

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 REPLY BRIEF
IN SUPPORT OF ITS MOTION TO STRIKE**

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TABLE OF EXHIBITS

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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

Petitioner's Opposition (Paper 49, "Opp.") confirms the deficiencies identified by Patent Owner ("PO") in its Motion to Strike (Paper 48, "Mot."). Petitioner concedes that EX1080 "is not cited in any paper and was inadvertently submitted." Opp. at 1 n.1. Petitioner also admits that "EX1076 (Maggio) and EX1079 (IUPAC) are not relied on by Petitioner or Dr. Donovan in *this* IPR." Opp. at 5. Petitioner was required to, but did not, state the relevance of the evidence it submits. See 37 C.F.R. §§42.104(b)(2), 42.22(a)(2), 42.23(a). These and Petitioner's other 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 provides a table of exhibits cited in Dr. Brown's deposition (Opp. at 2), but Petitioner does not ever cite Dr. Brown's deposition transcript (EX1077) in Petitioner's Reply. See Paper 43. Dr. Donovan cites Dr. Brown's deposition transcript only a single time, but for an undisputed point about opinions Dr. Brown has not offered. EX1078 ¶ 12. If Petitioner wanted to simply ensure a "complete deposition transcript" was in the record (Opp. at 2), Petitioner should have stipulated in its brief that the Board and PO can give the uncited exhibits no weight. Petitioner also 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 declaration also does not justify filing uncited exhibits. Dr. Donovan herself does not cite some exhibits (EX1074, EX1076, EX1079-EX1080), and she uses others for a *prima facie* case. Indeed, Petitioner admits that “Petitioner’s Reply cites paragraphs 21 and 26 (referencing EX1073 and EX1075) to support the argument that a POSA would have a ‘motivation to combine the teachings of Gwozdz with Meezan’” Opp. at 3. While uncited exhibits can be used for background knowledge, they cannot be used “to meet claim elements or to prove [a] *prima facie* case.” See *TwinStrand Biosciences, Inc. v. Guardant Health, Inc.*, IPR2022-01400, Paper 41 at 47 (P.T.A.B. Jan. 26, 2024).

PO does not seek expungement of the exhibits from the record. But, PO should not need to address these exhibits in its sur-reply, and the Board should “not rely on these exhibits” or give them any weight. *Intex*, IPR2018-00875, Paper 129 at 88.

II. PETITIONER VIOLATES WORD LIMITS

Petitioner does not dispute that numerous exhibits remain uncited in Petitioner’s 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. 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 and/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 5-6. 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 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.

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

Petitioner’s Reply modifies both of its prior art references to backfill holes in

¹ Petitioner excuses its new theories in Petitioner’s Reply based on the POPR. Opp. at 7. Whether a theory in reply is “new” is assessed against the Petition, not the POPR. Also, PO was not required in its POPR to raise all of its arguments against motivation to combine, or to even file a POPR. *See* 37 C.F.R. § 42.107 (“may file”).

the Petition. “[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 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 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. Petitioner is not presenting background “general knowledge” as a backdrop for obviousness. *See* July 31, 2005 USPTO memo.²

Petitioner also claims it is a “proper rebuttal” to PO’s arguments about the Petition’s failure to identify a non-aqueous solution in Gwozdz. Opp. at 9. But Petitioner oversteps by citing new embodiments of Gwozdz. Mot. at 5-7; *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”).

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

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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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