UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Padagis US LLC,
Petitioner

v.

Neurelis, Inc.,
Patent Owner

Case No. IPR2025-00466
Patent No. 11,793,786

PATENT OWNER'S MOTION TO STRIKE

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37 C.F.R. § 42.24(c)(1) 2
37 C.F.R. § 42.26(a)(3) 3

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(adding Exhibits 2082-2083)

Exhibit	Description of Exhibits
2001	*Clinical Superiority Findings*, U.S. FOOD & DRUG ADMIN. (Dec. 18, 2024) https://www.fda.gov/industry/designating-orphan-product-drugs-and-biological-products/clinical-superiority-findings
2002	Scheduling Order entered in *Neurelis, Inc. v. Padagis LLC*, 1:24-cv-00562, D.I. 20 (D. Del. Aug. 28, 2024)
2003	Preliminary Invalidity Contentions served in *Neurelis, Inc. v. Padagis LLC*, 1:24-cv-00562 (D. Del. Dec. 20, 2024)
2004	Markman Order entered in *Gilead Sciences, Inc. v. Lupin Ltd.*, 1:22-cv-00615-MN, D.I. 280 (D. Del. Feb. 21, 2025)
2005	Markman Order entered in *Spinal Generations, LLC v. Depuy Synthes, Inc.*, 1:22-cv-01368 (MN), D.I. 147 (D. Del. Oct. 16, 2024)
2006	Orange Book Listing for U.S. Patent No. 11,793,786
2007	Declaration of Nicholas A. Peppas, Sc.D., dated December 6, 2018 in *Aquestive Therapeutics, Inc. v. Hale Biopharma Ventures, LLC*, IPR2019-00451, Exhibit 1041 (Jan. 29, 2019)
2008	Declaration of Daniel P. Wermeling, Pharm.D., dated January 27, 2020 in *Aquestive Therapeutics, Inc. v. Hale Biopharma Ventures, LLC*, IPR2019-00451, Exhibit 1150 (Jan. 28, 2020)
2009	Application No. 18/782,666 ("'666 Application")
2010	Information Disclosure Statements filed with the Application No. 18/782,666 ("'666 Application") Prosecution History

Exhibit	Description of Exhibits
2011	Sai H. S. Boddu, Sneha Kumar, A Short Review on the Intranasal Delivery of Diazepam for Treating Acute Repetitive Seizures. Pharmaceutics 2020; 12, 1167
2012	Cornett et al., VALTOCO® (Diazepam Nasal Spray) for the Acute Treatment of Intermittent Stereotypic Episodes of Frequent Seizure Activity, Neurology International 2021; 13:64–78
2013	Scheduling Oral Order entered in *Neurelis, Inc. v. Padagis LLC*, 1:24-cv-00562, D.I. 47 (D. Del. March 11, 2025) Order Granting Stipulation to Extend Certain Fact Discovery Deadlines entered in *Neurelis, Inc. v. Padagis LLC*, 1:24-cv-00562, D.I. 65 (D. Del. May 15, 2025)
2014	Jacqueline A. French, Timothy A. Pedley, *Initial Management of Epilepsy*, New England Journal of Medicine 2008; 359:166-76 ("French & Pedley 2008")
2015	Penovich et al., *Burden of Seizure Clusters on Patients With Epilepsy and Caregivers*, The Neurologist 2017; 22: 207-214
2016	Cloyd et al., *Overcoming the Challenges of Developing an Intranasal Diazepam Rescue Therapy for the Treatment of Seizure Clusters*, Epilepsia 2021; 62:846-856
2017	Hogan, R.E., et al., *Bioavailability and Safety of Diazepam Intranasal Solution Compared to Oral and Rectal Diazepam in Healthy Volunteers*, Epilepsia, 61:455-464 (Feb. 2020)
2018	Lindsay M. Higdon and Michael R. Sperling, *A Review of a Diazepam Nasal Spray for the Treatment Of Acute Seizure Clusters and Prolonged Seizures*, J Expert Review of Neurotherapeutics 2021; 21(11):1207-1212
2019	Bechgaard et al., *Solubilization of Various Benzodiazepines for Intranasal Administration, a Pilot Study*, Pharmaceutical Development and Technology 1997; 2(3):293-296

Exhibit	Description of Exhibits
2020	Gizurarson, S., et al., *Intranasal Administration of Diazepam Aiming at the Treatment of Acute Seizures: Clinical Trials in Healthy Volunteers*, Biol. Pharm. Bull., 22(4):425-427 (Apr. 1999)
2021	Ivaturi, V.D., et al., *Bioavailability and Tolerability of Intranasal Diazepam in Healthy Adult Volunteers*, Epilepsy Res., 84:120-126 (2009)
2022	Schrier, L., et al., *Pharmacokinetics and Pharmacodynamics of a New Highly Concentrated Intranasal Midazolam Formulation for Conscious Sedation*, Brit. J. Clin. Pharmacol., 83:721-731 (Apr. 2017)
2023	Penovich et al., *Benzodiazepines for the Treatment of Seizure Clusters*, CNS Drugs 2024; 38:125-140
2024	Kapoor et al., *A Review of Intranasal Formulations for the Treatment of Seizure Emergencies*, Journal of Controlled Release 2016; 237: 147-159
2025	Rabinowicz et al., *Improvement of Intranasal Drug Delivery with Intravail® Alkylsaccharide Excipient as a Mucosal Absorption Enhancer Aiding in the Treatment of Conditions of the Central Nervous System*, Drugs in R&D 2021; 21:361-369
2026	Acorda Therapeutics, Letter to Plumiaz Clinical Trial Participants, May 20, 2016
2027	U.S. Patent No. 6,193,985 ("Sonne")
2028	Corrected Opening Brief for Appellee Aquestive Therapeutics, Inc. in *Neurelis, Inc. v. Aquestive Therapeutics, Inc.* (Fed. Cir. 21-1038), dated March 31, 2021 (D.I. 21)
2029	Certified transcription of October 5, 2021 oral hearing in *Neurelis, Inc. v. Aquestive Therapeutics, Inc.* (Fed. Cir. 21-1038)

Exhibit	Description of Exhibits
2030	Written joint research agreement, titled "Master Service Agreement" (7 pages), between Particle Sciences, Inc. and Questcor Pharmaceuticals, Inc., dated April 1, 2007 **[FILED UNDER SEAL]**
2031	Asset Purchase Agreement between Hale BioPharma Ventures, LLC and Questcor Pharmaceuticals, Inc., dated June 27, 2008 **[FILED UNDER SEAL]**
2032	H.R. Rep. No. 108-425 (2004)
2033	150 Cong. Rec. S7520-05 (2004)
2034	Non-disclosure Agreement between Aegis Therapeutics, LLC and Questcor Pharmaceuticals, Inc., dated August 15, 2005 **[FILED UNDER SEAL]**
2035	Confidentiality Agreement between Particle Sciences, Inc. and Questcor Pharmaceuticals, Inc., dated January 19, 2007 **[FILED UNDER SEAL]**
2036	Email between Questcor Pharmaceuticals, Inc. and Aegis Therapeutics, LLC, dated February 15, 2007 **[FILED UNDER SEAL]**
2037	Quote No. QCR 135 between Particle Sciences, Inc. and Questcor Pharmaceuticals, Inc., dated March 28, 2007 **[FILED UNDER SEAL]**
2038	QSC-002 Project Email Thread between Aegis Therapeutics, LLC and Questcor Pharmaceuticals, Inc., dated March 26, 2007
2039	Redline Comparison between U.S. Patent No. 11,793,786 and U.S. Patent No. 11,241,414
2040	QC and PSI Agreement between Particle Sciences, Inc. and Questcor Pharmaceuticals, Inc., dated April 2, 2008 **[FILED UNDER SEAL]**

Exhibit	Description of Exhibits
2041	Letter Agreement, with Term Sheet between Neurelis, Inc. and Aegis Therapeutics, LLC, dated August 28, 2007 **[FILED UNDER SEAL]**
2042	Supply Agreement Neurelis, Inc. and Aegis Therapeutics, LLC, dated May 22, 2008 **[FILED UNDER SEAL]**
2043	License Agreement Neurelis, Inc. and Aegis Therapeutics, LLC, dated May 22, 2008 **[FILED UNDER SEAL]**
2044	Transmittal Notice of Intravail from Aegis Therapeutics, dated October 2, 2008 **[FILED UNDER SEAL]**
2045	Declaration of Steven Cartt **[FILED UNDER SEAL]**
2046	Declaration of Dr. Mark Mitchnick **[FILED UNDER SEAL]**
2047	Declaration of David Hale
2048	Redline Comparison between U.S. Patent Application No. 15/955,397 and U.S. Patent Application No. 17/228,514
2049	Marc Brown *Curriculum Vitae*
2050	Joint Claim Construction Brief, *Neurelis, Inc. v. Padagis LLC et al.*, 1:24-cv-00562, D.I. 87 (D. Del. August 15, 2025) ("Joint CC Brief")
2051	Andrew Streitwieser, INTRODUCTION TO ORGANIC CHEMISTRY (4th ed. 1992) ("Streitwieser")
2052	David W. Oxtoby et al., PRINCIPLES OF MODERN CHEMISTRY (4th ed. 1999) ("Oxtoby")
2053	European Pharmacopoeia 6.0, Vol 2 (6th ed. 2007) ("PhEur 6.0")
2054	Panayiotis P. Constantinides et al., *Advances in the Use of Tocols as Drug Delivery Vehicles*, 23 PHARM RES. 243 (2006) ("Constantinides-2006")

Exhibit	Description of Exhibits
2055	Rowe, Sheskey, & Owen, HANDBOOK OF PHARMACEUTICAL EXCIPIENTS, (6th ed. 2009) ("Rowe-2009")
2056	Afaf Kamal-Eldin, *Effect of Fatty Acids and Tocopherols on the Oxidative Stability of Vegetable Oils*, 108 EUR. J. OF LIPID SCI. & TECH. 1051 (2006) ("Kamal-Eldin-2006")
2057	Branka Rozman & Mirjana Gašperlin, *Stability of Vitamins C and E in Topical Microemulsions for Combined Antioxidant Therapy*, 14 DRUG DELIVERY 235 (2008) ("Rozman-2007")
2058	Afaf Kamai-Eldin & Lars-Ake Appelqvist, *The Chemistry and Antioxidant Properties of Tocopherols and Tocotrienols*, 31 LIPIDS 671 (1996) ("Kamai-Eldin-1996")
2059	March 2009 FDA Inactive Ingredient Database
2060	Redline Comparison between U.S. Patent Application No. 12/413/439 and U.S. Patent Application No. 15/955,397
2061	David Ward, *Optimizing Nasal Products for Systemic Delivery*, 106 ONDRUGDELIVERY 56 (2020) ("Ward-2020")
2062	C. Holvoet et al., *Inclusion Complexation of Diazepam with Different Cyclodextrins in Formulations for Parenteral Use*, 60 PHARMAZIE 598 (2005) ("Holvoet-2005")
2063	Sila-On et al., *Influence of Incorporation Methods on Partitioning Behavior of Lipophilic Drugs into Various Phases of a Parenteral Lipid Emulsion*, 9 PHARMSCITECH 684 (2008) ("Sila-On-2008")
2064	D. J. Van Drooge et al., *Incorporation of Lipophilic Drugs in Sugar Glasses by Lyophilization using a Mixture of Water and Tertiary Butyl Alcohol as Solvent*, 93 J. OF PHARM. SCI. 713 (2004) ("Van Drooge-2004")
2065	L. M. A. Monzon & L. M. Yudi, *Voltammetric Analysis of Lipophilicity of Benzodiazepine Derivatives at the Water 1,2-*

Exhibit	Description of Exhibits
	dichloroethan Interface, 495 J. OF ELECTROANALYTICAL CHEM. 146 (2001) ("Monzon-2001")
2066	M. Molero-Monfort et al., *Retention-activity Relationship Studies of Benzodiazepines by Micellar Liquid Chromatography*, 13 BIOMED. CHROMATOGRAPHY 394 (1999) ("Molero-Monfort-1999")
2067	M. Molero-Monfort et al., *Micellar Liquid Chromatography for Prediction of Drug Transport*, 870 J. OF CHROMATOGRAPHY 1 (2000) ("Molero-Monfort-2000")
2068	Neurelis Patent Family Tree
2069	Declaration of Mareen Donovan, Ph.D. in Support of Defendants' Responsive Claim Construction Brief, *Neurelis, Inc. v. Padagis LLC et al.*, 1:24-cv-562, D.I. 88-28 (D. Del. August 22, 2025) ("Donovan-CC Decl.")
2070	Certified transcription of December 10-11, 2025, Volume I and II Deposition of Maureen Donovan, Ph.D. in *Padagis US LLC vs. Neurelis, Inc.*, IPR2025-00464, IPR2025-00465, IPR2025-00466 ("Donovan Transcript")
2071	*What is Log P and How Does It Predict Chemical Behavior?*, BIOLOGY INSIGHTS, (August 16, 2025), https://biologyinsights.com/what-is-log-p-and-how-does-it-predict-chemical-behavior/ ("Log P")
2072	NOT USED
2073	NOT USED
2074	Declaration of Dr. Marc Brown regarding U.S. Patent No. 11,793,786
2075	NOT USED
2076	Patent Owner Response, dated November 5, 2019 in *Aquestive Therapeutics, Inc. v. Neurelis, Inc.*, IPR2019-00451

Exhibit	Description of Exhibits
2077	U.S. Patent No. 12,268,664 (the "'664 Patent")
2078	Certificate of Correction for U.S. Patent No. 12,268,664
2079	Defendants' Notice of Non-Party Subpoenas, *Neurelis, Inc. v. Padagis LLC et al.*, 1:24-cv-562, D.I. 63 (D. Del. May 13, 2025)
2080	Non-Party Inventors' Responses to Subpoenas (D. Del. May 27, 2025)
2081	Email from Board (Nov. 18, 2025) authorizing moving Due Date 1 (highlighting added)
2082	IPR2025-00466, Paper 43, Petitioner's Reply to Patent Owner's Response (Mar. 31, 2026), with highlighting added to show portions that Patent Owner seeks to strike
2083	IPR2025-00466, Exhibit 1078, Reply Declaration of Maureen Donovan, Ph.D. (Mar. 31, 2026), with highlighting added to show portions that Patent Owner seeks to strike

I. Statement of Precise Relief Requested

With the Board's authorization (EX3005), Patent Owner Neurelis, Inc. ("PO") requests that the Board strike two categories of materials.

First, PO seeks to strike EX1073-EX1075, EX1079, and EX1080, which were filed with Petitioner's Reply (Paper 43), but were not discussed or even cited therein.

Second, PO seeks to strike new invalidity theories that could have been (but were not) presented in the original petition. These materials to be stricken include: EX1075-EX1076 and EX1079; portions of Petitioner's Reply and of Dr. Donovan's Reply Declaration (EX1078), highlighted in EX2082 and EX2083, respectively.

PO requests that the Board disregard these materials and give them no weight, such that PO does not need to address them in its upcoming Due Date 3 sur-reply.

II. The Board Should Strike Exhibits Not Discussed in Petitioner's Reply

"37 C.F.R. § 42.24(a) sets word limits for … replies, and § 42.6(a)(3) prohibits incorporating arguments by reference from one document into another. Thus, parties that incorporate expert testimony by reference in their … replies without providing explanation of such testimony risk having the testimony not considered by the Board." Trial Practice Guide § I.G (Dec. 12, 2025) ("TPG").

A. The Board Should Strike EX1074 and EX1080

Two exhibits are not cited in Petitioner's Reply (Paper 43) or Dr. Donovan's Reply Declaration (EX1078). These include: EX1074, a patent assigned to U&I

Pharms., an unrelated entity; and EX1080, an anticancer drug patent listing Dr. Brown as an inventor. PO and the Board should not need "to play archeologist with the record" to guess the relevance of these documents. *See Cisco Sys., Inc. v. C-Cation Techs., LLC*, IPR2024-00454, Paper 12 at 10 (P.T.A.B. Aug. 29, 2014) (informative); 77 Fed. Reg. at 48,617 (similar). Rather, the Board should "exclude or give no weight" to these exhibits, because Petitioner "has failed to state its relevance or to identify specific portions of the evidence that support the challenge." 37 C.F.R. § 42.104(b)(5); 37 C.F.R. § 42.22(a)(2) (requiring "a detailed explanation of the significance of the evidence"); 37 C.F.R. § 42.23(a) (similar rule for replies).

B. <u>The Board Should Strike EX1073, EX1075, and EX1079</u>

Three exhibits are not cited in Petitioner's Reply, but are cited in Dr. Donovan's Reply Declaration (EX1078). These include: pages from textbooks (EX1073 and EX1079); and part of the prosecution history (EX1075) of Meezan. Using these materials improperly expands the word limit, as Petitioner's Reply is already at 5,592 words—eight words shy of the limit. *See* Paper 43 at 29; 37 C.F.R. § 42.24(c)(1). The Board should "not consider arguments that are not made" in the Reply "but are instead incorporated by reference to the cited paragraphs" of the expert declaration. *See Cisco*, IPR2014-00454, Paper 12 at 10.

It would be improper to incorporate EX1073, EX1075, and EX1079 by reference into the Reply, but here, Petitioner <u>does not even cite</u> these references.

Rather, Petitioner bulk-cites Donovan's Reply Declaration, who then discusses the exhibits at length. *See* EX1078 ¶18 (EX1079), ¶¶37-38 (EX1073), ¶47 (EX1075).

Petitioner does not cite with specificity Paragraph 47 of Donovan's Reply Declaration. The only cite to Paragraph 47 (itself discussing EX1075) is buried within a bulk-cite "*Id.*, ¶¶21, 43-48." Paper 43 at 15. Likewise, the only cites to Paragraph 18 of Donovan's Reply (itself discussing EX1079) are in bulk: "EX1078, ¶¶14-22, 40-42," "*Id.*, ¶¶17-21," and "*Id.*, ¶¶17-18." Paper 43 at 13. And, Paragraphs 37-38 of Donovan's Reply (itself citing EX1073) are within a bulk cite relating to IPR2019-00451, which is unrelated to EX1073, EX1075, or EX1079. Paper 43 at 19 (citing "EX1078, ¶¶34-39").

It was incumbent upon Petitioner, not its expert, to provide "a detailed explanation of the significance of the evidence." 37 C.F.R. § 42.104(b)(5); *see* 37 C.F.R. § 42.22(a)(2); 37 C.F.R. § 42.26(a)(3) (improper to incorporate arguments by reference). Other panels have held that "reliance on seven paragraphs of [expert declaration] is an improper incorporation by reference, as [party] did not discuss that testimony" in its brief. *See Google LLC v. MindbaseHQ*, IPR2021-01252, Paper 41 at 37 (P.T.A.B. Jan. 6, 2023). Here, EX1073, EX1075, and EX1079 are not even cited, let alone discussed, in Petitioner's Reply.

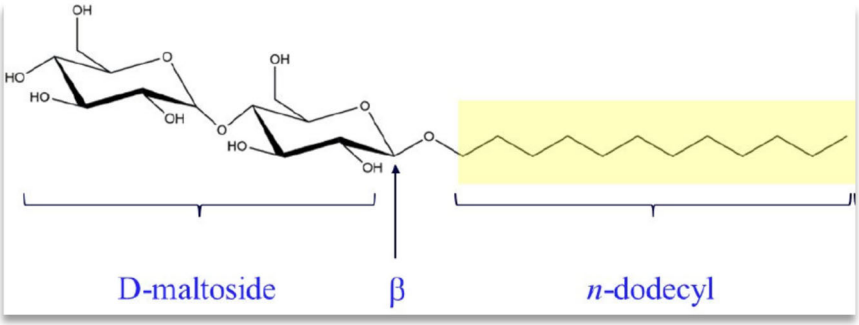
III. <u>The Board Should Strike New Theories in Reply</u>

"Petitioner may not submit new evidence or argument in reply that it could

have presented earlier. … It is also improper for a reply to present new evidence (including new expert testimony) that could have been presented in a prior filing." TPG § II.I. Although a reply may respond to a prior brief, the word "'Respond,' in the context of 37 C.F.R. § 42.23(b), does not mean proceed in a new direction with a new approach as compared to the positions taken in a prior filing." *Id.* The Federal Circuit has "repeatedly held that the Board acts within its discretion when it declines under section 42.23(b) to consider a new theory of unpatentability raised for the first time in reply." *Yita LLC v. Macneil IP LLC*, 69 F.4th 1356, 1366 (Fed. Cir. 2023). "[T]he Board should also not have to decode a petition to locate additional arguments beyond the ones clearly made" when deciding whether a reply argument "had no basis in the original petition." *Netflix, Inc. v. DivX, LLC*, 84 F.4th 1371, 1377-78 (Fed. Cir. 2023) (collecting cases).

A. <u>New Theories Concerning Disclosure Of Claim Limitations</u>

Petitioner introduces a new theory for the sole independent claim, in which Element 1(d) is limited to one species ("*n*-dodecyl beta-D-maltoside"). This species has a linear (unbranched) alkyl moiety, highlighted below:



Paper 28 at 18. This particular chemical is a member of broader classes of compounds. For example, hundreds of species fall within the genus of "dodecyl maltoside" due to isomers, stereochemistry, linkages, and other structural configurations. *Id.* at 18, 59. Only one isomer of "dodecyl" is linear (unbranched), and the remainder are branched. *Id.* at 18. The challenged claims, however, are limited to the linear (unbranched) configuration.

1. <u>The Petition Does Not Address n-Dodecyl-Beta-D-Maltoside</u>

The Petition does not identify any disclosure or teachings in the prior art for *n*-dodecyl beta-D maltoside (i.e., the "*n*-" (linear/unbranched) isomer). The Petition never uses the terms "linear" or "branched." *See generally* Paper 2. Rather, for Claim Element 1(d), the Petition includes one conclusory paragraph directed to the broader genera of "alkyl glycosides, including dodecyl maltoside." Paper 2 at 41 (citing to EX1062 ¶150). The Petition points to no disclosure of teachings in the prior art of the claimed species—"n-dodecyl beta-D-maltoside."

Dr. Donovan's opening declaration fares no better. She does not use the term "linear." Rather, she relies on "branching" and "highly branched alkyl chains" for "the alkyl glycoside … to be utilized in the compositions"—the opposite of the claimed linear species. EX1062 ¶93. Within her analysis of Claim Element 1(d) (EX1062 ¶¶147-152), Paragraphs 147-149 discuss the broader classes of "alkyl glycoside" and "dodecyl maltoside," but not the claimed species. Paragraphs 150-

152 are conclusory, with no contention that the linear species (*n*-dodecyl-beta-D maltoside) is disclosed or taught in the prior art, let alone why anyone would select it. Dr. Donovan did not even understand the "*n*-" prefix in the recited claims:

> Q. Do you have an understanding of what that "n" prefix means in the context of n-Dodecyl-beta-D-maltoside?
>
> A. It's a structural arrangement indicator that escapes me at the moment.
>
> Q. If I told you it it's an indicator that stands for "normal," would that make sense?
>
> A. [I]t makes sense because it's in keeping that I know … that's what "n" stands for, but what "normal" is being attributed to is where I – I'm not willing to state that I know that clearly right now.
>
> Q. You don't recall what structural information the "n" conveys in n-Dodecyl-beta-D-maltoside; is that correct?
>
> A. Not at this moment to testify to.

EX2070 at 193:2-25. She admitted that in Meezan, "there is nothing that indicates … any specifics about arrangement of the alkyl chain." EX2070 at 99:19-21; *see* 119:10-120:22, 138:23-141:2 (unaware of disclosed structure besides branched).

2. <u>Petitioner's Reply Now Addresses n-Dodecyl-Beta-D-Maltoside</u>

Petitioner's Reply, for the first time, presents theories on the arrangement of the alkyl chain in Meezan (i.e., whether it is linear or branched) and how "*n*-dodecyl beta-D-maltoside" is purportedly disclosed. Despite the claims expressly reciting the "*n*-" prefix and Dr. Donovan's ignorance of the prefix's meaning, Petitioner changes course, arguing for the first time that this "*n*-" prefix is surplusage and that Meezan discloses the linear species. Paper 43, 13-15; EX1078 ¶¶11, 15-19, 21-23,

39-43, 45; EX1079. This is despite Dr. Donovan's previous reliance on—and quotation of *without further comment or criticism*—Meezan's description of dodecyl maltoside as "highly branched." EX1062 ¶93.

To support their new theory that the "*n*-" is surplusage, Petitioner and Dr. Donovan cite EX1076, a hearsay declaration from Ed Maggio (one of the inventors) buried in the file history of a different patent. Paper 43 at 15; EX1078 ¶¶49-50. Exhibit 1076 was signed in September 2013, more than seven years after Meezan's 2006 publication date (EX1010) and more than four years after the priority date of the '786 Patent. This precisely the type of "new theory of invalidity by reference to new evidence" cited for the first time in reply that should be stricken. *See Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1369 (Fed. Cir. 2016).

"[A]n entirely new theory of *prima facie* obviousness [cannot be raised in reply] even if the new theory is responsive to the patent owner's response." *Corephotonics, Ltd. v. Apple Inc.*, 84 F.4th 990, 1008 (Fed. Cir. 2023). Petitioner's new evidence and arguments relate to a new theory of the meaning of "*n*-dodecyl beta-D-maltoside," a claim limitation, and how it is allegedly disclosed in Meezan. The new theories (Paper 43 § II.F.1) should be stricken and given no weight in the Board's decision. Petitioner cannot advance a new theory based on a premise that, at the time of submitting the Petition and under cross examination, its own expert did not even know the meaning of. EX2070 at 193:2-25; Paper 28 at 41-42.

B. New Theories Concerning Different References

The Petition identifies a two-reference combination—Gwozdz-PCT (EX1009) and Meezan (EX1010, US2006/0046962)—to allege obviousness of the challenged claims. Paper 2 at 6; *see* 37 C.F.R. § 42.104(b)(2) (requiring identification of "the patents or printed publications relied upon for each ground"). PO asserted that the two-reference combination does not render obvious any claims, as Meezan does not teach the claimed linear (unbranched) species; instead, its only disclosure of the isomeric configuration refers to "branching" and "highly branched alkyl chains." *See* EX1062 ¶93 (citing EX1010 ¶¶0149-0151); EX2070 at 99:19-21, 119:10-120:22, 138:23-141:2 (unaware of disclosed structure besides branched).

In reply, Dr. Donovan rewrites the disclosures of Meezan by pointing to new exhibits—purportedly a "corrected" version of Meezan and a Maggio declaration—never discussed in the Petition. *See* EX1078 ¶¶47-50 (citing EX1075-EX1076). EX1076 is discussed above. EX1075 contains a portion of the prosecution history of Meezan in which those applicants sought to amend the specification. Meezan was then abandoned. Importantly, the printed publication used in the Petition (EX1010) did not include the revised language from EX1075.

This is precisely the impermissible situation of "newly cited prior art references intended to 'gap-fill' by teaching a claim element that was not present in the prior art presented with the petition." *See* TPG § II.I. EX1075 is a "new" theory

of invalidity that could have been (but was not) raised in the Petition, and Petitioner cannot assert a new embodiment from the "corrected" Meezan in reply. 37 C.F.R. § 42.23(b); *see Corephotonics, Ltd.*, 84 F.4th at 1001 ("The IPR petition, thus, must provide an understandable explanation of the element-by-element specifics of the patentability challenges, including the identification of particular portions of prior art on which the petitioner is relying."). EX1075 was not cited in the Petition, is not a patent or printed publication under 35 U.S.C. § 311(b) and 37 C.F.R. § 42.104(b)(2), and was not filed as part of the published application of Meezan. *See Apple Inc., v. DoDots Licensing Solutions LLC*, IPR2023-00939, Paper 12 at 15-17 (P.T.A.B. Jan. 3, 2024) (declining to consider documents within the file history of a prior art reference, "as they are not part of the patent" and not prior art).

C. <u>New Theories Relating to Non-Aqueous Embodiments</u>

Each of the challenged claims requires a formulation "consisting of" various elements, none of which is water. In the parallel district court litigation, Petitioner and Dr. Donovan narrowly construed "consisting of" to mean that the claims cannot include even trace impurities of water. EX2050 at 27, 46; EX2069 ¶¶26, 33. The Petition does not identify these positions or explain how the prior art combination is non-aqueous. Paper 28 at 9 (discussing *Revvo Techs., Inc. v. Cerebrum Sensor Techs., Inc.*, IPR2025-00632, Paper 20 at 3-4 (P.T.A.B. Nov. 3, 2025) (precedential)). Rather, the Petition cites the "other pharmaceutically acceptable

additives" embodiment of Gwozdz-PCT for its motivation to combine, and this embodiment is expressly aqueous—in "saline solution or water." EX1009 at 10:2-16; Paper 2 at 19, 20, 21 (citing this embodiment).

Faced with this inconsistency and failure to satisfy the "consisting of" in the prior art, Petitioner seeks a mulligan. The day before Petitioner's Reply was due, Petitioner unilaterally filed a "stipulation" in district court, purporting to withdraw its claim-construction position. EX1083. Dr. Donovan also asks the Board to ignore her district court declaration. EX1078 ¶¶32-33. Petitioner then pivots to a different embodiment of Gwozdz-PCT (relating to injectable compositions) as purportedly teaching non-aqueous intranasal solutions. Paper 43 at 17-18, 22 (citing EX1009 at 11:17-26); EX1078 ¶11. This embodiment was not cited in the Petition and is improper in reply. *See Ariosa Diagnostics v. Verinata Health, Inc.*, 805 F.3d 1359, 1367 (Fed. Cir. 2015) ("Not until Dr. Morton's Reply declaration did Ariosa identify specific embodiments of Dhallan that do not use restriction-enzyme digestible primers."); *Corephotonics*, 84 F.4th at 1009 (reply is improper if it "'point[s] to any new embodiments' of a prior art reference not previously identified in the petition").

IV. CONCLUSION

For the reasons discussed above, Patent Owner requests that the Board strike the highlighted portions of the Reply (EX2082), the highlighted portions of Dr. Donovan's Reply Declaration (EX2083), and Exhibits 1073-1076 and 1079-1080.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that the foregoing PATENT OWNER'S MOTION TO STRIKE was served on counsel of record for the Petitioner by filing this document through PTAB P-TACTS and by sending the same via electronic mail to the following addresses:

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