UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Padagis US LLC,
Petitioner

v.

Neurelis, Inc.,
Patent Owner

Case No. IPR2025-00464
Patent No. 8,895,546

PATENT OWNER'S MOTION FOR LEAVE TO FILE PETITION FOR CERTIFICATE OF CORRECTION

TABLE OF CONTENTS

TABLE OF CONTENTS i
TABLE OF AUTHORITIES ii
EXHIBIT LIST iv
I. INTRODUCTION 1
II. LEGAL BACKGROUND 2
III. THE CLAIMED INVENTIONS ARE THE SUBJECT OF A TIMELY, WRITTEN JRA 4
A. Questcor and PSI's Joint Research Agreement 4
B. The '558 Provisional was Filed on March 27, 2008 5
C. Assignment of the JRA to HBV and Subsequently to Neurelis 5
IV. IF GRANTED BY THE DIRECTOR, THE REQUESTED CORRECTION WILL ALLOW THE BOARD TO DETERMINE THE APPLICABILITY OF THE SECTION 103 SAFE HARBOR 6
V. THE BOARD SHOULD GRANT NEURELIS LEAVE TO SEEK A COC OF THE '546 PATENT TO DISCLOSE THE JRA 7
A. The Rules Expressly Permit Correction to Disclose a JRA 7
B. Neither the Board nor Petitioner Will Suffer Cognizable Prejudice 8
VI. CONCLUSION 10
CERTIFICATE OF COMPLIANCE 12
CERTIFICATE OF SERVICE 13

TABLE OF AUTHORITIES

Page(s)

Cases

Arkema Inc. v. Honeywell Int'l Inc.,
PGR2016-00011, Paper 77 (P.T.A.B Apr. 27, 2020) 3

Commonwealth Sci. & Indus. Res. Org. v. BASF Plant Science GmbH,
PGR2020-00033, Paper 26 (Mar. 18, 2021) 3, 8

E.I. du Pont de Nemours & Co. v. MacDermid Printing Sols., L.L.C.,
525 F.3d 1353 (Fed. Cir. 2008) 8

Honeywell Int'l Inc. v. Arkema Inc.,
939 F.3d 1345 (Fed. Cir. 2019) 2, 3, 8

Neurelis, Inc. v. Padagis LLC et al.,
1:24-cv-00562 (D. Del.) 9

Statutes

35 U.S.C. § 102 ..... 2, 6

35 U.S.C. § 103 ..... *passim*

35 U.S.C. § 255 ..... 1, 2, 7

Other Authorities

37 C.F.R. § 1.323 ..... 1, 2, 7

37 C.F.R. § 1.71(g)(3) 1, 7

37 C.F.R. § 1.9(e) 7

37 C.F.R. § 42.20(b) 2

150 Cong. Rec. S7520-05 (2004) 5

H.R. Rep. No. 108-425 (2004) 2, 5

MPEP § 1485 2

MPEP § 2146.02 7

EXHIBIT LIST

Exhibit	Description
2001	*Clinical Superiority Findings*, 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 *Neurelis, Inc. v. Padagis LLC*, 1:24-cv-00562, D.I. 20 (D. Del. Aug. 28, 2024)
2003	Preliminary Invalidity Contentions served in *Neurelis, Inc. v. Padagis LLC*, 1:24-cv-00562 (D. Del. Dec. 20, 2024)
2004	Markman Order entered in *Gilead Sciences, Inc. v. Lupin Ltd.*, 1:22-cv-00615-MN, D.I. 280 (D. Del. Feb. 21, 2025)
2005	Markman Order entered in *Spinal Generations, LLC v. Depuy Synthes, Inc.*, 1:22-cv-01368 (MN), D.I. 147 (D. Del. Oct. 16, 2024)
2006	Orange Book Listing for U.S. Patent No. 8,895,546
2007	Declaration of Nicholas A. Peppas, Sc.D., dated December 6, 2018 in *Aquestive Therapeutics, Inc. v. Hale Biopharma Ventures, LLC*, IPR2019-00451, Exhibit 1041 (Jan. 29, 2019)
2008	Declaration of Daniel P. Wermeling, Pharm.D., dated January 27, 2020 in *Aquestive Therapeutics, Inc. v. Hale Biopharma Ventures, LLC*, IPR2019-00451, Exhibit 1150 (Jan. 28, 2020)
2009	NOT USED
2010	NOT USED
2011	NOT USED
2012	NOT USED
2013	Scheduling Oral Order entered in *Neurelis, Inc. v. Padagis LLC*, 1:24-cv-00562, D.I. 47 (D. Del. March 11, 2025)

	Order Granting Stipulation to Extend Certain Fact Discovery Deadlines entered in *Neurelis, Inc. v. Padagis LLC*, 1:24-cv-00562, D.I. 65 (D. Del. May 15, 2025)
2014	Jacqueline A. French, Timothy A. Pedley, *Initial Management of Epilepsy*, New England Journal of Medicine 2008; 359:166-76 ("French & Pedley 2008")
2015	Penovich et al., *Burden of Seizure Clusters on Patients With Epilepsy and Caregivers*, The Neurologist 2017; 22: 207-214
2016	Cloyd et al., *Overcoming the Challenges of Developing an Intranasal Diazepam Rescue Therapy for the Treatment of Seizure Clusters*, Epilepsia 2021; 62:846-856
2017	Hogan, R.E., et al., *Bioavailability and Safety of Diazepam Intranasal Solution Compared to Oral and Rectal Diazepam in Healthy Volunteers*, Epilepsia, 61:455-464 (Feb. 2020)
2018	Lindsay M. Higdon and Michael R. Sperling, *A Review of a Diazepam Nasal Spray for the Treatment Of Acute Seizure Clusters and Prolonged Seizures*, J Expert Review of Neurotherapeutics 2021; 21(11):1207-1212
2019	Bechgaard et al., *Solubilization of Various Benzodiazepines for Intranasal Administration, a Pilot Study*, Pharmaceutical Development and Technology 1997; 2(3):293-296
2020	Gizurarson, S., et al., *Intranasal Administration of Diazepam Aiming at the Treatment of Acute Seizures: Clinical Trials in Healthy Volunteers*, Biol. Pharm. Bull., 22(4):425-427 (Apr. 1999)
2021	Ivaturi, V.D., et al., *Bioavailability and Tolerability of Intranasal Diazepam in Healthy Adult Volunteers*, Epilepsy Res., 84:120-126 (2009)
2022	Schrier, L., et al., *Pharmacokinetics and Pharmacodynamics of a New Highly Concentrated Intranasal Midazolam Formulation for Conscious Sedation*, Brit. J. Clin. Pharmacol., 83:721-731 (Apr. 2017)

2023	Penovich et al., *Benzodiazepines for the Treatment of Seizure Clusters*, CNS Drugs 2024; 38:125-140
2024	Kapoor et al., *A Review of Intranasal Formulations for the Treatment of Seizure Emergencies*, Journal of Controlled Release 2016; 237: 147-159
2025	Rabinowicz et al., *Improvement of Intranasal Drug Delivery with Intravail® Alkylsaccharide Excipient as a Mucosal Absorption Enhancer Aiding in the Treatment of Conditions of the Central Nervous System*, Drugs in R&D 2021; 21:361-369
2026	Acorda Therapeutics, Letter to Plumiaz Clinical Trial Participants, May 20, 2016
2027	U.S. Patent No. 6,193,985 ("Sonne")
2028	NOT USED
2029	NOT USED
2030	Written joint research agreement, titled "Master Service Agreement" (7 pages), between Particle Sciences, Inc. and Questcor Pharmaceuticals, Inc., dated April 1, 2007 **[FILED UNDER SEAL]**
2031	Asset Purchase Agreement between Hale BioPharma Ventures, LLC and Questcor Pharmaceuticals, Inc., dated June 27, 2008 **[FILED UNDER SEAL]**
2032	H.R. Rep. No. 108-425 (2004)
2033	150 Cong. Rec. S7520-05 (2004)

I. INTRODUCTION

As authorized by the Board (Paper 23), Neurelis, Inc. ("Neurelis" or "Patent Owner") moves for leave to petition the Director of the U.S. Patent and Trademark Office for a certificate correcting U.S. Patent No. 8,895,546 (EX1001) (the "'546 Patent") to include a disclosure of a joint research agreement ("JRA") as set forth in 35 U.S.C. § 103(c)(3) (hereinafter, "Section 103"). *See* 35 U.S.C. § 103(c)(2)(C) (pre-AIA); 35 U.S.C. § 255; 37 C.F.R. §§ 1.323, 1.71(g)(3). Patent Owner has filed substantively identical motions in IPR2025-00465 and IPR2025-00466, merely updating them with exhibit numbering for the respective proceeding.

The JRA was entered into by and between Particle Sciences, Inc. ("PSI") and Questcor Pharmaceuticals, Inc. ("Questcor"),[1] and the JRA was in effect prior to March 28, 2008, which is the earliest claimed priority date of the '546 Patent.[2] The correction to the specification was necessitated by the Board instituting trial based

[1] Questcor is the predecessor in interest to Hale BioPharma Ventures ("HBV"), which is the predecessor in interest to Neurelis, the Patent Owner.

[2] The parties dispute whether the '546 Patent traces priority to 3/27/2009 (first non-provisional) or 3/28/2008 (provisional), but in any event, the JRA predates both.

on the primary reference WO 2009/120933 (EX1009) ("Gwozdz-PCT"),[3] which was owned and filed by Neurelis's joint-research partner PSI, and Gwozdz-PCT is asserted to be prior art solely under 35 U.S.C. § 102(e) (pre-AIA). To the extent Gwozdz-PCT qualifies as prior art—which Patent Owner disputes—Gwozdz-PCT cannot be used for obviousness because it resulted from the activities undertaken by PSI within the scope of the JRA. Accordingly, the amendment is requested to comply with 35 U.S.C. § 103(c)(2)(C) and assert the safe harbor defense.

II. LEGAL BACKGROUND

This motion represents step two of a three-part process to request a certificate of correction ("CoC") during an IPR proceeding:

> [A] patent owner subject to a post-issuance review proceeding must take three steps in order to file a petition for a Certificate of Correction: (1) seek authorization from the Board to file a motion, 37 C.F.R. § 42.20(b); (2) if authorization is granted, file a motion with the Board, asking the Board to cede its exclusive jurisdiction so that the patentee can seek a Certificate of Correction from the Director, 37 C.F.R. § 1.323; MPEP § 1485; and (3) if the motion is granted, petition the Director for a Certificate of Correction under 35 U.S.C. § 255.

Honeywell Int'l Inc. v. Arkema Inc., 939 F.3d 1345, 1349 (Fed. Cir. 2019). The Board previously authorized Patent Owner to file this motion. Paper 23.

[3] Because Mr. Gwozdz is a named inventor of the '546 Patent, we refer to EX1009 as "Gwozdz-PCT" to avoid confusion between the person and the reference.

In enacting Section 103, Congress specifically granted patent owners the right to request amendment of issued patents to add the identities of parties to a JRA in order to invoke the obviousness safe-harbor provisions. *See*, 35 U.S.C. § 103(c)(2)(C) (pre-AIA) ("amended to disclose"); Ex. 2032, H.R. Rep. No. 108-425, p. 9 (2004) ("[t]his information may be . . . added by an amendment to the patent (e.g., by a certificate of correction)"). In so doing, Congress explained that "[t]he omission of the names of parties to the agreement is not an error that would justify commencement of a reissue or reexamination proceeding." *Id.*

"[A]uthority is expressly granted to the Director," rather than the Board, to decide the ultimate merits of the requested correction. *Honeywell*, 939 F.3d at 1349; *see Arkema Inc. v. Honeywell Int'l Inc.*, PGR2016-00011, Paper 77 at 11 (P.T.A.B Apr. 27, 2020). The "Board's role is simply 'to determine whether there is sufficient basis supporting Patent Owner's position that the mistake may be correctable.'" *Commonwealth Sci. & Indus. Res. Org. v. BASF Plant Science GmbH*, PGR2020-00033, Paper 26 at 4 (Mar. 18, 2021) (quoting *Honeywell*, 939 F.3d at 1349). As explained below, that standard is met, and filing the petition for correction will not result in cognizable prejudice to either the Board or Padagis US LLC ("Petitioner"). On the other hand, denying leave to file the petition to invoke the statutory protections afforded under Section 103, contravenes the statute and the

Congressional mandate, and severely prejudices Neurelis's rights. Accordingly, the Board should grant Neurelis's motion.

III. THE CLAIMED INVENTIONS ARE THE SUBJECT OF A TIMELY, WRITTEN JRA

The '546 Patent claims priority to U.S. Provisional Application No. 61/040,558 (the "'558 Provisional"), filed on March 28, 2008. Before that date, a JRA was in effect. More specifically, a written agreement existed that was entered into by Questcor and PSI for the performance of experimental, developmental, and research work in the field of the claimed invention. *See* 35 U.S.C. § 103(c)(3) (pre-AIA). Currently, however, the '546 Patent's specification does not disclose that agreement, which is the omission Neurelis now seeks to correct.

A. QUESTCOR AND PSI'S JOINT RESEARCH AGREEMENT

Questcor and PSI worked jointly to research and develop the inventions claimed in the '546 Patent. As part of that process, the parties executed a Master Services Agreement ("MSA"), dated April 1, 2007. *See* Ex. 2030. The MSA formalized Questcor's and PSI's partnership to perform formulation work (among other things) for the Diazepam Nasal Spray Development Program (the "Program"). The MSA expressly outlined the scope and purpose of the collaboration between Questcor and PSI concerning the development of the nasal sprays that are the subject of the inventions claimed in the '546 Patent. *See* Ex. 2030, MSA, at p. 1 (providing the background and outlining the services of the MSA).

The MSA demonstrates the existence of a JRA under Section 103, because it is a written contract entered into by two or more parties for the performance of experimental, developmental, or research work in the field of the claimed invention. 35 U.S.C. §103(c)(3) (pre-AIA). Additional documents, communications, and experimental details that were shared between the parties provide further evidence that a JRA existed between Questcor and PSI. Ex. 2032, H.R. Rep. No. 108-425, p. 9 ("Congress does not intend to prescribe the specific form of the agreement parties must use to benefit from this Act nor to require the writing be contained in a single instrument."); Ex. 2033, 150 Cong. Rec. S7520-05, S7521 (2004) (statement of Sen. Hatch) ("The House indicated in its committee report that a joint research agreement may be evidenced by one or more writings.").

B. THE '558 PROVISIONAL WAS FILED ON MARCH 27, 2008

Almost one year after the MSA was signed, Questcor filed the '558 Provisional pursuant to the terms of the MSA. The '558 Provisional identifies inventors from both Questcor and PSI that worked jointly to develop the inventions disclosed therein.

C. ASSIGNMENT OF THE JRA TO HBV AND SUBSEQUENTLY TO NEURELIS

In June 2008, Questcor transferred its interest and all rights to the Program, including the inventions claimed in the '546 Patent, to HBV pursuant to an Asset Purchase Agreement ("APA") dated June 27, 2008. The JRA between Questcor and

PSI was expressly assigned to HBV. *See* Ex. 2031, APA at p. 2 (defining "Development Program"), Section 4.5 (defining "Scope of Purchased Assets") and p. 38, Schedule 2.2(a) (assigning the MSA from Questcor to HBV).

In December 2018 and February 2019, Neurelis was assigned all of the Program assets including the '546 Patent and each of the patent applications to which it claims priority (see EX1001 (codes (60, 63)), as evidenced by assignments recorded in the PTO's assignment database. *See, e.g.,* Reel/Frame Nos. 48211/0840, 48271/0304, 58369/0292, and 58369/0412.

IV. IF GRANTED BY THE DIRECTOR, THE REQUESTED CORRECTION WILL ALLOW THE BOARD TO DETERMINE THE APPLICABILITY OF THE SECTION 103 SAFE HARBOR

Petitioner has relied upon Gwozdz-PCT, which it asserts is prior art to the '546 Patent under 35 U.S.C. § 102(e)(1) (pre-AIA), in an obviousness combination. In its anticipated Response, Patent Owner will demonstrate that Gwozdz-PCT is unavailable under Section 103 because, among other reasons, the inventions of the '546 Patent were made on behalf of parties to a JRA in effect prior to the date such inventions were made. Accordingly, Neurelis seeks to ask the USPTO Director to issue a CoC to insert the following text at the beginning of the '546 Patent specification:

PARTIES TO A JOINT RESEARCH AGREEMENT

The subject matter disclosed herein was developed and the claimed

> invention was made by or on behalf of the following parties to a joint research agreement: Particle Sciences, Inc. and Questcor Pharmaceuticals, Inc. (as predecessor-in-interest to Hale BioPharma Ventures, LLC).

To request that CoC, Patent Owner moves the Board for leave to seek such correction.

V. THE BOARD SHOULD GRANT NEURELIS LEAVE TO SEEK A COC OF THE '546 PATENT TO DISCLOSE THE JRA

Patent Owner has a clear legal basis to seek the CoC during this IPR and doing so will not affect any scheduled deadlines.

A. THE RULES EXPRESSLY PERMIT CORRECTION TO DISCLOSE A JRA

USPTO regulations explicitly authorize corrections to identify the parties to a JRA. For patents that have already issued, such as the '546 Patent, Rule 1.71 provides:

> If the patent as issued does not include the names of the parties to the joint research agreement, the patent must be corrected to include the names of the parties to the joint research agreement by a certificate of correction under 35 U.S.C. 255 and § 1.323 for the amendment to be effective.

Id. § 1.71(g)(3); *see also* MPEP § 2146.02 ("It is unnecessary to file a reissue application or request for reexamination of the patent to submit the amendment and other information necessary to take advantage of pre-AIA 35 U.S.C. 103(c) as amended by the CREATE Act."). Rule 1.9(e), in turn, expansively defines a JRA to mean "a written contract, grant, or cooperative agreement entered into by two or

more persons or entities for the performance of experimental developmental, or research work in the field of the claimed invention." *See also* 35 U.S.C. § 103(c)(3) (pre-AIA) (same).

As discussed above, Patent Owner has submitted a copy of the JRA (Ex. 2030), and Patent Owner identifies the text it proposes to insert at the beginning of the '546 patent specification. The Board requires nothing more to conclude that the omission *may be* correctable. *Honeywell*, 939 F.3d at 1349; *Commonwealth Sci. & Indus. Res. Org.*, PGR2020-00033, Paper 26 at 4-5.

B. NEITHER THE BOARD NOR PETITIONER WILL SUFFER COGNIZABLE PREJUDICE

Granting Neurelis leave to request a CoC will not prejudice the Board. This IPR was instituted on September 16, 2025, leaving more than eight months before the statutory deadline for a final written decision on September 16, 2026. Patent Owner will explain in its Patent Owner Response how Gwozdz-PCT would be disqualified as obviousness prior art if the Director issues the requested CoC, and no supplemental briefing should be necessary to resolve that straightforward issue.

Nor will Petitioner suffer prejudice. The governing statutes and regulations impose no time limit on seeking a CoC. *See also E.I. du Pont de Nemours & Co. v. MacDermid Printing Sols., L.L.C.*, 525 F.3d 1353, 1362 (Fed. Cir. 2008) (noting the absence of a time period in the analogous § 254).

It should come as no surprise to Petitioner that Patent Owner could correct certain mistakes through the CoC process. Indeed, Gwozdz-PCT lists as inventors the exact same three PSI inventors that are identified on the '546 Patent—Garry Gwozdz, Andrew Loxley, and Mark Mitchnick. By relying on Gwozdz-PCT to challenge patentability, Petitioner understood Patent Owner could respond by disputing the prior art status of Gwozdz-PCT and its availability for obviousness under the Section 103 Safe Harbor defense.

Additionally, Padagis has long possessed the joint research agreement between Questcor and PSI. In fact, Neurelis produced the MSA to Padagis on December 23, 2024, in connection with ongoing litigation, before Padagis had even filed its IPR petition on January 17, 2025.[4] And six weeks later, Padagis was informed in the ongoing litigation that (i) the invention claimed in the '546 Patent was developed pursuant to the joint research agreement between Questcor and PSI; and (ii) Neurelis intended to invoke the safe harbor provisions of 35 U.S.C. § 103(c). Any claim of prejudice or lack of knowledge lacks credibility.

Moreover, Petitioner still retains an opportunity to reply. *See Scheduling Order*, Paper 18, at 2 (authorizing reply due March 24, 2026). Whether Petitioner

[4] Neurelis also produced the APA to Padagis on April 14, 2025 as part of this same litigation.

ultimately succeeds is not cognizable prejudice. Should Petitioner's opposition raise prejudice concerns, the Board can mitigate them while preserving Patent Owner's right to seek the CoC that all relevant authorities permit.

VI. CONCLUSION

Clear and controlling authority permits Neurelis to seek a certificate of correction to disclose parties to a JRA under Section 103. Exercising that right would impose no cognizable prejudice on either the Board or Petitioner. By contrast, denying Neurelis the right to seek correction to assert a Section 103 Safe Harbor defense would deprive Neurelis of its substantive right to assert such a defense. The Board should therefore grant this motion and allow Neurelis to file its CoC with the Director and pursue the correction authorized by statute, regulation, and precedent.

Respectfully submitted,

/David J. Tobin/

David J. Tobin
(Reg. No. 60,776)
MCDERMOTT WILL & SCHULTE LLP
2801 North Harwood Street, Suite 2600
Dallas, TX 75201
Tel: (214) 210-2793
dtobin@mwe.com

Counsel for Patent Owner

CERTIFICATE OF COMPLIANCE

The undersigned certifies that this paper complies with the 10-pages limit the Board set in its December 15, 2025, Order (Paper 23). The undersigned also certifies that this paper complies with the typeface requirements of 37 C.F.R. § 42.6(a)(2)(ii), because this paper was prepared using 14-point, Times New Roman proportional font, and complies with the spacing requirements of 37 C.F.R. § 42.6(a)(2)(iii).

Dated: December 23, 2025 */David J. Tobin/*

CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. §§ 42.8 and 42.6(e), the undersigned hereby certifies that the foregoing document was served on counsel of record for the Petitioner by filing this document through PTAB P-TACTS and by sending this document via electronic mail to the following addresses:

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

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

Mark Deming
Registration No. 69,263
Polsinelli PC
150 N. Riverside Plaza Suite 300
Chicago, IL 60606
mdeming@polsinelli.com

Chad A. Landon
Provisionally Recognized Pro Hac Vice
Polsinelli PC
1401 I St. NW Suite 800
Washington, DC 20005
clandmon@polsinelli.com

Dated: December 23, 2025

/David J. Tobin/
David J. Tobin
(Reg. No. 60,776)
MCDERMOTT WILL & SCHULTE LLP
2801 North Harwood Street, Suite 2600
Dallas, TX 75201
Tel: (214) 210-2793
dtobin@mwe.com

Counsel for Patent Owner