

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
STRIKE**

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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, Sigurjonsdittur 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

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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)
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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)

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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

Patent Owner's Motion to Strike (Paper 48, "PO Mot.") should be denied in full. First, the exhibits not cited in Petitioner's Reply were cited in either an expert declaration or a deposition and provide context for the expert's testimony.

Second, Patent Owner's arguments that Petitioner raises new legal theories in its Reply are belied by the record. Patent Owner's request to strike portions of Petitioner's Reply and Dr. Donovan's Reply Declaration is a transparent attempt to eliminate consideration of highly compelling rebuttal evidence that undercuts the central premise of Patent Owner's Response. Rebuttal evidence is permissible in a reply brief, as numerous Federal Circuit and Board decisions hold.

II. THE BOARD SHOULD NOT STRIKE EXHIBITS 1073-1075 AND 1079 SINCE THEY WERE RELIED ON IN EXPERT TESTIMONY¹

To provide context and determine how much weight to give expert testimony, the Board frequently considers exhibits relied on by experts even if they 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) (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 strike

¹ Exhibit 1080 is not cited in any paper and was inadvertently submitted.

because the exhibits at issue “were used in conducting [an expert’s deposition] and the complete deposition transcript is in the record”). That is the case here with Exs. 1073-1075 and 1079, 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
1074	160:4-164:10	N/A
1075	171:18-178:12	¶ 47
1079	N/A	¶ 18

Patent Owner acknowledges that Exs. 1073, 1075, and 1079 were relied on by Dr. Donovan, but overlooks the use of Exs. 1073-1075 in Dr. Brown’s deposition. PO Mot. at 2-3. The Board should refuse to strike Exs. 1073-1075 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.

Moreover, Patent Owner’s suggestion that Petitioner improperly incorporates arguments because Dr. Donovan relies on Exs. 1073, 1075, and 1079, makes little sense. PO Mot. at 2-3. Dr. Donovan, having reviewed Dr. Brown’s deposition testimony, relies on these exhibits as factual evidence on relevant issues—Petitioner did not incorporate arguments by reference to Dr. Donovan’s declaration. *Silicon Laboratories, Inc. v. Cresta Technology Corp.*, IPR2015-00615, Paper 64 at 17 (PTAB Aug. 11, 2016) (“37 C.F.R. § 42.6(a)(3) prohibits incorporation of arguments, and an expert declaration, such as that at issue here, generally is

considered evidence, not argument”); *see also SK Hynix Inc. v. Netlist, Inc.*, IPR2017-00561, Paper 36 at 61-62 (PTAB July 5, 2018) (Holding expert’s reference to exhibit did not introduce “argument that was not contained in the petition”).

Petitioner properly relies on Dr. Donovan’s testimony concerning the challenged exhibits to support its Reply arguments. For instance, Petitioner’s Reply relies on paragraph 18 of Dr. Donovan’s Reply Declaration (referencing EX1079) to support the argument that, under IUPAC nomenclature, “straight-chain alkanes need no prefix, including no ‘n-’ prefix.” Paper 43 at 13 (citing EX1078 at ¶¶17-18). Next, the Reply cites paragraph 37 (referencing EX1073) to support the argument that a POSA would have “a motivation to modify Gwozdz with Meezan.” Paper 43 at 19 (citing EX1078 at ¶¶34-39). Lastly, the Reply cites paragraph 47 (referencing EX1075) to support the argument that “a branched 12-carbon alkane would carry a prefix identifying the branch and would not include the base ‘dodecane’ or ‘dodecyl.’” Paper 43 at 15 (citing EX1078 at ¶¶21, 43-48).

Notwithstanding the above, Patent Owner points to cases in which the Board found egregious abuses in expert-declaration citation amounting to improper incorporation by reference to circumvent word limits, but the facts here fall comfortably within the cases where the Board has found no such violation. *See, e.g., Arista Networks, Inc. v. Cisco Systems, Inc.*, IPR2016-00309, Paper 52 at 17 (PTAB June 1, 2017) (limited factual citations were not “imposing on the Board’s time

and/or unfairly circumventing word limits”). Petitioner’s Reply arguments are straightforward, as is the factual analysis in Dr. Donovan’s Reply Declaration.

Indeed, this case is nothing like cases where the Board found expert-testimony citations excessive. *See Cisco Sys., Inc. v. C-Cation Techs., LLC*, IPR2014-00454, Paper 12 at 7-10 (PTAB Aug. 29, 2014) (informative) (holding that a single citation to “seven pages” of an expert declaration was excessive); *see also Texas Instruments Inc. v. ParkerVision, Inc.*, IPR2024-00934, Paper 54 at 81-82 (PTAB Nov. 21, 2025) (Board applying *Cisco* and holding that a single citation to “over fifty paragraphs” of an expert declaration was excessive but that more limited citations to expert declaration were not excessive). The citation of specific paragraphs from Dr. Donovan’s Reply Declaration, all of which discuss and support the express positions set forth in the Reply for which they are cited, is not precluded under *Cisco*.

Additionally, Patent Owner argues that under *Google*, the fact that Exs. 1073, 1075, and 1079 are not expressly cited in the Reply means these exhibits should be stricken. PO Mot. at 3 (citing *Google LLC v. MindbaseHQ*, IPR2021-01252, Paper 41 at 37 (PTAB Jan. 6, 2023)). But Patent Owner’s reliance on *Google* is inapposite, as that decision turned on the fact that the sur-reply brief “did not discuss that testimony,” included in the cited expert declaration paragraphs. *Google*, IPR2021-01252, Paper 41 at 37. That is not the case here because the Reply cites the paragraphs of Dr. Donovan’s Declaration that discuss Exs. 1073, 1075, and 1079.

Further, Exs. 1073, 1075, and 1079 are relevant to issues discussed in Petitioner's Reply. EX1073 (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. EX1075 (Meezan Spec. Amendment) is discussed in Dr. Donovan's Reply Declaration to rebut Dr. Brown's opinions and to show that Meezan discloses and emphasizes alkyl glycosides with straight-chain ("long") alkyl groups, EX1078 at ¶47, consistent with Petitioner's Reply arguments. Paper 43 at 13, 15. And, Dr. Donovan relies on EX1079 (IUPAC) to rebut Dr. Brown's opinions and to show that POSAs knew the "n-" prefix was not required to name straight chain alkanes or alkyl groups, EX1078 at ¶18, again consistent with Petitioner's Reply arguments. Paper 43 at 13.

Consequently, Exs. 1073-1075 and 1079 should not be stricken.

III. THE REPLY MAINTAINS THE SAME LEGAL THEORIES RAISED IN THE PETITION

Patent Owner asks the Board to strike portions of Petitioner's Reply and Dr. Donovan's Reply Declaration for allegedly raising "new theories." *See* PO Mot. at 3. But Petitioner's Reply merely responds to issues raised in Patent Owner's Response, and discusses the same prior-art combination raised in the Petition to explain why the "n-dodecyl beta-D-maltoside" ("n-DDM") and "consisting of" limitations are obvious. *Apple Inc. v. Gesture Tech. Partners, LLC*, 127 F.4th 364, 372 (Fed. Cir. 2025) ("a party is not barred from elaborating on its arguments on

issues previously raised”) (citation modified); *accord Chamberlain Grp., Inc. v. One World Techs., Inc.*, 944 F.3d 919, 925 (Fed. Cir. 2019). The arguments in Petitioner’s Reply directly rebut Patent Owner’s arguments. Paper 28 at 39, 42.

Patent Owner also complains that the Reply and Dr. Donovan address new exhibits submitted with the Reply, including a declaration from one of the inventors that directly undercuts Patent Owner’s expert on these issues. PO Mot. at 7; *see also* EX1076 (Inventor Maggio declaring “dodecyl- β -D-maltoside (also referred to as n-dodecyl- β -D-maltoside)”). Reliance on such rebuttal evidence is so routine that the Federal Circuit has noted that “we have regularly held, ‘the petitioner in an inter partes review proceeding may introduce new evidence after the petition stage if the evidence is a legitimate reply to evidence introduced by the patent owner.’” *Apple Inc. v. Andrea Elecs. Corp.*, 949 F.3d 697, 706–07 (Fed. Cir. 2020) (quoting *Anacor Pharm., Inc. v. Iancu*, 889 F.3d 1372, 1380–81 (Fed. Cir. 2018)); *see also Provisur Techs., Inc. v. Weber, Inc.*, 50 F.4th 117, 122 (Fed. Cir. 2022).

As discussed below, Petitioner’s Reply and Dr. Donovan’s Declaration rely on the same legal theory as the Petition and merely rebut specific issues raised in Patent Owner’s Response. Patent Owner provides no basis for the “exceptional remedy” of striking the contested arguments. Trial Practice Guide at 80.

A. The Petition and Reply Address “n-dodecyl beta-D-maltoside” Under the Same Theory

As the Board recognized in the Institution Decision, one argument raised in

the Petition is that a POSA would have understood Meezan's disclosure of dodecyl maltoside (or "dodecyl- β -D-maltoside") to be n-DDM. Paper 13 at 32-33; Paper 2 at 40-41; EX1062 at ¶¶147-153. That is exactly the same theory raised in Petitioner's Reply and Dr. Donovan's Reply Declaration that Patent Owner moves to strike.

As a threshold issue, Patent Owner did not meaningfully contest this issue in its Preliminary Response. *See, e.g.*, Paper 11 at 35 (Patent Owner agreeing that "the Petition relies [on] combining the pharmaceutical solution of Gwozdz PCT – including diazepam, vitamin E or other tocopherols or tocotrienols, and one or more alcohols – with the mucosal absorption enhancer, *n-dodecyl beta-D-maltoside that Meezan discloses*") (emphasis added); Paper 13 at 37 (Board noting that "although we appreciate that the language of the challenged claims in the two proceedings is not identical (e.g., an 'alkyl glycoside' was a component of claim 1 in the 451 IPR, while the specific alkyl glycoside in claim 1 here is 'n-dodecyl beta-D-maltoside'), we do not see at present how those differences materially alter the motivation-to-combine issue"). Thus, Patent Owner was aware of Petitioner's theory that Meezan disclosed n-DDM based on arguments initially raised in the Petition, but chose to raise its detailed arguments on these issues for the first time in its post-Institution Response. Paper 28 at 39-42. Petitioner and its expert are entitled to respond in kind, particularly where the same theory raised in the Petition is being advanced.

For example, Patent Owner moves to strike portions of Petitioner's Reply and

Dr. Donovan's Declaration that elaborate on this argument by explaining that "the 'n-' prefix is unnecessary to understand that Meezan's dodecyl beta-D-maltoside includes a straight-chain dodecane," based on overwhelming corroborating evidence, including: (1) Dr. Brown's Streitwieser textbook; (2) IUPAC rules for naming compounds; (3) naming conventions used in the challenged patent; and (4) the sworn statement of inventor Ed Maggio. *See* EX2082 at 13-15; EX2083 at 11, 15-19, and 21-23; *see also* EX1076 at 2. Petitioner's and Dr. Donovan's Reply arguments and evidence showing why Meezan discloses n-DDM are consistent with the theory raised in the Petition and directly rebuts Patent Owner's and Dr. Brown's Response argument that Meezan does not teach n-DDM. Paper 28 at 40-41; *see also*, *e.g.*, EX2074 at ¶¶217-223. There is no basis to strike such evidence.

B. Reply Does Not Rely on EX1075 or EX1076 for a New Rejection

Patent Owner asserts that Petitioner's reliance on EX1075 (prosecution history of Meezan) and EX1076 (Maggio Declaration) somehow means that Petitioner has "assert[ed] a new embodiment from the 'corrected' Meezan" and thus raises a new ground of rejection. PO Mot. at 8-9. Yet, Patent Owner offers no citation from the Reply to show that Petitioner abandoned Meezan for a "corrected" Meezan. Rather, the Reply and Dr. Donovan consistently cite the exact same Meezan reference (EX1010) relied on in the Petition for the proposed grounds of rejection.

Dr. Donovan's analysis of Meezan's prosecution history (*i.e.*, EX1075) was

that it “supports [her] opinions” that Meezan discloses straight-chain alkyl groups and “underscores that [Dr. Brown’s] opinions on this issue are incorrect.” EX1078 at ¶47. Thus, Meezan’s prosecution history (EX1075) and Maggio’s Declaration (EX1076) support Petitioner’s arguments as to how a POSA would understand Meezan’s disclosure, but they do not alter the proposed ground of rejection itself. *Randall Mfg. v. Rea*, 733 F.3d 1355, 1362-63 (Fed. Cir. 2013) (party can submit evidence supporting a POSA’s understanding of prior art used in a rejection); *Koninklijke Philips N.V. v. Google LLC*, 948 F.3d 1330, 1337 (Fed. Cir. 2020).

C. Petition and Reply Apply the Same Meaning of “Consisting Of”

Patent Owner complains that Petitioner withdrew its litigation claim-construction positions to ensure consistency with this IPR. PO Mot. at 9-10. Petitioner explained that it did so based on recent decisions provided by the USPTO Director. Paper 43 at 6; EX1083 at 1-3. Patent Owner provides no explanation why aligning claim construction between the litigation and this IPR should be a basis for striking anything, particularly where the legal theory for the “consisting of” limitation raised in the Petition is the same as that elaborated on in the Reply. Paper 13 at 10, n. 9; *see also* EX2050 at 27. Indeed, Petitioner’s obviousness arguments in the Petition *and* Reply are premised on “consisting of” having its conventional meaning, i.e. containing only the claimed ingredients. *Compare* Paper 2 at 36 *with* Paper 43 at 16; *compare* EX1062 at ¶131 *with* EX1078 at ¶33.

Patent Owner also notes that the Reply cites a paragraph in Gwozdz disclosing that “parenteral administration can be aqueous or non-aqueous injection solutions,” which the Petition did not cite. PO Mot. at 10 (citing EX1009 at 11:17-26). This additional disclosure in Gwozdz is proper rebuttal to Patent Owner’s argument that Gwozdz fails to disclose a non-aqueous solution. *See, e.g.*, Paper 28 at 44 (“every embodiment in Gwozdz-PCT includes water”). Indeed, the disclosure cited in the Reply is not a “new embodiment” of Gwozdz—it merely provides additional detail about Gwozdz’s “injectable” formulations for parenteral administration.

For example, Patent Owner argues that Gwozdz discusses “penetration enhancers” in reference to formulations “for injection,” and because Gwozdz states that injectable formulation may be combined with other components (e.g., saline solution or water) the formulation must contain water. Paper 28 at 44. Petitioner responds directly to Patent Owner’s arguments by pointing out that Gwozdz’s injectable formulations may be aqueous (water-containing) or non-aqueous (not containing water) injections for parenteral administration. Paper 43 at 17-18. Thus, Petitioner’s Reply merely rebuts Patent Owner’s position, which the Federal Circuit has found to be proper under similar circumstances. *Rembrandt Diagnostics, LP v. Alere, Inc.*, 76 F.4th 1376, 1385 (*Fed. Cir.* 2023); *Apple*, 949 F.3d at 706-07.

IV. CONCLUSION

Petitioner requests that the Board deny Patent Owner’s Motion to Strike.

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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 April 27, 2026, upon the following:

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