

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Padagis US LLC,
Petitioner

v.

Neurelis, Inc.,
Patent Owner

Case No. IPR2025-00464
Patent No. 8,895,546

PATENT OWNER'S MOTION TO STRIKE

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TABLE OF EXHIBITS**(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. 8,895,546
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	NOT USED
2010	NOT USED
2011	NOT USED
2012	NOT USED

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
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	NOT USED
2029	NOT USED
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]
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”)
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-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	Declaration of Dr. Marc Brown regarding U.S. Patent No. 8,895,546
2073	NOT USED
2074	NOT USED
2075	Statutory Disclaimer for Claims 1-16 and 18-21 of ’546 Patent
2076	Patent Owner Response, dated November 5, 2019 in Aquestive Therapeutics, Inc. v. Neurelis, Inc., IPR2019-00451
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	IPR2025-00464, 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	IPR2025-00464, 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, EX1076, EX1079 and EX1080

Four 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; EX1076, a declaration from Ed Maggio (one of the inventors) buried in the file history of a different patent and dated years after the '546 Patent's priority date; EX1079, pages from a textbook; 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. The Board Should Strike EX1073 and EX1075

Two exhibits are not cited in Petitioner's Reply, but are cited in Dr. Donovan's Reply Declaration (EX1078). These include: pages from a textbook (EX1073); and part of the prosecution history (EX1075) of Meezan. Using these materials improperly expands the word limit, as Petitioner's Reply is already at 5,581 words—19 words shy of the limit. *See* Paper 43 at 28; 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 and EX1075 by reference into the Reply, but here, Petitioner does not even cite these references. Rather, Petitioner bulk-cites Donovan’s Reply Declaration, who then discusses the exhibits at length. *See* EX1078 ¶¶21-22 (EX1073), ¶26 (EX1075).

Petitioner does not cite with specificity any of Paragraphs 21, 22, or 26 of Donovan’s Reply Declaration. The only cites to these paragraphs of Dr. Donovan’s Reply Declaration (itself discussing EX1073 and EX1075) is buried within a bulk cite: “EX1078 ¶¶18-29.” Paper 43 at 22.

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. The Board Should Strike New Theories in Reply

“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. 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 5; *see* 37 C.F.R. § 42.104(b)(2) (requiring identification of “the patents or printed publications relied upon for each ground”).

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 ¶26 (citing EX1075). 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).

B. New Theories Relating to Non-Aqueous Embodiments

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 8-11 (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 26-27, 30, 44, 56 (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 ¶¶16-17. Petitioner then pivots to a different embodiment of Gwozdz-PCT (relating to injectable compositions) as purportedly teaching non-aqueous intranasal solutions. Paper 43 at 15, 22 (citing EX1009 at 11:17-26). 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.

Date: April 20, 2026

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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