UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Padagis US LLC,
Petitioner

v.

Neurelis, Inc.,
Patent Owner

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

PATENT OWNER'S REQUEST FOR PANEL REHEARING

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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. 11,241,414
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	Application No. 18/782,666 ("'666 Application")
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2011	Sai H. S. Boddu, Sneha Kumar, A Short Review on the Intranasal Delivery of Diazepam for Treating Acute Repetitive Seizures. Pharmaceutics 2020; 12, 1167
2012	Cornett et al., VALTOCO® (Diazepam Nasal Spray) for the Acute Treatment of Intermittent Stereotypic Episodes of Frequent Seizure Activity, Neurology International 2021; 13:64–78
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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
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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	Corrected Opening Brief for Appellee Aquestive Therapeutics, Inc. in *Neurelis, Inc. v. Aquestive Therapeutics, Inc.* (Fed. Cir. 21-1038), dated March 31, 2021 (D.I. 21)
2029	Certified transcription of October 5, 2021 oral hearing in *Neurelis, Inc. v. Aquestive Therapeutics, Inc.* (Fed. Cir. 21-1038)

Exhibit	Description of Exhibits
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)
2034	Non-disclosure Agreement between Aegis Therapeutics, LLC and Questcor Pharmaceuticals, Inc., dated August 15, 2005 **[FILED UNDER SEAL]**
2035	Confidentiality Agreement between Particle Sciences, Inc. and Questcor Pharmaceuticals, Inc., dated January 19, 2007 **[FILED UNDER SEAL]**
2036	Email between Questcor Pharmaceuticals, Inc. and Aegis Therapeutics, LLC, dated February 15, 2007 **[FILED UNDER SEAL]**
2037	Quote No. QCR 135 between Particle Sciences, Inc. and Questcor Pharmaceuticals, Inc., dated March 28, 2007 **[FILED UNDER SEAL]**
2038	QSC-002 Project Email Thread between Aegis Therapeutics, LLC and Questcor Pharmaceuticals, Inc., dated March 26, 2007
2039	Redline Comparison between U.S. Patent No. 11,793,786 and U.S. Patent No. 11,241,414
2040	QC and PSI Agreement between Particle Sciences, Inc. and Questcor Pharmaceuticals, Inc., dated April 2, 2008 **[FILED UNDER SEAL]**

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2041	Letter Agreement, with Term Sheet between Neurelis, Inc. and Aegis Therapeutics, LLC, dated August 28, 2007 **[FILED UNDER SEAL]**
2042	Supply Agreement Neurelis, Inc. and Aegis Therapeutics, LLC, dated May 22, 2008 **[FILED UNDER SEAL]**
2043	License Agreement Neurelis, Inc. and Aegis Therapeutics, LLC, dated May 22, 2008 **[FILED UNDER SEAL]**
2044	Transmittal Notice of Intravail from Aegis Therapeutics, dated October 2, 2008 **[FILED UNDER SEAL]**
2045	Declaration of Steven Cartt **[FILED UNDER SEAL]**
2046	Declaration of Dr. Mark Mitchnick **[FILED UNDER SEAL]**
2047	Declaration of David Hale
2048	Redline Comparison between U.S. Patent Application No. 15/955,397 and U.S. Patent Application No. 17/228,514
2049	Marc Brown *Curriculum Vitae*
2050	Joint Claim Construction Brief, *Neurelis, Inc. v. Padagis LLC et al.*, 1:24-cv-00562, D.I. 87 (D. Del. August 15, 2025) ("Joint CC Brief")
2051	Andrew Streitwieser, INTRODUCTION TO ORGANIC CHEMISTRY (4th ed. 1992) ("Streitwieser")
2052	David W. Oxtoby et al., PRINCIPLES OF MODERN CHEMISTRY (4th ed. 1999) ("Oxtoby")
2053	European Pharmacopoeia 6.0, Vol 2 (6th ed. 2007) ("PhEur 6.0")
2054	Panayiotis P. Constantinides et al., *Advances in the Use of Tocols as Drug Delivery Vehicles*, 23 PHARM RES. 243 (2006) ("Constantinides-2006")

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2055	Rowe, Sheskey, & Owen, HANDBOOK OF PHARMACEUTICAL EXCIPIENTS, (6th ed. 2009) ("Rowe-2009")
2056	Afaf Kamal-Eldin, *Effect of Fatty Acids and Tocopherols on the Oxidative Stability of Vegetable Oils*, 108 EUR. J. OF LIPID SCI. & TECH. 1051 (2006) ("Kamal-Eldin-2006")
2057	Branka Rozman & Mirjana Gašperlin, *Stability of Vitamins C and E in Topical Microemulsions for Combined Antioxidant Therapy*, 14 DRUG DELIVERY 235 (2008) ("Rozman-2007")
2058	Afaf Kamai-Eldin & Lars-Ake Appelqvist, *The Chemistry and Antioxidant Properties of Tocopherols and Tocotrienols*, 31 LIPIDS 671 (1996) ("Kamai-Eldin-1996")
2059	March 2009 FDA Inactive Ingredient Database
2060	Redline Comparison between U.S. Patent Application No. 12/413/439 and U.S. Patent Application No. 15/955,397
2061	David Ward, *Optimizing Nasal Products for Systemic Delivery*, 106 ONDRUGDELIVERY 56 (2020) ("Ward-2020")
2062	C. Holvoet et al., *Inclusion Complexation of Diazepam with Different Cyclodextrins in Formulations for Parenteral Use*, 60 PHARMAZIE 598 (2005) ("Holvoet-2005")
2063	Sila-On et al., *Influence of Incorporation Methods on Partitioning Behavior of Lipophilic Drugs into Various Phases of a Parenteral Lipid Emulsion*, 9 PHARMSCITECH 684 (2008) ("Sila-On-2008")
2064	D. J. Van Drooge et al., *Incorporation of Lipophilic Drugs in Sugar Glasses by Lyophilization using a Mixture of Water and Tertiary Butyl Alcohol as Solvent*, 93 J. OF PHARM. SCI. 713 (2004) ("Van Drooge-2004")

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2065	L. M. A. Monzon & L. M. Yudi, *Voltammetric Analysis of Lipophilicity of Benzodiazepine Derivatives at the Water 1,2-dichloroethan Interface*, 495 J. OF ELECTROANALYTICAL CHEM. 146 (2001) ("Monzon-2001")
2066	M. Molero-Monfort et al., *Retention-activity Relationship Studies of Benzodiazepines by Micellar Liquid Chromatography*, 13 BIOMED. CHROMATOGRAPHY 394 (1999) ("Molero-Monfort-1999")
2067	M. Molero-Monfort et al., *Micellar Liquid Chromatography for Prediction of Drug Transport*, 870 J. OF CHROMATOGRAPHY 1 (2000) ("Molero-Monfort-2000")
2068	Neurelis Patent Family Tree
2069	Declaration of Mareen Donovan, Ph.D. in Support of Defendants' Responsive Claim Construction Brief, *Neurelis, Inc. v. Padagis LLC et al.*, 1:24-cv-562, D.I. 88-28 (D. Del. August 22, 2025) ("Donovan-CC Decl.")
2070	Certified transcription of December 10-11, 2025, Volume I and II Deposition of Maureen Donovan, Ph.D. in *Padagis US LLC vs. Neurelis, Inc.*, IPR2025-00464, IPR2025-00465, IPR2025-00466 ("Donovan Transcript")
2071	*What is Log P and How Does It Predict Chemical Behavior?*, BIOLOGY INSIGHTS, (August 16, 2025), https://biologyinsights.com/what-is-log-p-and-how-does-it-predict-chemical-behavior/ ("Log P")
2072	NOT USED
2073	Declaration of Marc Brown regarding U.S. Patent No. 11,241,414
2074	NOT USED
2075	NOT USED

Exhibit	Description of Exhibits
2076	Patent Owner Response, dated November 5, 2019 in *Aquestive Therapeutics, Inc. v. Neurelis, Inc.*, IPR2019-00451
2077	U.S. Patent No. 12,268,664 (the "'664 Patent")
2078	Certificate of Correction for U.S. Patent No. 12,268,664

I. INTRODUCTION

Patent Owner respectfully requests rehearing of the Panel's Decision (Paper 36, "Decision") denying Patent Owner's Motion for Leave to File Petition for Certificate of Correction (Paper 26, "MFL"). Rehearing is warranted for two independent reasons: the Panel (1) abused its discretion by addressing the merits of the certificate of correction, a task reserved for the Director; and (2) misapprehended the law and overlooked facts when addressing those merits by questioning whether addition of a JRA is a mistake of "minor" character, by finding lack of good faith, and by finding prejudice to Padagis while ignoring prejudice to Patent Owner.

II. LEGAL STANDARD

A party may file a request for rehearing without obtaining prior authorization, and the request should be granted if the movant shows that the underlying decision "should be modified." 37 C.F.R. § 42.71(d). The Panel reviews its Decision for an abuse of discretion. 37 C.F.R. § 42.71(c). An abuse of discretion occurs when a "decision … is based on an erroneous conclusion of law." *Ultratec, Inc. v. CaptionCall, LLC*, 872 F.3d 1267, 1272 (Fed. Cir. 2017).

Evidence not already of record at the time of the decision at issue may be admitted upon a showing of good cause. *Huawei Device Co., Ltd. v. Optis Cellular Tech., LLC*, IPR2018-00816, Paper 19, at 3-4 (P.T.A.B. Jan. 8, 2019) (precedential). A party seeking to admit new evidence may "argue 'good cause' exists in the

rehearing itself." *Id.* at 4. Good cause exists when the evidence is "highly relevant" to the decision under review and could not have been submitted as part of the requesting party's prior briefing on that decision. *See Dish Network L.L.C. v. Broadband iTV, Inc.*, IPR2020-01267, Paper 25 at 5 (P.T.A.B. Apr. 1, 2021).

III. IT WAS NOT THE PANEL'S PURVIEW TO ASSESS THE MERITS

The Panel exceeded its authority when denying leave to seek the Certificate of Correction, based on its view that Neurelis had not demonstrated that the omission of the JRA was "minor" or that "the mistake 'occurred in good faith.'" Decision at 7-9 (quoting 35 U.S.C. § 255). As the Federal Circuit has explained, "Section 255 does not grant the Board authority to determine whether a mistake in an issued patent is of 'minor character' or 'occurred in good faith.'" *Honeywell Int'l Inc. v. Arkema Inc.*, 939 F.3d 1345, 1349 (Fed. Cir. 2019) (quoting 35 U.S.C. § 255). "[E]valuating the merits of [the] § 255 request when [Patent Owner] was merely requesting authorization to file a motion for leave to petition the Director" was an "abuse of discretion." *Id.* at 1350. That authority belongs to the Director, who "has not delegated its Section 255 authority to the Board." *Id.* at 1349. The role of the Board is simply to "determine whether there is *sufficient basis* supporting Patent Owner's position that the mistake *may* be correctable," a much lower bar. *See id.*

The Board has interpreted that standard to mean that if "there appears to be a legitimate question as to whether the issuance of a Certificate of Correction is an

appropriate course of action," then "the logical conclusion" is that there is "a sufficient basis" and "the matter should be considered by" the Director. *Intuitive Surgical, Inc. v. Ethicon LLC*, IPR2020-00050, -00051, Paper 13 at 4-5 (P.T.A.B. Feb. 6, 2020) ("As is made abundantly clear by the Federal Circuit, it is not our purview to decide whether Patent Owner's Motion is meritorious.").

The Panel therefore exceeded its authority when it faulted Neurelis for "not identify[ing] when it first discovered the alleged mistake, much less provid[ing] any reasoned explanation for its yearslong delay in seeking to add the JRA disclosure." Decision at 9. Other panels have granted leave without requiring such an explanation because their role was "not to decide whether Patent Owner's request for a certificate of correction is meritorious"; rather, "it is up to the Director to decide whether to exercise the authority under § 255 and issue a certificate of correction." *Sandoz Inc. v. Acerta Pharma B.V.*, IPR2023-00478, Paper 17 at 22 (P.T.A.B. Aug. 7, 2023); *see also ASM IP Holding B.V. v. Kokusai Elec. Corp.*, IPR2019-00378, Paper 17 at 6 (P.T.A.B. July 5, 2019) (eight-year-delayed priority correction aimed at removing prior-art reference); *NXP USA, Inc. v. Impinj, Inc.*, IPR2020-00552, Paper 11 at 2 (P.T.A.B. July 21, 2020) (correction to perfect priority claim and render petitioner's asserted references "no longer … prior art"). So too here.

Most notably, in *Sandoz*, the Board found sufficient basis that the mistake may be correctable, despite the patent owner's motion not delineating between whether

the mistaken omission was "clerical" or "minor" or providing any meaningful good-faith analysis beyond the bare assertion that the omission was "inadvertent and made in 'good faith.'" *Sandoz*, IPR2023-00478, Paper 11 at 5-6. Here, the Panel erred by conducting a far more searching inquiry into the merits. Neurelis could not have anticipated such an inquiry, nor was such an inquiry proper, under existing law.

IV. THE PANEL MISAPPREHENDED THE LAW AND OVERLOOKED EVIDENCE

Beyond the Panel's error in assessing the merits in the first place, it also assessed the merits incorrectly, as demonstrated by the Director's recent issuance of an identical Certificate of Correction for a child of the '414 Patent.

A. ADDING REFERENCE TO A JRA IS A MISTAKE OF MINOR CHARACTER

The Federal Circuit has "interpreted the phrase 'mistake ... of minor character' of 35 U.S.C. § 255 to exclude those mistakes, the correction of which would broaden a claim." *Superior Fireplace Co. v. Majestic Prods. Co.*, 270 F.3d 1358, 1376 (Fed. Cir. 2001). Such a correction to the claims would necessitate further examination, which is more properly assessed in a reissue or reexamination. Similarly, the Director has denied correction when the resulting patent would have to be reexamined under a different legal framework. *Arkema Inc. v. Honeywell Int'l Inc.*, PGR2016-00011, EX3006 (PTAB Apr. 27, 2020); M.P.E.P. § 2146.02(III). In contrast, Neurelis seeks to add reference to a JRA in the specification to invoke the safe harbor defense of 35 U.S.C. § 103(c)(2). This correction is of "minor"

character, as a matter of law, because it would not alter the claims at all or require reexamination, unlike in the *Kingston* case the Board cites. *See Kingston Tech., Inc. v. CATR Co.,* IPR2015-00559, Paper 44 at 2 (P.T.A.B. Nov. 6, 2015).

1. <u>JRA is "minor" in character under statute and regulations</u>

Section 103(c)(2) states that patent applications can be "amended to disclose the names of the parties to the joint research agreement" and imposes no time limit on the amendment. Regulations also expressly authorize the Director to permit correction of a specification to disclose a JRA:

> The specification may disclose or be amended to disclose the names of the parties to a joint research agreement as defined in § 1.9(e).
>
> . . . . 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.

37 C.F.R. §§1.71(g)(1), (g)(3); *see also* M.P.E.P. §2146.02(III). That is dispositive.

2. <u>JRA is "minor" under a Director decision for this family</u>

Correcting a specification to add reference to a JRA has been classified as a mistake of a minor character by the Director. *See Intuitive Surgical*, IPR2020-00050, Paper 13 at 5. Indeed, the current Director confirmed this classification *in a child application to the '414 Patent*, issued after the Panel's Decision.

The same day the Panel granted authorization to file the MFL (EX3002), Neurelis asked the Director to authorize correction of U.S. Patent No. 12,268,664

('664 Patent). The '664 Patent is a descendent of the '414 and '786 Patents. *See* EX2077. This request sought precisely the same correction disclosing the same parties to the same JRA as Neurelis sought for the '414 Patent, and the Director granted the correction soon after. EX2078.

Good cause exists for the Patent Owner to submit Exhibits 2077 and 2078 ('664 Patent and COC). These materials are "highly relevant" to the decision under review and could not have been submitted as part of the MFL. *Dish Network*, IPR2020-01267, Paper 25 at 5. The Certificate of Correction for the '664 Patent issued four days *after* the Board's Decision. It is "highly relevant" to the '414 Patent, because: (a) it is a descendant application with the same specification as the '414 Patent; (b) Patent Owner sought correction of the '664 Patent the same time it sought correction of the '414 Patent; and (c) the Director granted correction, adding *identical* JRA language to the '664 Patent specification as Patent Owner seeks to add to the '414 specification. *Compare* EX2078 *with* MFL at 6-7.

Since "§ 255 authorizes the Director—not the Board—to determine whether a Certificate of Correction should be issued" (*Honeywell*, 939 F.3d at 1349), and the Director has *already decided* that this correction is proper, there can be no question that the Board's lesser *Honeywell* standard is satisfied.

3. <u>Other panels have found such corrections of "minor" character</u>

It is irrelevant that the '414 Patent is involved in an IPR proceeding and the '664 Patent is not. Prior Board decisions have granted leave to correct a patent involved in IPR by amending the specification to disclose a JRA. In *CSIRO*, the patent owner moved for leave to seek correction by providing the JRA and stated that the claimed inventions were covered by it, but did not address whether the mistake was of minor character or occurred in good faith. *Commonwealth Sci. & Indus. Res. Org. v. BASF Plant Science GmbH*, PGR2020-00033, Paper 19 at 7 (P.T.A.B. Dec. 16, 2020). The Board granted leave without ruling on those elements because "[t]he statute gives [such] authority to the Director, and the Director has not delegated this authority to the Board." *CSIRO*, Paper 26 at 4-5 (Mar. 18, 2021).

Likewise, Neurelis provided the JRA and stated that the invention was made under it, relying on "Office rules, the MPEP, and excerpts of legislative history related to pre-AIA § 103(c)(2)(C), all of which state or suggest that issued patents can be corrected to include the names of parties to a joint research agreement." Decision at 6. This showing establishes a "legitimate question" as to the correctability (*Intuitive Surgical*, IPR2020-00050, Paper 13, at 4-5) and a "*sufficient basis* … that the mistake *may* be correctable" (*Honeywell*, 939 F.3d at 1349).

The case cited by the Board is inapposite. Decision at 9 (citing *In re Arnott*, 19 U.S.P.Q.2d 1049, at *9 (Comm'r Pat. & Trademarks 1991)). *Arnott* involved an

attempt to insert a new claim into a reissued patent and expand the scope of the claims. 19 U.S.P.Q.2d 1049, at *9. *Arnott* was decided before the Federal Circuit clarified in *Superior Fireplace* that such corrections are *not* of a "minor character."

Past practice confirms that the USPTO "has previously allowed" the corrections (as in the '664 Patent), so the Board should "defer to the Director's judgment as to whether Patent Owner's proposed request should be granted." *Arkema*, PGR2016-00011, Paper 77 at 10 (citing *Honeywell*, 939 F.3d at 1350).

B. THE PANEL ERRED IN ITS GOOD FAITH ANALYSIS

Although the Panel should not have evaluated good faith (that is the Director's role), its conclusions on this element were in error. The Panel suggests that Patent Owner sat on its hands "for at least seven years" since conclusion of IPR2019-00451 ("451 IPR") before referencing the JRA in the patent specification. Decision at 8. But the Panel overlooked the prosecution history of the '414 Patent family.

On August 6, 2020, the Board issued its final written decision in the 451 IPR concerning Patent No. 9,763,876 ('876 Patent). EX1040. The '876 Patent claims were found to lack support in the '558 Provisional for the broad genus of "alkyl glycoside" required by every claim. *Id.* at 19-20. Gwozdz-PCT, consequently, was available as prior art against those claims, leading to their invalidation. *Id.* at 23.

Neurelis responded by taking corrective action to narrow its claims. In both the '414 Patent (filed as 17/332,800 on May 27, 2021) and the '786 Patent (filed as

17/228,514 on April 12, 2021), Neurelis expressly limited all claims to "n-dodecyl beta-D-maltoside." After reviewing the 451 IPR record, the Office determined that these narrower claims "are considered to be supported in the priority documents" because "[t]he provisional Application incorporates a listing of n-dodecyl β-D-maltoside by reference to a Sigma Catalog" and that "[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*." EX1002 at 27-28 (emphasis added).

The '414 Patent issued on February 8, 2022, and the '786 Patent issued on October 24, 2023. EX1001; EX1003. Neurelis relied on the Office's finding that Gwozdz-PCT was *not* prior art as fully addressing the issues raised in the 451 IPR. *See* 35 U.S.C. §282; *Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1574 (Fed. Cir. 1992) ("this presumption [of validity] is based in part on the expertise of patent examiners presumed to have done their job"). Neurelis had no need to search for JRA documents or contemplate amending the specifications of these recently issued patents to reference the JRA.

Circumstances changed when Neurelis received the Board's Institution Decision in September 2025, predicated on a preliminary finding that the '414 and '786 Patents could not claim priority to the provisional. Paper 13 at 29-30. Neurelis subsequently determined that the subject matter disclosed in Gwozdz-PCT and the subject matter recited in the '414 Patent claims were covered by a written JRA. *See*

EX2030. Far from "yearslong delay," Neurelis promptly emailed the Board on December 4, 2025, requesting authorization to file the instant motion, and concurrently sought correction of the '664 Patent. EX3002; EX2078.

The Board's concern over Neurelis's "yearslong delay in seeking to add the JRA disclosure" has already been addressed—and rejected—by the Director's approval of correction of the '664 Patent. The Director necessarily determined that any delay did not defeat the "good faith" requirement of 35 U.S.C. § 255.

The present facts are similar to those presented in *CSIRO*, in which the petitioner's opposition brief in 2020 argued that the art patent owner sought to exclude had been raised during prosecution in 2006, so the patent owner should have amended the specification then. PGR2020-00033, Paper 21 at 1-2 (Dec. 21, 2020). But the panel correctly found that evaluating the merits of that request was for "the Director—not the Board"—and granted the motion. PGR2020-00033, Paper 26 at 4 (Mar. 18, 2021). The Director approved the requested correction notwithstanding the elapse of time between 2006 and 2021. PGR2020-00033, Paper 33 (May 20, 2021). The Board here should likewise send Patent Owner's request to the Director.

V. THE PANEL ERRED IN ITS PREJUDICE INQUIRY

A. THE PREJUDICE INQUIRY IS IMPROPER

Nowhere does the statute or the regulations require consideration of prejudice in evaluating whether to grant a patent owner's MFL. Nor does mandatory authority

require such consideration. *But see* Decision at 5 (citing *Kingston*, IPR2015-00559, Paper 44 at 3). *Kingston* cites no authority for this proposition either and concerns a different situation entirely: a patent owner's attempt to change the scope of the claims. *Kingston* at 2. Such corrections are definitionally not "minor." *See Superior Fireplace* 270 F.3d at 1365-1368 (excluding claim broadening from qualifying as a "correction of a mistake of minor character."). Nor is *Honeywell* to the contrary; there, the Federal Circuit only mandated that the Board should evaluate *whether* consideration of prejudice was appropriate. 939 F.3d at 1351. It did not hold that such consideration was required.

B. PREJUDICE TO PETITIONER IS NOT DETERMINATIVE

In petitioning for IPR, Padagis *chose* to rely solely on § 102(e) art that names overlapping inventors as its sole primary reference in an obviousness argument. That Petitioner may be "statutorily time-barred from filing another IPR petition against the challenged patents" does not justify denying the MFL. *See* Decision at 10. In *Arkema*, the petitioner opposed the patent owner's MFL on the same basis, arguing it would be prejudicial because petitioner no longer could bring "intervening art in a new post-grant or inter partes review proceeding" and that it "contravenes [its] statutory right to file PGRs and have them decided within the statutory time frame." PGR2016-00011, Paper 77 at 10. The Board recognized that granting leave would "necessarily result in some prejudice to Petitioner in terms of time to final

judgment," but such prejudice was "outweighed by prejudice that Patent Owner will experience should it not be allowed to pursue its request for a Certificate of Correction with the Director." *Id.* at 12. So too here.

The Decision cites *Kingston* to support denying Neurelis leave to seek the requested correction. Decision at 5. But the patent owner in *Kingston* sought a correction to *amend the claims themselves*. IPR2015-00559, Paper 44 at 3. This proposed correction is definitionally improper under mandatory authority, necessitating additional examination. *See Superior Fireplace*, 270 F.3d at 1368-1369. Accordingly, the *Kingston* panel concluded that allowing a claim-altering correction at that stage would have upended the proceedings completely. IPR2015-00559, Paper 44 at 3-4. Here, Neurelis does not seek to alter the claims in any respect. And Padagis has the opportunity to respond to the proposed correction.

The "prejudice" the Board identifies appears to be a concern about perceived gamesmanship. Any such concern can be (and has been) addressed by requiring Patent Owner to provide the full set of MFL briefing (including Padagis's opposition) to the Director to evaluate the correction. *See ASM IP*, IPR2019-00378, Paper 17 at 2-6 (granting leave to seek eight-year-delayed priority correction aimed at removing prior-art reference and requiring patent owner to provide the parties' briefing to USPTO branch considering request); *Arkema*, PGR2016-00011, Paper 77 at 5, 13 (granting leave to seek priority correction and concluding that it may

"accommodate prejudice to Petitioner" by requiring the patent owner provide the parties' briefing with its correction request); *CSIRO*, PGR2020-00033, Paper 26 at 5-6 (requiring patent owner to submit the parties' briefing with its request).

C. THE PANEL OVERLOOKED THE PREJUDICE TO NEURELIS

Denying Neurelis the right to seek correction to assert the safe harbor defense of Section 103(c)(2) deprives Neurelis of its statutory right to assert such a defense. Yet nowhere in its Decision did the Board address, let alone weigh, the prejudice to Neurelis that would result if denied any opportunity to invoke that statutory defense.

The Board has expressly recognized that a patent owner is prejudiced when denied the opportunity to pursue a certificate of correction. *Arkema*, PGR2016-00011, Paper 77 at 12 (finding that prejudice to patent owner if certificate of correction was not granted outweighed any potential prejudice to petitioner). Here the prejudice is profound, where Neurelis seeks correction to assert a defense to invalidity that Congress expressly authorized and the regulations provide.

As the Board's Decision concedes, no statute or regulation imposes timing restrictions that would justify stripping Neurelis of its right to seek correction. To the contrary, "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." MFL at 3 (citing 35 U.S.C. § 103(c)(2)(C) (pre-AIA) & Ex. 2032, H.R. Rep. No. 108-425, at 9 (2004)).

D. THE PANEL MISAPPREHENDED THE PREJUDICE INQUIRY

The Board's Decision incorrectly frames Patent Owner's request as an effort "to halt an ongoing IPR to pursue a certificate of correction." Decision at 5. This assertion is baffling, as the requested correction would not affect any scheduled deadlines. *See* MFL at 8. The recently issued '664 Patent correction confirms this assessment. Patent Owner filed the petition for a certificate of correction on December 15, 2025, and the certificate issued less than two months later. Even now, seven months remain before the statutory deadline for a final written decision. The requested correction will not disrupt the schedule of this proceeding.

The Panel asserts in its Decision that "inaction and delay" in seeking correction "may have caused" "waste and prejudice" to the Board and the Federal Circuit panel in their prior consideration of the 451 IPR. Decision at 10. These assertions are mistaken for at least three reasons.

First, it assumes the reasoning from the 451 IPR applies equally to the '414 Patent. But whether the 451 IPR has *any* preclusive effect in this proceeding remains disputed, and the Panel already expressed skepticism that collateral estoppel should apply. Paper 13 at 22-24, 34 n.18.

Second, the Decision assumes that the JRA "would have applied to the challenged patent in the 451 IPR" (Decision at 10-11). But the 451 IPR cannot have preclusive effect concerning the JRA, because that issue was never litigated.

Third, the Board provides no authority for the proposition that supposed prejudice authorizes the Board to deny the statutory right to seek correction. The Supreme Court has confirmed that "it cannot be presumed that related patents rise and fall together." *See Comair Rotron, Inc. v. Nippon Densan Corp.*, 49 F.3d 1535, 1539 (Fed. Cir. 1995). Establishing estoppel requires finding four specific elements to be true: "that in the prior action the party against whom estoppel is sought had a full and fair opportunity to litigate the issue; the issue was actually litigated; the controlling facts and applicable legal rules were the same in both actions; resolution of the particular issue was essential to the final judgment in the first action; and the identical issue was decided in the first action." *Id*. Padagis did not seek to prove those factors in its MFL, and the Board did not evaluate them. *See* Paper 28 (Patent Owner Response) at 64-74 (explaining why collateral estoppel does not apply from the 451 IPR). Insofar as the Board seeks to apply a form of "estoppel-lite," that application is forbidden by mandatory authority. *Comair*, 49 F.3d at 1536-37 ("The evidence provided by the nonmovant is to be believed, and all justifiable inferences are to be drawn in the nonmovant's favor.").

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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@mcdermottlaw.com

Counsel for Patent Owner

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
jpmurphy@polsinelli.com

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

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: February 20, 2026

/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@mcdermottlaw.com

Counsel for Patent Owner