UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PADAGIS US LLC
Petitioner,

v.

NEURELIS, INC.
Patent Owner.

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

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

TABLE OF CONTENTS

I. INTRODUCTION 1

II. PROCEDURAL HISTORY 2

III. THE BOARD SHOULD STRIKE THE HALE, MITCHNICK, AND CARTT DECLARATIONS 5

IV. LATE DEPOSITIONS DO NOT CURE PREJUDICE TO PETITIONER 8

V. CONCLUSION 10

TABLE OF AUTHORITIES

Page(s)

Cases

Adobe Inc. v. Rah Color Technologies, LLC,
IPR2019-00627, Paper No. 124 (PTAB Aug. 31, 2020) 8

Greene v McElroy,
360 U.S. 474 (1959) 6

HTC Corporation et al. v. NFC Technology, LLC,
IPR2014-01198, Paper 41, 3 (PTAB Nov. 6, 2015) 5, 9

Netflix Inc. et al. v. DivX, LLC,
IPR2020-00646, Paper No. 34 (PTAB April 26, 2021) 8

New World Medical, Inc. v. Microsurgical Technology, Inc.,
IPR2020-01573, Paper 49, 5-6 (PTAB Nov. 5, 2021) 5, 6, 8

Stride Rite Children's Group, LLC v. Shoes by Firebug LLC,
IPR2017-01809, Paper 64, 20-22 (PTAB Jan. 16, 2019) 6, 10

Statutes

35 U.S.C. § 316(a)(5) 5

Other Authorities

37 C.F.R. § 42.5(a) 5, 8

37 C.F.R. 42.7(a) 5, 8

37 C.F.R. 42.20(a) 5, 8

37 C.F.R. 42.12(a)-(b) 5, 8

37 C.F.R. §§ 42.51–42.53 ..... 1, 5

37 C.F.R. § 42.51(b)(1)(ii) 5, 6

37 CFR § 42.51(b)(1)(iii) 3

37 C.F.R. § 42.53(d)(2) 1, 7

LIST OF EXHIBITS

Exhibit No.	Description
1001	U.S. Patent No. 11,241,414, Administration Of Benzodiazepine Compositions, filed May 27, 2021 ("'414 Patent")
1002	File History for 11,241,414, Ser. No. 17/332,800 ("'414 FH")
1003	U.S. Patent No. 11,793,786, Administration of Benzodiazepine Compositions, filed April 12, 2021 ("'786 Patent")
1004	File History for 11,793,786 Patent, Ser. No. 17/228,514 ("'786 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")

Exhibit No.	Description
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", "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")

Exhibit No.	Description
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")
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

Exhibit No.	Description
	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 pharamcodynamics 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")
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")

Exhibit No.	Description
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")
1043	Wang HC, Chang WN, Chang HW, et al., Factors predictive of outcome in postraumatic 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")
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")

Exhibit No.	Description
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")
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 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")

Exhibit No.	Description
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	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 1-18 of the '414 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 *Inter Partes* Review of U.S. Patent No. 9,763,876
1073	Lim et al., *Physiological Factors Affecting Nasal Drug Delivery*, *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 *Padagis US LLC vs. Neurelis, Inc.*, 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, *Neurelis, Inc. v. Aquestive Therapeutics, Inc.*, No. 2021-1038 (Fed. Cir. Feb. 2, 2021).
1082	Appellant Neurelis Inc.'s Reply Brief, *Neurelis, Inc. v. Aquestive Therapeutics, Inc.*, No. 2021-1038 (Fed. Cir. Feb. 2, 2021).
1083	Stipulation Regarding Claim Construction, *Neurelis, Inc. v. Padagis LLC et al*., 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 Stitzman to Murphy (Feb. 19, 2026)

Exhibit No.	Description
1097	Email from Murphy to Stitzman (Feb. 23, 2026)
1098	Email from Stitzman 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)

I. INTRODUCTION

In accordance with the Board's prior orders, Petitioner Padagis US LLC moves to strike the Declarations of Steve Cartt (EX2045), Mark Mitchnick (EX2046), and David Hale (EX2047) (collectively, the "Inventor Declarations") from the record in this proceeding. *See* Paper 38; *see also* EX3004.

To ensure the parties are "on a level playing field" and to "streamline[] the proceeding," the Board's rules require that if a party proffers a witness's testimony via a declaration, that party *must* make that witness available for cross-examination. PTAB Consolidated Trial Practice Guide (Nov. 2019) at 22-23; *see also, e.g.*, 37 C.F.R. §§ 42.51–42.53. The fundamental purpose of the Board's rules is to ensure that the parties can timely depose the witness *before* their respective papers are due, and so that the Board is not burdened with *routine* discovery. *See, e.g.*, 37 C.F.R. § 42.53(d)(2); PTAB Consolidated Trial Practice Guide (Nov. 2019) at 22-23.

Here, Patent Owner[1] refused to make the inventor-declarants available for cross-examination in a timely manner and rejected Petitioner's repeated attempts to reach a compromise on this issue. Accordingly, the Board should strike the Inventor Declarations and expunge them from the record.

[1] This brief attributes actions or statements by Patent Owner's counsel to Patent Owner and actions or statements by Petitioner's counsel to Petitioner.

II. PROCEDURAL HISTORY

Pursuant to the Board's April 2, 2026 order, Petitioner summarizes timing issues related to the depositions of the inventor-declarants. EX3004. On January 5, 2026, Patent Owner filed its Response to the Petition, in which it relied on the Inventor Declarations to support its argument that the Gwozdz[2] prior art reference does not qualify as prior art. *See, e.g.*, Paper 28 at 36. Specifically, Patent Owner relied on the Inventor Declarations to argue that Gwozdz and the '414 patent were developed under a joint research agreement. *Id*. As Patent Owner explained in its Response, a certificate of correction was necessary for Patent Owner to prevail in its effort to disqualify Gwozdz as prior art for, which Patent Owner had previously sought leave from the Board to seek. Paper 28 at 32-33; *see also* Paper 26.

On January 20, 2026, Petitioner requested deposition dates for the inventor-declarants. EX1090 at 1. On February 2, Patent Owner proposed deposition dates of March 4 (Mitchnick and Hale) and March 5 or 6 (Cartt). EX1091 at 1. On February 4, Petitioner accepted all three of Patent Owner's proposed deposition dates for the inventor-declarants. EX1092 at 1.

On February 6, the Board denied Patent Owner's motion for leave to petition the Director for a certificate of correction. Paper 36. Shortly thereafter, on February 10, Patent Owner stated that "we are cancelling … the depositions" of the inventor-

[2] Gwozdz et al., WO 2009/120933 A2, published Oct. 1, 2009 (EX1009).

declarants "[i]n view of the Board's February 6 order." EX1093 at 1. Petitioner responded on February 12, explaining that "[w]e do not agree to cancel the depositions while Patent Owner's arguments regarding the alleged JRA are still of record in the IPRs" and proposed that, as an alternative solution, a joint motion to strike the Inventor Declarations would resolve the issue. EX1094 at 1.

Petitioner did not receive a response from Patent Owner, and followed up on February 18 to explain that these depositions "are required as routine discovery under 37 CFR §42.51(b)(1)(iii)." EX1095 at 1. On February 19, Patent Owner reiterated its position that "we do not see any basis for taking [the] depositions in these proceedings in view of the Board's February 6 Order." EX1096 at 1. Instead, Patent Owner stated that Petitioner could depose the inventor-declarants in the parallel district court litigation and that Patent Owner would not object "to Padagis using, in the IPR proceedings, those portions of the deposition transcripts of these individuals relating to their respective declarations." *Id*. However, Patent Owner did not offer any deposition dates for the inventor-declarants in either the IPR or district court proceedings. *Id*. And on February 20, Patent Owner requested rehearing of the Panel's Decision denying Patent Owner's motion to file a petition for a certificate of correction. Paper 37.

Petitioner responded on February 23 and explained that "there is no guarantee that any depositions of the declarants in the litigation would occur more than a week

before our reply in the IPR is due" and that "the differing protective orders in place in the IPR and the underlying litigation adds potential complications that are avoided with separate depositions" for the IPRs. EX1097 at 1. In response, Patent Owner maintained its position and refused to make the inventor-declarants available for cross-examination in these proceedings. EX1098 at 1.

On February 26, Petitioner contacted the Board to request authorization to file a motion to strike the Inventor Declarations. EX3003. On March 9, the Board issued an Order stating that Patent Owner was not required to make the inventor-declarants available for deposition while Patent Owner's rehearing request was pending. Paper 38 at 3. The Board also stated that the parties were to meet and confer on deposition dates within five days of the Board's decision on Patent Owner's rehearing request and that, if Patent Owner does not make the inventor-declarants available for deposition, Petitioner could move to strike the Inventor Declarations. *Id*.

On March 20, the Board denied Patent Owner's rehearing request. Paper 39. The parties met and conferred about the deposition dates on March 25, and despite being aware that Petitioner's Reply was due on March 31, Patent Owner offered deposition dates of April 29 (Hale), May 5 (Mitchnick), and May 7 (Cartt). EX1099 at 1. Petitioner explained that those dates were not feasible in view of the Reply deadline, but proposed that if the inventor-declarants were made available by April 10, the dates for Petitioner's Reply and Patent Owner's Sur-Reply could be extended

without affecting the remaining deadlines. EX1100 at 1. Patent Owner refused to make the inventor-declarants available by April 10, and Petitioner filed its Reply on March 31 without being afforded an opportunity to cross-examine the inventor-declarants. EX1101 at 1.

III. THE BOARD SHOULD STRIKE THE HALE, MITCHNICK, AND CARTT DECLARATIONS

Pursuant to 35 U.S.C. § 316(a)(5), the Director is tasked with "setting forth standards and procedures for discovery of relevant evidence, including … the deposition of witnesses submitting … declarations." 35 U.S.C. § 316(a)(5). To that end, the Board's rules define certain discovery as "routine," which "places the parties on a level playing field and streamlines the proceeding." PTAB Consolidated Trial Practice Guide (Nov. 2019) at 22-23; *see also* 37 C.F.R. § 42.51(b)(1)(ii). Thus, as the Board has explained previously, "[a]s a guiding principle of *routine discovery*, as defined by our Rules, if a party proffers a witness's testimony, that party ***must*** make that witness available for cross-examination by the other party." *See, e.g.*, *HTC Corporation et al. v. NFC Technology, LLC*, IPR2014-01198, Paper 41, 3 (PTAB Nov. 6, 2015) (citing 37 C.F.R. §§ 42.51–42.53) (second emphasis added). When a party refuses to make a declarant available for cross-examination, the Board has authority to strike the declaration. *See* 37 C.F.R. §§ 42.5(a), 42.7(a), 42.20(a), 42.12(a)-(b); *see also* IPR2014-01198, Paper 41 at 3-4; *New World Medical, Inc. v. Microsurgical Technology, Inc.*, IPR2020-01573, Paper 49, 5-6 (PTAB Nov. 5,

2021); *Stride Rite Children's Group, LLC v. Shoes by Firebug LLC*, IPR2017-01809, Paper 64, 20-22 (PTAB Jan. 16, 2019).

Here, the Board should strike the Inventor Declarations because Patent Owner refused to make the inventor-declarants available for cross-examination and impeded the very purpose of routine discovery (i.e., "plac[ing] the parties on a level playing field and streamlin[ing] the proceeding"). PTAB Consolidated Trial Practice Guide (Nov. 2019) at 22-23; *see also* 37 C.F.R. § 42.51(b)(1)(ii). As explained above, despite initially agreeing to make the inventor-declarants available for deposition, Patent Owner unilaterally canceled the depositions after the Board denied Patent Owner's certificate of correction motion. EX1093 at 1; EX1096 at 1. That was not Patent Owner's decision to make—the Board's rules and the PTAB's trial practice guide require that "when a party proffers a witness's testimony by [declaration], that party ***must*** make the witness available for cross-examination." IPR2020-01573, Paper 49 at 5 (emphasis added); *see also* IPR2017-01809, Paper 64 at 21 (striking declaration of witness not made available for deposition and explaining "[t]he right to cross-examine an adversarial witness is a long-standing and vital feature of the law in all cases including administrative actions") (citing *Greene v McElroy*, 360 U.S. 474, 497 (1959)).

Further, Patent Owner wrongly believed it did not need to comply with the Board's routine discovery rules by suggesting that Petitioner could depose the

inventor-declarants in the parallel district court litigation. *See, e.g.*, EX1096 at 1. As a threshold issue, Petitioner explained that Patent Owner's proposal was impractical at least because the parallel proceedings involve different deadlines, different protective orders, and an additional party is involved with the district court litigation that is not under the protective order in the IPRs. EX1097 at 1. Even if those concerns could have been addressed such that the inventor-declarants were deposed in both the IPR proceedings and the parallel district court litigation, Patent Owner *never* responded to Petitioner's repeated attempts to schedule deposition dates for the inventor-declarants in the parallel district court litigation. Put simply, Patent Owner flatly refused to make the inventor-declarants available for cross-examination despite Petitioner's requests.

Indeed, it was not until March 25, after the Board denied Patent Owner's rehearing request, that Patent Owner finally offered deposition dates, all of which were well-past Petitioner's Reply deadline. EX1099 at 1. But the entire purpose of the Board's rules regarding cross-examination is to ensure that declarants are deposed in a timely manner *before* the deposing party's response is due so that the deposition testimony can be relied on in that response. *See, e.g.*, 37 C.F.R. § 42.53(d)(2). Petitioner advised Patent Owner those dates were not feasible in light of the schedule, but offered a compromise that if the inventor-declarants could be made available before April 10, the parties could extend the Reply due date to

accommodate the depositions. EX1100 at 1. Patent Owner again refused Petitioner's attempt to find a solution and informed Petitioner that it could not alter the dates it offered. EX1101 at 1.

Thus, Petitioner had no choice but to file its Reply without the benefit of deposition testimony taken from the inventor-declarants. The Board's rules and prior decisions show that declarations should be stricken from the record when a party must file its response without the opportunity to cross-examine and rely on the testimony from those declarants. *See* 37 C.F.R. §§ 42.5(a), 42.7(a), 42.20(a), 42.12(a)-(b); *see also* IPR2020-01573, Paper 49 at 5-6.

IV. LATE DEPOSITIONS DO NOT CURE PREJUDICE TO PETITIONER

In its April 2 Order, the Board asked: "given Patent Owner's apparent offer of April 29, May 5, and May 7 as dates for deposition, the parties should address how such deposition testimony can be used in the proceeding now that Petitioner's opportunity to take and cite that testimony in its Reply, which has now been filed, has expired." EX3004. Other Board panels that have considered this issue have found that later depositions and additional briefing would be prejudicial to the party seeking the deposition. *Adobe Inc. v. Rah Color Technologies, LLC*, IPR2019-00627, Paper No. 124 at 20-23 (PTAB Aug. 31, 2020); *see also Netflix Inc. et al. v. DivX, LLC*, IPR2020-00646, Paper No. 34 at 5 (PTAB April 26, 2021). Similar reasons counsel against permitting this approach in this proceeding as Patent

Owner's refusal to simply make the witnesses available for cross-examination over the past three months has resulted in an unnecessarily bloated record that has placed a significant burden on the Board and the parties. *See* IPR2014-01198, Paper 41 at 5 (granting motion to strike declaration, and noting that "the efforts to obtain the deposition of [the witness] resulted in a considerable delay in the schedule for this review and placed a significant burden on the panel, as well as the parties, to complete the review prior to the statutory deadline"). The PTAB's trial practice guide also explains that *routine* discovery should be conducted in a manner that *streamlines* the proceeding—Patent Owner's actions here do the exact opposite, as noted above.

Further, Petitioner's Reply has already been filed, and Petitioner addressed Gwozdz's prior art status even *if* Patent Owner obtained a certificate of correction. Paper 43 at 13-14. Petitioner explained that Gwozdz would not be disqualified as prior art because the '558 Provisional and the Gwozdz-provisional were subject to different ownership under the agreements between Questcor and PSI. *Id*. The relationship and agreements between Questcor, PSI, and Hale BioPharma Ventures, LLC were addressed in the Inventor Declarations, and that was the very issue on which Petitioner sought deposition testimony that it could have relied on in its Reply. Patent Owner now has the benefit of Petitioner's Reply on this issue and could prepare its declarants for deposition, if the depositions were to proceed. This

prejudice cannot be cured—Petitioner will never have a clean slate on which to depose the inventor-declarants to properly take their testimony under cross-examination. IPR2017-01809, Paper 64 at 21.

Finally, Petitioner is not authorized to file any additional papers in these proceedings, and Patent Owner's Sur-Reply is currently due on May 12, 2026. Paper 33. Thus, even if the parties were able to agree to the late April and early May deposition dates, the *earliest* Petitioner would be able to file an amended Reply (or sur-sur-reply, if authorized) would be mid-to-late May, with Patent Owner's Sur-Reply (or sur-sur-sur reply, if authorized) being due sometime even later. Those hypothetical deadlines are impractical, if not impossible, in light of the scheduled June 16, 2026 Oral Argument (and other intervening deadlines related to motions to exclude, demonstratives, etc.).

V. CONCLUSION

For the reasons discussed above, Petitioner respectfully requests that the Board strike and expunge the Inventor Declarations (Exs. 2045-2047).

Dated April 6, 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 6, 2026 upon the following:

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