

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SUN PHARMACEUTICAL INDUSTRIES, INC.
Petitioner

v.

BIOFRONTERA INC.
Patent Owner

Case No. PGR2026-00021
U.S. Patent No. 12,280,146

PETITIONER'S OPPOSITION
TO PATENT OWNER'S DISCRETIONARY DENIAL REQUEST

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1007	Hill, “Preservation of cosmetics and toiletries,” <i>Handbook of Biocide and Preservative Use</i> 1995, Chapter 13. (“Hill”)
1008	U.S. Patent No. 6,858,200
1009	Jaworska et al., “The influence of glycerides oil phase on O/W nanoemulsion formation by pic method,” <i>Periodic Polytechnica Chemical Engineering</i> 2014, 58(Sup), 43-48.
1010	Fiume et al., “Safety Assessment of Monoglyceryl Monoesters as Used in Cosmetics,” <i>International Journal of Toxicology</i> 2020, Vol. 39 (Supplement 3), 93S-126S.
1011	Kale et al., “Emulsion Micro Emulsion and Nano Emulsion: A Review,” <i>Sys Rev Pharm</i> 2017, 8(1):39-47.
1012	Bailey et al., “Polyoxyalkylenes,” <i>Ullmann’s Encyclopedia of Industrial Chemistry</i> 2012.
1013	Nelson et al., “Carbohydrates And Glycobiology,” <i>Lehninger Principles of Biochemistry Eighth Edition</i> 2021, Chapter 7.
1014	Bunke et al., “Degradation Mechanism and Stability of 5-Aminolevulinic Acid,” <i>Journal of Pharmaceutical Sciences</i> 2000, Vol. 89 No. 10, 1335-1341.
1015	McCarron et al., “Stability of 5-Aminolevulinic Acid in Novel Non-Aqueous Gel and Patch-Type Systems Intended for Topical Application,” <i>Journal of Pharmaceutical Sciences</i> 2005, Vol. 94 No. 8, 1756-1771.
1016	Fiume et al., “Final Report on the Safety Assessment of Sodium Cetearyl Sulfate and Related Alkyl Sulfates as Used in Cosmetics,” <i>International Journal of Toxicology</i> 2010, Vol. 29(Supplement 2), 115S-132S.
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1020	Singh et al, “Nanoemulsion: Concepts, development and applications in drug delivery,” <i>Journal of Controlled Release</i> 2017, Vol. 252, 28-49.
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All emphases have been added unless indicated otherwise.

I. INTRODUCTION

Petitioner Sun Pharmaceutical Industries, Inc. (“SPI Inc.”) provides photodynamic therapy (“PDT”) for the treatment of actinic keratoses (“AKs”). Its predecessor, DUSA Pharmaceuticals, Inc. (“DUSA”), began selling its PDT therapy, Levulan® Kerastick® in combination with the BLU-U® illuminator, in 1999. Over the next two decades, SPI Inc. invested significant amounts of time and money to manufacture both products in the United States as the only FDA-approved PDT therapy for the treatment of AKs. Biofrontera did not enter the U.S. market for PDT until 2016, with its combination therapy of Ameluz®¹ and the RhodoLED® illuminator. Unlike SPI Inc., Biofrontera manufactured—and continues to manufacture—both its drug and device outside of the United States.

Patent Owner Biofrontera Inc. (“Patent Owner”) incorrectly argues that SPI Inc. should have named its parent company, Sun Pharmaceutical Industries, Ltd. (“SPI Ltd.”), as a real party-in-interest (“RPI”) for the purpose of this Petition. But the Petition already identifies the proper RPI: SPI Inc. The mere fact that SPI Ltd. owns 100% of SPI Inc. does not automatically make SPI Ltd. an RPI. *See Syngenta Crop Prot. AG v. FMC Corp.*, PGR2020-00028, Paper 8, 15 (PTAB Sept. 15, 2020)

¹ Patent Owner argues “[t]he ’146 Patent is part of Patent Owner’s portfolio for Ameluz® as recognized in the FDA Orange Book.” Paper 8, 5.

(“the preservation of the common-law meaning of RPI . . . suggests that the mere establishment of parent-company status is insufficient to render a non-party an RPI”). Moreover, the consolidation of financial information and mere use of certain letterheads in press releases do not make SPI Ltd. or any of the other Sun Pharma entities an RPI.

Additional factors favor institution. There is no parallel proceeding—hence denial of institution under *Fintiv* is not warranted. Denial under § 325(d) is also unwarranted because the Examiner did not consider Uhlmann or Palazzolo—prior art references in SPI Inc.’s Petition—during prosecution of the ’146 Patent. Lastly, the Petition’s merits are exceptionally strong, as the Petition presents two anticipation grounds covering more than half of the Challenged Claims, including the sole independent claim.

Accordingly, Petitioner respectfully requests that the Director institute post-grant review, hold the Challenged Claims unpatentable, and cancel the Challenged Claims.

II. PATENT OWNER HAS NO SETTLED EXPECTATIONS FOR THE ’146 PATENT

A. The ’146 Patent Has Been In Force For Less Than One Year

As the Director has consistently noted, “Petitions for post-grant review are favored because they must be filed no later than nine months from the grant of the patent (35 U.S.C. § 321(c)), are close in time to examination, and occur before

expectations in the patent rights are strongly settled.” *Multi-Color Corp. v. Brook & Whittle Ltd.*, PGR2025-00025, Paper 10, 2-3 (PTAB July 16, 2025) (precedential).

B. Patent Owner Has Not Made Significant Investments In U.S. Manufacturing

Patent Owner holds itself out as a “small US-based business that controls and runs its clinical trials in the US.” Paper 8, 6-7. However, it is Biofrontera’s ***German*** Entities (Biofrontera AG, Biofrontera Bioscience GmbH, and Biofrontera Pharma GmbH) that have made U.S.-based investments in the commercial development and market for Ameluz® and the RhodoLED® lamps. For example, from the FDA’s approval of Ameluz® in 2016 until December 2025 (when Patent Owner acquired the New Drug Application for Ameluz®), Patent Owner did not handle regulatory filings and communications with the FDA. *See* EX1024; *see also* EX1025, 33 (“Biofrontera AG has committed to maintaining the FDA approval, manufacturing the products, providing a pharmacovigilance database and conducting previously defined clinical trials.”), EX1025, 33 (“Biofrontera AG group maintains the FDA approval and remains NDA- and IND-holder.”). In fact, in an ongoing District of New Jersey litigation, Patent Owner argued that it ***did not have access to regulatory documents for Ameluz® because they were solely maintained by the German Entities***, even after listing Dr. Annika Wedeking—then the Senior Manager of Regulatory Affairs at Biofrontera Bioscience—as the only person on its initial disclosures with information related to the regulatory approval of Ameluz®. *See*

EX1026, 13-14. Indeed, Patent Owner refused to produce communications between Biofrontera and the FDA, claiming “that it had ‘few to no responsive documents in its possession, custody, or control’ related to FDA approvals or the submission of marketing materials to the FDA *because ‘that responsibility falls to [German Entities] Biofrontera Pharma GmbH and Biofrontera Bioscience GmbH.’*” *Id.*, 14 (internal citations omitted).

In addition, Biofrontera’s Ameluz®—the product that Patent Owner alleges embodies the claims of the ’146 Patent (Paper 8, 5)—is produced outside the United States by two European contract manufacturers—Glaropharm AG in Switzerland and Pharbil Waltrop GmbH in Germany. EX2012, 7; EX1027, 3. Similarly, Biofrontera’s RhodoLED® lamps are manufactured in Germany—not in the United States. EX2012, 7; EX1027, 3; *see also* EX1028, 34 (“In June 2025, Biofrontera Inc. and Biofrontera AG agreed to transfer the PDT-Lamp manufacturing to Biofrontera Discovery GmbH, a subsidiary of Biofrontera Inc, located in Leverkusen, Germany.”).

Furthermore, as of December 2025, 19 of Patent Owner’s employees were located in Germany. EX2012, 23; *see also id.*, 25 (“All employees of our wholly owned subsidiary, Biofrontera Discovery GmbH, and a majority of the employees and former employees of Biofrontera AG, our former licensor, work in Germany and are subject to German employment law.”). When the Biofrontera German

Entities transferred certain responsibilities to Patent Owner in 2024, “operational responsibility for clinical development was transferred in June 2024 to Biofrontera Discovery GmbH”—*i.e.*, transferred to a subsidiary whose employees are all in Germany. EX1028, 48. “Since that time, Biofrontera Discovery GmbH has financed and coordinated activities related to clinical trials in the United States” *Id.*

C. Petitioner Has Made Substantial Investments In U.S. Manufacturing

In contrast, Petitioner SPI Inc. is a U.S.-based company that has made significant investments in U.S. manufacturing related to PDT. For example, SPI Inc. has invested substantial resources in the United States for nearly three decades to research, develop, manufacture, and commercialize its PDT products. EX1027, 2. SPI Inc. first obtained FDA approval for the BLU-U® 4170 illumination device in combination with Levulan® Kerastick® to treat non-hyperkeratotic AKs of the face, scalp, and upper extremities in 1999. *Id.*; EX1021, ¶¶8-14; EX1032; EX1033; EX1034; EX1035; EX1036. SPI Inc. launched Levulan® Kerastick® in combination with its BLU-U® 4170 device in September 2000. EX1027, 2; EX1029, 1. SPI Inc. began research and development of the BLU-U® 4170E, its next-generation illumination device, around 2014. EX1027, 2; EX1021, ¶15; EX1037.

SPI Inc.’s Levulan® Kerastick® is exclusively manufactured in SPI Inc.’s Massachusetts facility. EX1027, 3. Additionally, all of DUSA’s (now SPI Inc.’s) work related to the BLU-U® 4170E device takes place in the United States. *Id.*, 2-3. The majority of the work on the BLU-U® 4170E device occurs in SPI Inc.’s Massachusetts facility. *Id.* SPI Inc. spends many millions of dollars annually—amounting to eight figures per year—on PDT-related expenses in the United States. EX1021, ¶11; *see also* EX1027, 30; EX1040 (10 full-time U.S.-based employees dedicated to R&D in FY 2022); EX1041 (12 full-time U.S.-based employees dedicated to R&D in FY 2023); EX1042 (12 full-time U.S.-based employees dedicated to R&D in FY 2024); EX1043 (15 full-time U.S.-based employees dedicated to R&D in FY 2025); EX1039, 2-3 (ALJ finding that SPI Inc. satisfied the economic prong of domestic industry, which requires “significant investment in plant and equipment,” “significant employment of labor or capital,” or “substantial investment in its exploitation, including engineering, research and development, or licensing”), 6-7 (“I find that [SPI Inc.]’s value-added analysis suggests its domestic investments related to the patented articles are significant.”), 9, 11. SPI Inc.’s Levulan® Kerastick® is a competitor to Ameluz®, which Patent Owner asserts embodies the claims of the ’146 Patent. Paper 8, 5; *cf.* Memorandum, “Additional Discretionary Institution Considerations – U.S. Manufacturing and Small Business Use of AIA Proceedings,” 2-3 (Mar. 11, 2026).

Accordingly, due to Patent Owner's insubstantial investments in U.S. manufacturing operations and Petitioner's significant investments in the same, discretionary denial is unwarranted.

III. SPI INC. IS THE PROPER REAL PARTY-IN-INTEREST

Despite Petitioner SPI Inc. having properly named itself as the sole Petitioner and RPI in the instant PGR, Patent Owner argues that SPI Ltd. (SPI Inc.'s parent) and other entities related to SPI Ltd. should additionally have been named as RPIs. Paper 8, 2-5. Not so.

The RPI analysis is a narrowly tailored inquiry into the “relationship between a party and a *proceeding*,” not “the relationship between *parties*.” *See Aruze Gaming Macau, Ltd. v. MGT Gaming, Inc.*, IPR2014-01288, Paper 13, 11 (PTAB Feb. 20, 2015). The mere existence of a parent-subsidiary relationship “does not establish a relationship sufficient to make the parent a real party in interest.” *TRW Auto. U.S. LLC v. Magna Elecs. Inc.*, IPR2014-01499, Paper 7, 11 (PTAB Mar. 19, 2015). Nor does the mere existence of some association with another party tie them as RPIs. *See Corning Optical Commc'ns RF, LLC v. PPC Broadband, Inc.*, IPR2014-00440, Paper 68, 14 (PTAB Aug. 18, 2015) (precedential) (“A party does not become a RPI merely through association with another party in an endeavor unrelated to the IPR proceeding.”); *see also* Consolidated Trial Practice Guide

(“CTPG”), 17 (“generally a party does not become a ‘real party-in-interest’ or a ‘privy’ of the petitioner merely through association with another party”).

“[T]here are ‘multiple factors relevant to the question of whether a non-party may be recognized as’ an RPI.” *Applications in Internet Time, LLC v. RPX Corp.*, 897 F.3d 1336, 1342 (Fed. Cir. 2018); *see also* CTPG, 13 (citing *Taylor v. Sturgell*, 553 U.S. 880, 893-95, 893 n.6 (2008)). “[T]here is no ‘bright-line test’ for determining the necessary quantity or degree of participation to qualify as a ‘real party-in-interest.’” CTPG, 15-16 (citing *Gonzalez v. Banco Cent. Corp.*, 27 F.3d 751, 759 (1st Cir. 1994)). “Relevant factors include: Party A’s relationship with the petitioner; Party A’s relationship to the petition itself, including the nature and/or degree of involvement in the filing; and the nature of the entity filing the petition.” CTPG, 17-18; *see also Taylor*, 553 U.S. at 893-95, 893 n.6.

A. SPI Inc. Is The Proper RPI Because SPI Inc. Has Maintained A Clear Corporate Distinction From The Other Entities For The Instant PGR

SPI Inc. is the proper RPI in the instant PGR. There is a clear corporate distinction between SPI Inc. and SPI Ltd. and other Sun Pharma entities as it relates to the instant PGR proceeding.

First, DUSA—the first company to present aminolevulinic acid (“ALA”) to the FDA for the treatment of AKs of the face and scalp—was merged into SPI **Inc.**, not any of the other Sun Pharma entities. EX1021, ¶¶6-7, 9, 26. Indeed, it was SPI

Inc.’s President and CEO that signed the relevant merger documents in 2024. *Id.* ¶9.

Second, pursuant to the Declaration of Dr. Edward Gimmi (Associate Vice President for SPI Inc.), SPI Inc. is the only entity that has paid, and will pay, for the preparation and filing of the instant Petition and associated costs and legal fees, and SPI Inc.’s billing department keeps invoice payment for the instant Petition accurate. *See* EX1021, ¶¶1, 22, 25, 16-18, 20, 28. For example, when outside counsel’s accounting department inadvertently included a typographical error identifying SPI *Ltd.* (albeit with the correct SPI Inc. address) in an invoice dated January 14, 2026, a SPI *Inc.* employee timely noted that “[t]he pdf is addressed to the wrong entity” and requested revision of the invoice to “Sun Pharmaceutical Industries, *Inc.* 2 Independence Way Princeton NJ 08540 USA.” EX1022; EX1023.

Third, SPI Inc. maintains a separate legal department from SPI Ltd. In fact, “SPI Ltd.’s legal department has not and does not currently employ any U.S. licensed attorneys. In contrast, SPI Inc.’s legal department employs at least 17 U.S. licensed attorneys—none of whom are employed by SPI Ltd.” EX1021, ¶5. Therefore, U.S. attorneys employed by SPI Inc. are controlling U.S. instant PGR before the United States Patent and Trademark Office—not SPI Ltd., which does not employ any U.S. attorneys. *Cf. Par Pharm., Inc. v. Jazz Pharms., Inc.*, IPR2015-00546, Paper 25, 16

(PTAB July 28, 2015) (finding that the parent companies did not direct or control the proceeding because they did not “have legal departments of their own”).

Fourth, SPI Inc. and its in-house counsels were—and are—the sole corporate entities ultimately responsible for directing and funding the preparation and filing of the instant Petition. *See* EX1021, ¶¶16, 28. The in-house counsels employed by SPI Inc.—not SPI Ltd. or any other Sun Pharma entities—selected and hired outside counsel for this PGR proceeding. *See* EX1021, ¶¶19, 28.

Fifth, SPI Inc.—not SPI Ltd. or any of the other Sun Pharma entities—is the entity that manufactures, markets, and sells Levulan® Kerastick® in combination with the BLU-U® 4170D illuminator and the BLU-U® 4170E illuminator (the “PDT Products”), which compete with Patent Owner’s Ameluz® and RhodoLED®. EX1021 ¶¶6-8, 10-15, 21, 23, 27; *see Par Pharm.*, IPR2015-00546, Paper 25, 12-13 (finding that the parent companies were not RPIs in part because the petitioner had shown “that [it] makes, sells, and distributes pharmaceuticals, and that [it] prepared and filed the abbreviated new drug application” in the relevant product space). SPI Inc. owns, manufactures, and markets Levulan® Kerastick® and earns U.S. revenue for its PDT Products. EX1021 ¶¶6, 10-11, 21; *see Samsung Elecs. Co. v. Netlist, Inc.*, PGR2025-00071, Paper 16, 1 (PTAB Dec. 18, 2025) (petitioner arguing that it identified the proper RPIs at least because it was “responsible for manufacturing the Accused [Products]” while its subsidiary was “responsible for marketing and

facilitating sales of [the Accused Products] in the United States”); *Samsung*, PGR2025-00071, Paper 20, 2 (PTAB Jan. 9, 2026) (permitting PGR2025-00071 to be reviewed for merits and non-discretionary considerations).

Sixth, SPI Inc. has not blurred the lines of corporate separation with any of the other Sun Pharma entities named by Patent Owner (*i.e.*, Sun Pharma New Milford Parent LLC, SP Housatonic LLC, SP Housatonic II LLC, SP Housatonic III LLC, or Checkpoint Therapeutics, Inc.). *See* EX1021 ¶¶2-3 (stating that SPI Inc. and its executive leaders are located in the United States), ¶23 (Sun Pharma New Milford Parent LLC, SP Housatonic LLC, SP Housatonic II LLC, and SP Housatonic III LLC are holding companies that do not manufacture, market, or sell the PDT Products, and Checkpoint Therapeutics, Inc. developed immunotherapies to treat solid tumor cancers), ¶26 (aforementioned entities were not involved with the DUSA/SPI Inc. merger), ¶24 (aforementioned entities do not have any full-time employees).

Hence, SPI Inc. was properly named as the sole RPI for the purposes of this PGR proceeding.

B. Patent Owner Has Not Provided Credible Evidence That Other Entities Should Be Named As RPIs

In any case, Patent Owner has failed to offer credible evidence that SPI Ltd., or any other entity, should have been named as RPIs. *See Corning Optical*, IPR2014-00440, Paper 68, 13 (“A patent owner challenging a Petitioner’s RPI

disclosure must provide sufficient evidence to show the disclosure is inadequate.”); *see also Compass Bank v. Intell. Ventures II*, IPR2014-00719, Paper 11 at 8-9 (PTAB Oct. 24, 2014) (“Although Patent Owner’s evidence demonstrates a parent-subsidiary relationship . . . Patent Owner does not provide a sufficient factual basis to conclude that [parent company] should have been identified as a real party-in-interest.”).

1. SPI Ltd.’s Mere Status As A Parent Company Does Not Make It An RPI

Patent Owner argues that because SPI Ltd. owns 100% of Petitioner, SPI Ltd. should have been named as an RPI. Paper 8, 2-3. However, SPI Ltd.’s mere status as SPI Inc.’s parent company does not make it an RPI to this matter. *See Syngenta*, PGR2020-00028, Paper 8, 15 (three companies, including a parent company that owned 100% of the petitioner, were not RPIs, as “the mere overlap of personnel between [different parent entities] does not indicate a sufficient blurring of corporate separation such that the parent corporations could have controlled the filing and participation of the Petition”); *see also Par Pharm.*, IPR2015-00546, Paper 25, 12, 19 (petitioner did not need to list all parent companies as RPIs even though it was a “wholly-owned subsidiary of a series of holding companies, *i.e.*, the Par parents”); *Kifle v. Google LLC*, 2023 WL 5538289, at *3 (N.D. Ga. Aug. 28, 2023) (finding plaintiff had failed to show Google and its wholly-owned subsidiary, YouTube, were in privity given the lack of “factual allegations about the nature of their

relationship—about, for instance, Google’s right or ability to control YouTube and whether these entities operate together or independently”). The “mere status as a corporate parent is insufficient to render an entity an RPI (or even a privy).” *Syngenta*, PGR2020-00028, Paper 8, 15.

2. SPI Ltd.’s Press Releases And Financial Disclosures Do Not Make It An RPI For This Proceeding

Patent Owner also argues that SPI Ltd.’s financial disclosures and certain press releases demonstrate that it should have been named as an RPI in this proceeding. Paper 8, 3-5. Patent Owner’s argument lacks merit.

The Board previously rejected similar arguments in *Par Pharmaceutical*, where the patent owner “point[ed] to financial disclosure documents indicating that Par Inc. and its parents refer to themselves and act collectively as ‘we,’ that the companies undertake acquisitions as a single unit, and that the companies operate from a single website that does not differentiate among them.” *Par Pharm.*, IPR2015-00546, Paper 25, 11. The Board “accept[ed] Patent Owner’s evidence that [the petitioner] and its parents, in certain capacities, act as a single unit.” *Id.*, 15. The Board noted, however, that even if “it is difficult for both insiders and outsiders to determine precisely where one ends and another begins,” that is only one relevant factor in the RPI analysis. *Id.* And based on the totality of the record evidence, the Board held that the petitioner had properly identified all RPIs. *Id.*, 19. Here, SPI Ltd.’s financial disclosures and press releases are insufficient to suggest that SPI

Ltd. is an RPI, just as a single website and certain financial disclosure documents were insufficient to establish that a parent company was an RPI in *Par Pharmaceutical*. Exhibit 2002, a SPI Inc. press release, merely mentions SPI Ltd. in the announcement of a new Vice President, Corporate Affairs in North America. *See* EX2002. The document does not indicate that SPI Ltd. directs the instant PGR proceeding, and only SPI Inc.’s CEO was quoted in the release. Similarly, the SPI Inc. copyright symbol in Exhibit 2003 only shows up in reference to a trademark for a product that is unrelated to PDT. EX2003, 4. SPI Ltd.’s letterhead in this press release has no relation to the fact that SPI Inc. directs and controls the instant PGR proceeding.

In fact, the entire press release in Exhibit 2003 has nothing to do with any patent or product at issue here. Instead, the press release describes the availability of UNLOXCYT™, which is an anti-PD-L1 treatment for advanced cutaneous squamous cell carcinoma. *See* EX2003, EX1021, ¶23; *see also* *Aruze*, IPR2014-01288, Paper 13, 16-18 (holding that the petitioner’s sister company was not an RPI even though a website listed both companies under a joint name and a press release stated that the companies were “affiliate[s]”). Patent Owner’s reliance on press releases is therefore without merit.

Despite Patent Owner’s failure to proffer credible evidence of its RPI assertions, SPI Inc. provides additional supporting evidence to demonstrate that SPI

Inc.—and *not* SPI Ltd. or any other entities—is properly named as the sole RPI in the instant PGR.²

IV. ADDITIONAL FACTORS FAVOR INSTITUTION

Although not addressed by the Patent Owner, at least three additional factors warrant referral of the instant PGR Petition to the merits panel.

A. The Lack of Parallel Proceedings Favors Institution

The lack of parallel proceedings favors institution. *Intas Pharms. Ltd v. Atossa Therapeutics, Inc.*, PGR2025-00043, Paper 12, 2-3 (PTAB Aug. 29, 2025)

² In the interest of conserving judicial resources, Petitioner has sought and obtained permission from SPI Ltd. to add it as an additional RPI solely if it will moot the issue, provided that the Director allows Petitioner to maintain the original filing date accorded. This request is made in light of *Curium US LLC v. Universität Heidelberg*, IPR2025-01582, Paper 11 (PTAB Feb. 25, 2026) (informative), as obtaining a filing date now would place the instant proceeding outside the 9-month window for filing a PGR. Alternatively, if a new filing date must be accorded, SPI Inc. requests conversion of the instant PGR proceeding into an IPR proceeding. Indeed, the instant Petition satisfies all of the requirements under 35 U.S.C. §§ 311 and 315(a), (b); and 37 CFR §§ 42.24(a), 42.102(a), 42.15(a), 42.104, 42.8(b)(2), 42.8(b)(4), 42.6(a)(3), and 42.105.

(finding that where there was no parallel proceeding, “there is no concern of inconsistent outcomes or significant duplication of efforts resulting from two proceedings operating in parallel”); *Ascend Elements, Inc. v. Duesenfeld GmbH*, PGR2025-00037, Paper 9, 2 (PTAB Aug. 14, 2025) (rejecting discretionary denial request where district court proceeding was stayed, as there was “no immediate concern of inconsistent outcomes or significant duplication of efforts”). Because there is no concern of inconsistent outcomes or duplication of efforts, discretionary denial is unwarranted here.

B. This Is The First PGR Challenge After Original Prosecution

This PGR raises issues of first impression before the Office. The two-part framework set forth in *Advanced Bionics* to determine whether denial under § 325(d) is appropriate involves: (1) whether the same or substantially the same art or arguments were previously presented to the Office; and (2) if the first part is satisfied, whether the Office erred in a manner material to the patentability of the challenged claims. *Advanced Bionics, LLC v. MED-EL Elektromedizinische Geräte GmbH*, IPR2019-01469, Paper 6 (PTAB Feb. 13, 2020) (precedential). At the outset, neither Uhlmann nor Palazzolo was considered during prosecution of the ’146 Patent, so neither reference meets the first prong of *Advanced Bionics*. Additionally, the Examiner erred in overlooking Uhlmann and Palazzolo because neither reference was the basis for rejection during examination, the references are

not substantially the same as the prior art that the Examiner did apply during prosecution, and both references include specific teachings (regarding nanoemulsion formulations of ALA without propylene glycol and levels of preservatives in formulations, respectively) that are material to the patentability of the Challenged Claims of the '146 Patent. *Ecto World, LLC v. Rai Strategic Holdings, Inc.*, IPR2024-01280, Paper 13, 5-6 (PTAB May 19, 2025) (precedential). Accordingly, denial under § 325(d) is unwarranted here.

C. The Merits Of The Petition Are Exceptionally Compelling

The Petition presents compelling grounds based on Uhlmann and Palazzolo. For example, the Petition presents *two anticipation grounds* based on Uhlmann covering over half of the Challenged Claims, including the sole independent claim. *See* Pet., 3, 17-38, 44-66. The Petition presents two single-reference obviousness grounds for the remainder of the claims. *See* Pet., 3, 39-44, 66-74. The strength and simplicity of the merits favor institution.

V. CONCLUSION

For the reasons discussed above, Petitioner respectfully requests that the Director institute post-grant review, hold the Challenged Claims unpatentable, and cancel the Challenged Claims.

Dated: April 27, 2026

Respectfully submitted,

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CERTIFICATE OF SERVICE

Under 37 C.F.R. § 42.6(e), the undersigned certifies that on April 27, 2026, complete copies of the foregoing and any accompanying exhibits were caused to be served on counsel of record for the Patent Owner by filing this document through PTACTS and by sending this document via electronic mail to the following addresses:

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