NON-PUBLIC VERSION—PROTECTIVE ORDER MATERIAL

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Paper 36
Date: February 6, 2026

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PADAGIS US LLC,
Petitioner,

v.

NEURELIS, INC.,
Patent Owner.

IPR2025-00464 (Patent 8,895,546 B2)
IPR2025-00465 (Patent 11,241,414 B2)
IPR2025-00466 (Patent 11,793,786 B2)[1]

Before GRACE KARAFFA OBERMANN, ANNETTE R. REIMERS, and TIMOTHY G. MAJORS, *Administrative Patent Judges*.

MAJORS, *Administrative Patent Judge*.

ORDER
Denying Patent Owner's Motion for Leave to File Petition for Certificate of Correction on Patents Undergoing *Inter Partes* Review
37 C.F.R. §§ 1.323, 42.20

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[1] This Order addresses issues common to the listed cases. Therefore, we exercise our discretion to issue one Order to be filed in each case. The parties are not authorized to use this style heading.

I. BACKGROUND

On December 4, 2025, Patent Owner wrote to the Board seeking authorization to file a motion for leave to petition for a certificate of correction on each of the patents challenged in the above-captioned proceedings. Ex. 3001.[2] The Board authorized the filing of the present motion (Paper 26, hereafter "Motion" or "Mot.") and allowed Petitioner to file an opposition (Paper 30, hereafter "Opposition" or "Opp."). Paper 23 (Order dated Dec. 15, 2025, authorizing briefing and additional filings concerning exhibits submitted in support of the Motion).

Patent Owner's Motion asks the Board to cede its jurisdiction over the challenged patents in the ongoing IPRs so that Patent Owner may file a petition with the Director for a certificate of correction that adds to each patent a disclosure related to a "Joint Research Agreement" ("JRA") and the parties to that agreement. Mot. 1–2. More specifically, Patent Owner seeks to add the following text at the beginning of each patent's 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).

[2] Unless otherwise noted, all citations are filings in IPR2025-00465. Similar papers and exhibits were filed in IPR2025-00464 and IPR2025-00466.

Mot. 6–7; *see also id.* at 1 n.1 (stating "Questcor is the predecessor in interest to Hale BioPharma Ventures ('HBV'), which is the predecessor in interest to Neurelis, the Patent Owner").

The reason Patent Owner seeks to "correct" the patents with this additional language is clear—Patent Owner hopes to disqualify the primary prior art reference asserted by Petitioner in these proceedings; namely, Gwozdz. Mot. 1–4.

On September 16, 2025, the Board instituted *inter partes* review, finding Petitioner was reasonably likely to prevail in showing that the challenged claims would have been obvious over the combination of Gwozdz and Meezan.[3] Paper 13, 2, 6, 30–36. Gwozdz is a published international patent application filed March 27, 2009, and it further claims the priority benefit of a provisional application filed March 28, 2008. Ex. 1009, codes (22), (30). The three named inventors on Gwozdz are named inventors (among several others) on the challenged patents. *Compare id.* at code (72), *with* Ex. 1001, code (72). According to Patent Owner, Gwozdz was owned and filed by Patent Owner's joint-research partner Particle Sciences, Inc. ("PSI"), the JRA predates the relevant

[3] IPR2025-00464 and IPR225-00465 include only one ground (Gwozdz plus Meezan); IPR2025-00466 includes one primary ground (Gwozdz plus Meezan), and two subsidiary grounds against a handful of the dependent claims based on Gwozdz and Meezan, in further combination with additional references. *See* IPR2025-00466, Paper 13, 7.

application filing dates for Gwozdz and the challenged patents,[4] and Gwozdz allegedly arose from PSI's activities under the JRA. Mot. 1–2. If the Specifications are amended as proposed, Patent Owner plans to invoke the "safe harbor defense" of 35 U.S.C. § 103(c)(2)(C) (pre-AIA) and argue Gwozdz, as a § 102(e) reference, "cannot be used for obviousness." *Id.* at 1–3 (noting Gwozdz is "asserted to be prior art solely under 35 U.S.C. § 102(e) (pre-AIA)"), 6–10.

In short, the relief Patent Owner is seeking may eliminate Gwozdz from Petitioner's obviousness grounds and be case dispositive across all three proceedings.

II. DISCUSSION

Whether a certificate of correction may be entered on an already-issued patent is informed by 35 U.S.C. § 255, which reads as follows:

> Whenever a mistake of a clerical or typographical nature, or of a minor character, which was not the fault of the Patent and Trademark Office, appears in a patent and a showing has been made that such mistake occurred in good faith, the Director may, upon the payment of the required fee, issue a certificate of correction, if the correction does not involve such changes in the patent as would constitute new matter or would require re-examination. Such patent, together with the certificate, shall have the same effect and operation in law on the trial of actions for causes thereafter arising as if the same had been originally issued in such corrected form.

[4] The '414 patent, for example, issued from an application filed May 27, 2021, and claims the priority benefit of several non-provisional applications, the earliest of which was filed March 27, 2009 (Ex. 1039), as well as a provisional application filed March 28, 2008 (Ex. 1008). Ex. 1001, codes (22), (60), (63).

35 U.S.C. § 255. As the Federal Circuit has explained, the Director—not the Board—is responsible for deciding whether a certificate of correction is appropriate under § 255. *Honeywell Int'l Inc. v. Arkema Inc.*, 939 F.3d 1345, 1348–50 (Fed. Cir. 2019) (holding the Board abused its discretion in assuming authority that § 255 expressly delegates to the Director).

Notwithstanding the above, when a patentee seeks a certificate of correction on a patent that is undergoing a post-issuance review proceeding before the Board, the filing of a petition for correction requires the Board's approval. That is, a "patentee must first file a motion with the Board seeking authorization to petition the Director for a Certificate of Correction, asking the Board to temporarily cede its exclusive jurisdiction over the proceedings." *Honeywell*, 939 F.3d at 1348–49 (citing 37 C.F.R. §§ 1.323, 42.3).

Although the decision on the merits of a patentee's petition rests with the Director, the Board is not merely a rubber stamp and need not cede jurisdiction whenever a patentee moves to halt an ongoing IPR to pursue a certificate of correction. To the contrary, the Board "determine[s] whether there is a *sufficient basis* supporting [a patentee's] position that the mistake *may* be correctable" under § 255. *Id.* at 1349–50. Furthermore, the Board may, in deciding the motion, evaluate the parties' arguments related to prejudice. *Id.* at 1350–51; *see Kingston Tech., Inc. v. CATR Co., Ltd.*, IPR2015-00559, Paper 44 at 3 (PTAB Nov. 6, 2015) (denying motion for leave and noting patentee's delay in pursuing "correction" of claim language and unfairness to petitioner if the relief sought by patentee was granted).

Here, Patent Owner summarizes some of the details of the JRA and argues it "has a clear legal basis" to seek a certificate of correction. Mot. 4–7 (citing Master Services Agreement dated April 1, 2007 (Ex. 2030) and an Asset Purchase Agreement dated June 27, 2008, including an apparent assignment of rights from Questcor to HBV (Ex. 2031)). In support, Patent Owner cites 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. *Id.* at 3, 7–8. For example, Rule 1.71(g)(3) 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 [37 C.F.R.] § 1.323 for the amendment to be effective." 37 C.F.R. § 1.71(g)(3); *see also* MPEP § 2146.02 (citing Rule 1.71(g)(3) for same); Ex. 2032 (H.R. Rep. No. 108–425, p. 9 (2004) ("This information [(i.e., identities of parties to a joint research agreement)] may be . . . added by amendment to the patent (e.g., by a certificate of correction)" and stating "[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")).

Beyond the above, Patent Owner notes that it has submitted a copy of the JRA, identified the text it wants to add to the Specifications, and argues that "[t]he Board requires nothing more to conclude that the omission *may be* correctable." Mot. 8. For the reasons discussed below, we disagree.

There are several requirements that Patent Owner must meet to be entitled to the proposed certificate of correction under 35 U.S.C. § 255. Among them, Patent Owner must establish that the omission of the JRA and the parties to that agreement in the Specifications is "a mistake of a *clerical or typographical nature*, or of a *minor character*," and also make a showing that "such mistake *occurred in good faith*." 35 U.S.C. § 255 (emphases added). Patent Owner never squarely addresses why the alleged mistake here qualifies as clerical, typographical, or minor. Even if Patent Owner's citation to the rules and MPEP may suggest that correction of a patent to add the names of the parties to a joint research agreement can be a "minor" and correctable mistake in some cases, Patent Owner never argues, much less provides any supporting evidence that might show, that it is a minor change in the circumstances of these cases. Opp. 3–4 (arguing "this correction is sought to effect a substantive change . . . that would potentially result in the unpatentable claims of the '414 Patent being found patentable").[5]

But, assuming Patent Owner has done enough to put at issue for a merits decision by the Director whether the absence of disclosure about the JRA is a "clerical," "typographical," or "minor" mistake, Patent Owner does not address the additional terms of § 255, which require a showing that the mistake "occurred in good faith." On that, Patent Owner's filing is silent.

[5] Petitioner also argues that proposed changes to the patents cannot be minor because Patent Owner is not merely adding the names of parties of the JRA but proposing a "correction that discloses the JRA in the first instance." Opp. 4–5 (noting that the cited rule and legislative history speak to the addition of "names of parties" to a JRA).

See generally Mot. On this record, Patent Owner has not set forth a "sufficient basis" supporting its position that the alleged mistake may be correctable. *Honeywell*, 939 F.3d at 1349.

In fact, the record here suggests that the correction being sought did not arise from a simple "good faith" mistake.

As Petitioner explains, Patent Owner has been (or should have been) aware of the alleged mistake *for at least seven years*. Opp. 5–6. On January 29, 2019, an IPR petition was filed against a patent that is a family member to the challenged patents here, with nearly identical claims. *Id.* at 5 (citing IPR2019-00451, Paper 3 ("the 451 IPR")). Like here, the 451 IPR was based on asserted obviousness of the claims over Gwozdz and Meezan. IPR2019-00451, Paper 3, 5. The 451 IPR was instituted, the Board held all claims unpatentable in a Final Written Decision dated August 6, 2020, and the Federal Circuit affirmed that holding on October 7, 2021. Ex. 1040[6]; Ex. 1068. Patent Owner did not seek a certificate of correction to add any reference to the JRA before or during the 451 IPR. And despite Patent Owner's longstanding knowledge that Gwozdz had been successfully asserted against its related patent, Patent Owner did not previously seek a

[6] In the 451 IPR (challenging U.S. Patent No. 9,763,876), Patent Owner attempted (unsuccessfully) to remove Gwozdz as prior art by arguing there was sufficient written description support in, and priority entitlement to, an earlier application in the 451 IPR patent's priority chain. Ex. 1040, 17–23 (rejecting Patent Owner's priority arguments and finding Gwozdz was § 102(e) prior art). Patent Owner sought to remove Gwozdz for similar reasons in its earlier filings in the present proceedings, which we also rejected on the preliminary record. *See, e.g.*, Paper 13, 14–30.

certificate of correction to the '546 patent (now challenged in IPR2025-00464), which is the parent to the patent at issue in the 451 IPR. Nor did Patent Owner seek to add the JRA disclosure at any time during prosecution of the '414 and '786 patents, which issued from applications that Patent Owner filed in April and May, 2021—after the Board's Final Written Decision in the 451 IPR and before the Federal Circuit's affirmance.[7]

Against that backdrop, we find insufficient Patent Owner's statement that "[t]he correction to the specification was necessitated by the Board instituting trial" based on Gwozdz. Mot. 1–2. Tellingly, Patent Owner does not identify when it first discovered the alleged mistake, much less provide any reasoned explanation for its yearslong delay in seeking to add the JRA disclosure to its portfolio of related patents and applications—from at least 2019 when Gwozdz was first asserted against that portfolio. It is only now, some seven years later and after Patent Owner's other arguments have repeatedly failed to persuade the Board (or the Federal Circuit) that Gwozdz was not only available but invalidating prior art, that Patent Owner's strategy has changed course. Opp. 2, 3 (citing *In re Arnott*, 1991 WL 326548, *9 (Comm'r Pat. & Trademarks May 22, 1991) (explaining that "a mistake in judgment" is not correctable under § 255)).

We further agree with Petitioner that "Patent Owner's inexcusable seven-year delay to seek a [certificate of correction] creates unfair prejudice to Petitioner." Opp. 7–10. Petitioner contends that, when it prepared and

[7] Petitioner provides a family tree showing the relationships between these various patents and applications, including filing dates. Paper 2, 13–14.

filed its petitions challenging the patents in these proceedings, it "reasonably relied on Patent Owner's many years of silence" since Gwozdz was first successfully asserted in the 451 IPR. *Id.* at 8–9. But now, given Patent Owner's delay in pursuing a certificate of correction for these patents that would putatively eliminate Gwozdz as available prior art, Petitioner is prejudiced. Based on the timing of Patent Owner's district court complaint in parallel litigation, Petitioner is statutorily time-barred from filing another IPR petition against the challenged patents. *Id.* (citing 35 U.S.C. § 315(b) (petitions must be filed within 1 year after the date a petitioner is served with a complaint alleging infringement of the relevant patents)); Ex. 1063 (complaint filed May 8, 2024); Pet. 4.

We determine, on this record, that Petitioner is substantially prejudiced by Patent Owner's delay. Furthermore, we also recognize the waste and prejudice that Patent Owner's inaction and delay may have caused to the Board and the Federal Circuit panels that decided the 451 IPR. The public (including Petitioner here) reasonably relies on final outcomes at the Board and before the courts. If the alleged mistake in omitting the JRA applies to these challenged patents, so too it would have applied to the challenged patent in the 451 IPR—where Patent Owner might have removed Gwozdz as prior art applying similar reasoning. Yet that case held in a final and affirmed decision that Gwozdz was § 102(e) art that (together with Meezan) proved that the nearly identical claims would have been obvious. *See generally* Ex. 1040; Ex. 1068. We see no indication in the prior matter

that Patent Owner ever suggested Gwozdz might be subject to the safe harbor provisions of § 103(c)(2)(C).

We find unpersuasive Patent Owner's counterargument that there is no prejudice to Petitioner. Mot. 8–10. According to Patent Owner, the statute and regulations impose no time limit on seeking a certificate of correction and, Patent Owner contends, Petitioner will have a chance to file further briefing in these proceedings. *Id.* (noting the date for Petitioner's Reply as March 24, 2026).

The absence of any specified time period in § 255 or the related regulations, however, does not negate the substantial prejudice to Petitioner caused by Patent Owner's delay and inaction. Petitioner's opportunity to file a reply brief in these proceedings does little to remedy this prejudice. Such reply cannot raise new grounds of unpatentability and, as noted above, Petitioner is now time-barred from filing any new challenge that does not rely on Gwozdz.

Patent Owner further argues that it "should come as no surprise" to Petitioner that Patent Owner could correct the alleged mistake in the patents and, thereby, invoke the "Section 103 Safe Harbor defense." Mot. 9. Patent Owner notes the partial overlap in listed inventors on Gwozdz and the challenged patents and contends that Petitioner has "long possessed the joint research agreement" because Patent Owner produced the agreement as part of discovery in the parallel litigation. *Id.* (stating that the Master Services

Agreement was produced on December 23, 2024, prior to the filing of the petitions on January 17, 2025).[8]

Petitioner may well have possessed the JRA several weeks before its petitions were filed, but Patent Owner (or its predecessors-in-interest) possessed the agreement since it was signed *in 2007*. And, as already explained above, Patent Owner was put on direct notice that Gwozdz was being asserted against its related patent in early 2019 yet Patent Owner did nothing to correct the alleged mistake until late 2025. Patent Owner provides no persuasive explanation as to why it waited over these many years and until now to seek a certificate of correction that adds disclosure related to the JRA. Accordingly, we determine that Petitioner has the better position on the issue.

Considering the Motion and Opposition, and for the reasons given above, we determine that Patent Owner has not provided a sufficient basis to support its position that the challenged patents may be corrected for the alleged mistake. In addition, as explained above, we determine that substantial prejudice to Petitioner warrants denial of the Motion.

[8] Patent Owner further states (without citing evidence) that, six weeks after it produced the agreement, it "informed" Petitioner in the related litigation that it intended to invoke the safe harbor provisions of § 103(c). Mot. 9.

III. ORDER

In consideration of the foregoing, it is:

ORDERED that Patent Owner Motion for Leave to File Petition for Certificate of Correction is *denied*; and

ORDERED that within ten (10) days of this Order, the parties will meet and confer regarding any redactions to this Order and, as appropriate, file a motion to seal that includes, as an exhibit, a proposed redacted version of the Order; if no motion is filed, the unredacted version of the Order herein will be made available to the public.

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