

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

**PETITIONER'S OPPOSITION TO PATENT OWNER'S
MOTION TO EXCLUDE**

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LIST OF EXHIBITS

Exhibit No.	Description
1001	U.S. Patent No. 11,793,786, Administration Of Benzodiazepine Compositions, filed April 12, 2021 (“786 Patent”)
1002	File History for 11,793,786 Patent, Ser. No. 17/228,514 (“786 FH”)
1003	U.S. Patent No. 11,241,414, Administration of Benzodiazepine Compositions, filed May 27, 2021 (“414 Patent”)
1004	File History for 11,241,414, Ser. No. 17/332,800 (“414 FH”)
1005	Non-Provisional Patent Application Serial No. 15/955,397, filed April 17, 2018 (“397 Application”)
1006	File History for Non-Provisional Patent Application Serial No. 15/955,397, filed April 17, 2018 (“397 FH”)
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”)
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”)

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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”, “Olive Oil”, “Polyethylene Glycol”, “Propylene Glycol”, “Sesame Oil”, and “Triacetin”, American Pharmaceutical Association, Washington DC (“Rowe”)
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”)

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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")
1025	Bhattacharyya M, Kalra V, Gulati S. Intranasal midazolam vs rectal diazepam in acute childhood seizures. Pediatric Neurology 2006; 34: 355-359 ("Bhattacharyya")
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, Sigurjonsdittir JF, et al. Cyclodextrin solubilization of benzodiazepines: formulation of midazolam nasal spray. Int J Pharm 2001; 212:29-40 ("Loftsson")
1030	Gudmundsdottir H, Sigurjonsdottir JF, Masson M, et al. Intranasal administration of midazolam in a cyclodextrin based formulation: bioavailability and clinical evaluation in humans. Pharmazie 2001; 56: 963-966 ("Gudmundsdottir")
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 pharmacodynamics 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 administration. Br J Clin Pharmacol, 1995; 39: 449-451 ("Schols-Hendricks")

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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”)
1036	Wermeling DP, Miller JL, Archer SM, et al. Bioavailability and pharmacokinetics of lorazepam after intranasal, intravenous, and intramuscular administration. J Clin Pharmacol, 2001; 41: 1225-1231 (“Wermeling III”)
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 (“‘439 Application”)
1040	Final Written Decision issued in IPR 2019-00451 filed against U.S. 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”)
1043	Wang HC, Chang WN, Chang HW, et al., Factors predictive of outcome in posttraumatic seizures. J Trauma 2008; 64: 883-888 (“Wang”)
1044	Stavem K, Bjornaes H, Langmoen IA. Long-term seizures and quality of life after epilepsy surgery compared with matched controls. Neurosurgery 2008; 62: 326-334 (“Stavem”)
1045	Logroscino G, Hessdorffer DC, Cascino G, et al., Time Trends in incidence, mortality, and case-fatality after first episode of status epilepticus, Epilepsia 2001; 42:1031-1035 (“Logroscino”)
1046	Feen ES, Bershad EM, Suarez JI, Status Epilepticus, South Med J 2008; 101: 400-406 (“Feen”)
1047	Pang T, Hirsch L, Treatment of convulsive and nonconvulsive status epilepticus, Cur Treat Options Neurol 2005; 7:247-259 (“Pang”)

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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, Krishnan 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”)
1054	Rudy AC, Coda BA, Archer SM, et al., A multiple dose phase I study of intranasal hydromorphone hydrochloride in healthy volunteers, Anesth Analg 2004; 99:1379-1386 (“Rudy”)
1055	Mittal P, Manohar R, Rawat A, Comparative study of intranasal midazolam and intravenous diazepam sedation for procedures and seizures, Ind J Pediatrics 2006; 73:975-78 (“Mittal”)
1056	Mahmoudian T, Zadeh M, Comparison of intranasal midazolam with intravenous diazepam for treating acute seizures in children, Epilepsy and Behavior 2004; 5:253-255 (“Mahmoudian”)
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

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	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 (“Wermeling IV”)
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”)
1065	U.S. Publication No. 2008/0279784 to Cartt et al. (“Cartt”)
1066	USP 23/NF 18 1995, The Official Compendia of Standards, Vitamin E, Copyright 1994 (“USP 23/NF 18”)
1067	U.S. Provisional Patent App. No. 60/916,550 (“’550 Provisional”)
1068	Neurelis, Inc. v. Aquestive Therapeutics, Inc., No. 2021-1038, (Fed. Cir. Oct. 7, 2021)
1069	Chart comparing claims 1-27 of the ’786 Patent to claims 1-36 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

Exhibit No.	Description
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
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).
1084	USPTO Assignment Record of US Pub. No. 2008/0279784 to Cartt
1085	USPTO Assignment Record of the ’786 Patent
1086	USPTO Assignment Record of U.S. Patent Application 12/413,439
1087	Federal Register Volume 61, Number 27, Pages 4822-23 (February 8, 1996)
1088	US Patent No. 6,383,513 to Watts
1089	USPTO Assignment Document for U.S. Patent Application 12/413,439 Recorded on June 30, 2009 at Reel/Frame 022897/0583
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)
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)

Exhibit No.	Description
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)
1104	File History for Non-Provisional Patent Application Serial No. 11/127,786

I. INTRODUCTION

Pursuant to 37 C.F.R. § 42.23, Petitioner opposes Patent Owner's Motion to Exclude (Paper 55). In the words of Yogi Berra, it's like déjà vu all over again: in its Motion to Exclude, Patent Owner moves to exclude many of the same exhibits it moved to strike in Patent Owner's Motion to Strike (Paper 48), again arguing that the exhibits at issue are not relevant. But as explained in Petitioner's Opposition to Patent Owner's Motion to Strike (Paper 49), Exhibits 1073-1076 are relevant to the issues in this proceeding, and are properly relied on by Petitioner and its expert, Dr. Donovan. *See generally* Paper 49.¹ Indeed, the exhibits not cited in Petitioner's Reply were cited in either an expert declaration or an expert deposition and provide context for the expert's testimony.

In addition, Patent Owner argues that Exhibit 1075 should be excluded as "incomplete and taken out of context." Paper 55 at 4-5. But Patent Owner acknowledges that Petitioner served the "full prosecution history of EX1075 as supplemental evidence," which it agrees will "resolve the FRE 106 objection." *Id.*

Finally, Patent Owner argues that Exhibits 1075 (the Meezan specification

¹ Patent Owner also moves to exclude Exhibit 1080. Paper 55 at 1. As explained in Petitioner's Opposition to Patent Owner's Motion to Strike, Exhibit 1080 is not cited in any paper and was inadvertently submitted. Paper 49 at 1, n. 1.

amendment) and 1076 (the declaration of inventor Edward Maggio) are hearsay. *Id.* at 5-6. Patent Owner's hearsay arguments with respect to Exhibits 1075 and 1076 are supported by virtually no analysis or explanation, and therefore lack a sufficient explanation as a basis to exclude under 37 C.F.R. § 42.64(c). Regardless, as explained below, Patent Owner is incorrect that these exhibits are hearsay.

Accordingly, the Board should deny Patent Owner's motion to exclude Exhibits 1073-1076.

II. THE BOARD SHOULD NOT EXCLUDE EXHIBITS 1073-1076 BECAUSE THEY ARE RELEVANT

Patent Owner argues that Exhibits 1073-1076 are not relevant. Paper 55 at 2-4. With respect to Exhibit 1076, Patent Owner mischaracterizes the record by stating that "EX1076 was only cited in a single paragraph of Petitioner's reply expert declaration." *Id.* at 5. In fact, Petitioner cited and relied on Exhibit 1076 in its Reply, in addition to citing and relying on Dr. Donovan's discussion of Exhibit 1076. Paper 43 at 16-17. Thus, Patent Owner's relevance objection to Exhibit 1076 is meritless.

Patent Owner also argues that Exhibits 1073-1075 should "be excluded for lack of relevance under FRE 401-403" because they were "not cited in the Petition or Petitioner's Reply." *Id.* Whether an exhibit was expressly cited in a petition or reply relates to how much weight the evidence at issue should be afforded, which is not the standard for a motion to exclude. *BioMarin Pharma Inc., v. Genzyme Therapeutic Prods. L.P.*, IPR2013-00537, Paper 79 at 25 (PTAB Feb 23, 2015) ("It

is better to have a complete record of the evidence submitted by the parties than to exclude particular pieces of evidence”); *Corning Inc. v. DSM IP Assets B.V.*, IPR2013-00053, Paper 66 at 19 (PTAB May 1, 2014) (denying exclusion and holding “the Board, sitting as a non-jury tribunal with administrative expertise, is well-positioned to determine and assign appropriate weight to evidence presented”). Rather, the question is whether the exhibits at issue are admissible under the Federal Rules of Evidence. Consolidated Trial Practice Guide §§ I (“Admissibility of evidence is generally governed by the Federal Rules of Evidence”); II (“A motion to exclude is not a vehicle for addressing the weight to be given evidence”).

Further, with respect to Exhibits 1073-1076, Patent Owner’s vague reference to “FRE 401-403” as a basis for its relevance objections does not satisfy the requirements of 37 C.F.R. § 42.64(c), which states that a motion to exclude “must identify the objections in the record in order and *must explain the objections.*” 37 C.F.R. § 42.64(c) (emphasis added). Patent Owner failed to *explain* why the challenged exhibits here are irrelevant under FRE 401 and 402 or prejudicial under FRE 403. Patent Owner’s vague objections do not warrant exclusion rather than allowing the Board to assign the weight it feels these exhibits should be afforded.

Accordingly, for those reasons alone, the Board should deny Patent Owner’s motion to exclude. Regardless, as explained below, Exhibits 1073-1076 are relevant to issues in this proceeding and were properly relied on by Petitioner, Dr. Donovan,

and are part of the deposition testimony of Patent Owner’s expert, Dr. Brown.

A. Exhibits 1073-1076 Are Relevant Under FRE 401 Because They Were Relied on in Expert Testimony

To provide context and determine how much weight to give expert testimony, the Board frequently considers exhibits relied on by experts, including in declarations or that were the subject of deposition questioning, even if such exhibits were not cited in a party’s brief. *TwinStrand Biosciences, Inc. v. Guardant Health, Inc.*, IPR2022-01400, Paper 41 at 47 (PTAB Jan. 26, 2024) (denying motion to exclude and holding exhibits relied on in expert declarations “are relevant to understanding the weight to be given the declarants’ testimony”); *Intex Recreation Corp. v. Team Worldwide Corp.*, IPR2018-00875, Paper 129 at 88 (PTAB Sept. 11, 2019) (denying motion to exclude because exhibits “were used in conducting [an expert’s deposition] and the complete deposition transcript is in the record”). Such contextual evidence for expert testimony is relevant since it “has [a] tendency to make a fact more or less probable than it would be without the evidence.” FRE 401.

That is the case here with Exhibits 1073-1076, as shown in the table below:

Ex. No.	Cited in Dr. Brown Deposition (Ex. 1077)	Cited in Dr. Donovan Reply Declaration (Ex. 1078)
1073	130:21-142:3	¶¶ 37-38
1074	160:4-164:10	N/A
1075	171:18-178:12	¶¶ 47-48
1076	184:17-192:12	¶¶ 49-50

Patent Owner acknowledges that Exhibits 1073, 1075, and 1076 were relied on by Dr. Donovan, but again overlooks the use of Exhibits 1073-1076 in Dr. Brown's deposition, just as it did in its motion to strike. *See generally* Papers 48, 55; *see also* Paper 49 at 2, 6. The Board should not exclude Exhibits 1073-1076 because they "were used in conducting Dr. [Brown's deposition] and the complete deposition transcript [EX1077] is in the record." *Intex*, IPR2018-00875, Paper 129 at 88.

B. Petitioner and Dr. Donovan Properly Relied on Exhibits 1073, 1075, and 1076

Patent Owner's argument that Exhibits 1073, 1075, and 1076 should be excluded for lack of relevance because they are not cited in the Petition or Reply, but are cited in Dr. Donovan's Reply Declaration, makes little sense. Paper 55 at 2-6. As explained above, Petitioner *did* rely on Exhibit 1076 in its Reply by citing a specific page to support a specific argument. Paper 43 at 15. Thus, there is no basis to exclude Exhibit 1076 under FRE 401-403.

With respect to Exhibits 1073 and 1075 (but not Exhibit 1076), Patent Owner relies on 37 C.F.R. § 42.104(b)(5), which states in part that "[t]he Board may exclude or give no weight to the evidence where a party has failed to state its relevance or to identify specific portions of the evidence that support the challenge." *Id.* (quoting 37 C.F.R. § 42.104(b)(5)). But Petitioner, and Petitioner's expert, explained the relevance of Exhibits 1073 and 1075, and identified specific portions of those exhibits that support Petitioner's challenge.

For example, Petitioner properly relies on Dr. Donovan's testimony concerning the challenged exhibits to support its Reply arguments. Petitioner's Reply cites paragraphs 37-38 of Dr. Donovan's declaration to support the argument that a POSA would have a "motivation to modify Gwozdz with Meezan," including to use a penetration enhancer. Paper 43 at 19 (citing EX1078 at ¶¶34-39). And paragraphs 37-38 of Dr. Donovan's declaration explain the relevance of, and cite specific portions of, Exhibit 1073 for that same point. EX1078 at ¶37 (citing and quoting pages 18, 23, and 32 of Exhibit 1073 to opine that "Dr. Brown's 2007 textbook repeatedly emphasizes why a POSA would have been motivated to develop an intranasal formulation of lipophilic small molecule drug compounds (which would include diazepam) with a reasonable expectation of success").

Petitioner's Reply also cites paragraph 47 of Dr. Donovan's declaration to support the same "motivation" argument. Paper 43 at 15 (citing EX1078 at ¶¶21, 43-48). And paragraph 47 of Dr. Donovan's declaration explains the relevance of, and cites specific portions of, Exhibit 1075 for that same point. EX1078 at ¶47 (citing and quoting specific excerpts from page 6 of Exhibit 1075).

Thus, contrary to Patent Owner's vague assertions about relevance, Petitioner and Dr. Donovan clearly explained the "relevance" of Exhibits 1073, 1075, and 1076, and "identif[ied] specific portions of the evidence that support the challenge." 37 C.F.R. § 42.104(b)(5). Patent Owner's motion to exclude these exhibits should

be denied, and the Board should instead “determine and assign appropriate weight to evidence presented.” *Corning*, IPR2013-00053, Paper 66 at 19.

Notwithstanding the above, Patent Owner cites one case to support its position on these relevance issues with respect to Exhibits 1073 and 1075 (but not Exhibit 1076). Paper 55 at 2 (citing *Cisco Sys., Inc. v. C-Cation Techs., LLC*, IPR2014-00454, Paper 12 at 8 (Aug. 29, 2014) (informative)). But *Cisco* did not even address a motion to exclude, and was instead a decision denying institution of an IPR. *Id.* And, in *Cisco*, the Board found egregious abuses in expert-declaration citation amounting to improper incorporation by reference to circumvent word limits. *Id.* at 7-10 (holding that a single citation to “seven pages” of an expert declaration was excessive). The citation of specific paragraphs from Dr. Donovan’s Reply Declaration, which discuss and rely on Exhibits 1073 and 1075 as support for the express positions set forth in the Reply, does not warrant exclusion.

C. Exhibits 1073-1076 Are Relevant To Issues in this Proceeding

Patent Owner repeats vague assertions that Exhibits 1073-1076 “should be excluded under FRE 401-403, as Petitioner has not demonstrated [their] relevance to this proceeding.” Paper 55 at 2-4. But as explained above, the relevance of these exhibits is clear based on expert testimony and Petitioner’s Reply arguments.

For example, Patent Owner contradicts itself when it asserts that Petitioner has not demonstrated why Exhibits 1075 and 1076 are relevant. *Id.* Patent Owner

first claims that Petitioner has not established the relevance of Exhibit 1075, but in the context of its hearsay objection, states that “Petitioner relies on EX1075” because it shows that “the ‘highly branched’ description of the alkyl chains in ¶[0117] of Meezan (EX1010) was actually intended to mean ‘long.’” *Id.* at 5 (quoting EX1078 ¶47). And Patent Owner acknowledges that Exhibit 1076 is relevant because it is a declaration from inventor Edward Maggio. *Id.* at 6 (citing Paper 43 at 15-16; EX1078 ¶¶49-50). As Patent Owner acknowledges, the relevance of Exhibits 1075-1076 is clear from Petitioner’s Reply and Dr. Donovan’s declaration.

Indeed, Exhibits 1073, 1075, and 1076 are relevant to issues discussed in Petitioner’s Reply. Exhibit 1073 (Dr. Brown’s textbook) discusses the use of penetration enhancers in intranasal formulations, EX1078 at ¶¶37-38, an issue squarely addressed in Petitioner’s Reply. Paper 43 at 19, 21-23. Exhibit 1075 (Meezan Spec. Amendment) is discussed in Dr. Donovan’s Reply Declaration to rebut Dr. Brown’s opinions and to show that a POSA would have understood that Meezan discloses and emphasizes alkyl glycosides with straight-chain (“long”) alkyl groups like dodecyl maltoside, EX1078 at ¶47, consistent with Petitioner’s Reply arguments. Paper 43 at 13, 15. And Exhibit 1076 (Maggio Declaration) is cited and discussed in Petitioner’s Reply (Paper 43 at 15) and Dr. Donovan’s declaration (Ex. 1078 at ¶ 50) to support the argument that a POSA would have understood Meezan’s reference to “dodecyl-β-D-maltoside” (“DDM”) to be a reference to “n-dodecyl-β-

D-maltoside” (“n-DDM”).

The experts’ testimony about these exhibits also shows that they are relevant to issues in these proceedings. As explained above, Dr. Donovan, in response to Dr. Brown’s declaration and deposition transcript, relies on Exhibits 1073, 1075, and 1076 to opine that a POSA would have had a motivation and reasonable expectation of success to make the claimed diazepam nasal spray formulations. EX1078 at ¶37 (citing and quoting pages 18, 23, and 32 of Exhibit 1073 to opine that “Dr. Brown’s 2007 textbook repeatedly emphasizes why a POSA would have been motivated to develop an intranasal formulation of lipophilic small molecule drug compounds (which would include diazepam) with a reasonable expectation of success”); ¶47 (citing and quoting excerpts from Exhibit 1075 to opine that “the corrected language” from the Meezan specification amendment “specifically emphasizes that ‘DDM’ has a ‘long alkyl chain[.]’”); ¶50 (citing and quoting excerpts from Exhibit 1076 as support for her opinion “that a POSA would have understood that the recitation of [DDM] is a reference to [n-DDM]”). Dr. Brown also testified about Exhibits 1073-1076 at his deposition, which likewise shows that they are directly relevant to his opinions and the issues in this proceeding. Ex. 1077 at 130:21-142:3; 160:4-164:10; 171:18-178:12; 184:17-192:12.

D. FRE 403 Is Not Applicable

Patent Owner raises FRE 403 but does not address the “probative value” of

the evidence or how it is “substantially outweighed” by countervailing factors. *See Captioncall LLC v. Ultratec, Inc.*, IPR2014-00780, Paper No. 35 at 8 (PTAB Dec. 1, 2015) (“Patent Owner fails to address the ‘substantially outweighed’ aspect of [FRE 403]”). Moreover, the risk of “prejudice” contemplated by FRE 403 is eliminated or diminished in IPRs since the fact finder is the Board, not a jury. *Neste Oil Oyj v. Reg Synthetic Fuels, LLC.*, IPR2013-00578, Paper No. 53 at 10 (PTAB Mar. 12, 2015) (“Proceedings before the Board are not jury trials; in the absence of a jury, the risk of unfair prejudice against which Rule 403 guards is diminished, if not eliminated entirely.”); *accord Trend Micro Inc. v Cupp Computing AS*, IPR2019-00764, Paper No. 34 at 5 (PTAB Aug. 25, 2020); *see also* Wright & Miller, 22A Fed. Prac. & Proc. Evid. § 5213 (2d ed.) (“In bench trials... appellate courts have said that exclusion of evidence on grounds of ‘prejudice’ makes little sense because the judge has to see the putatively prejudicial evidence in order to rule.”).

III. THE BOARD SHOULD NOT EXCLUDE EXHIBIT 1075 AS INCOMPLETE

Patent Owner argues that Exhibit 1075 should be excluded because it is “incomplete and taken out of context.” Paper 55 at 4-5. Petitioner disagrees at least because Exhibit 1075 is a complete copy of an August 13, 2007 Response to an Office Action and Amendments filed during the prosecution of the Meezan prior art reference relied on by Petitioner. *See generally* Ex. 1075. Nor did Patent Owner

argue that any of the other office actions and responses identified in its motion to exclude are somehow relevant or provide missing “context.” Paper 55 at 4.

Regardless, Petitioner is concurrently filing the entire file history of Meezan that was previously served on Patent Owner as supplemental evidence. Ex. 1104. Accordingly, consistent with Patent Owner’s statement that Petitioner has resolved this objection, this issue is now moot and the Board should not exclude Exhibit 1075 as incomplete, as Patent Owner initially argued. Paper 55 at 4-5.

IV. THE BOARD SHOULD NOT EXCLUDE EXHIBITS 1075 AND 1076 AS HEARSAY

Patent Owner argues that Exhibits 1075 and 1076 “should be excluded as hearsay under FRE 801-802” because (1) “Petitioner relies on EX1075 for the truth of the matter asserted as alleged evidence of the subjective belief of the authors that the ‘highly branched’ description of the alkyl chains in ¶[0117] of Meezan (EX1010) was actually intended to mean ‘long’” and (2) “Petitioner relies on EX1076 for the truth of the matter asserted regarding the subjective belief of one of the inventors of Meezan, Edward Maggio, as of September 2013.” Paper 55 at 5 (quoting EX1078 ¶26), 6 (citing Paper 43 at 16-17; EX1078 ¶¶49-50). Petitioner disagrees.

First, based on those vague, one-sentence statements, which are unsupported by any case law, it’s unclear to Petitioner why Patent Owner contends Exhibits 1075 and 1076 are hearsay, or what Patent Owner’s arguments mean. For instance, it’s unclear to Petitioner what “authors” Patent Owner is referring to or how the

straightforward specification amendment made in Exhibit 1075 somehow relates to a “subjective belief.” Nor does Patent Owner explain what “truth” or “subjective belief” from inventor Edward Maggio’s sworn declaration in Exhibit 1076 are at issue. Patent Owner’s vague references to “hearsay” without sufficient explanations as a basis to exclude Exhibits 1075-1076 do not satisfy 37 C.F.R. § 42.64(c).

Regardless, Exhibits 1075 and 1076 are not hearsay because they are not being relied on “for the truth of the matter asserted.” Paper 55 at 5-6. Rather, Exhibit 1075 is offered as evidence of how a POSA would understand Meezan, not what the intent of the “authors” was (to the extent Exhibit 1075’s straightforward specification amendment can somehow relate to subjective intent). Exhibit 1078 at ¶47 (Dr. Donovan opining that in view of Exhibit 1075, “a POSA would understand that Meezan discloses alkyl glycosides having straight-chain (i.e., ‘long’) alkyl groups, *not* branched structures”). And Exhibit 1076 is offered as evidence “that a POSA would have understood that the recitation of [DDM] is a reference to [n-DDM].” Paper 43 at 16-17; EX1078 ¶50.

Similarly, Exhibit 1075 is not hearsay because it is merely being used as evidence of what the Meezan specification, as corrected by the applicant during prosecution, describes. 37 C.F.R. § 42.61(c) (“A specification ... is admissible as evidence only to prove what the specification ... describes”); *see also Sienna Biopharmaceuticals, Inc. v. William Marsh Rice Univ.*, IPR2017-00045, Paper 52 at

56 (PTAB Apr. 5, 2018) (denying exclusion because Petitioner and expert merely relied on specification of prior art reference for what it describes); *Noven Pharms., Inc. v. Novartis AG*, IPR2014–00550, Paper 69 at 41 (PTAB Sept. 28, 2015) (denying motion to exclude under 37 C.F.R. § 42.61(c) because the statement was only offered to prove what the specification describes). And Exhibits 1075-1076 are admissible because “[c]ertification is not necessary as a condition to admissibility when the evidence to be submitted is a record of the Office to which all parties have access.” 37 C.F.R. § 42.61(b).

In addition, while Exhibits 1075 and 1076 are not hearsay, they also qualify for admission under several hearsay exceptions. For example, an attorney’s sworn response to an examiner’s office action, like Exhibit 1075, satisfies the business records exception to hearsay. FRE 803(6). Specifically, Exhibit 1075 was (A) submitted by “someone with knowledge” (the prosecuting DLA Piper attorney), (B) “kept in the course of a regularly conducted activity of” patent prosecution duties, (C) made as part of “a regular practice of” patent prosecution activities, (D) signed and certified by the prosecuting attorney, and (E) not shown to be lacking in “trustworthiness.” FRE 803(6). Indeed, Exhibit 1075 is a prosecution history statement signed by an attorney from DLA Piper, one of the firms representing Patent Owner in these proceedings, that was authorized to enter the specification amendments at issue, subject to the requirements of 37 C.F.R. § 11.18(b). Ex. 1075

at 2; *see also* 37 C.F.R. § 11.18(b).

Further, Exhibits 1075 and 1076 qualify under FRE 807's residual exception to hearsay. FRE 807. Exhibit 1075 "is supported by sufficient guarantees of trustworthiness—after considering the totality of circumstances under which it was made and evidence, if any, corroborating the statement" at least because it was submitted by an attorney subject to a duty of candor and good faith dealings with the Office as well as 37 C.F.R. § 11.18(b). FRE 807(1). And Exhibit 1075 "is more probative on the point for which it is offered than any other evidence that the proponent can obtain through reasonable efforts" because it expressly shows what the Meezan specification describes. FRE 807(2).

Exhibit 1076 is also "supported by sufficient guarantees of trustworthiness" under FRE 807(1) because it was executed by Dr. Maggio under 18 U.S.C. § 1001 and was based on his "expert[ise] in the field of pharmaceutical chemistry and in particular in the area of pharmaceutical formulations." Ex. 1076 at 1, 3. And Exhibit 1076 is "more probative" on the point that Dr. Maggio agreed that a POSA would understand Meezan's reference to DDM to mean n-DDM than "any other evidence that [Petitioner] can obtain through reasonable efforts" because Dr. Maggio is deceased. FRE 807(2). Indeed, Exhibit 1076 is probative on the DDM nomenclature issues in this proceeding, particularly because (1) Dr. Maggio was an inventor of *both* Meezan *and* the '786 patent challenged in this proceeding, and (2) because in

his declaration, Dr. Maggio was characterizing the “invention” described in the Meezan specification (albeit, in the context of a continuation application that claims priority to Meezan but shares a specification with Meezan). Ex. 1076 at 1-3.

Finally, as explained above, Petitioner and Dr. Donovan rely on Exhibits 1075-1076 in support of the position that a POSA would have been motivated and had a reasonable expectation of success to make the claimed diazepam nasal spray formulations in view of Meezan. EX1078 at ¶¶47-50; Paper 43 at 15. Under FRE 703, evidence “need not be admissible for the [expert’s] opinion to be admitted” when “the expert has been made aware of or personally observed” the evidence at issue. FRE 703; *see also Ebay Inc. v. Glob. Equity Mgmt. (Sa) Pty. Ltd.*, IPR2016-01829, Paper 60 at 3 (PTAB Apr. 18, 2018) (denying motion to exclude based on hearsay objection based on FRE 703). Thus, even if Exhibits 1075-1076 are hearsay, which they are not, Dr. Donovan’s reliance on them, and the admission of her opinions based on those exhibits in these proceedings, is permitted under FRE 703.

Accordingly, for the reasons discussed above, the Board should not exclude Exhibits 1075 and 1076 as hearsay.

V. CONCLUSION

For the reasons discussed above, Petitioner requests that the Board deny Patent Owner’s Motion to Exclude.

Dated June 2, 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 foregoing document and all associated exhibits are being served via electronic mail on June 2, 2026, upon the following:

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