

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 8,895,546

**PETITIONER’S REPLY BRIEF IN SUPPORT OF ITS MOTION TO
STRIKE THE DECLARATIONS OF DAVID HALE, MARK MITCHNICK,
AND STEVE CARTT**

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LIST OF EXHIBITS

Exhibit No.	Description
1001	U.S. Patent No. 8,895,546, Administration Of Benzodiazepine Compositions, filed June 13, 2012 (“’546 Patent”)
1002	File History for ’546 Patent, Ser. No. 13/495,942 (“’546 FH”) Part 1: Pages 1-350 Part 2: Pages 351-700 Part 3: Pages 701-1050 Part 4: Pages 1051-1400 Part 5: Pages 1401-1750 Part 6: Pages 1751-2100 Part 7: Pages 2101-2450 Part 8: Pages 2451-2681
1003	U.S. Patent No. 9,763,876, Administration Of Benzodiazepine Compositions, filed October 29, 2014 (“’876 Patent”)
1004	File History for 9,763,876 Patent, Ser. No. 14/527,613 (“’876 FH”) Part 1: Pages 1-270 Part 2: Pages 271-530
1005	Provisional Patent Application No. 61/497,017, filed June 14, 2011 (“’017 Provisional”)
1006	Provisional Patent Application No. 61/570,110, filed December 13, 2011 (“’110 Provisional”)
1007	File History for Non-Provisional Patent Application Serial No. 12/413,439, filed March 27, 2009 (“’439 FH”) Part 1: Pages 1-400 Part 2: Pages 401-800 Part 3: Pages 801-1200 Part 4: Pages 1201-1600 Part 5: Pages 1601-2000 Part 6: Pages 2001-2400 Part 7: Pages 2401-2800 Part 8: Pages 2801-3200 Part 9: Pages 3201-3488
1008	Provisional Patent Application No. 61/040,558, filed March 28, 2008 (“’558 Provisional”)
1009	Gwozdz et al., WO 2009/120933, Pharmaceutical Solutions And Method For Solubilizing Therapeutic Agents, published October 1, 2009, International Filing Date March 27, 2009 (PCT/US2009/038518) (“Gwozdz”)

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1010	Meezan et al., U.S. Patent Application Publication No. US 2006/0046962, Absorption Enhancers for Drug Administration, Serial No. 11/127,786, published March 2, 2006 (“Meezan”)
1011	Ritschel, Handbook of Basic Pharmacokinetics, Chapter 36 (Bioavailability and Bioequivalence), Drug Intelligence Publications, Illinois, 1992 (“Ritschel”)
1012	Osborne et al., Skin Penetration Enhancers Cited in the Technical Literature, Pharmaceutical Technology, November 1997 (“Osborne”)
1013	Lindhardt et al., Electroencephalographic effects and serum concentrations after intranasal and intravenous administration of diazepam to healthy volunteers, Blackwell Science Ltd Br J Clin Pharmacol, 52, 521-527, 2001 (“Lindhardt”)
1014	Illum L, Nasal drug delivery-possibilities, problems and solutions, Journal of Controlled Release 87 (2003) 187198 (“Illum I”)
1015	Ivaturi et al., Pharmacokinetics and tolerability of intranasal diazepam and midazolam in healthy adult volunteers, Acta Neurol Scand. 2009 Nov;120(5):353-7. Doi: 10.1111/j.1600- 0404.2009.01170.x. Epub 2009 May 14 (“Ivaturi”)
1016	Rowe et al., editors, Handbook of Pharmaceutical Excipients, Fourth Edition (2003), Monographs for “Alcohol” (i.e., ethanol), “Alpha Tocopherol”, “Benzyl Alcohol”, “Glycerin”, “OliveOil”, “PolyethyleneGlycol”, “Propylene Glycol”, “Sesame Oil”, and “Triacetin”, American Pharmaceutical Association, Washington DC (“Rowe”)

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1017	PDR 54th Edition 2000, DIASTAT® (diazepam rectal gel); MIACALCIN® (Calcitonin Nasal Spray); VALIUM® (diazepam injection), Physicians' Desk Reference ("PDR")
1018	Knoester PD, Jonker DM, Van Der Hoeven RT, et al. Pharmacokinetics and pharmacodynamics of midazolam administered as a concentrated intranasal spray. A study in healthy volunteers. Br J Clin Pharmacol. 2002; 53: 501-507 ("Knoester")
1019	Florida Regional Common EMS Protocols Field Guide, Jones and Barlett Publishers, MA (2005) ("EMS")
1020	Valium® Tablet Label, Roche, January 2008 ("Valium label")
1021	Wolfe T, Macfarlane T. Intranasal midazolam therapy for pediatric status epilepticus. Am J Emerg Med 2006; 24:43-346 ("Wolfe")
1022	Holsti M, Sill B, Firth S, et al., Prehospital intranasal midazolam for the treatment of pediatric seizures. Ped Emerg Care 2007; 23: 148- 153 ("Holsti")
1023	Greenblatt D, Gan L, Harmatz, et al. Pharmacokinetics and pharmacodynamics of single-dose triazolam: EEG compared with digital symbol substitution test. Br J Clin Pharmacol 2005; 60: 244- 248 ("Greenblatt")
1024	O'Regan M, Brown J, Clarke M. Nasal rather than rectal benzodiazepines in the management of acute childhood seizures. Develop Med and Child Neurol 1996; 38: 1037-1045 ("O'Regan")
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1026	SIGMA Chemical Company Catalog (1988) (“Sigma Catalog”)
1027	Wermeling DP, et al., Intranasal Delivery of Antiepileptic Medications for Treatment of Seizures, Neurotherapeutics: The Journal of the American Society for Experimental Neurotherapeutics, Vol. 6, 352-353, April 2009 (“Wermeling I”)
1028	Hardman, et al., Editors, Goodman & Gilman’s, The Pharmacological Basis of Therapeutics, 10th Edition (2001) (“Goodman & Gilman”)
1029	Loftsson T, Gudmundsdottir H, Sigurjonsdittur JF, et al. Cyclodextrin solubilization of benzodiazepines: formulation of midazolam nasal spray. Int J Pharm 2001; 212:29-40 (“Loftsson”)
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1031	Dale O., Nilsen T., Loftsson T. Intranasal midazolam: a comparison of two delivery devices in human volunteers. J Pharmacy Pharmacol 2006; 58: 1311- 1318 (“Dale”)
1032	Burstein AH, Modica R, Hatton M, et al. Pharmacokinetics and pharmacodynamics of midazolam after intranasal administration. J Clin Pharmacol 1997; 37: 711-718 (“Burstein”)
1033	Wermeling, D, Record K, Kelly T, et al., Pharmacokinetics and 15osttraumatic15cs of a new intranasal midazolam formulation in healthy volunteers. Anesth Analg 2006; 103:344-349 (“Wermeling II”)
1034	Schols-Hendriks MWG, Lohman JJHM, Janknegt R, et al. Absorption of clonazepam after intranasal and buccal

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1035	Lau SWJ, Slattery JT. Intl J Pharmaceutics. Absorption of diazepam and lorazepam following intranasal administration. Int J Pharmaceutics 1989; 54: 171-174 (“Lau”)
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1037	Budavari, et al., Editors, The Merck Index, 12th Edition (1996) (“Merck Index”)
1038	USP 26/NF 21 2003, The Official Compendia of Standards, Ethanol, Copyright 2002 (“USP 26/ NF 21”)
1039	U.S. App. No. 12/413,439, filed March 27, 2009 (“’439Application”)
1040	Final Written Decision issued in IPR 2019-00451 filed against U.S. Patent No. 9,763,876, August 6, 2020 (“IPR 2019-00451 Final Written Decision”)
1041	Lowenstein DH, Alldredge BK. Status epilepticus, N Eng J Med 1998; 338:970-976 (“Lowenstein I”)
1042	Lowenstein DH, Bleck T, Macdonald RL. It’s time to revise the definition of status epilepticus. Epilepsia 1999; 40:120-122 (“Lowenstein II”)
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1044	Stavem K, Bjornaes H, Langmoen IA. Long-term seizures and quality of life after epilepsy surgery compared with

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1048	Smith B, Treatment of status epilepticus, Neurol Clin 2001; 19:347- 369 (“Smith”)
1049	Ericksson K, Kalviainen R. Pharmacologic management of convulsive status epilepticus in childhood, Expert Rev Neurotherapeutics 2005; 5:777-783 (“Ericksson”)
1050	Meierkord H, Engelsen B, Gocke K, et al., EFNS guideline on the management of status epilepticus, Eur J Neurol 2006; 13: 445-450 (“Meierkord”)
1051	Prasad K, Krishman P, Al-Roomi K, et al., Anticonvulsant therapy for status epilepticus, Br J Clin Pharmacol 2007; 63:640-647 (“Prasad”)
1052	Illum L., Nasal Clearance in Health and Disease, J Aerosol Med 2006; 19:92-99 (“Illum II”)
1053	Constantino HR, Illum L, Brandt G et al., Intranasal delivery: Physicochemical and therapeutic aspects, Intl J Pharmaceutics 2007; 337:1-24 (“Constantino”)
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1057	Lahat E, Goldman M, Barr J, et al., Comparison of intranasal midazolam with intravenous diazepam in treating febrile seizures in children: prospective randomized study, BMJ 2000; 321:83-87 (“Lahat”)
1058	Sharma S, et al., Permeation enhancers in the transmucosal delivery of macromolecules, Pharmazie 2006; 61(6): 495-504 (“Sharma”)
1059	Ahsan F. et al., Effects of the permeability enhancers, tetradecylmaltoside and dimethyl- β -cyclodextrin, on insulin movement across human bronchial epithelial cells, Eur J Pharm Sciences 2003; 20:27-34 (“Ahsan”).
1060	U.S. Patent No. 5,661,130 to Meezan and Pillion (“Meezan II”)
1061	U.S. Patent No. 6,610,271 to Wermeling (“WermelingIV”)
1062	Declaration of Dr. Maureen Donovan, Ph.D.
1063	Complaint filed in Neurelis, Inc. v. Padagis LLC et al., Civil Action No. 1:24-cv-11637 (D. Mass) (complaint filed on June 25, 2024).
1064	U.S. Provisional Patent App. No. 61/040,281 (“281 Provisional”)

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1065	NOT USED
1066	NOT USED
1067	NOT USED
1068	Neurelis, Inc. v. Aquestive Therapeutics, Inc., No. 2021-1038, (Fed. Cir. Oct. 7, 2021)
1069	Chart comparing claims 1-22 of the '546 Patent to claims 1-16 and 24-36 of the '876 Patent
1070	Declaration of Chad Landmon in Support of Being a Provisionally Recognized PTAB Attorney
1071	US Patent No. 9,763,876 to Cartt (“’876 Patent”)
1072	Expert Declaration of Professor Sveinbjorn Gizurarson in Support of Patent Owner’s Response to Petition for <i>Inter Partes</i> Review of U.S. Patent No. 9,763,876
1073	Lim et al., <i>Physiological Factors Affecting Nasal Drug Delivery</i> , in ENHANCEMENT IN DRUG DELIVERY (Elka Touitou & Brian W. Barry, 2007)
1074	US Patent No. 6,962,691 to Lulla
1075	File History for Non-Provisional Patent Application Serial No. 11/127,786, Response to Office Action and Amendments filed August 13, 2007
1076	File History for Non-Provisional Patent Application Serial No. 13/371,274, Declaration of Dr. Edward T. Maggio filed September 19, 2013
1077	Certified Transcript of Deposition of Marc Brown, Ph.D. in <i>Padagis US LLC vs. Neurelis, Inc.</i> , IPR2025-00464, IPR2025-00465, IPR2025-00466 (March 17, 2026)
1078	Supplemental Declaration of Dr. Maureen Donovan

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1079	Panico et al., A GUIDE TO IUPAC NOMENCLATURE OF ORGANIC COMPOUNDS, Recommendations (1993) (“IUPAC”)
1080	US Patent No. 8,278,292 to Brown (“292 Patent”)
1081	Appellant Neurelis Inc.’s Opening Brief, <i>Neurelis, Inc. v. Aquestive Therapeutics, Inc.</i> , No. 2021-1038 (Fed. Cir. Feb. 2, 2021).
1082	Appellant Neurelis Inc.’s Reply Brief, <i>Neurelis, Inc. v. Aquestive Therapeutics, Inc.</i> , No. 2021-1038 (Fed. Cir. Feb. 2, 2021).
1083	Stipulation Regarding Claim Construction, <i>Neurelis, Inc. v. Padagis LLC et al.</i> , 1-24-cv-00562 (D.Del. May 8, 2024).
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1090	Email from Murphy to Tobin (Jan. 20, 2026)
1091	Email from Tobin to Murphy (Feb. 2, 2026)
1092	Email from Murphy to Tobin (Feb. 4, 2026)
1093	Email from Tobin to Murphy (Feb. 10, 2026)
1094	Email from Murphy to Tobin (Feb. 12, 2026)
1095	Email from Murphy to Tobin (Feb. 18, 2026)
1096	Email from Sitzman to Murphy (Feb. 19, 2026)

Exhibit No.	Description
1097	Email from Murphy to Sitzman (Feb. 23, 2026)
1098	Email from Sitzman to Murphy (Feb. 25, 2026)
1099	Email from Tobin to Murphy (March 25, 2026)
1100	Email from Murphy to Tobin (March 26, 2026)
1101	Email from Tobin to Murphy (March 27, 2026)
1102	Email from Deming to Sitzman (March 10, 2026)
1103	Email from Deming to Sitzman (June 16, 2025)

I. INTRODUCTION

Petitioner reiterates its request that the Board strike and expunge the Declarations of Steve Cartt (EX2045), Mark Mitchnick (EX2046), and David Hale (EX2047) (collectively, the “Inventor Declarations”). *See* Paper 38; *see also* EX3004. As discussed below, Patent Owner is wrong on both the facts and law: the Inventor Declarations are neither “irrelevant” nor “moot,” and Patent Owner, not Petitioner, prevented timely cross-examination of the inventor-declarants. Paper 46 at 1-2. The prejudice to Petitioner cannot be cured by late depositions.

II. THE DECLARATIONS AND DEPOSITIONS ARE RELEVANT AND THE BOARD SHOULD STRIKE THE DECLARATIONS

Patent Owner argues that the Inventor Declarations “no longer affect the final written decision,” and that Petitioner’s motion should “be denied as moot.” Paper 46 at 6. Not so. As Petitioner previously explained, the Inventor Declarations and arguments regarding Gwozdz’s prior art status remain live issues. Paper 44 at 9-10.

First, as Patent Owner acknowledges, it “presented multiple independent reasons why Gwozdz (EX1009) does not qualify as prior art.” Paper 46 at 6. Indeed, Patent Owner argued Gwozdz is disqualified as prior art if the “three conditions” of 35 U.S.C. §103(c)(2) are met. Paper 28 at 19. Only one of those conditions turns on the certificate of correction (i.e., the third condition, requiring the patent “is amended”), but the other conditions involve separate issues, for which Patent Owner relied on the Inventor Declarations for support. *Id.* at 21-24. As Petitioner argued on

Reply, the Board should separately determine that Patent Owner failed to disqualify Gwozdz as prior art under the other conditions of 35 U.S.C. §103(c), including whether the invention and Gwozdz were “owned...or subject to an obligation of assignment to the same person.” Paper 28 at 19; Paper 43 at 10-12. The Inventor Declarations are relevant to that issue, which remains live even if the denial of a certificate of correction is dispositive on the third condition of 35 U.S.C. §103(c)(2).

Second, Patent Owner “reserves the right to pursue [Director review or appeal] after the final written decision.” Paper 46 at 7. The fact that Patent Owner reserves the right to challenge the Board’s decision on the certificate of correction as part of Director review or on appeal shows that the Inventor Declarations and Patent Owner’s arguments regarding all conditions of 35 U.S.C. §103(c) remain live issues. It also underscores why the Board should address Petitioner’s argument on the other conditions, as it provides an independent basis for determining that Gwozdz is prior art. Addressing this argument would provide the most complete record to avoid piecemeal determinations of the issues, thereby reducing the potential of a remand to address the other conditions of 35 U.S.C. §103(c). If the Board does not strike the Inventor Declarations, the record will contain testimony of key witnesses that were *not* subject to cross-examination because Patent Owner did not make them available prior to Petitioner’s Reply.

Further, as explained previously, it would be fundamentally unfair and

prejudicial to Petitioner to allow the Inventor Declarations to remain in the record after Patent Owner refused to allow Petitioner to cross-examine the inventor-declarants on those issues *before* its Reply was filed. Paper 44 at 8-10. Patent Owner’s dismissal of *Adobe*, in which the Board looked at a similar circumstance, is misplaced because the Inventor Declarations *do* pertain to live issues, as discussed above. Paper 46 at 9, n. 3; *see also Adobe Inc. v. Rah Color Technologies, LLC*, IPR2019- 00627, Paper No. 124 at 20-23 (PTAB Aug. 31, 2020) (determining that it would be prejudicial, not curative, to allow late depositions).

Finally, Patent Owner argues that the Inventor Declarations are not “routine” discovery because they “were prepared for purposes of obtaining a certificate of correction.” Paper 46 at 8. That is incorrect—Patent Owner filed its certificate of correction motion on December 23, 2025 and did *not* cite or rely on the Inventor Declarations in support of its motion. *See generally*, Paper 26. Rather, the Inventor Declarations were filed on January 5, 2026 and relied on by Patent Owner in support of its Response, which again underscores the fact that they are still relevant notwithstanding the denial of the certificate of correction. Paper 28 at 1. Thus, the Inventor Declarations were clearly “prepared for the proceeding” and are subject to the Board’s rules for routine discovery. 37 C.F.R. § 42.51(b)(1)(ii).

III. PARALLEL LITIGATION DOES NOT EXCUSE PATENT OWNER’S REFUSAL TO MAKE THE DECLARANTS AVAILABLE

Petitioner disagrees with Patent Owner’s claims that Petitioner has not

followed through on its efforts to depose the inventor-declarants. Paper 46 at 2-4. Most importantly, Patent Owner unilaterally cancelled “the agreed on deposition dates in this IPR proceeding.” *Id.* at 3. Patent Owner tries to excuse this action by suggesting it “offered Petitioner the ability to cross-use the Delaware depositions ... in the IPR proceedings” in February. *Id.* But Patent Owner did not actually offer deposition dates at that time, and Petitioner explained in *February* that Patent Owner’s solution was unworkable because of the unknown timing for the parallel litigation depositions, which also involves other defendants. Exs. 1096-1097.

In addition, Patent Owner’s allegations that Petitioner has not followed through on its efforts to depose the declarants is wrong. Patent Owner’s discussion of 2025 correspondence is irrelevant to the issues here at least because those discussions occurred *months* before the Inventor Declarations and Patent Owner’s Response were filed in January 2026—Petitioner could not have deposed the declarants on their declarations in 2025. Paper 46 at 2 (citing Exs. 2079-2080). Further, Patent Owner failed to explain that the parallel litigation depositions have been delayed twice, once in 2025 and again in March of 2026, because Patent Owner asserted new patents against Petitioner and filed suits against other defendants, which required consolidation and amended case schedules with later fact discovery deadlines. Regardless, in both cases, Patent Owner ignored Petitioner’s repeated attempts to schedule depositions. *See generally, e.g.*, Exs. 1097, 1100, 1102-1103.

Further, Patent Owner’s argument that Petitioner “has still not accepted” the late April and May dates exemplifies Patent Owner’s misguided approach. Paper 46 at 4.¹ Patent Owner *insists* that the depositions cover *both* the litigation and IPRs, but also urges the Board to order late depositions that would only apply to *this proceeding*. *Id.* at 8-10. Thus, Patent Owner contradicts itself, and in any case Petitioner cannot unilaterally accept dates for both the IPRs and parallel litigation because its co-defendants in the district court must also participate in the depositions.

Finally, Patent Owner’s argument that Petitioner should have requested an extension of Petitioner’s Reply (Due Date 2) to accommodate depositions through May is unreasonable in view of the existing schedule, including the scheduled oral argument (June 16) and other intervening deadlines. *Id.* at 3; Paper 33 at 1; *see also* Paper 44 at 10. Had Petitioner agreed to Patent Owner’s April and May dates, Petitioner’s Reply would have required an extension to mid-May, leaving inadequate time for Patent Owner’s Sur-Reply and intervening motion deadlines before the scheduled oral argument in June.

IV. CONCLUSION

For the reasons discussed in Petitioner’s opening and reply briefs, Petitioner requests that the Board strike and expunge the Inventor Declarations.

¹ Patent Owner stated that it “will release the[se] dates” on April 1 and never followed up with Petitioner to extend its offer on those dates. EX1101 at 1.

Dated April 20, 2026

Respectfully submitted,
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CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. §§ 42.6(e)(4)(i) *et seq.* and 42.105(b), the undersigned certifies that a complete copy of the forgoing document and all associated exhibits are being served via electronic mail on April 20, 2026 upon the following:

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