

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

**PATENT OWNER'S REQUEST TO THE DIRECTOR FOR
DISCRETIONARY DENIAL OF INSTITUTION**

Mail Stop PATENT BOARD
Patent Trial and Appeal Board
U.S. Patent & Trademark Office
P.O. Box 1450
Alexandria, VA 22313

TABLE OF CONTENTS

I.	INTRODUCTION	1
II.	PRELIMINARY STATEMENT	2
III.	FACTUAL BACKGROUND.....	13
	A. The ’876 IPR	13
	B. The ’786 Patent	14
	C. Padagis’s Petition	16
IV.	ARGUMENT.....	18
	A. The Director Should Deny Institution under 35 U.S.C. §314(a).	19
	1. <i>Fintiv factor 1</i> : No stay has been requested.....	20
	2. <i>Fintiv factor 2</i> : A district court trial is scheduled to conclude seven months before the projected statutory deadline for a final written decision.	21
	3. <i>Fintiv factor 3</i> : The parties have invested significant resources in the district court proceeding.....	23
	4. <i>Fintiv factor 4</i> : Padagis pursues identical invalidity issues in the district court and the Petition.....	24
	5. <i>Fintiv factor 5</i> : Both parties are parties in the parallel litigation.....	26
	6. <i>Fintiv factor 6</i> : The petition does not present compelling evidence of unpatentability.	27
	7. The Balance of the <i>Fintiv</i> Factors Weighs Against Institution.....	28
	B. The Director Should Deny Institution under 35 U.S.C. §325(d).	32
	1. The Exact Same Art and Substantially the Same Arguments Were Presented to the Examiner	35
	a) <i>Becton factor (a)</i> : the similarities and material differences between the asserted art and the prior art involved during examination and <i>Becton factor (b)</i> : the cumulative nature of the asserted art and the prior art evaluated during examination	35

b) <i>Becton factor (d)</i> : the extent of the overlap between the arguments made during examination and the manner in which Petitioner relies on the prior art.....	35
2. Padagis Fails to Identify Material Error by the PTO	36
a) <i>Becton factor (c)</i> : the extent to which the asserted art was evaluated during examination, including whether the prior art was the basis for rejection.....	36
b) <i>Becton factor (e)</i> : whether Petitioner has pointed out sufficiently how the Examiner erred in its evaluation of the asserted prior art	38
c) <i>Becton factor (f)</i> : the extent to which additional evidence and facts presented in the petition warrant reconsideration of the prior art or arguments	40
C. The Director Should Deny Institution Because the Unpatentability Challenge of the Petition Is Weak and Based on Compromised Expert Testimony.....	41
1. Gwozdz PCT Is Not Prior Art Because the ’786 Patent Perfected Priority to the ’558 Provisional.....	42
2. The Motivation to Combine the Petition Advances Is Not Prior Art.....	44
3. The Petition Relies on Compromised Expert Witness Testimony	45
a) Padagis’s Donovan Declaration Copies from Expert Declarations in the ’876 IPR	45
b) Important Passages of the Donovan Declaration Are Unsupported by Evidence	48
V. CONCLUSION.....	50

TABLE OF AUTHORITIES

	Page(s)
Cases	
<i>Advanced Bionics LLC v. MED-EL Elektromedizin-ische Geräte GmbH,</i> IPR2019-01469, Paper 6 (PTAB Feb. 13, 2020).....	32, 34, 36
<i>Apple Inc. v. Fintiv, Inc.,</i> IPR2020-00019, Paper 11 (PTAB Mar. 20, 2020)	<i>passim</i>
<i>Apple Inc. v. Haptic, Inc.,</i> IPR2024-01475, Paper 11 (PTAB April 4, 2025)	22, 26, 31
<i>Aquestive Therapeutics, Inc. v. Hale Biopharma Ventures, LLC,</i> IPR2019-00451, Paper 1 (Jan. 29, 2019).....	13
<i>Aquestive Therapeutics, Inc. v. Hale Biopharma Ventures, LLC,</i> IPR2019-00451, Paper 14 (Sept. 27, 2019).....	13
<i>Becton, Dickinson & Co. v. B. Braun Melsungen AG,</i> IPR2017-01586, Paper 8 (PTAB Dec. 15, 2017)	33
<i>Charter Commcn’s, Inc. v. Adaptive Spectrum & Signal Alignment, Inc.,</i> IPR2024-01379, Paper 16 (PTAB April 17, 2025)	22, 26, 31
<i>Cisco Systems, Inc. v. Estech Systems, Inc.,</i> IPR2021-00332, Paper 11 (PTAB July 7, 2021)	<i>passim</i>
<i>Commscope Techs. LLC v. Dali Wireless, Inc.,</i> IPR2022-01242, Paper 23 (PTAB Feb. 27, 2023).....	28
<i>Dell Inc. v. Universal Connectivity Techs., Inc.,</i> IPR2024-01480, Paper 12 (PTAB April 24, 2025)	22, 25, 31
<i>Ensung Global Corp. v. Hydrafacial LLC,</i> IPR2024-01491, Paper 17 (PTAB April 11, 2025)	22
<i>General Plastic Indus. Co. v. Canon Kabushiki Kaisha,</i> IPR2016-01357, Paper 19 (PTAB Sept. 6, 2017)	22

<i>Google LLC v. Cerence Operating Co.</i> , IPR2024-01464, Paper 15 (PTAB April 23, 2025)	22, 25, 31
<i>Harmonic Inc. v. Avid Tech., Inc.</i> , 815 F.3d 1356 (Fed. Cir. 2016)	1, 18, 19
<i>HP Inc. v. Universal Connectivity Techs., Inc.</i> , IPR2024-01478, Paper 12 (PTAB April 7, 2025)	22, 26, 31
<i>Kiosoft Tech., LLC v. Payrange, Inc.</i> , IPR2021-00086, Paper 12 (PTAB Mar. 22, 2021)	22
<i>Luxshare Precision Indus. v. Amphenol Corp.</i> , IPR2022-00132, Paper 10 (PTAB May 3, 2022)	21
<i>Ex parte Maziere</i> , 27 USPQ2d 1705 (Bd. Pat. App. & Inter. 1993)	43
<i>Motorola Solutions v. Stellar</i> , IPR2024-01205, Paper 19 (PTAB Mar. 28, 2025)	26, 31
<i>NHK Spring Co. v. Intri-Plex., Inc.</i> , IPR2018-00752, Paper 8 (PTAB Sept. 12, 2018)	19, 20, 22
<i>Nokia of Am. Corp. v. Pegasus Wireless Innovation LLC</i> , IPR2025-00036, Paper 14 (PTAB April 25, 2025)	21, 25, 31
<i>Padagis US, LLC v. Neurelis, Inc.</i> , IPR2025-00464, Paper 2 (Jan. 17, 2025)	16
<i>Padagis US, LLC v. Neurelis, Inc.</i> , IPR2025-00465, Paper 2 (Jan. 17, 2025)	16
<i>In re Riggs</i> , 131 F.4th 1377 (Fed. Cir. 2025)	10, 44
<i>Samsung Elecs. Am., Inc. v. Collision Commc’ns, Inc.</i> , IPR2025-00011, Paper 12 (PTAB April 28, 2025)	21, 24, 25, 31
<i>Samsung Elecs. Co. v. Truesight Commcn’s LLC</i> , IPR2024-01477, Paper 12 (PTAB April 21, 2025)	22, 26, 31

<i>Solus Advanced Materials Co. v. SK Nexilis Co.</i> , IPR2024-01460, Paper 14 (PTAB April 22, 2025)	22, 25, 31
<i>Sotera Wireless, Inc. v. Masimo Corp.</i> , IPR2020-01019, Paper 12 (PTAB Dec. 1, 2020)	<i>passim</i>
<i>Virtek Vision Int’l ULC v. Assembly Guidance Sys, Inc.</i> , 97 F.4th 882 (Fed. Cir. 2024)	45
<i>Vizio, Inc. v. Maxell, Ltd.</i> , IPR2022-01459, Paper 7 (PTAB Apr. 11, 2023)	26
<i>Xerox Corp. v. Bytemark, Inc.</i> , IPR2022-00624, Paper 9 (Aug. 24, 2022)	12, 50

Statutes

35 U.S.C. §311(b)	48
35 U.S.C. §314(a)	4, 18, 19
35 U.S.C. §325(d)	6, 12, 18, 32
Hatch-Waxman Act.....	21

Other Authorities

21 C.F.R. §316.3(b)(3)(iii).....	3, 40
37 C.F.R. §42.65(a).....	48
Guidance on USPTO’s rescission of Interim Procedure for Discretionary Denials in AIA Post-Grant Proceedings with Parallel District Court Litigation” (the “Boalick Memorandum”)	<i>passim</i>
Interim Procedure for Discretionary Denials in AIA Post-Grant Proceedings with Parallel District Court Litigation (“2022 Memorandum”)	5, 30, 31
Interim Processes for PTAB Workload Management” (“Stewart Memorandum”).....	<i>passim</i>
MPEP 608.01(p)(I)(B)	43

Patent Owner’s Request for Discretionary Denial of Institution
of Petition for *Inter Partes* Review
Patent No. 11,793,786

United States Patent and Trademark Office, <i>FAQs for Interim Processes for PTAB Workload Management</i>	25
United States Patent and Trademark Office, <i>Patent Trial and Appeal Board Consolidated Trial Practice Guide November 2019</i>	29

EXHIBIT LIST

Exhibit	Description
2001	<i>Clinical Superiority Findings</i> , U.S. FOOD & DRUG ADMIN. (Dec. 18, 2024) https://www.fda.gov/industry/designating-orphan-product-drugs-and-biological-products/clinical-superiority-findings
2002	Scheduling Order entered in <i>Neurelis, Inc. v. Padagis LLC</i> , 1:24-cv-00562, D.I. 20 (D. Del. Aug. 28, 2024)
2003	Preliminary Invalidity Contentions served in <i>Neurelis, Inc. v. Padagis LLC</i> , 1:24-cv-00562 (D. Del. Dec. 20, 2024)
2004	Markman Order entered in <i>Gilead Sciences, Inc. v. Lupin Ltd.</i> , 1:22-cv-00615-MN, D.I. 280 (D. Del. Feb. 21, 2025)
2005	Markman Order entered in <i>Spinal Generations, LLC v. Depuy Synthes, Inc.</i> , 1:22-cv-01368 (MN), D.I. 147 (D. Del. Oct. 16, 2024)
2006	Orange Book Listing for U.S. Patent No. 11,793,786
2007	Declaration of Nicholas A. Peppas, Sc.D., dated December 6, 2018 in <i>Aquestive Therapeutics, Inc. v. Hale Biopharma Ventures, LLC</i> , IPR2019-00451, Exhibit 1041 (Jan. 29, 2019)
2008	Declaration of Daniel P. Wermeling, Pharm.D., dated January 27, 2020 in <i>Aquestive Therapeutics, Inc. v. Hale Biopharma Ventures, LLC</i> , IPR2019-00451, Exhibit 1150 (Jan. 28, 2020)
2009	Application No. 18/782,666 (“’666 Application”)
2010	Information Disclosure Statements filed with the Application No. 18/782,666 (“’666 Application”) Prosecution History
2011	Sai H. S. Boddu, Sneha Kumar, <i>A Short Review on the Intranasal Delivery of Diazepam for Treating Acute Repetitive Seizures</i> . Pharmaceutics 2020; 12, 1167

Patent Owner's Request for Discretionary Denial of Institution
of Petition for *Inter Partes* Review
Patent No. 11,793,786

2012	Cornett et al., <i>VALTOCO® (Diazepam Nasal Spray) for the Acute Treatment of Intermittent Stereotypic Episodes of Frequent Seizure Activity</i> , <i>Neurology International</i> 2021; 13:64–78
2013	Scheduling Oral Order entered in <i>Neurelis, Inc. v. Padagis LLC</i> , 1:24-cv-00562, D.I. 47 (D. Del. March 11, 2025) Order Granting Stipulation to Extend Certain Fact Discovery Deadlines entered in <i>Neurelis, Inc. v. Padagis LLC</i> , 1:24-cv-00562, D.I. 65 (D. Del. May 15, 2025)

I. INTRODUCTION

The PTO “is permitted, but never compelled, to institute an IPR proceeding.” *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1367 (Fed. Cir. 2016). To “promote consistent application of discretionary considerations in the institution of AIA proceedings,” the Director has created a process to “determine whether discretionary denial of institution is appropriate.” March 26, 2025 Memorandum entitled “Interim Processes for PTAB Workload Management” (“Stewart Memorandum”), 1, 3. Based on applicable authority and the new interim process, Padagis’s Petition fails to justify institution for multiple, independent reasons.

First, under *Fintiv* the Petition should not be instituted because Padagis inexplicably waited so long to present this Petition that a parallel district court trial on the same patent and the same invalidity challenge will conclude more than seven months before the statutory deadline for a Final Written Decision. Second, the Office has addressed the same art and the same arguments on which the Petition relies and granted the challenged claims regardless. There is nothing new in this Petition. Third, the Petition’s substantive merits are weak. The primary reference upon which the Petition relies (Gwozdz PCT) is not prior art because Neurelis perfected priority to a provisional application filed the same day as the Gwozdz Provisional application. The Petition relies heavily on an expert declaration of which substantial portions were copied nearly verbatim from declarations of other

experts in other proceedings already considered by the Office. Other portions of Padagis's expert declaration wholly lack supporting evidence. Any of these reasons alone justifies denying institution.

II. PRELIMINARY STATEMENT

In the past patients with epilepsy suffering from seizure clusters needed an acute rescue therapy that they or their caregivers could administer without help from medical professionals. Benzodiazepines, particularly diazepam, were effective and could be administered intravenously in the emergency room but not at school, home, or work, where most seizure episodes occur. The only diazepam rescue product approved for seizure clusters and that could be used outside the medical clinic was a gel that had to be administered rectally. The discomfort and social embarrassment of this route of administration compromised utilization. Some environments refused to administer it at all due to perceived legal risks and privacy restrictions. Nevertheless, this product remained the only marketed rescue therapy for seizure clusters for more than twenty years due to the difficulty of developing alternatives.

Patent Owner Neurelis solved that problem. Neurelis developed a tailored class of pharmaceutical solutions for nasal administration that could be used in any setting, without medical assistance, to deliver a highly effective, well-tolerated dose of diazepam to a patient before, during, or after a seizure cluster. Neurelis researchers found that dissolving diazepam in vitamin E, benzyl alcohol, and ethanol

yielded a concentrated, stable, and well-tolerated nasal spray that possessed physicochemical properties (*e.g.*, viscosity) that were suitable for intranasal administration. They also believed the addition of the absorption enhancer (n-dodecyl beta-D-maltoside) could increase diazepam absorption across the nasal mucosa. The Patent Office recognized this innovation and awarded Neurelis several patents directed to pharmaceutical solutions, including the challenged U.S. Patent No. 11,793,786 (the “’786 Patent”). This patent covers Neurelis’s anti-seizure product, Valtoco, which FDA awarded Orphan Drug Exclusivity due to its clinical superiority that provides “a major contribution to patient care.” 21 C.F.R. §316.3(b)(3)(iii); EX2001, 4.

Consistent with the Office’s recent guidance “aim[ed] to improve PTAB efficiency . . . and promote consistent application of discretionary considerations in the institution of AIA proceedings,” Neurelis respectfully requests that the Director exercise discretion and deny institution of the Petition for its threshold deficiencies.¹ Stewart Memorandum, 3.

¹ In parallel, Padagis also filed belated Petitions addressing the two other patents asserted in the parallel district court litigation. *See* IPR2025-00464 and IPR2025-00465. Those Petitions suffer from the same procedural and substantive infirmities that exist herein. Accordingly, Neurelis has filed companion Requests for Discretionary Denial in those actions as well.

First, institution should be denied under 35 U.S.C. §314(a) on *Fintiv* grounds.

Well before the earliest time the statutory deadline could arrive in this proceeding (September 2026), a district court trial *will have been conducted seven months earlier* (February 2026). Even the institution decision deadline in September 2025 will arrive after substantial and significant aspects of the district court case will have concluded – including final infringement and invalidity contentions, fact discovery, and claim construction – and the parties will have expert report deadlines looming.

The advanced state of the district court case between Neurelis and Padagis in comparison with the timing of this Petition is a circumstance entirely of Padagis's own making. Padagis indisputably knew of the '786 Patent no less than fourteen months ago when it sent Neurelis a Paragraph IV letter asserting the '786 Patent's invalidity on the same basis this Petition advances. In reality, Padagis likely knew of the '786 Patent even earlier, when it was deciding whether to pursue an ANDA application in the first place. Neurelis had listed the '786 Patent in FDA's Orange Book in October 2023 in connection with its intranasal diazepam spray, Valtoco. Padagis would have devoted considerable effort to preparing its proposed ANDA product and its ANDA for filing well before sending the Paragraph IV letter. Thus, Padagis almost certainly has known of the patent since October 2023. Nevertheless, Padagis delayed filing this Petition until January 2025 – months after the district court case was filed and the parties were set for a February 2026 trial date (a date to

which Padagis acceded). This action was surprising in view of the “[s]ettled expectations of the parties” that if Padagis wanted to bring IPR challenges, it should have done so much earlier. *See* Stewart Memorandum, 2. Padagis has not sought a stay of the district court case, and it would be unlikely to prevail if it did so. Significantly, the arguments Padagis raises in this belated Petition are identical to both its Paragraph IV notice letter and its invalidity contentions in the district court litigation.

Padagis's sole effort to counterweigh these factors is to offer to file a *Sotera* stipulation. No such stipulation has been filed even though four months have passed since Padagis filed this Petition, and its terms are simply hypothetical. Regardless, the other *Fintiv* factors heavily outweigh Padagis's effort to address the one factor implicated by such a stipulation. Moreover, the Office's recent actions raise a question as to the weight such stipulation should be afforded, assuming the district court would accept it. The Office's recent withdrawal of the 2022 memorandum entitled “Interim Procedure for Discretionary Denials in AIA Post-Grant Proceedings with Parallel District Court Litigation” (“2022 Memorandum”), and entry of a memorandum entitled “Guidance on USPTO's rescission of ‘Interim Procedure for Discretionary Denials in AIA Post-Grant Proceedings with Parallel District Court Litigation’” (the “Boalick Memorandum”), “restore policy in this area to the guidance in place before” the 2022 Memorandum, including prior precedent.

Boalick Memorandum, 1. In that precedent the Board addressed similar circumstances to those obtaining here. In *Cisco Systems, Inc. v. Estech Systems, Inc.*, the Board found the parties' investment in the advanced state of a parallel district court case, and its trial many months before any IPR would conclude, to outweigh a *Sotera* stipulation. IPR2021-00332, Paper 11 at 10 (PTAB July 7, 2021) ("*Cisco*"). Since the Office issued the Boalick and Stewart Memoranda, the Board has repeatedly found other *Fintiv* factors to outweigh a *Sotera* stipulation. So too here.

Second, institution should be denied under 35 U.S.C. §325(d) because the Office allowed the subject claims after considering the same art and arguments the Petition raises. The Petition asserts a single ground of invalidity contending that the claims are obvious over a PCT application, Gwozdz PCT (EX1009), in view of a published U.S. application to Meezan (EX1010). During prosecution of the '786 Patent, Neurelis presented the Office with the same Gwozdz PCT and Meezan references on which this Petition relies. Neurelis also already had presented the Office with the *entire* trial and appellate record of another IPR proceeding on which Padagis relies heavily and from which it draws all of its arguments in this proceeding. That other IPR proceeding was filed several years ago by another petitioner (Aquestive Therapeutics) against a different Neurelis patent, No. 9,763,876 (the "'876 IPR"). Like the instant Petition, the '876 IPR relied upon a

single obviousness ground based on Gwozdz PCT in view of Meezan. With all of the same art, the same arguments, and the '876 IPR record before it the Office issued the claims of the '786 Patent. The instant Petition asks the Board to ignore the Office's analysis and consideration of the same art and arguments, instead revert back to the '876 IPR, and blindly apply the outcome there to the '786 Patent.

Unlike the patent in this Petition, the claims of the '876 Patent covered methods of administering a composition, where that composition was construed to include – in every claim – the limitation “an alkyl glycoside.” This limitation referred to a genus of alkyl glycoside compounds. In contrast, no claim of the '786 Patent recites “an alkyl glycoside.” Rather, every claim recites “n-dodecyl beta-D-maltoside.” In the '876 IPR the Board found that the '876 Patent is not entitled to the March 28, 2008 priority date of the provisional application to which it claimed priority (No. 61/040,558, the “'558 Provisional,” EX1008). (The '786 Patent also claims priority to the '558 Provisional.) In particular, the Board found that the '558 Provisional did not provide adequate written description for method of treatment claims including the full breadth of the family of compounds reflected in the “alkyl glycoside” limitation. The Board *made no findings on* whether the '558 Provisional supports “*n-dodecyl beta-D-maltoside*.” The earliest claimed effective filing date of Gwozdz PCT is also March 28, 2008, although the parties did not litigate whether Gwozdz was entitled to that priority date. Thus, in the '876 IPR, Gwozdz PCT was

held to be prior art and the claims of the '876 Patent were found obvious over Gwozdz PCT and Meezan. That judgment was affirmed without opinion by the Federal Circuit and the '876 Patent was revoked.

During prosecution of the '786 Patent, the Office was given all of these arguments and details: the same Gwozdz PCT and Meezan art, the parties' arguments in the '876 IPR (as contained in filings with the Board and appellate briefs), and the Board's decisions. Examiner Milligan was well-acquainted with the '876 IPR since he was simultaneously responsible for other Neurelis patent applications, including his *previous* examination of a child application of the '786 Patent, which ultimately issued as U.S. Patent 11,241,414 (the "'414 Patent"). In an interview during his previous examination of the '414 Patent, the Examiner discussed with Neurelis's counsel the issues the '876 IPR raised. EX1004, 29. They specifically discussed where the '558 Provisional discloses support for the n-dodecyl beta-D-maltoside element that every claim of the '414 Patent – and the '786 Patent – requires. The Examiner concluded that the '558 Provisional "incorporates a listing of n-dodecyl β -D-maltoside by reference to a Sigma Catalog. The instant claims receive a priority date of March 28, 2008." *Id.*, 28. Since the earliest priority date Gwozdz PCT can claim is also March 28, 2008, the Examiner specifically concluded that "Gwozdz (WO 2009120933) does not qualify as prior art," and allowed the claims that issued in the '414 Patent. *Id.*

During *later* prosecution of the '786 Patent by the *same Examiner*, he and Neurelis's counsel once again specifically discussed the '876 IPR during an interview. EX1002, 59; *id.*, 42. Having previously found Gwozdz PCT was not prior art to the '414 Patent because the '558 Provisional provides support for n-dodecyl beta-D-maltoside, the same finding was applicable to the '786 claims, which – like the '414 claims – all required n-dodecyl beta-D-maltoside.

In challenging the '786 Patent, this Petition regurgitates the very same arguments previously made against the '876 Patent, despite the differences in claim language that overcame these arguments during prosecution of the '414 Patent, for reasons equally applicable to the '786 Patent. And while Padagis contends the Office erred in finding that the '558 Provisional supports n-dodecyl beta-D-maltoside, relevant caselaw and the MPEP directly contravene this contention. The Board should decline to rehash prosecution and should exercise its discretion to deny institution under Section 325(d).

Third, institution should be denied because the strength of the unpatentability challenge is very weak – both on its merits and in the expert testimony offered in its support. The Stewart Memorandum instructs that two considerations for exercising discretion to deny institution are “[t]he strength of the unpatentability challenge” and “[t]he extent of the petition’s reliance on expert testimony.” Stewart Memorandum, 2. Here, the Petition is weak and the expert testimony is even weaker.

The Petition's sole ground relies on a principal reference, Gwozdz PCT, that is not prior art. As Neurelis's Preliminary Response will detail at length, every claim of the '786 Patent is entitled to the March 28, 2008 priority date of the '558 Provisional, for the same reasons as the Office previously determined the '414 Patent's claims had perfected priority to that Provisional.

Further, regardless of the priority date of the '786 Patent claims, the Petition fails to provide prior art evidence of a motivation for a person of ordinary skill to have combined Gwozdz PCT with Meezan. A provisional application must provide support for subject matter carried forward into a published application and used in a patentability challenge for that subject matter to be entitled to the filing date of the provisional. *See In re Riggs*, 131 F.4th 1377, 1384 (Fed. Cir. 2025). The only evidence on which the Petition relies to establish a motivation to combine these references is subject matter in Gwozdz PCT that was first disclosed in Gwozdz PCT, itself (*i.e.*, the March 27, 2009 application). That subject matter was not disclosed in the provisional application to which Gwozdz PCT claims priority (No. 61/040,281, the "Gwozdz Provisional," EX1064). Consequently, the particular subject matter ("penetration enhancer") on which the Petition relies is not prior art regardless of which priority date is accorded to the '786 Patent's claims. Without that disclosure, the Petition cannot prevail even as to a single claim.

The Petition's principal argument asserts that Neurelis is collaterally estopped from disputing various discrete issues that purportedly were addressed in the '876 IPR. But Padagis cannot carry its burden of establishing estoppel on the foregoing issues because they either differ from those previously litigated or were never litigated. In issuing the claims of the '786 Patent in light of the entire record of the '876 IPR, the Office rejected any notion that collateral estoppel would prevent Neurelis from establishing priority and eliminating Gwozdz PCT as prior art.

Padagis's expert declaration by Donovan (EX1062) further enervates the arguments the Petition advances. Its first serious flaw is that Padagis obviously copied significant portions of it from the expert declarations submitted by the petitioner in the '876 IPR. Amongst other examples, these portions include discussions by Dr. Donovan of what "her" opinion (really, the opinion of Aquestive's expert, Dr. Peppas) is concerning whether the cited art discloses the elements of the '786 Patent's claims; what "her" opinion (again, actually Peppas) is on the key issue of priority support for "n-dodecyl beta-D-maltoside"; what "her" opinion (again, Peppas) is on a skilled artisan's understanding and modification of the cited art; and what "her" opinion (really, the opinion of Aquestive's other expert, Dr. Wermeling) is about the supposed motivation for adding a penetration enhancer to the formulation of Gwozdz PCT.

Setting aside the impropriety of the copy-and-paste job, the mere fact that it compromises the so-called “opinion” undermines the very Petition it is meant to support. By copying the prior expert declarations used in the '876 IPR, which were specifically cited to the Office, Padagis inadvertently ***confirms*** that the exact same art and arguments ***were already reviewed and considered by the Office***. See 35 U.S.C. §325(d).

Likewise, significant passages of the Donovan Declaration present unsupported statements utterly lacking an evidentiary basis in the art. For example, Dr. Donovan asserts without support that the use of organic solvents and the omission of water from a nasal formulation was “a common approach” and that notwithstanding the risk of intolerability and toxicity from such solvents, “the risk-benefit assessment clearly still favors use of such products in treatment of life-threatening circumstances such as seizures.” EX1062, ¶70. She also asserts without support that “larger molecules inherently have a more difficult time crossing the cell membrane than do smaller molecules,” and that a penetration enhancer will work at least equally well for smaller molecules as for larger molecules. *Id.* at ¶105. The Petition repeats these conclusory assertions essentially verbatim. Petition, 32. The conclusory and unsupported declaration testimony is entitled to little weight. See *Xerox Corp. v. Bytemark, Inc.*, IPR2022-00624, Paper 9 at 15-16 (Aug. 24, 2022) (precedential).

For these and other reasons below, Neurelis respectfully requests that the Director exercise discretion to deny institution.

III. FACTUAL BACKGROUND

A. The '876 IPR

In January 2019, Aquestive Therapeutics filed a petition for *inter partes* review against every claim of Neurelis's '876 Patent. *Aquestive Therapeutics, Inc. v. Hale Biopharma Ventures, LLC*, IPR2019-00451, Paper 1 (Jan. 29, 2019). The petition asserted two grounds of invalidity, for obviousness over Gwozdz PCT in view of Meezan (claims 1-16 and 24-36) or for obviousness over Gwozdz PCT in view of Meezan and Cartt (claims 17-23). *Id.* at 5. There was no dispute that Meezan was prior art. And as the Board noted, "Patent Owner does not contest that Gwozdz [PCT] is entitled to [the] filing date" of its provisional application. EX1040, 14. There was a dispute as to the priority date of the claims of the '876 Patent. The Board found that at the preliminary stage, Neurelis had failed to carry its burden of production to show that all of the '876 claims were supported throughout the priority chain. *Aquestive Therapeutics*, IPR2019-00451, Paper 14 at 5-6 (Sept. 27, 2019). Consequently, the Board instituted on all claims.

As the Board noted, the '876 Patent set forth one independent claim (claim 1), from which all the other claims depended. EX1040, 4-5. That claim recited, in addition to other elements, "an alkyl glycoside." *Id.* The Board construed every

claim of the '876 Patent to “require the presence of ‘an alkyl glycoside.’” *Id.* at 14, n.6. The Board found that the disclosure in the '558 Provisional “is not sufficient to provide written description support for the ‘alkyl glycoside’ limitation in the claims.” *Id.* at 19, n.7. Consequently, the Board found that Patent Owner had failed to perfect priority of the '876 Patent's claims to the '558 Provisional, and as a result Gwozdz PCT was prior art. *Id.* at 23. The Board then evaluated whether the '876 Patent's claims were obvious in view of the cited art, and found that Aquestive had proven by a preponderance of the evidence that every '876 claim was unpatentable. *Id.* at 68. This decision was affirmed without decision by the Federal Circuit.

B. The '786 Patent

The '786 Patent issued from a U.S. application No. 17/228,514, (“the '514 Application,”) that claims priority, through an intervening continuation, to the '439 Application, filed March 27, 2009, and to the '558 Provisional, filed March 28, 2008. None of the then-pending claims of the '514 Application, which issued as the claims of the '786 Patent, recited “an alkyl glycoside.” Instead, every claim recited “n-dodecyl beta-D-maltoside.” *See* EX1002, 176-78.

Almost immediately after filing the '514 Application, Neurelis submitted all the art on which this Petition relies (specifically including Meezan and Gwozdz PCT). *Id.*, 487-515. Neurelis also submitted the entire record from the '876 IPR on which the Petition relies, including the '876 IPR Petition, Petitioner and Patent

Owner briefs, expert declarations and other exhibits, Institution Decision and requests for rehearing of it, the Final Written Decision, and appellate briefs. *Id.*, 374-94.

Examiner Milligan, considered all those documents. *Id.*, 72-100.

The obviousness argument on which Padagis relies (Gwozdz PCT and Meezan) had *previously* been specifically discussed with the *same Examiner* during an interview in the prosecution of the '414 Patent, on November 5, 2021. EX1004, 29. The '876 IPR also was discussed at that time. *Id.* The question of whether priority of the then-pending claims had been perfected to the '558 Provisional was addressed. *Id.* ("Examiner discussed the priority of the recitation of n-dodecyl beta-D-maltoside. Applicant[']s representative pointed out where Applicants believed that priority existed in the priority documents."). After review, in the subsequent Notice of Allowance the Examiner agreed that priority existed for the '414 claims, all of which recited n-dodecyl beta-D-maltoside. *Id.* at 27-28 ("Reasons for Allowance"). Examiner Milligan stated that "Applicants['] claims are considered to be supported in the priority documents" and "[t]he provisional Application incorporates a listing of n-dodecyl β -D-maltoside by reference to a Sigma Catalog" and that as a consequence "[t]he instant claims receive a priority date of March 28, 2008. As such Gwozdz [PCT] (WO 2009-120933) does not qualify as prior art." *Id.*

Like the claims of the '414 Patent, every claim of the '786 Patent requires n-dodecyl beta-D-maltoside. EX1001, 36-37.

Furthermore, Examiner Milligan also issued a rejection of the then-pending claims during prosecution of the '786 Patent based on Meezan (EX1010), on which this Petition relies, and Sonne (U.S. 6,193,985). EX1002, 66. Following that rejection, Neurelis's counsel discussed these matters with the Examiner, including discussing the withdrawal of the '876 Patent due to the '876 IPR. *Id.*, 59. This IPR had been the subject of previous discussion with Examiner Milligan in the '414 prosecution, as discussed above. Neurelis overcame the obviousness rejection based in part on Meezan (*id.*, 43-46), and the Examiner withdrew it, allowing the claims (*id.*, 20-22).

C. Padagis's Petition

Padagis filed this Petition on January 17, 2025, along with two other petitions. All three petitions rely on declarations from Dr. Maureen Donovan, which are substantially identical to each other, and substantially reiterate the language included in the petitions. *See Padagis US, LLC v. Neurelis, Inc.*, IPR2025-00464, Paper 2 (Jan. 17, 2025); *Padagis US, LLC v. Neurelis, Inc.*, IPR2025-00465, Paper 2 (Jan. 17, 2025); Petition. Every ground Padagis asserts for unpatentability relies on obviousness over Gwozdz PCT in view of Meezan. *See* Petition, 6. For claims 20-21 of the '786 Patent, Padagis asserts obviousness in further view of Cartt (EX1065),

which is added for purported disclosure of diazepam doses (Petition, 63-65). For claims 26-27, Padagis asserts obviousness in further view of USP 23/NF 18 (EX1066), which is added for purported disclosure of the characteristics of Vitamin E USP (Petition, 65-67). For every claim of the '786 Patent, Gwozdz PCT is the principal piece of art on which the Petition relies, and Meezan is the secondary piece of art on which it relies. The Petition reiterates the argument made in the '876 IPR, overcome during prosecution, and attempts to invoke collateral estoppel to support this position.

Padagis asserts that Neurelis should be collaterally estopped from disputing certain discrete issues that the '876 IPR purportedly addressed. Specifically:

- The '558 Provisional “does not provide adequate written description support for the ‘alkyl glycoside’ limitation”;
- Gwozdz PCT is entitled to the filing date of the Gwozdz Provisional;
- The elements of the '876 Patent's claims are taught or suggested by the combination of Gwozdz PCT and Meezan;
- A skilled artisan “would have had reason to add alkyl glycoside as a penetration enhancer, as disclosed in Meezan '962, with a formulation of benzodiazepine, tocopherol, ethanol, and benzyl alcohol, as disclosed in Gwozdz [PCT]”;

- A skilled artisan would have had a reasonable expectation of successfully combining Gwozdz PCT and Meezan, and Cartt as well; and,
- The record in the '876 IPR provided weak objective evidence of nonobviousness and a lack of nexus to the '876 Patent claims.

Id., 9-10. The Petition also asserts that Neurelis should be collaterally estopped from disputing whether Cartt is prior art. *Id.* at 23-24.

IV. ARGUMENT

The institution decision is given entirely to the Office's discretion. *See, e.g., Harmonic*, 815 F.3d at 1367. The Director should exercise this discretion to deny institution under 35 U.S.C. §314(a) because institution would be an inefficient use of the Board's limited resources, notwithstanding the offer of a *Sotera* stipulation, given the advanced state of the district court case and its trial date several months before a Final Written Decision could issue. The Director also should deny institution under 35 U.S.C. §325(d) because the same art and the same arguments were previously before the Office during prosecution of the '786 Patent, the claims issued over them, and Padagis has failed to show that the Office committed error in doing so. The Director also should deny institution due to the Petition's weakness, particularly its reliance on an erroneous assertion of collateral estoppel and its reliance on compromised expert opinion.

A. The Director Should Deny Institution under 35 U.S.C. §314(a).

The Director should deny institution because the overwhelming weight of the six *Fintiv* factors demands discretionary denial. Section 314(a) provides the Office total discretion to deny instituting an IPR to promote efficiency when, as here, the same patent is subject to parallel proceedings in another forum. *See Harmonic*, 815 F.3d at 1367; *NHK Spring Co. v. Intri-Plex., Inc.*, IPR2018-00752, Paper 8 at 11 (PTAB Sept. 12, 2018) (precedential) (“*NHK*”).

The parallel district court case involving the '786 Patent is scheduled for trial at least seven months before the Board might issue a Final Written Decision. EX2002, 11. Padagis chose to file this Petition extremely late, even though it has long known of the '786 Patent and how it applies to the proposed ANDA product. Padagis also chose to assert the exact same art and the exact same arguments in this Petition as in its invalidity contentions in the district court. EX2003, 28, 33. Consequently, by now the parties have invested substantial time and effort into litigating the same issues that this Petition raises. While Padagis has offered a *Sotera* stipulation (Petition, 68-69), no stipulation has been filed. Even if filed, the balance of factors set forth in *Apple Inc. v. Fintiv, Inc.* far outweigh it:

1. whether the court granted a stay or evidence exists that one may be granted if a proceeding is instituted...;
2. proximity of the court's trial date to the Board's projected statutory deadline;

3. investment in the parallel proceeding by the court and parties;
4. overlap between issues raised in the petition and in the parallel proceeding;
5. whether the petitioner and the defendant in the parallel proceeding are the same party;
6. other circumstances that impact the Board's exercise of discretion, including the merits.

IPR2020-00019, Paper 11 at 6-14 (PTAB Mar. 20, 2020) (precedential) ("*Fintiv*").

The Office should take "a holistic view of whether efficiency and integrity of the system are best served by denying or instituting review." *Fintiv*, 6. In the Boalick Memorandum the Office recently emphasized the importance of this holistic analysis under the Board's precedent. The goal of the AIA was "to provide an effective and efficient alternative" to district court litigation. *NHK*, 19-20. This goal and the general welfare of the patent system would be advanced best by a decision to deny institution pursuant to the Director's authority under Section 314(a) and instead allow the district court to resolve the dispute this Petition presents.

1. *Fintiv* factor 1: No stay has been requested.

Fintiv factor 1 asks "whether the court granted a stay or evidence exists that one may be granted if a proceeding is instituted." *Fintiv* at 6. The indisputable answer to both questions is **no**: the court has not granted a stay, and Padagis has identified no "evidence [] that one may be granted if a proceeding is instituted." *Id.* The Board has found factor 1 to favor discretionary denial where (as here)

“Petitioner present[ed] no evidence that it has requested a stay [] or that a stay is likely.” *Luxshare Precision Indus. v. Amphenol Corp.*, IPR2022-00132, Paper 10, at 9 (PTAB May 3, 2022). Moreover, the parallel district court litigation was brought under the Hatch-Waxman Act. The court is unlikely to substantially delay trial because it would risk expiration of Neurelis’s 30-month stay of FDA approval for Padagis’s proposed ANDA product.

This factor favors denial.

2. *Fintiv* factor 2: A district court trial is scheduled to conclude seven months before the projected statutory deadline for a final written decision.

Trial in the District of Delaware is scheduled to begin February 9, 2026, a date to which Padagis agreed and which is less than nine months from now. *See* EX2013. The earliest the Board is projected to issue a Final Written Decision, if it instituted proceedings on this Petition, is September 17, 2026 – more than seven months *after* trial concludes. The Board has repeatedly exercised its discretion to deny institution when a parallel trial is scheduled to occur before a proceeding could conclude. *See, e.g., Cisco*, 9-10 (trials scheduled seven and eleven months before statutory deadline). *See also Samsung Elecs. Am., Inc. v. Collision Commc’ns, Inc.*, IPR2025-00011, Paper 12 at 20-21 (PTAB April 28, 2025) (seven months); *Nokia of Am. Corp. v. Pegasus Wireless Innovation LLC*, IPR2025-00036, Paper 14 at 9-11 (PTAB April 25, 2025) (six to seven months); *Dell Inc. v. Universal Connectivity*

Techs., Inc., IPR2024-01480, Paper 12 at 9-10 (PTAB April 24, 2025) (six months);
Google LLC v. Cerence Operating Co., IPR2024-01464, Paper 15 at 7-8 (PTAB
April 23, 2025) (seven months); *Solus Advanced Materials Co. v. SK Nexilis Co.*,
IPR2024-01460, Paper 14 at 15-16 (PTAB April 22, 2025) (five to six months);
Samsung Elecs. Co. v. Truesight Commcn's LLC, IPR2024-01477, Paper 12 at 11
(PTAB April 21, 2025) (six months); *Charter Commcn's, Inc. v. Adaptive Spectrum
& Signal Alignment, Inc.*, IPR2024-01379, Paper 16 at 8-11 (PTAB April 17, 2025)
(two to seven months); *Ensung Global Corp. v. Hydrafacial LLC*, IPR2024-01491,
Paper 17 at 12 (PTAB April 11, 2025) (four months); *HP Inc. v. Universal
Connectivity Techs., Inc.*, IPR2024-01478, Paper 12 at 5-6 (PTAB April 7, 2025)
(six months); *Apple Inc. v. Haptic, Inc.*, IPR2024-01475, Paper 11 at 10-11 (PTAB
April 4, 2025) (six months). *Kiosoft Tech., LLC v. Payrange, Inc.*, IPR2021-00086,
Paper 12 at 10-11 (PTAB Mar. 22, 2021) (five months); *NHK*, 19-20 (six months).

Granting institution here would frustrate one of the primary objectives of the
AIA, which is “to provide an effective and efficient alternative” to parallel litigation.
NHK, 19-20 (quoting *General Plastic Indus. Co. v. Canon Kabushiki Kaisha*,
IPR2016-01357, Paper 19, 16-17 (PTAB Sept. 6, 2017) (precedential)). Any
potential Final Written Decision would issue so long after trial concludes that this
IPR cannot be viewed as an “alternative” to litigation. It simply would be more
litigation.

This factor heavily favors denial.

3. *Fintiv* factor 3: The parties have invested significant resources in the district court proceeding.

An institution decision on this Petition is not projected to issue before September 17, 2025. By that time the parties will have concluded fact discovery, served final invalidity and infringement contentions and responses to them, concluded claim construction, and completed substantial work drafting expert reports – including on invalidity. *See* EX2013. And although to date the district court has not issued substantive orders related to the '786 Patent, Judge Noreika is known to provide her claim constructions at the *Markman* hearing. *See, e.g.*, EX2004, 5 (“[t]he court’s ruling regarding the disputed claim terms...was announced during the *Markman* hearing”); EX2005, 6 (same). Only one claim construction dispute has arisen, and it is on a term (“consisting of”) that has a well-established legal significance. Since the *Markman* hearing is scheduled for September 12, 2025 – before the date an institution decision must issue – it is likely there will be a *Markman* order by that time. “[C]laim construction orders may indicate that the court and parties have invested sufficient time in the parallel proceeding to favor denial.” *Fintiv*, 10. In any event, evaluation of this factor is not contingent on whether claim construction occurs before the institution decision. *See*

Samsung, IPR2025-00011, Paper 12 at 21-22 (Factor 3 favored denying institution even where no claim construction order had issued).

Padagis's delay in filing this Petition – a circumstance entirely of Padagis's own making – further weighs for denial. *See Fintiv*, 11-12 (“if the petitioner cannot explain the delay in filing its petition, these facts have favored denial”). Padagis has known of the '786 Patent at least since it filed its ANDA early in 2024 and provided its Paragraph IV certification shortly thereafter. Padagis doubtlessly worked on its proposed ANDA product long before its submission, and the '786 Patent has been listed in the Orange Book since October 2023. EX2006, 1. Consequently, Padagis likely has known of the '786 Patent for quite some time and, thus, has known it must overcome the patent in pursuit of its ANDA application. Since August 2024, Padagis has known that trial would occur in Delaware in February 2026. Yet Padagis waited until January 2025 – about one year before trial – to file this Petition. Padagis offers no excuse for this delay.

This factor heavily favors denial.

4. *Fintiv* factor 4: Padagis pursues identical invalidity issues in the district court and the Petition.

Fintiv explains that “concerns of inefficiency and the possibility of conflicting decisions [are] particularly strong” where “the Board [is] presented with substantially identical prior art arguments . . . at issue in district court.” *Fintiv*, 12.

“Accordingly, if the petition includes the same or substantially the same claims, grounds, arguments, and evidence as presented in the parallel proceeding, this fact has favored denial.” *Id.* In this Petition Padagis relies on the exact same art and arguments set forth in its invalidity contentions. EX2003, 13-16, 18.

To address this factor – and only this factor – Padagis contends that it will file a *Sotera* stipulation. It has not done so, and so the scope of any stipulation is uncertain. More importantly, four months have elapsed since the Petition was filed and two months since the Office accorded the Petition a filing date. Indeed, Padagis has not filed a stipulation even considering the Board’s guidance in its April 25, 2025 FAQs that the stipulation be filed “as soon as practicable.” *See e.g.*, United States Patent and Trademark Office, *FAQs for Interim Processes for PTAB Workload Management*, USPTO (Apr. 25, 2025, last updated May 7, 2025), available at <https://www.uspto.gov/patents/ptab/faqs/interim-processes-workload-management>.

Even if Padagis files a *Sotera* stipulation, in circumstances like those present here the Board has declined to institute proceedings notwithstanding such a stipulation. *See, e.g.*, *Samsung*, IPR2025-00011, Paper 12 at 25 (weight of *Fintiv* factors against institution notwithstanding *Sotera* stipulation); *Nokia*, IPR2025-00036, Paper 14 at 18 (same); *Dell*, IPR2024-01480, Paper 12 at 22-23 (same); *Google*, IPR2024-01464, Paper 15 at 15 (same); *Solus*, IPR2024-01460, Paper 14 at

31-32 (same); *Samsung*, IPR2024-01477, Paper 12 at 16 (same); *Charter Commcn's*, IPR2024-01379, Paper 16 at 16-17 (same); *HP*, IPR2024-01478, Paper 12 at 17 (same); *Apple*, IPR2024-01475, Paper 11 at 17-18 (same); *Motorola Solutions v. Stellar*, IPR2024-01205, Paper 19 at 2-4 (PTAB Mar. 28, 2025) (same); *Cisco*, 14 (same); Section IV(A)(7), below. As the Boalick Memorandum states, a *Sotera* stipulation “is highly relevant, but will not be dispositive.” Boalick Memorandum, 3. Accordingly, while this factor might weigh in favor of institution because a *Sotera* stipulation was offered, when weighed against the other factors – as discussed below – and in consideration that the stipulation is hypothetical at this point, institution should be denied.

5. *Fintiv* factor 5: Both parties are parties in the parallel litigation.

Under *Fintiv*, “[i]f a petitioner is unrelated to a defendant in an earlier court proceeding, the Board has weighed this fact against exercising discretion to deny institution.” *Fintiv* 13-14. That is not the case here because Padagis is a defendant in the parallel litigation. Accordingly, the circumstances raise no fairness concerns that denial would deprive Padagis of its “day in court.” See *Vizio, Inc. v. Maxell, Ltd.*, IPR2022-01459, Paper 7 at 21-22 (PTAB Apr. 11, 2023) (“Because Petitioner is the litigation defendant, factor 5 weighs in favor of discretionary denial.”); *Sotera Wireless, Inc. v. Masimo Corp.*, IPR2020-01019, Paper 12 at 19 (PTAB Dec. 1,

2020) (precedential as to §II.A) (“[If] the parties are the same in the inter partes proceeding and in the parallel proceeding. . . . this factor supports denying institution.”) (“*Sotera*”).

This factor favors denial.

6. *Fintiv* factor 6: The petition does not present compelling evidence of unpatentability.

Fintiv Factor 6 asks whether circumstances other than the previous five factors, including (and typically limited to) the merits, should affect the institution analysis. If the merits seem particularly strong (not relevant here) that finding can favor institution although it does not compel that outcome. *See* Boalick Memorandum, 3 (“compelling merits alone is not dispositive”). In contrast, where the merits are “a closer call, then that fact has favored denying institution when other factors favoring denial are present.” *Fintiv*, 15. The merits of this Petition are poor.

The same art and arguments on which this Petition relies were presented to the Office during prosecution and overcome following substantial discussion, consideration, and explanation. *See* Section IV(B), below. As the Office found, the principal reference on which the Petition relies, Gwozdz PCT, is not prior art because Neurelis perfected priority for the claims of the '786 Patent to the '558 Provisional. *See* Section IV(C), below. The priority issue relevant to the '786 Patent (support for “n-dodecyl beta-D-maltoside”) was not actually litigated in the '876 IPR, and so

collateral estoppel cannot compel a contrary result. Regardless of which priority date is accorded to the claims of the '786 Patent, the only evidence the Petition supplies for a motivation to combine Gwozdz PCT with Meezan is not prior art subject matter because Gwozdz PCT does not disclose that subject matter until the 2009 PCT. Since the priority date of the Gwozdz PCT subject matter was not disputed in the '876 IPR, collateral estoppel cannot compel a contrary result. Finally, the Petition relies on an expert declaration compromised by plagiarism and inadequate evidentiary support.

Even if the petition could conceivably pass the threshold of “reasonable likelihood” (it does not), it certainly would not pass the higher threshold of a “compelling” unpatentability. “[T]he compelling merits standard is a higher standard than the standard for institution set by statute.” *Commscope Techs. LLC v. Dali Wireless, Inc.*, IPR2022-01242, Paper 23 at 3 (PTAB Feb. 27, 2023). Such a finding requires determining that the Padagis’s chances of succeeding on the merits are “highly likely.” *Id.* at 4. But the opposite is true here.

This factor strongly favors denial.

7. The Balance of the *Fintiv* Factors Weighs Against Institution

The decision whether to exercise discretion to deny institution under Section 314(a) rests on “a balanced assessment of all relevant circumstances in the case,

including the merits.” United States Patent and Trademark Office, *Patent Trial and Appeal Board Consolidated Trial Practice Guide November 2019*, USPTO (Nov 14, 2019, last updated Nov. 20, 2019), *available at* <https://www.uspto.gov/sites/default/files/documents/tpgnov.pdf> at 58. At least five of the *Fintiv* factors disfavor institution. Only Factor 4 arguably favors institution, but the other factors – particularly Factors 2 and 3 – substantially outweigh it. *Cisco* is instructive.

Like *Cisco*, trial in the parallel litigation will have concluded several months before the statutory deadline. *Cisco*, 9 (seven and eleven months in two parallel cases versus seven months here). Like *Cisco*, by the date the institution decision is likely to issue the district court case will be in an advanced state, and the parties will have invested substantial resources in it. *Id.* at 9-10 (fact discovery, contentions, and claim construction concluded). Like *Cisco*, the petitioner has offered no explanation for its delay in filing the petition. *Id.* at 10. Like *Cisco*, the petitioner pursues the same arguments in litigation and the petition and seeks to ameliorate that overlap with the offer of a *Sotera* stipulation. *Id.* at 10-12. Like *Cisco*, no stay has been sought; the petitioner is the same real party in interest as the litigation defendant (hence Factor 5 favored denying institution); and the merits are not compelling. *Id.* at 9, 12-14. On these facts, in *Cisco* the petitioner's actual *Sotera* stipulation was outweighed by the balance of the other factors, principally the advanced state of the parallel district court litigation, the parties' investment of resources in it, and the fact

that that trial would occur many months before the statutory deadline. *Cisco*, 9-12, 14.

Sotera, itself, is equally instructive, as the Board observed in *Cisco*. *Id.* at 12. As is true here, in *Sotera* no stay was in place (although unlike here, the *Sotera* petitioner had sought one), the parties were identical, a *Sotera* stipulation had been offered, and the merits were not compelling. *Sotera*, 14, 18-20. Importantly, **unlike** the present case, in *Sotera* trial was scheduled to occur approximately contemporaneously with the statutory deadline, rendering Factor 2 neutral. *Id.* at 15. And unlike Padagis, the *Sotera* petitioner had offered explanations for its delay in filing the petition (including pending settlement talks and Covid-related office closures and disruptions). *Id.* at 17. The case in *Sotera* was not in an advanced stage, with fact discovery ongoing and all claim construction deadlines vacated indefinitely at the institution decision date. *Id.* at 16. In contrast, by the time of an expected institution decision, fact discovery, invalidity contentions, infringement contentions, and claim construction will be concluded; a *Markman* order likely will have issued, and substantial work on expert reports will have been done. On those facts – which do not exist here – the Board instituted. *Id.* at 20-21.

In rescinding the 2022 Memorandum, the Office has directed focus on the Board's precedent to guide discretionary denials under *Fintiv*. Boalick Memorandum, 1 (“the USPTO rescinded the Interim Procedure [of the 2022

Memorandum] to restore policy in this area to the guidance in place before the” 2022 Memorandum). Accordingly, many recent Board decisions find discretionary denial appropriate under circumstances similar to those here. *See, e.g., Samsung*, IPR2025-00011, Paper 12 at 25; *Nokia*, IPR2025-00036, Paper 14 at 18; *Dell*, IPR2024-01480, Paper 12 at 22-23; *Google*, IPR2024-01464, Paper 15 at 15; *Solus*, IPR2024-01460, Paper 14 at 31-32; *Samsung*, IPR2024-01477, Paper 12 at 16; *Charter Commcn's*, IPR2024-01379, Paper 16 at 16-17; *HP*, IPR2024-01478, Paper 12 at 17; *Apple*, IPR2024-01475, Paper 11 at 17-18; *Motorola Solutions*, IPR2024-01205, Paper 19 at 2-4.

Indeed, on multiple occasions the Board has exercised discretion to deny institution under *Fintiv* on weaker grounds than obtain here. In *Solus*, only Factors 2, 5, and 6 favored denying institution, Factor 4 was strongly against denial, and Factors 1 and 3 were neutral. *Solus*, IPR2024-01460, Paper 14 at 31-32. And yet on what was a weaker case for denial than is present here the Board nonetheless denied institution. *Id.* Similarly, in *Samsung*, three Factors favored denial (2, 3, and 5), two were neutral (1 and 6), and Factor 4 strongly favored institution. *Samsung*, IPR2024-01477, Paper 12 at 16. Once again, the Board denied institution on *Fintiv* grounds. *Id.* And in *HP*, only Factors 2 and 5 were explicitly found to favor exercising discretion to deny institution (*HP*, IPR2024-01478, Paper 12 at 6, 10), Factors 1 and 3 were neutral (*id.* at 5, 7), Factor 4 was strongly against exercising

discretion (*id.* at 8), and on Factor 6 the Board found that the Petition “does not present particularly strong merits” (*id.* at 16). On that record the Board again exercised discretion to deny institution. *Id.* at 17.

As the Board's contrasting decisions in *Sotera* and *Cisco* (and in many recent decisions) show, the underlying facts matter in determining whether to exercise discretion under *Fintiv* to deny institution. The facts of this case sharply contrast *Sotera* and closely mirror *Cisco* and the more recent proceedings cited above. The same result should obtain as did in *Cisco*: institution should be denied.

B. The Director Should Deny Institution under 35 U.S.C. §325(d).

Section §325(d) authorizes the Director to deny institution if “the same or substantially the same prior art or arguments previously were presented to the Office.” These are two independent grounds for denial: “[W]e determine that the ‘same or substantially the same prior art’ previously was presented to the Office. Accordingly, the first condition of the first part of the framework is satisfied, and we need not reach whether ‘the same or substantially the same arguments’ previously were presented to the Office.” *Advanced Bionics LLC v. MED-EL Elektromedizinische Geräte GmbH*, IPR2019-01469, Paper 6 at 20 (PTAB Feb. 13, 2020) (precedential). If the Office previously considered either the same art or the same arguments, the Office assesses whether the petitioner has shown that the PTO materially erred. *Id.* at 8-9. “[T]his framework reflects a commitment to defer to

previous Office evaluations of the evidence of record unless material error is shown.” *Id.* at 9. The Petition constitutes a mere recapitulation of prosecution at step one and identifies no legitimate error at step two.

The Board set out a non-exclusive list of factors to aid in evaluating each of these steps in *Becton, Dickinson & Co. v. B. Braun Melsungen AG*:

- a. the similarities and material differences between the asserted art and the prior art involved during examination;
- b. the cumulative nature of the asserted art and the prior art evaluated during examination;
- c. the extent to which the asserted art was evaluated during examination, including whether the prior art was the basis for rejection;
- d. the extent of the overlap between the arguments made during examination and the manner in which Petitioner relies on the prior art or Patent Owner distinguishes the prior art;
- e. whether Petitioner has pointed out sufficiently how the Examiner erred in its evaluation of the asserted prior art; and
- f. the extent to which additional evidence and facts presented in the Petition warrant reconsideration of the prior art or arguments.

IPR2017-01586, Paper 8 at 17-18 (PTAB Dec. 15, 2017), 17-18 (precedential as to § III.C.5, first paragraph). The Board has further clarified its analysis of these criteria: “If, after review of factors (a), (b), and (d), it is determined that the same or substantially the same art or arguments previously were presented to the Office, then

factors (c), (e), and (f) relate to whether the petitioner has demonstrated a material error by the Office.” *Advanced Bionics*, IPR2019-01469, Paper 6 at 10.

Every ground Padagis advances holds that the claims of the '786 Patent are purportedly obvious over PCT and Meezan for the same reasons the petitioner in the '876 IPR argued.² But not only were both *references* before the Office during prosecution of the '786 Patent, so was the *entire record* of the '876 IPR where the prior petitioner had prevailed. The Examiner was already familiar with this proceeding, having previously examined Neurelis's '414 Patent, which is a child of the '786 Patent. During his previous examination of the '414 Patent, the Examiner discussed with Neurelis's counsel both the art and the arguments advanced in the '876 IPR. He allowed the claims, specifically finding that the '414 Patent's claims are entitled to March 28, 2008 priority date of the '558 Provisional. The Examiner acknowledged that this outcome differed from the '876 IPR because the claims of the '414 Patent were different than those of the '876 Patent. That reasoning applies equally to the claims of the '786 Patent. Padagis fails to offer a legitimate explanation of any error in the Office's allowance. There was none; the petition should be denied.

² As noted above, the Petition adds to Gwozdz PCT and Meezan the disclosures of Cartt (for claims 20-21) and USP 23/NF 18 (for claims 26-27).

**1. The Exact Same Art and Substantially the Same Arguments
Were Presented to the Examiner**

- a) *Becton factor (a)*: the similarities and material differences between the asserted art and the prior art involved during examination and *Becton factor (b)*: the cumulative nature of the asserted art and the prior art evaluated during examination

The art on which this Petition relies – Gwozdz PCT and Meezan – is not merely cumulative, it is ***identical*** to what the Examiner reviewed during prosecution of the '786 Patent. Neurelis provided both Gwozdz PCT and Meezan, as well as Cartt, to the Examiner upon filing the application. EX1002, 493-94, 499. Padagis concedes as much. Petition, 67. And while USP 23/NF 18 was not before the Office, it is merely a tertiary reference pertinent solely to claims 26-27. What Padagis omits from the Petition is that Neurelis also submitted the entire record from the '876 IPR on which the Petition relies, including the '876 IPR Petition, Petitioner and Patent Owner briefs, expert declarations and other exhibits, Institution Decision and requests for rehearing of it, the Final Written Decision, and appellate briefs. *Id.*, 487-515. Examiner Milligan considered all those documents. *Id.*, 72-100.

These factors strongly favor Neurelis.

- b) *Becton factor (d)*: the extent of the overlap between the arguments made during examination and the manner in which Petitioner relies on the prior art

Padagis's argument of obviousness based on Gwozdz PCT and Meezan closely follows the argument made in the '876 IPR based on the same art – so closely, in fact, that Padagis asserts collateral estoppel. While there are issues on which collateral estoppel does not apply (some of which are discussed in Section IV(C), below), the arguments in the '876 IPR and this Petition closely parallel each other. Those arguments were presented in full to the Office in the form of the '876 IPR petition, responses, Board findings, and briefs. Moreover, the file history shows that the Office was well aware of the potential to assert obviousness based on Gwozdz PCT, but after review did not do so.

This factor strongly favors Neurelis as well.

2. Padagis Fails to Identify Material Error by the PTO

Under *Advanced Bionics*, the petitioner bears the burden of showing that the Office erred in evaluating the art and arguments. *See Advanced Bionics*, IPR2019-01469, Paper 6 at 8-9 (“If reasonable minds can disagree regarding the purported treatment of the art or arguments, it cannot be said that the Office erred in a manner material to patentability.”). Padagis has not carried its burden.

- a) *Becton factor (c)*: the extent to which the asserted art was evaluated during examination, including whether the prior art was the basis for rejection

While Padagis concedes the same art was before the Office, Padagis omits the fact that the very *arguments* it now advances, as stated in the record of the '876 IPR,

were also before the Office. The submitted record included every brief, petition, and opposition filed by either the petitioner or patent owner in the '876 IPR and its appeal to the Federal Circuit. EX1002, 374-94. These documents extensively discuss Gwozdz PCT, Meezan, Cartt, the priority date, and other obviousness arguments that were made against the '876 Patent. Padagis argues that the Office did not consider the art and arguments made in this Petition because it issued no rejection based on the combination of Gwozdz PCT and Meezan (with or without Cartt) during prosecution of the '786 Patent. Petition, 67. But this argument ignores the Office's detailed explanation not only that it considered this art, but that it considered the same obviousness argument, discussed that argument with Neurelis's counsel, and found that the claims were patentable.

Specifically, both the obviousness argument on which Padagis relies (Gwozdz PCT and Meezan) and the '876 IPR were discussed during an interview on November 5, 2021 in the prosecution of Neurelis's '414 Patent. EX1004, 29. In particular, the Examiner commented that he considered "the obviousness rejections presented by the BPAI in the IPR of" the '876 Patent, which relied on the same Gwozdz PCT and Meezan art on which Padagis relies here. *Id.* He also stated that he "would have included" the same rejections to the then-pending '414 Patent claims if "priority to the provisional did not exist." *Id.*

Further, the question of whether priority to the '558 Provisional had been perfected was also specifically discussed. *Id.* (“Examiner discussed the priority of the recitation of n-dodecyl beta-D-maltoside. Applicant[']s representative pointed out where Applicants believed that priority existed in the priority documents.”). The Examiner concluded that Neurelis had perfected priority for the claims issuing in the '414 Patent because those claims “are considered to be supported in the priority documents” and therefore “receive a priority date of March 28, 2008. As such, Gwozdz [PCT] . . . does not qualify as prior art.” EX1004, 27-28.

Every claim of the '786 Patent – like those of the '414 Patent before it – requires n-dodecyl beta-D-maltoside. The same Examiner reviewed the '786 Patent as had previously reviewed the '414 Patent. His reasoning with respect to the '414 Patent applies equally to the claims of the '786 Patent.

Furthermore, the Examiner issued a rejection during prosecution of the '786 Patent based on the same Meezan prior art on which the instant Petition relies. *See* EX1002, 65.

This factor strongly favors Neurelis.

- b) *Becton factor (e)*: whether Petitioner has pointed out sufficiently how the Examiner erred in its evaluation of the asserted prior art

Padagis asserts essentially that the Examiner erred in examining the '786 Patent because he came to a different conclusion than the Board had done in the '876

IPR. Petition, 67-68. But this was no error given that the claims of the '786 Patent differ from those of the '876 Patent, requiring a different priority analysis, as detailed in Section IV(C)(1), below. Briefly, the Board in the '876 IPR found that every claim of the '876 Patent requires "an alkyl glycoside," where "alkyl glycoside" refers to a genus of compounds. EX1040, 14, n.6. None of the claims of the '786 Patent recite or otherwise require "alkyl glycoside." Rather, every claim of the '786 Patent recites "n-dodecyl beta-D-maltoside." Unlike the term "alkyl glycoside," the '558 Provisional indisputably sets forth verbatim support for n-dodecyl beta-D-maltoside. EX1008, 30. Consequently, the claims of the '786 Patent are entitled to the '558 Provisional's filing date, regardless of any outcome in the '876 IPR.

In fact, the arguments this Petition advances have been before the Office a second time, before a second Examiner, and for a second time they similarly were dismissed. In prosecuting a subsequent Neurelis patent application covering pharmaceutical compositions for intranasal administration containing diazepam and n-dodecyl beta-D-maltoside (Application No. 18/782,666, "'666 Application," EX2009, now U.S. Patent No. 12,268,664), Neurelis not only presented to the Examiner the same Gwozdz PCT and Meezan art and the '876 IPR arguments on which this Petition relies, but also *this Petition itself and select supporting documents*. EX2010, 63-71. A second Examiner allowed the claims over this

material, corroborating that there was no error in the findings during prosecution of the '786 Patent.

This factor strongly favors Neurelis.

- c) *Becton factor (f)*: the extent to which additional evidence and facts presented in the petition warrant reconsideration of the prior art or arguments

Padagis cites no new evidence or facts in this Petition or its supporting expert declaration to explain why reconsideration of the Examiner's allowance of the '786 Patent is warranted. Yet, in comparison to the '876 IPR, there is additional objective evidence of nonobviousness that tilts this factor in Neurelis's favor. Since that time Neurelis's Valtoco product has obtained FDA approval. Every challenged claim of the '786 Patent covers Valtoco. The product was awarded Orphan Drug Exclusivity because it possesses clinical superiority and provides "a major contribution to patient care." 21 C.F.R. §316.3(b)(3)(iii); EX2001, 4. This superiority has met with industry praise and has supported substantial commercial success:

- "On the basis of pharmacokinetic results, tolerability and safety, [Valtoco®] diazepam nasal spray has the potential to be a game-changing treatment" for acute repetitive seizures. EX2011, 14.
- Valtoco® is ideal for self-administration outside of a hospital setting. EX2012, 2. It "shows predictable pharmacokinetics and represents a potential novel therapeutic approach to control bouts of increased seizure activity (cluster seizures,

acute repetitive seizures).” *Id.* at 7. “Prior to Valtoco[®], rectal diazepam gel [and Nayzilam[®] were] the only FDA-approved rescue medication for seizure clusters. The intranasal administration of Valtoco[®] is more desirable by patients and has less variability than the rectal gel.” *Id.* “This new intranasal form of diazepam will help improve the lives of patients suffering with epilepsy.” *Id.* at 13.

This factor favors Neurelis.

Every *Becton* factor favors Neurelis. By design, Padagis relies on the same art and arguments that the Examiner already considered. Nowhere does Padagis provide a legally-correct reason the examiner erred, nor additional facts that could warrant the Office revisiting allowance of this patent. The Petition should be denied.

C. The Director Should Deny Institution Because the Unpatentability Challenge of the Petition Is Weak and Based on Compromised Expert Testimony

The Stewart Memorandum guides the parties to address other considerations that may be relevant to the Director's consideration of discretionary denial. Amongst those considerations are “[t]he strength of the unpatentability challenge” and “[t]he extent of the petition's reliance on expert testimony.” Stewart Memorandum, 2-3. As Neurelis's Preliminary Response will detail, on the merits this Petition is weak because the principal reference on which it relies, Gwozdz PCT, is not prior art given that the '786 Patent claims are entitled to the priority date of

the '558 Provisional. The Petition also falters because the only evidence it advances for a motivation to combine Gwozdz PCT with Meezan is not prior art regardless of what priority date is accorded to the '786 Patent.

The expert testimony submitted to support the Petition ultimately detracts from it. In substantial and important parts, Padagis's Donovan Declaration was copied from declarations by other experts in the '876 IPR, and already considered by the Office in granting the '786 Patent. And other key passages simply provide *ipse dixit* testimony without supporting evidence, which the Board's precedent mandates should carry little weight.

1. Gwozdz PCT Is Not Prior Art Because the '786 Patent Perfected Priority to the '558 Provisional

Both the '786 Patent and Gwozdz PCT claim priority to separate provisional applications filed in concert on the same day: March 28, 2008. The only challenge the Petition makes to the '786 Patent's priority claim is to argue that the '558 Provisional does not disclose the "n-dodecyl beta-D-maltoside" limitation that every claim of the '786 Patent requires. First the Petition argues that Neurelis is collaterally estopped from disputing that the '558 Provisional "does not provide adequate written description support for the 'alkyl glycoside' limitation." Petition, 8-9. But this issue is irrelevant because no claim of the '786 Patent recites or requires the inclusion of "alkyl glycoside." Rather, every claim requires n-dodecyl beta-D-

maltoside. There is verbatim support for n-dodecyl beta-D-maltoside in the '558 Provisional. Thus, for the same reason that the Office explicitly found priority support for the claims of the '414 Patent, the claims of the '786 Patent are “supported in the priority documents” and therefore “[t]he instant claims receive a priority date of March 28, 2008.” EX1004, 27-28.

Padagis alternatively argues that the verbatim incorporation of “n-dodecyl beta-D-maltoside” in the '558 Provisional by reference to the Sigma Catalogue (EX1026) – to supply the supporting disclosure for “n-dodecyl beta-D-maltoside.” Petition, 14-16. Not only is there no rule against a provisional providing disclosure through incorporation by reference – the MPEP *approves* of doing just that:

The limitations on the material which may be incorporated by reference in U.S. patent applications which are to issue as U.S. patents do not apply to applications relied on only to establish an earlier effective filing date under 35 U.S.C. 119 or 35 U.S.C. 120. Neither 35 U.S.C. 119(a) nor 35 U.S.C. 120 places any restrictions or limitations as to how the claimed invention must be disclosed in the earlier application to comply with 35 U.S.C. 112(a). Accordingly, ***an application is entitled to rely upon the filing date of an earlier application, even if the earlier application itself incorporates essential material by reference to another document.*** See *Ex parte Maziere*, 27 USPQ2d 1705, 1706-07 (Bd. Pat. App. & Inter. 1993).”

MPEP 608.01(p)(I)(B) (emphasis added). Accordingly, the claims of the '786 Patent are entitled to the priority date of the '558 Provisional, and therefore Gwozdz PCT is not prior art to those claims.

2. The Motivation to Combine the Petition Advances Is Not Prior Art

The Petition contends that Gwozdz PCT includes every element of the challenged claims except for n-dodecyl beta-D-maltoside, which, indisputably, Gwozdz PCT does not disclose. For this missing element, the Petition relies on Meezan. But the sole evidence the Petition cites to establish that a skilled artisan would have had a motivation to combine Gwozdz PCT with Meezan is a statement *not* from the Gwozdz Provisional, but instead the later-filed Gwozdz PCT application. Padagis argues that Gwozdz PCT suggests that “penetration enhancers” could be added to certain embodiments of the disclosed formulations. (Petition, 29, 31-32, 41). But this citation and this subject matter were first disclosed not in March 2008 but in March 2009 (*i.e.*, the March 27, 2009 PCT application, EX1064). The March 2008 Gwozdz Provisional application to which Gwozdz PCT claims priority (EX1009) does not disclose this subject matter.

A provisional application must provide support for subject matter carried forward into a published application and used in a patentability challenge for that subject matter to be entitled to the filing date of the provisional. *See In re Riggs*, 131 F.4th at 1384-85. The subject matter of Gwozdz PCT mentioning “penetration enhancers” *was not present* in the Gwozdz Provisional. Therefore, the earliest priority date that can be accorded to that subject matter is March 27, 2009 – the filing

date of Gwozdz PCT. Since the Petition does not argue for an effective filing date of the '786 Patent claims any later than the March 27, 2009 filing date of the '439 Application, this "penetration enhancer" subject matter is not prior art regardless of which priority date is accorded the '786 Patent. And since this subject matter provides the sole evidence for a motivation to combine, the Petition should be denied. *See Virtek Vision Int'l ULC v. Assembly Guidance Sys, Inc.*, 97 F.4th 882, 888 (Fed. Cir. 2024) ("It does not suffice to simply be known. A reason for combining must exist.").

3. The Petition Relies on Compromised Expert Witness Testimony

a) Padagis's Donovan Declaration Copies from Expert Declarations in the '876 IPR

Not merely content to copy the invalidity allegations the prior petitioner made in the '876 IPR, Padagis also cribbed substantial portions of the prior petitioner's expert declarations and included them in the Donovan Declaration submitted to support this Petition. This conduct illuminates how little weight the Board and the Director should put on the Donovan Declaration and on the statements in the Petition that rely upon it for support.

Four specific examples serve to illustrate. In each instance, Dr. Donovan's Declaration was compared to either Dr. Peppas's or Dr. Wermeling's declarations

from the '876 IPR.³ At almost the very beginning of the Donovan Declaration, the summary of the opinion is copied nearly verbatim from Dr. Peppas:

I have been asked to provide my opinion in regards to the state of technology relevant to the ~~'876~~'786 Patent's disclosure and its claims based on knowledge existing prior to March 27, 2009, prior to June 14, 2011, and prior to December 13, 2011.

I have been asked to provide my opinion regarding whether one of ordinary skill in the art at the relevant time would have understood that certain prior art references, alone or in combination, disclose or teach each of the elements and limitations recited in the claims of the ~~'876~~'786 Patent. I have also been asked to provide my opinion regarding whether a person of ordinary skill in the art (a ~~"POSITA"~~"POSITA POSA") would have been motivated or had a rationale or reason to modify or combine those certain prior art references to arrive at the elements recited in the claims of the ~~'876~~'786 Patent. In my opinion, the references discussed below disclose or teach each of the elements and limitations recited in the claims of the ~~'876~~'786 Patent, and a ~~POSITA~~POSITA POSA would have had a strong rationale to combine the references.

EX1062, ¶¶3-4; EX2007, ¶¶ 2-3. On the key issue addressed at length above on whether the '786 Patent is entitled to claim priority to the '558 Provisional, the Donovan Declaration borrows heavily again from Dr. Peppas:

In my opinion, the first mention, disclosure, and written support of alkyl glycosides~~(or any particular species thereof, e.g., specifically n-dodecyl beta-D-maltoside)~~ is in the ~~'439~~'439 ~~A~~application, filed on March 27, 2009. ~~In my further opinion~~See, e.g., '439 Application, Ex. 1039, ¶¶ 018, 043, 047, 056. Conversely, the ~~'558~~'558 Provisional does not

³ The text they have in common is in black type. Text removed from the Aquestive declarations is in red type. Text added in the Donovan Declaration is in blue type. The comparisons were generated using a tool provided by Litera that is integrated into Microsoft Word.

mention, disclose, or provide any written support for alkyl glycosides (or any particular species thereof, e.g., dodecyl maltoside).

EX1062, ¶46; EX2007, ¶68. On a central question relevant to obviousness – a skilled artisan's understanding and view on modifying the prior art – again, Dr. Donovan quotes Dr. Peppas all-but-verbatim:

A ~~POSITA~~POSA would easily be able to understand the references discussed below, would easily be able to draw inferences from these references, and would also be able to easily modify these references (including conducting routine experiments based on their singular and/or combined teachings).

EX1062, ¶79; EX2007, ¶170. Notably, “the references discussed below” were not even identical as between the two declarations. Later, Dr. Donovan parrots Dr. Wermeling in addressing the key issue of whether a skilled artisan would have had a reasonable expectation of successfully combining Gwozdz PCT with the penetration enhancer of Meezan:

Additionally, it is well-known that larger molecules inherently have a more difficult time crossing the cell membrane than do smaller molecules, ~~and therefore, the improvement in transmembrane efficiency is inherent~~. If a ~~penetration~~permeation enhancer increases penetration for a large molecule, it will be expected to also increase penetration for a small molecule, simply because molecular size ~~is~~can be one of the primary constraints ~~for~~ ~~of~~ passing through and between epithelial cells.

EX1062, ¶111; EX2008, ¶149.

While it certainly is true that other portions of the Donovan Declaration were written anew, this practice of cloning previous opinions discredits the value of Dr.

Donovan's opinions (whichever are actually *her* opinions, that is). Moreover, taking opinions from other experts (where the Office already considered those opinions in granting the '786 Patent) and folding them into a declaration from a new expert does not make the opinions new.

b) Important Passages of the Donovan Declaration Are Unsupported by Evidence

Further eroding the value of the Donovan Declaration is the fact that many of the stated opinions lack any evidentiary basis in the prior art. 35 U.S.C. §311(b) permits petitioners to request cancellation of claims for alleged unpatentability “only on the basis of prior art” – not on the unsupported say-so of expert witnesses. Accordingly, conclusory declaration testimony lacks the foundation in the prior art that can justify reliance on it. *See* 37 C.F.R. §42.65(a) (“Expert testimony that does not disclose the underlying facts or data on which the opinion is based is entitled to little or no weight.”). With respect to several important issues Dr. Donovan's Declaration fails to root itself in the evidence as both the statute and regulations require.

For example, whether the composition of the claimed pharmaceutical solution would have been obvious is the central question the Petition poses. Amongst the key contributions the inventors made was the observation that a solution of vitamin E and alcohols could yield a stable, concentrated solution of diazepam suitably

tolerable for nasal administration. Dr. Donovan minimizes that contribution by offering the following:

Due to the water insoluble nature of benzodiazepines, a common approach to nasal delivery formulation is to employ organic solvents or co-solvents with or without water. While there is a risk of transient irritation from such formulations, the risk-benefit assessment clearly still favors use of such products in treatment of life-threatening circumstances such as seizures.

EX1062, ¶71. (Notably, this paragraph was copied essentially verbatim from Dr. Wermeling, EX2008, ¶77.) No prior art is cited to support either the proposition that use of organic solvents (such as alcohols) was “a common approach,” or the proposition that “the risk-benefit assessment” favors using even poorly-tolerated products. The Petition then relies on this unsupported testimony to help argue obviousness. Petition, 19.

Another key question the Petition poses is whether a skilled artisan would have expected that combining the formulation of Gwozdz PCT (assuming Gwozdz PCT to be prior art, which it is not) with the absorption enhancers of Meezan. On this question Dr. Donovan muses:

Additionally, it is well-known that larger molecules inherently have a more difficult time crossing the cell membrane than do smaller molecules. If a permeation enhancer increases penetration for a large molecule, it will be expected to also increase penetration for a small molecule, simply because molecular size can be one of the primary constraints for passing through and between epithelial cells.

EX1062, ¶111. The Petition repeats this conclusory assertion essentially verbatim. Petition, 32-33. Setting aside whether this grossly overbroad statement is accurate (it is not), Dr. Donovan cites nothing to support it. The Petition takes her at her word, and tacitly asks the Board to do the same. But the Federal Circuit's precedent and that of the Board both hold that such conclusory statements carry little weight. *See Xerox*, IPR2022-00624, Paper 9 at 15-16 (citing Federal Circuit cases). This rule is particularly germane when the expert is merely quoting what the lawyers have said in the Petition. *Id.* at 16.

Under any lens, this is a substantively weak petition supported by a compromised expert declaration. Institution should be denied.

V. CONCLUSION

For the foregoing reasons, Neurelis respectfully requests that the Director exercise discretion and deny institution of Padagis's proposed ground for *inter partes* review.

Patent Owner's Request for Discretionary Denial of Institution
of Petition for *Inter Partes* Review
Patent No. 11,793,786

Respectfully submitted,

Date: May 15, 2025

/Michael Sitzman/
Michael Sitzman (Reg. No. 42,150)
MCDERMOTT WILL & EMERY LLP
415 Mission St Suite 5600
San Francisco, CA 94105-2616
Telephone: +1 628 218 3917
msitzman@mwe.com

Attorney for Patent Owner Neurelis, Inc.

CERTIFICATION OF WORD COUNT

The undersigned hereby certifies that the portions of the above-captioned PATENT OWNER'S REQUEST TO THE DIRECTOR FOR DISCRETIONARY DENIAL OF INSTITUTION specified in 37 C.F.R. § 42.24 have 11,598 words, in compliance with the 14,000 word limit set forth in 37 C.F.R. § 42.24. This word count was prepared using Microsoft Word 365 V.2202.

Date: May 15, 2025

/Michael Sitzman/
Michael Sitzman (Reg. No. 42,150)
MCDERMOTT WILL & EMERY LLP
415 Mission St Suite 5600
San Francisco, CA 94105-2616
Telephone: +1 628 2183917
msitzman@mwe.com

Attorney for Patent Owner Neurelis, Inc.

CERTIFICATION OF SERVICE

The undersigned hereby certifies that the foregoing PATENT OWNER'S REQUEST TO THE DIRECTOR FOR DISCRETIONARY DENIAL OF INSTITUTION and all supporting EXHIBITS 2001-2013 were served by filing the documents through the Patent Trial and Appeal Case Tracking System (P-TACTS) and courtesy copies were also served via electronic mail, in their entireties on the following:

James P. Murphy
Reg. No. 55,474
Polsinelli PC
1000 Louisiana Street
Suite 6400
Houston, Texas 77002
Tel: (713) 374-1600

jpmurphy@polsinelli.com

*Counsel for Petitioner
Padagis US LLC*

Date: May 15, 2025

Corey Casey
Reg. No. 66,950
Polsinelli PC
900 West 48th Place
Suite 900
Kansas City, Missouri 64112
Tel: (816) 572-4439

ccasey@polsinelli.com

/Michael Sitzman/
Michael Sitzman (Reg. No. 42,150)
MCDERMOTT WILL & EMERY LLP
415 Mission St Suite 5600
San Francisco, CA 94105-2616
Telephone: +1 628 2183917
msitzman@mwe.com

Attorney for Patent Owner Neurelis, Inc.