *voilà*: the multi-faceted, inter-related problem solved by the ‘958 Patent is recreated. However, Petitioner ignores the necessary requirement that there must be some motivation to combine elements from disparate prior art references.

As stated in *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007):

[A] patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art. ... [I]t can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does.

This is so because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known.

“[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). “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 F.4th 882, 887 (Fed. Cir. 2024).

Petitioner’s expert 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. At his deposition, Petitioner’s counsel repeatedly instructed him not to answer questions about whether he received any documents or information relating to the alleged motivation to combine. Ex. 2025, 77:16-79:11. Patent Owners were blocked from determining whether Petitioner is claiming that a motivation to combine existed.

Petitioner has not identified why a POSITA would be motivated to combine the three or four references. Petitioner’s Reply does not even contain the word “motivation.” But a POSITA would have to pick and choose parts of voluminous prior art references from disparate fields. Harder is a how-to book for midwives. *See* Ex. 2070, ¶s1-5, Ex. B. A POSITA would have to ignore the “most reliable option” presented for administering vitamin D and instead focus on a limited-case, dangerous method. A POSITA would then have to find and ignore the Wolf reference that indisputably teaches away from the solution claimed in the ‘958 Patent. *See* Paper 61, 19-20. A POSITA would have to select a general reference text, *European Pharmacopoeia*, which 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. *Id.*, 20-21. The POSITA then would have to identify Blass, which is in an entirely different field – pain

management – to supposedly identify the additional elements in claim 3. *Id.*, 21-22. Finally, the POSITA would have to select Gartner, a clinical report which 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 and therapeutic effective amount”. *Id.*, 23.

The Board cannot assume that a POSITA would be motivated to search for and combine bits and pieces from multiple prior art references in different fields to solve the inter-related problem solved by the ‘958 Patent. The Board’s job is not to fix the holes in Petitioner’s case. Petitioner cannot meet its burden by relying on mere say-so. Conclusory assertions that a POSITA could combine references with no specific evidence regarding motivation are legally insufficient. *See, e.g., TQ Delta, LLC v. Cisco Sys.*, 942 F.3d 1352, 1358-61 (Fed. Cir. 2019); *InTouch Techs., Inc. v. VGo Commc’ns, Inc.*, 751 F.3d 1327, 1351-54 (Fed. Cir. 2014).

F. A POSITA Would Not Rely on Harder

Harder is a collection of “how-to” chapters written by midwives. The target audience is midwives, not a POSITA. Harder distinguishes her co-edited book from “obstetric textbooks.” Ex. 2070, Ex. B; Ex. 2072, ¶53. The Table of Contents shows that none of the chapters would be of interest to a POSITA working in the

field of the ‘958 Patent. *See* Ex. 2072, ¶s55-57. A POSITA would not look to Harder as a reference. Ex. 1036, 55:6-14.

Although the Board preliminarily found that a POSITA would look at Harder because it “*conceivably* embraces delivering medicines and nutritional supplements to infants” (Paper 10, 34 (emphasis added)), the translation provided by Patent Owners shows this not the case. *See* Ex. 2070, Ex. B. Harder is from a different field than the ‘958 Patent. Nothing in §15.9 of Harder addresses a solution to the complex problem of efficiently and effectively “applying one drop ... of a nutritional or therapeutic effective amount of ... vitamin D ... wherein said drop adheres to the surface of said object....” Ex. 1001, 9:37-41. At most, it presents a special case alternative for providing some amount of vitamin D to an infant suffering from allergies or gastro-intestinal gas. The purposes of the claimed invention and this sub-part of a section of Harder clearly are different. *Unwired Planet, LLC v. Google Inc.*, 841 F.3d 995, 1000-01 (Fed. Cir. 2016). *See* Paper 61, 16-18, 30-31.

G. Patent Owners’ Experts are Qualified and Credible; Petitioner’s Experts are Not

Petitioner argues Patent Owners’ experts are not POSITAs. Paper 61, 21-22. Petitioner claims that Dr. Reid is a patent attorney who lacks any technical

expertise. That is false. Dr. Reid has a PhD in chemistry from M.I.T. where he studied under a Nobel Prize recipient. He has published in leading journals. He worked as a patent examiner and examined many applications arising in the pharmaceutical arts, including chemical entities, their formulations, and methods of medical uses. He has prosecuted patent applications in the fields of medicinal chemistry, pharmaceuticals, formulations, drug delivery and medical uses. His opinions are based solely on his technical expertise. Ex. 2072, ¶¶4-11, Ex. A; Ex. 1037, 7:10-11:14. Similarly, Dr. Horowitz is well-qualified to render his opinions based on his education, training and expertise. *See* Ex. 2069, ¶¶4(a)-(e), Ex. A; Ex. 1036, 8:2-12:5. He considers himself a person of ordinary skill in the art. *Id.*, 55:3-5.

Petitioner's reliance on *Sundance, Inc. v. DeMonte Fabricating Ltd.*, 550 F.3d 1356 (Fed. Cir. 2008), is wrong. *Sundance* involved a patent attorney with no relevant technical expertise and no experience in the pertinent art. *Id.* at 1362-64. Here, Drs. Reid and Horowitz have relevant technical expertise and are well-qualified to provide their opinions. *See, e.g., Calhoun v. Yamaha Motor Corp. U.S.A.*, 350 F.3d 316, 321 (3d Cir. 1996); *Midwest Energy Emissions Corp. & Mes*

Inc. v. Arthur J. Gallagher & Co., 2023 U.S. Dist. LEXIS 202160 at *15-26 (D. Del. Nov. 3, 2023).

Neither Dr. Horowitz nor Dr. Vieth are disqualified due to alleged financial interest. Dr. Horowitz sells the Ddrops product because when he first learned of it, he thought it was a “unique” and “terrific” product. Ex. 1036, 47:16-22. He sells a couple of bottles a week, and it amounts to no more than a couple of thousand dollars a year in sales. *Id.*, 49:10-15, 51:3-9. That Dr. Vieth receives royalties based on sales of products that embody his invention is hardly disqualifying. Most inventors receive some form of profit from their inventions. Further, Dr. Vieth accurately testified he never knew the composition of Vigantol oil. In the early 2000s, he received three unidentified vials and tasked one of his lab assistants to assay their contents. He only knew they were various solutions containing vitamin D. He has never obtained an authentic sample of Vigantol oil. Ex. 1039, 38:18-39:23, 40:11-41:15, 102:12-21; 142:24-144:9; Ex. 2082, 3.

In contrast, Petitioner’s experts’ opinions should be rejected and ignored. Williams was instructed not to answer over 90 times based on bogus claims of privilege. Paper 61, 23-27. Fed. R. Civ. P. 26(b)(4)(C) is not as broad as Petitioner apparently believes. It expresses a “limited work-product protection for

collaborative interactions between counsel and testifying experts.” *Davita Healthcare Partners, Inc. v. United States*, 128 Fed. Cl. 584, 589 (Fed. Cl. 2016). *See* Fed. R. Civ. P. 26(b)(4)(C), 2010 Advisory Note. “Communications that relate to expert compensation or identify facts, data or assumptions that the party’s attorney provided, and that the expert considered and relied upon in forming opinions to be expressed are not precluded from discovery.” *Medicines Co. v. Mylan Inc.*, 2013 U.S. Dist. LEXIS 82964 at *11 (N.D. Ill. June 13, 2013). The development, foundation or basis for an expert’s opinions, or information provided to the expert, are subject to discovery. *Jackson v. Wexford Health Sources, Inc.*, 2023 U.S. Dist. LEXIS 22419 at *10-16 (S.D. Ill. Dec. 15, 2023). Further, yes/no questions are preliminary and not protected. *See id.* at *16-18; *Hood v. City of Chicago*, 2021 U.S. Dist. LEXIS 263257 at *15-16 (N.D. Ill. Mar. 30, 2021).

The questions identified by Petitioner that Williams was instructed not to answer are preliminary questions or go to information provided to him that he relied upon in forming his opinions. *See* Paper 74, 23. Astonishingly, while Petitioner realized the error of its overly-broad instructions regarding the differences between Williams’ 2017 and 2023 reports, Petitioner continued to instruct him not to answer non-privileged questions. Ex. 2025, 81:9-19, 82:10-17;

83:7-16. The Board should not countenance Petitioner's blatant instructions to thwart permitted discovery. It therefore should disregard Williams' opinions. *See* Paper 61, 23-27.

Raj is a professional witness who is unqualified to opine here. She 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. She is a neonatologist specializing in the circulation in the lung. She has never testified as an expert witness in a patent action. She does not speak or read German. She has no training or expertise as a linguist. She has never previously testified how a pediatrician might read a foreign language document or given an opinion on competing translations. She never read the '958 Patent and does not know its priority date. She simply selected one of the multiple Harder translations provided by Petitioner because it was what she considered the most recent. Her opinion, of how a pediatrician at some time in the 2000s might read that translation, is worthless. *See* Ex. 2081, 8:25-9:2; 11:2-7; 12:16-18; 13:2-5; 17:17-19; 27:22-29:21; 31:3-32:1; 40:24-41:12; 43:5-21; 47:3-15; 48:16-20; 49:20-50:5; 51:13-19; 52:25-53:3; 64:21-65:9; 72:13-23; 77:2-12.

Raj's personal opinion of how a pediatrician might understand one translation at some point in time is unreliable. An expert's opinion based on

nothing more than subjective belief is not reliable or admissible. *See, e.g., Oddi v. Ford Motor Co.*, 234 F.3d 136, 145 (3d Cir. 2000); *Ely v. Cabot Oil & Gas Corp.*, 2016 U.S. Dist. LEXIS 165597, *5-9 (M.D. Pa. Feb. 17, 2016). *See generally Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993).

Similarly, her so-called “test” of small plastic spoons is of no benefit and not admissible. Petitioner’s counsel selected and sent her those spoons, along with a set of metal spoons and a bottle of Ddrops’ product. She did not keep any of the materials sent with the various products. Raj did not know that the small plastic spoons used in her tests were not available until 2012. She never tested the metal spoons, which she agreed would never be used with an infant (contrary to Harder’s suggestion). That said, her “test” agrees with Dr. Reid, that a drop of Ddrops’ Baby vitamin D product will roll into the bowl of the spoon and coat it. *See* Ex. 1040, ¶21; Ex. 2077; Ex. 2081, 78:5-85:25; 88:16-90:13; 91:12-18; 92:9-15; 110:24-111:9; 116:11-16. Raj’s “opinion” based on her “test” of some post-critical date random plastic spoons should be disregarded.

III. SECONDARY CONSIDERATIONS ESTABLISH THE VALIDITY OF CLAIMS 1 AND 3-5

Petitioner ignored secondary considerations in its Petition. Its expert ignored this factor despite being aware of the need to consider it. *See* Ex. 1004, ¶31; Ex.

2025, 75:20-76:4. However, secondary considerations are often the most probative evidence of non-obviousness and must be considered whenever such evidence is presented. *See, e.g., Liqwd, Inc. v. L’Oreal USA, Inc.*, 941 F.3d 1133, 1136-39 (Fed. Cir. 2019).

Petitioner has no evidence contradicting Patent Owners’ substantial evidence of secondary considerations. *See generally* Paper 61, 44-64. Petitioner instead makes conclusory arguments against that evidence. *See* Paper 74, 25-28. Petitioner ignores relevant caselaw and repeatedly misstates the evidence.

A. Nexus

Petitioner claims that Patent Owners have not established any nexus between the claimed inventions and the commercial products. However, a patentee is entitled to a rebuttable presumption of nexus if “the patentee shows that the asserted objective evidence is tied to a specific product and that product ‘embodies the claimed features, and is coextensive with them.’” *Polaris Indus., Inc. v. Arctic Cat, Inc.*, 882 F.3d 1056, 1072 (Fed. Cir. 2018). The Federal Circuit has “never held that the existence of one or more unclaimed features, standing alone, means nexus may not be presumed.” *Fox Factory, Inc. v. SRAM, LLC*, 944 F.3d 1366, 1374 (Fed. Cir. 2019), *cert. denied*, 141 S.Ct. 373 (2020). “[T]he degree of

correspondence between a product and a patent claim falls along a spectrum.” *Id.* Perfect correspondence is not required. Rather, all that is necessary is for the patent owner to “demonstrate that the product is essentially the claimed invention.” *Id.*

Petitioner has no evidence contradicting Patent Owners’ evidence that the Ddrops’ and Petitioner’s products embody the patent claims. *See* Ex. 2072, ¶104; Ex. 2071, ¶s19, 26-28, 31, Ex. B. Petitioner only argues that literally the last line of the product instructions on the products includes a non-infringing use. Paper 74, 25. However, the last line merely states *an alternative* use, not the primary or preferred use. Such alternative instructions hardly destroy the nexus between the product and the patent claims. Moreover, praise by consumers and researchers further establish the nexus between Ddrops’ product and method and the claimed inventions. *See, e.g.*, Ex. 2071 (“The reason for the popularity of D-Drops® may be their ease of administration requiring only a single drop that can be placed on the mother’s breast....”).

Petitioner relies on *Novartis AG v. Torrent Pharms. Ltd.*, 853 F.3d 1316, 1331 (Fed. Cir. 2017), to argue that the “objective indicia must be directed to what was not known in the prior art[.]” It then asserts (incorrectly) that each element of the claims is somewhere in the prior art. Petitioner’s argument is faulty. Petitioner

misleadingly omits the remainder of the quotation from *Novartis*, which states “what was not known in the prior art ... may well be the novel combination or arrangement of known individual elements.” *Id.* at 1331. In *Henny Penny Corp. v. Frymaster LLC*, 938 F.3d 1324, 1329, 1333-34 (Fed. Cir. 2019), *cert. denied*, 141 S.Ct. 373 (2020), the Federal Circuit rejected the same argument Petitioner is making and affirmed the Board’s determination of nexus where industry praise was directed toward the combination claimed in the patent as a whole. *See WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1330 (Fed. Cir. 2016) (“proof of nexus is not limited to only when objective evidence is tied to supposedly the new feature(s).”).

B. Commercial Success

Petitioner claims that Patent Owners cannot show commercial success, because the decline in Ddrops’ market share started before Petitioner introduced its copy-cat infringing product. It argues that the success of Petitioner’s product was due to other alleged “features.” This argument is without merit.

Petitioner presents no evidence to dispute the fact that the Ddrops’ product increased market share from [REDACTED] in the U.S. due to the patented features and instructions. Ex. 2071, ¶s 75-78, 81, Ex. S. This is strong, undisputed

evidence that the Ddrops product experienced huge commercial success due to the unique features claimed in the ‘958 Patent.

Ddrops’ market share declined substantially in 2021 after Petitioner introduced its copy-cat product. *See* Ex. 2071, Ex. S. Petitioner’s market share on [REDACTED], while Ddrops’ market share [REDACTED]. Ex. 2051 at 13. Petitioner admits its 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 at 12.

Petitioner’s president admitted that the only change to its product in 2021 was using the MCT formula copied from Ddrops. Ex. 2026, 122:24-123:6. Petitioner promoted its “new” vitamin D product in its post-copying marketing and sales materials, not any alleged change to the dropper design. *See* Ex. 2026, 144:23-145:12; Ex. 2027, 81:9-12; Ex. 2048 at 1. Similarly, the fact Petitioner’s product was organic since 2016 does not undercut Patent Owners’ commercial success. Despite selling an organic product for five years (since 2016), Petitioner’s market share vis-à-vis Ddrops’ product was lower – until it copied the MCT formula. *See* Ex. 2026, 121:9-122:9, 122:24-123:17; Ex. 2051 at 13; Ex. 2053.

Ddrops’ efforts to regain lost market share post-Petitioner’s nefarious acts do not negate the evidence of commercial success. Ddrops’ embodiment of the ‘958 Patent experienced commercial success after its introduction due to the unique combination of elements. That commercial success continued until Petitioner completed its copying by changing its product to precisely match Ddrops’ product instructions and formula. Petitioner stole Ddrops’ commercial success by introducing its knock-off product, experiencing, for the first time since introducing a vitamin D product five years earlier, commercial success attributable to the ‘958 Patent.

C. Copying

Petitioner does not address the unequivocal evidence that Petitioner copied the patented elements of the ‘958 Patent and Ddrops’ commercial embodiment in a two-step process that culminated in 2021. *See* Paper 61, 50-53. Patent Owners’ evidence of copying by Petitioner is un rebutted.

Petitioner only challenges Patent Owners’ evidence of copying by others. *See* Paper 74, 27. Yet again, Petitioner ignores the unrefuted evidence of Ddrops’ co-president that upon introduction in the U.S., two distributors copied it, just as companies in Canada had copied. Ex. 2071, ¶s86-101, Exs. U, V. These

competitors’ products, as direct copies, obviously embodied the claims of the ‘958 Patent. *See, e.g., Advanced Display Sys. v. Kent State Univ.*, 212 F.3d 1272, 1285 (Fed. Cir. 2000) (“copying may often be the most probative and cogent evidence of nonobviousness”); *Panduit Corp. v. Dennison Mfg. Co.*, 774 F.2d 1082, 1099 (Fed. Cir. 1985), *cert. granted judgment vacated on other grounds*, 475 U.S. 809 (1986) (copying is “strong evidence of nonobviousness”). *See generally Volvo Penta of the Americas, LLC v. Brunswick Corp.*, 81 F.4th 1202, 1212-13 (Fed. Cir. 2023) (summarizing cases).

D. Long-felt Need and Industry Praise

Petitioner briefly addresses the substantial evidence of long-felt but unmet need and industry praise. *See* Paper 74, 27-28. Petitioner relies on its incorrect argument that individual elements were present in the prior art. But it is the unique, first-of-its kind combination of elements claimed in the ‘958 Patent that satisfies long-felt but unmet need. *See* Paper 61, 54-59. The state of the art before Ddrops’ product was the deficient D-Vi-Sol product. Ex. 2069, ¶¶27-28; Ex. 2071, ¶¶44-46, Exs. D, E. In 2010, the FDA issued a warning about the risk of infant overdose when using a dropper, as with the D-Vi-Sol product. Ex. 2077. Prior to issuance of the ‘958 Patent, no other product with all the patented features existed in the

market or at anytime in the long-history of the need for a product and method comprising the elements claimed in the ‘958 Patent to easily and effectively administer vitamin D to humans, particularly infants.

Petitioner’s argument that industry and consumer praise evidence is inadmissible hearsay is wrong. Under Fed. R. Evid. 803(3) – the state of mind exception to the hearsay rule – such statements are not hearsay. *See, e.g., Lincare Holdings Inc. v. Doxo, Inc.*, 2024 U.S. Dist. LEXIS 34800, at *6 (M.D. Fla. Feb. 29, 2024); *Fit, Inc. v. Pleasonton Fitness, LLC*, 2013 U.S. Dist. LEXIS 18106 at *17, n.13 (M.D. Fla. Feb. 11, 2013); *Discover Fin. Servs. v. Visa U.S.A. Inc.*, 2008 U.S. Dist. LEXIS 80801 at *4-5 (S.D.N.Y. Oct. 9, 2008).

None of the consumers’ or competitors’ statements are being offered to prove the truth of the matter asserted. Rather, they are being offered to prove the then-existing state of mind of the declarant. Thus, the competitor statements are admissible. Similarly, the consumer statements reviewing the Ddrops’ product are admissible. *See* Ex. 2068, ¶s54-55; Ex. 2071, ¶s55-57.

Petitioner incorrectly argues that the industry awards presented to Ddrops and the use and praise by researchers are not tied to any novel limitation. *See* Paper 74, 28. Again, this is an incorrect standard. Neither the awards nor researcher

praise were based on only one aspect of the product. They were based on the complete Ddrops' product – the undisputed embodiment of the '958 Patent.

IV. CONCLUSION

For the foregoing reasons, as well as the reasons expressed in the Response, Petitioner has not established that claims 1 and 3-5 of the '958 Patent are invalid as obvious. Patent Owners request that the Board reject the Petitioner's arguments and affirm the validity of claims 1 and 3-5 of the '958 Patent.

Dated: May 15, 2024.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

The undersigned hereby certifies that the foregoing Patent Owners' Sur-Reply includes less than 5,600 words, as measured by the word-processing system used to prepare this Sur-Reply.

/Mark E. Ungerman/
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CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6(e), the undersigned certifies that the foregoing Patent Owners' Sur-Reply is being served on May 15, 2024, by filing this document through the Patent Trial and Appeal Case Tracking System (P-TACTS) and by electronic mail as directed by Petition upon the following counsel of record for Petitioners:

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