

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Padagis US LLC,
Petitioner

v.

Neurelis, Inc.,
Patent Owner

Case No. IPR2025-00465
Patent No. 11,241,414

**PATENT OWNER'S REPLY BRIEF
IN SUPPORT OF ITS MOTION TO STRIKE**

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<i>Yita LLC v. Macneil IP LLC</i> , 69 F.4th 1356 (Fed. Cir. 2023)	3

Other Authorities

C.M. Stewart, “Enforcement and Non-Waver of 37 C.F.R. § 42.104(b)(4) and Permissible Uses of General Knowledge in Inter Partes Reviews” (July 31, 2025), available at:

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Exhibit	Description of Exhibits
2001	<i>Clinical Superiority Findings</i> , 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 <i>Neurelis, Inc. v. Padagis LLC</i> , 1:24-cv-00562, D.I. 20 (D. Del. Aug. 28, 2024)
2003	Preliminary Invalidity Contentions served in <i>Neurelis, Inc. v. Padagis LLC</i> , 1:24-cv-00562 (D. Del. Dec. 20, 2024)
2004	Markman Order entered in <i>Gilead Sciences, Inc. v. Lupin Ltd.</i> , 1:22-cv-00615-MN, D.I. 280 (D. Del. Feb. 21, 2025)
2005	Markman Order entered in <i>Spinal Generations, LLC v. Depuy Synthes, Inc.</i> , 1:22-cv-01368 (MN), D.I. 147 (D. Del. Oct. 16, 2024)
2006	Orange Book Listing for U.S. Patent No. 11,241,414
2007	Declaration of Nicholas A. Peppas, Sc.D., dated December 6, 2018 in <i>Aquestive Therapeutics, Inc. v. Hale Biopharma Ventures, LLC</i> , IPR2019-00451, Exhibit 1041 (Jan. 29, 2019)
2008	Declaration of Daniel P. Wermeling, Pharm.D., dated January 27, 2020 in <i>Aquestive Therapeutics, Inc. v. Hale Biopharma Ventures, LLC</i> , 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
2011	Sai H. S. Boddu, Sneha Kumar, A Short Review on the Intranasal Delivery of Diazepam for Treating Acute Repetitive Seizures. <i>Pharmaceutics</i> 2020; 12, 1167

Exhibit	Description of Exhibits
2012	Cornett et al., VALTOCO® (Diazepam Nasal Spray) for the Acute Treatment of Intermittent Stereotypic Episodes of Frequent Seizure Activity, <i>Neurology International</i> 2021; 13:64–78
2013	Scheduling Oral Order entered in <i>Neurelis, Inc. v. Padagis LLC</i> , 1:24-cv-00562, D.I. 47 (D. Del. March 11, 2025) Order Granting Stipulation to Extend Certain Fact Discovery Deadlines entered in <i>Neurelis, Inc. v. Padagis LLC</i> , 1:24-cv-00562, D.I. 65 (D. Del. May 15, 2025)
2014	Jacqueline A. French, Timothy A. Pedley, <i>Initial Management of Epilepsy</i> , <i>New England Journal of Medicine</i> 2008; 359:166-76 (“French & Pedley 2008”)
2015	Penovich et al., <i>Burden of Seizure Clusters on Patients With Epilepsy and Caregivers</i> , <i>The Neurologist</i> 2017; 22: 207-214
2016	Cloyd et al., <i>Overcoming the Challenges of Developing an Intranasal Diazepam Rescue Therapy for the Treatment of Seizure Clusters</i> , <i>Epilepsia</i> 2021; 62:846-856
2017	Hogan, R.E., et al., <i>Bioavailability and Safety of Diazepam Intranasal Solution Compared to Oral and Rectal Diazepam in Healthy Volunteers</i> , <i>Epilepsia</i> , 61:455-464 (Feb. 2020)
2018	Lindsay M. Higdon and Michael R. Sperling, <i>A Review of a Diazepam Nasal Spray for the Treatment Of Acute Seizure Clusters and Prolonged Seizures</i> , <i>J Expert Review of Neurotherapeutics</i> 2021; 21(11):1207-1212
2019	Bechgaard et al., <i>Solubilization of Various Benzodiazepines for Intranasal Administration, a Pilot Study</i> , <i>Pharmaceutical Development and Technology</i> 1997; 2(3):293-296
2020	Gizurarson, S., et al., <i>Intranasal Administration of Diazepam Aiming at the Treatment of Acute Seizures: Clinical Trials in Healthy Volunteers</i> , <i>Biol. Pharm. Bull.</i> , 22(4):425-427 (Apr. 1999)

Exhibit	Description of Exhibits
2021	Ivaturi, V.D., et al., <i>Bioavailability and Tolerability of Intranasal Diazepam in Healthy Adult Volunteers</i> , <i>Epilepsy Res.</i> , 84:120-126 (2009)
2022	Schrier, L., et al., <i>Pharmacokinetics and Pharmacodynamics of a New Highly Concentrated Intranasal Midazolam Formulation for Conscious Sedation</i> , <i>Brit. J. Clin. Pharmacol.</i> , 83:721-731 (Apr. 2017)
2023	Penovich et al., <i>Benzodiazepines for the Treatment of Seizure Clusters</i> , <i>CNS Drugs</i> 2024; 38:125-140
2024	Kapoor et al., <i>A Review of Intranasal Formulations for the Treatment of Seizure Emergencies</i> , <i>Journal of Controlled Release</i> 2016; 237: 147-159
2025	Rabinowicz et al., <i>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</i> , <i>Drugs in R&D</i> 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 <i>Neurelis, Inc. v. Aquestive Therapeutics, Inc.</i> (Fed. Cir. 21-1038), dated March 31, 2021 (D.I. 21)
2029	Certified transcription of October 5, 2021 oral hearing in <i>Neurelis, Inc. v. Aquestive Therapeutics, Inc.</i> (Fed. Cir. 21-1038)
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]

Exhibit	Description of Exhibits
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]

Exhibit	Description of Exhibits
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 <i>Curriculum Vitae</i>
2050	Joint Claim Construction Brief, <i>Neurelis, Inc. v. Padagis LLC et al.</i> , 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., <i>Advances in the Use of Tocols as Drug Delivery Vehicles</i> , 23 PHARM RES. 243 (2006) (“Constantinides-2006”)
2055	Rowe, Sheskey, & Owen, HANDBOOK OF PHARMACEUTICAL EXCIPIENTS, (6th ed. 2009) (“Rowe-2009”)
2056	Afaf Kamal-Eldin, <i>Effect of Fatty Acids and Tocopherols on the Oxidative Stability of Vegetable Oils</i> , 108 EUR. J. OF LIPID SCI. & TECH. 1051 (2006) (“Kamal-Eldin-2006”)

Exhibit	Description of Exhibits
2057	Branka Rozman & Mirjana Gašperlin, <i>Stability of Vitamins C and E in Topical Microemulsions for Combined Antioxidant Therapy</i> , 14 DRUG DELIVERY 235 (2008) (“Rozman-2007”)
2058	Afaf Kamai-Eldin & Lars-Ake Appelqvist, <i>The Chemistry and Antioxidant Properties of Tocopherols and Tocotrienols</i> , 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, <i>Optimizing Nasal Products for Systemic Delivery</i> , 106 ONDRUGDELIVERY 56 (2020) (“Ward-2020”)
2062	C. Holvoet et al., <i>Inclusion Complexation of Diazepam with Different Cyclodextrins in Formulations for Parenteral Use</i> , 60 PHARMAZIE 598 (2005) (“Holvoet-2005”)
2063	Sila-On et al., <i>Influence of Incorporation Methods on Partitioning Behavior of Lipophilic Drugs into Various Phases of a Parenteral Lipid Emulsion</i> , 9 PHARMSciTECH 684 (2008) (“Sila-On-2008”)
2064	D. J. Van Drooge et al., <i>Incorporation of Lipophilic Drugs in Sugar Glasses by Lyophilization using a Mixture of Water and Tertiary Butyl Alcohol as Solvent</i> , 93 J. OF PHARM. SCI. 713 (2004) (“Van Drooge-2004”)
2065	L. M. A. Monzon & L. M. Yudi, <i>Voltammetric Analysis of Lipophilicity of Benzodiazepine Derivatives at the Water 1,2-dichloroethan Interface</i> , 495 J. OF ELECTROANALYTICAL CHEM. 146 (2001) (“Monzon-2001”)
2066	M. Molero-Monfort et al., <i>Retention-activity Relationship Studies of Benzodiazepines by Micellar Liquid Chromatography</i> , 13 BIOMED. CHROMATOGRAPHY 394 (1999) (“Molero-Monfort-1999”)

Exhibit	Description of Exhibits
2067	M. Molero-Monfort et al., <i>Micellar Liquid Chromatography for Prediction of Drug Transport</i> , 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, <i>Neurelis, Inc. v. Padagis LLC et al.</i> , 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 <i>Padagis US LLC vs. Neurelis, Inc.</i> , IPR2025-00464, IPR2025-00465, IPR2025-00466 (“Donovan Transcript”)
2071	<i>What is Log P and How Does It Predict Chemical Behavior?</i> , 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	Declaration of Marc Brown regarding U.S. Patent No. 11,241,414
2074	NOT USED
2075	NOT USED
2076	Patent Owner Response, dated November 5, 2019 in <i>Aquestive Therapeutics, Inc. v. Neurelis, Inc.</i> , 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, <i>Neurelis, Inc. v. Padagis LLC et al.</i> , 1:24-cv-562, D.I. 63 (D. Del. May 13, 2025)

Exhibit	Description of Exhibits
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	IPR2025-00465, 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	IPR2025-00465, Exhibit 1078, Reply Declaration of Maureen Donovan, Ph.D. (Mar. 31, 2026), with highlighting added to show portions that Patent Owner seeks to strike

Petitioner's Opposition (Paper 49, "Opp.") confirms the deficiencies identified by Patent Owner ("PO") in its Motion to Strike (Paper 48, "Mot.") and even concedes that EX1080 should not have been submitted. Opp. at 1 n.1. Petitioner's improper exhibits and new theories should be given no weight.

I. LAUNDERING EXHIBITS THROUGH EXPERTS

Petitioner asserts that it filed exhibits, without citing them, because they were used in Dr. Brown's deposition, cited in Donovan's Reply declaration, or "provide context for the expert's testimony." Opp. at 1-2. This is not justified.

Petitioner cites Dr. Brown's deposition transcript just once in its Reply, for an undisputed point and unrelated to EX1074 and EX1080. Paper 43 at 12. Petitioner relies on *Intex*, but there the parties "did not object to the evidence during the depositions." *Intex Recreation Corp. v. Team Worldwide Corp.*, IPR2018-00875, Paper 129 at 87-88 (P.T.A.B. Sept. 11, 2019). Here, PO objected to uncited exhibits as lacking foundation. EX1077 at 160:8-161:9 (EX1074), 171:18-173:9 (EX1075).

Dr. Donovan's testimony also does not justify filing uncited exhibits. Uncited exhibits can be used for background knowledge, but not "to meet claim elements or to prove [a] *prima facie* case." *TwinStrand Biosciences, Inc. v. Guardant Health, Inc.*, IPR2022-01400, Paper 41 at 47 (P.T.A.B. Jan. 26, 2024). Here, Dr. Donovan does not discuss some uncited exhibits (EX1074, EX1080), and she uses others for a *prima facie* case. See EX1078 ¶18 (EX1079), ¶¶37-38 (EX1073), ¶47 (EX1075).

PO does not seek expungement of the exhibits from the record. Rather, PO asks the Board to “not rely on these exhibits” and give them no weight. *Intex*, IPR2018-00875, Paper 129 at 88.

II. PETITIONER VIOLATES WORD LIMITS

Petitioner admits that “Exs. 1073, 1075, and 1079 are not expressly cited in the Reply,” but seeks a pass because Dr. Donovan “having reviewed Dr. Brown’s deposition testimony, relies on these exhibits as factual evidence.” Opp. at 2, 4. This argument is a pretense and swallows the word limits rule.

EX1075 was introduced, but Dr. Brown had not reviewed the document before. EX1077 at 171:18-172:5. And, EX1079 was not even used in Dr. Brown’s deposition. Petitioner’s theory would permit a party to flood the record with exhibits, so long as they were introduced at an opposing expert’s deposition or cited by its own expert. The Board would need “to play archeologist with the record” to guess at relevance. *See Cisco Sys., Inc. v. C-Cation Techs., LLC*, IPR2014-00454, Paper 12 at 10 (P.T.A.B. Aug. 29, 2014). Petitioner’s Reply abutted the word limits, improperly “circumvent[ed] the page [word] limits,” and violated 37 C.F.R. § 42.24 by shoehorning exhibits through Donovan. *See Silicon Labs., Inc. v. Cresta Tech. Corp.*, IPR2015-00615, Paper 64 at 17 & n.11 (P.T.A.B. Aug. 11, 2016).

III. PETITIONER’S NEW THEORIES AND EVIDENCE IN REPLY

Petitioner argues that “Petitioner’s Reply merely responds to issues in Patent

Owner’s Response.” Opp. at 5. But as PO explained, and Petitioner ignores, 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.” Trial Practice Guide § II.I; see *Yita LLC v. Macneil IP LLC*, 69 F.4th 1356, 1366 (Fed. Cir. 2023) (“declin[ing] under section 42.23(b) to consider a new theory of unpatentability raised for the first time in reply”).

Petitioner argues that “a party is not barred from elaborating on its arguments on issues previously raised.” Opp. at 5-6 (citing *Chamberlain Grp., Inc. v. One World Techs., Inc.*, 944 F.3d 919, 925 (Fed. Cir. 2019)). But Petitioner ignores the facts of its cited cases. In them, the party “did not introduce new evidence,” but instead “merely pointed to different portions of the claim language to clarify its claim construction position.” *Chamberlain*, 944 F.3d at 925; *Apple Inc. v. Gesture Tech. Partners, LLC*, 127 F.4th 364, 372 (Fed. Cir. 2025) (expert did not cite new exhibits). Dr. Donovan introduces new evidence and arguments that were not in the Petition.

A. Petitioner Improperly Relies on New Evidence

Petitioner does not dispute that the Petition never uses the terms “linear” or “branched,” does not rely on IUPAC, and does not rely on any extrinsic evidence to re-interpret Meezan. Petitioner’s expert did not understand the “*n*-” prefix in the claimed “*n*-dodecyl- β -D-maltoside” and did not investigate whether the linear isomer was disclosed in the prior art. Mot. at 5-6 (discussing EX2070 at 99:19-21,

119:10-120:22, 138:23-141:2, 193:2-25). Petitioner improperly supplements its Petition with new theories and exhibits “to show how certain elements were met by the prior art,” unlike the “limited scope” of the declaration in *Arista* discussing public availability of a reference. *See Arista Networks, Inc. v. Cisco Systems, Inc.*, IPR2016-00309, Paper 52 at 16-17 (P.T.A.B. June 1, 2017).

Petitioner contends it “may introduce new evidence after the petition stage if the evidence is a legitimate reply to evidence introduced by the patent owner.” *See Opp.* at 6 (quoting *Apple Inc. v. Andrea Elecs. Corp.*, 949 F.3d 697 (Fed. Cir. 2020)). But *Apple* also discusses when replies are not “legitimate,” those that: (i) include “previously unidentified portions of a prior-art reference to make a meaningfully distinct contention”; and (ii) cite “several new non-patent literature references” to support obviousness opinions. *Apple*, 949 F.3d at 706 (quoting *Ariosa Diagnostics v. Verinata Health, Inc.*, 805 F.3d 1359, 1367 (Fed. Cir. 2015)). Petitioner violates both conditions by citing new exhibits and new portions of Gwozdz and Meezan.¹

B. Petitioner Improperly Relies on New Embodiments

Petitioner’s Reply modifies both of its prior art references to backfill holes in the Petition. “[A]n entirely new theory of prima facie obviousness [cannot be raised

¹ Petitioner excuses its new theories in reply because the POPR did not dispute the Meezan discussion. *Opp.* at 7. Whether a theory in reply is “new” is assessed against the Petition, not the POPR, which was not required to present each dispute.

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 states that it relies on “the exact same Meezan reference” in the Reply. Opp. at 8. If true, then EX1073, EX1075, and EX1076 can be stricken as irrelevant. If false, these new exhibits should be stricken for presenting a new theory. Petitioner further claims that it is a “proper rebuttal” to PO’s arguments about Gwozdz’s failure to disclose a non-aqueous solution. Opp. at 10. But Petitioner oversteps by citing new embodiments of Gwozdz. *See Rembrandt Diagnostics, LP v. Alere, Inc.*, 76 F.4th 1376, 1385 (Fed. Cir. 2023) (petitioner did not “point to any new embodiments not previously identified to advance a meaningfully distinct contention from what it first asserted in its petition”).

Petitioner is not presenting background “general knowledge” as a backdrop for obviousness. *See* July 31, 2005 USPTO memo.² Petitioner asserts, but does not explain why, a POSITA would read the file history of Meezan (EX1075), and then jump to the file history of a different patent (EX1076) filed years after the priority date. At bottom, Petitioner uses EX1073, EX1075, and EX1076 in an attempt to backfill claim limitations (*e.g.*, the arrangement of the alkyl group and the “consisting of” preamble) that it failed to address in the Petition.

² C.M. Stewart, “Enforcement and Non-Waver of 37 C.F.R. § 42.104(b)(4) and Permissible Uses of General Knowledge in Inter Partes Reviews” (July 31, 2025).

Date: May 4, 2026

Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that the foregoing REPLY BRIEF IN SUPPORT OF 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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