

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SUN PHARMACEUTICAL INDUSTRIES, INC., and
SUN PHARMACEUTICAL INDUSTRIES, LTD.
Petitioner,
v.

BIOFRONTERA INC.,
Patent Owner.

Case No. IPR2026-00396
U.S. Patent No. 12,280,146

PATENT OWNER'S BRIEF ON DISCRETIONARY DENIAL

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PATENT OWNER’S EXHIBIT LIST

Exhibit No.	Description
2001	Declaration of Brian Larivee in support of being a provisionally recognized PTAB attorney
2002	<i>Not Used</i>
2003	<i>Not Used</i>
2004	Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations entry for U.S. Patent No. 12,280,146 (available at https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm) (last updated on March 19, 2026)
2005	Press Release, <i>Biofrontera Inc. Announces Patent for Propylene Glycol-Free Formula of Ameluz® (aminolevulinic acid HCl) Topical Gel, 10% Now Listed in FDA Orange Book</i> (published June 3, 2025)
2006	Press Release, <i>Biofrontera Inc. Announces Major Restructuring of Relationship With Biofrontera AG Backed By \$11 Million Investment</i> (published June 30, 2025)
2007	Press Release, <i>Biofrontera Inc. Completes Transfer of Ameluz® and RhodoLED® FDA approval and Associated Intellectual Property Portfolio</i> (published Dec. 18, 2025)
2008	Study Details for NCT03573401, Study to Evaluate the Safety and Efficacy of BF-200 ALA (Ameluz®) and BFRhodoLED® in the Treatment of Superficial Basal Cell Carcinoma (sBCC) With Photodynamic Therapy (PDT), sponsored by Biofrontera Inc. (available at https://clinicaltrials.gov/study/NCT03573401) (last updated on January 14, 2026)
2009	Webpage of Biofrontera Clinical Trials (available at https://survey.biofrontera.com/en/clinical-trials.html) (accessed on March 19, 2026)
2010	Max Beuroyre, Clinical-Trial Costing 101: Building a Phase-By-Phase Budget Your Board Will Trust, Abacum (June 25, 2025), (available at https://www.abacum.ai/blog/clinical-trial-costing) (last visited March 19, 2026)
2011	Sertkaya, A. <i>et. al.</i> , Costs of Drug Development and Research and Development Intensity in the US, 2000-2018. JAMA Network 2024;7(6):e2415445

Exhibit No.	Description
2012	U.S. Securities and Exchange Commission Form 10-K, Annual Report, submitted by Biofrontera Inc. on March 19, 2026
2013	Sun Pharmaceuticals Industries Ltd. Annual Report for 2024-2025

I. INTRODUCTION

This is Petitioner’s second petition challenging U.S. Patent No. 12,280,146 (the ’146 Patent). Petitioner’s first challenge was denied by the Director for failure “to carry its burden to establish that it has identified all RPIs [real parties in interest].” *Sun Pharmaceutical Industries, Inc. v. Biofrontera, Inc.*, PGR2026-0021, Paper No. 12 at 3 (Director May 26, 2026). The Director further found that converting the PGR to an IPR to permit correction of the real parties in interest was not possible, but instead noted that Petitioner “may file an IPR Petition” that would not be considered a repeat challenge. *Id.* at 4.

However, the instant IPR petition goes beyond the Director’s authorization to effectively convert the PGR petition into an IPR petition by including multiple pages of new substantive arguments. These new arguments by Petitioner in the IPR petition respond directly to arguments raised in Patent Owner’s Preliminary Response in the PGR concerning why, on the merits, the petition fails to show a likelihood of success. In essence, Petitioner appears to believe that it should be rewarded for its failure to properly name all real parties in interest with the opportunity to provide new and additional merits arguments in its petition to address the holes that Patent Owner identified. Petitioner’s abuse of this process is unjust and warrants denial. *See e.g., Toyota Motor Corp. v. Cellport Systems, Inc.*, IPR2015-01423, Paper 7 at 8 (PTAB

Oct. 28, 2015) (second filing denied in part because “the opportunity to read Patent Owner’s Preliminary Response in IPR2015-00634, prior to filing the Petition here, is unjust.”).

In addition, the instant petition still fails to comply with the statutory requirement to identify “all real parties in interest” because it does not name other entities publicly identified in Petitioner’s financial reports as having an interest in this proceeding. While Petitioner added its parent company as a real party in interest, it did not name as real parties in interest any of the other related entities for which Patent Owner presented evidence. The Director’s decision denying the PGR did not address any of these other entities since it found the failure to name the parent company was enough to warrant denial. Yet, the Director’s decision made clear that Petitioner has the burden to identify “all RPIs,” which Petitioner has again failed to do. *Sun Pharma v. Biofrontera*, PGR2026-0021, Paper No. 12 at 3.

Lastly, Patent Owner has made considerable U.S.-based investments in the ’146 Patent. Patent Owner is a U.S.-based company that purchased the ’146 Patent and other U.S. intellectual property assets related to the drug Ameluz[®] from its Germany-based former parent company. Ameluz[®] is undergoing multiple clinical trials in the United States to investigate its use as a treatment for various skin conditions, including skin cancer. These clinical trials require considerable investment and employ numerous U.S.-based workers to conduct them.

For at least these reasons, the Director should discretionarily deny the Petition.

II. PETITIONER’S NEW ARGUMENTS ABUSE THE DIRECTOR’S AUTHORIZATION TO FILE THE PRIOR PETITION AS AN IPR

In denying review of the petition in PGR2026-0021, the Director noted that correcting the real parties in interest was not possible within the 9-month window for a PGR and that there does not exist a statutory provision to convert a PGR to an IPR. *Sun Pharma v. Biofrontera*, PGR2026-0021, Paper No. 12 at 3. Instead, the Director permitted Petitioner to accomplish a similar outcome by refiling the petition as an IPR while naming the additional real parties in interest:

Petitioner requests that the instant PGR petition be converted into an IPR petition if the addition of SPI Ltd. requires a new filing date. *Id.* Adding an RPI requires according a new filing date to the Petition. See *Corning Optical*, Paper 68 at 23. There is no statutory provision or rule for converting a PGR into an IPR. Accordingly, this Petition is denied and Petitioner may file an IPR petition. [FN1. If Petitioner chooses to file an IPR petition, that petition will not be considered a repeat challenge for discretionary purposes.]

Id. at 3-4.

However, rather than refile the PGR petition in IPR format with an updated list of real parties in interest, Petitioner decided to bolster the IPR petition with new merit arguments. Indeed, Petitioner freely acknowledges that its IPR petition has been modified to address Patent Owner’s preliminary response arguments raised in the prior PGR. See IPR2026-00396, Petition at 12-16 (“In PGR2026-00021, Patent

Owner alleged...”). Petitioner then includes four pages of new merit arguments addressing claim construction issues raised in Patent Owner’s Preliminary Response in the PGR.

Using Patent Owner’s prior Preliminary Response as a roadmap to add new merit arguments to the petition is an unjust abuse of the Director’s authorization and a basis for denial. *Toyota v. Cellport*, IPR2015-01423, Paper 7 at 8 (second IPR filing denied in part because “the opportunity to read Patent Owner’s Preliminary Response in IPR2015-00634, prior to filing the Petition here, is unjust.”); *Metall Zug AG v. Carl Zeiss Meditec AG*, IPR2020-01074, Paper 8 at 8 (PTAB Jan. 5, 2021) (denying IPR where Petitioner “took advantage” of Patent Owner’s prior response to revise arguments in the second IPR petition).

If the Petition is not denied, Petitioner’s failure to comply with the real party in interest rules will ironically reward Petitioner with the opportunity to strengthen its petition. In addition, adding new merit arguments is not the same as converting the PGR petition to IPR format, which exceeds the Director’s authorization. Therefore, the Director should deny the instant petition.

III. PETITION STILL FAILS TO NAME ALL REAL PARTIES IN INTEREST

Pursuant to 35 U.S.C. § 322(a)(2), a PGR petition must identify all real parties-in-interest. See *Corning Optical Communications RF, LLC v. PPC Broadband, Inc.*, IPR2014-00440, Paper 68 at 4 (PTAB Aug. 18, 2015)

(Precedential except for § II.E.1) (“Because the Petitions fail to identify all real parties in interest as required by 35 U.S.C. § 312(a)(2), we grant Patent Owner’s Motions to Dismiss”). Here, the Petition identifies both Sun Pharmaceutical Industries, Inc. (“SPII”) and Sun Pharmaceutical Industries, Ltd. (“SPIL”) as joint petitioners and as real parties in interest. Pet. at 2. Petitioner asserts it does not need to name any other related corporation because “none of the other subsidiaries identified by Patent Owner have the ‘ability to control the proceeding.’” *Id.* (quoting *Sun Pharma v. Biofrontera*, PGR2026-0021, Paper No. 12 at 2-3).

Yet Petitioner overlooks that the real-party-in-interest test encompasses more than just entities with the ability to control the proceeding. The Federal Circuit has held that real parties in interest in an IPR include “a clear beneficiary that has a preexisting, established relationship with the petitioner.” *Applications in Internet Time, LLC v. RPX Corp.*, 897 F.3d 1336, 1351 (Fed. Cir. 2018).

Here, Petitioner SPII’s financial statements are consolidated with four other Sun Pharma entities: 1) Sun Pharma New Milford Parent LLC, 2) Sun Pharma Housatonic LLC, 3) Sun Pharma Housatonic II LLC, and 4) Sun Pharma Housatonic III LLC. Ex. 2013 at 309. As such, any financial benefits that accrue to SPII via success in this IPR would likewise benefit the four companies whose financial statements are consolidated with those of SPII. As such, at least these four entities are clear beneficiaries with preexisting relationships with Petitioner.

In the PGR, Petitioner asserted that these four companies should not be named as real parties in interest because they are “are holding companies that do not manufacture, market, or sell the PDT Products.” *Sun Pharma v. Biofrontera*, PGR2026-0021, Paper No. 10 at 11. Even if that assertion is accepted as true, it does not refute the fact that these companies could benefit from Petitioner’s commercial success with PDT products. At a minimum, improved finances for SPII improves consolidated financial statements which flows to these other entities. Further, these holding companies might have rights to receive revenue, payments, or other benefits from Petitioner even if the holding companies themselves “do not manufacture, market or sell the PDT products.” The fact that their finances are consolidated with Petitioner increases the likelihood of a mutually beneficial relationship.

In addition, it is not Patent Owner’s burden to prove the beneficial relationships between these entities (which would be difficult to prove without broad discovery), but rather it is Petitioner’s burden to establish that it properly named all real parties in interest in light of the facts suggesting a preexisting beneficial relationship. *Yangtze Memory Tech. Co., Ltd. v. Micron Tech., Inc.*, IPR2025-00098, Director Order Denying Institution, Paper No. 38 at 8 (Informative) (“With its identification of RPIs in dispute, it was Petitioner’s burden to bring forth evidence or arguments demonstrating that it named all RPIs.”). A conclusory statement that none of these four entities make, manufacture, or sell products is insufficient to show

that they would not benefit from Petitioner's success in this proceeding. There is no evidence corroborating the self-serving statements from Petitioner on this front.

Therefore, the Petition fails to meet its burden that it identified all real parties in interest and should be denied.

IV. PETITION SHOULD BE DENIED AS PATENT OWNER HAS SETTLED EXPECTATIONS VIA U.S.-BASED INVESTMENTS RELATED TO THE '146 PATENT

Patent Owner has made substantial U.S.-based investments in the commercial development of products encompassed by the '146 Patent and in the market for those products. The '146 Patent is part of Patent Owner's portfolio for Ameluz[®] as recognized in the FDA Orange Book. Ex. 2004. In addition, Patent Owner's press releases have publicized that the invention of the '146 Patent relates to the "propylene glycol-free formulation of Ameluz[®]." Ex. 2005 (noting the "patent for the revised formulation of Ameluz[®] was issued on April 22, 2025," which is a reference to the '146 Patent); see Ex. 1001 at cover ('146 Patent issued on "Apr. 22, 2025").

Significantly, Patent Owner "is a U.S.-based biopharmaceutical company" that in 2025 acquired all U.S. intellectual property associated with Ameluz[®], including the '146 Patent, from its Germany-based former parent company. Ex. 2007 (Patent Owner's Dec. 18, 2025, press release); Ex. 2006 (Patent Owner's June 30, 2025, press release); see also USPTO Assignment Records at Reel/Frame

73509/0006. This transfer of assets from the Germany-based former parent company to a U.S.-based company was “secured, in part, by an \$11.0 million investment.” Ex. 2007 at 1.

In addition to the \$11 million investment to transfer these assets to a U.S.-based company, clinical studies to further develop Ameluz[®] are also being conducted in the United States. *See, e.g.*, Ex. 2008 (“Phase 3” clinical trial studying Ameluz[®] for treatment of certain skin cancer conducted “at 15 sites in the United States of America.”); *see also* Ex. 2009 (listing multiple trials for Ameluz[®] that are “conducted in the US”). On average, phase 1 trials cost about \$5M, phase 2 trials cost \$7M-\$20M, and phase 3 trials cost \$20M-\$100M. Ex. 2010 at 3; Ex. 2011 at 1-2. Thus, these trials to study Ameluz[®] and expand its potential indications for treating patients represent a substantial additional investment in the United States related to the ’146 Patent. *See Amgen, Inc. v. BMS*, IPR2025-00601, Paper 9 at 2 (PTAB July 24, 2025) (“an extraordinary amount of investment, time, and resources dedicated to research, development, trials, and regulatory approval correlates to settled expectations”); *see also Empower Clin. Servs. LLC v. Eli Lilly & Co.*, IPR2025-01024, Paper 15 at 2 (citing investment in clinical trials as part of the reason for discretionary denial).

Biofrontera is a small U.S.-based business that controls and runs its clinical trials in the U.S. Presently, its only commercial pharmaceutical product is Ameluz[®],

which is approved for use in combination with its medical devices, the BF-RhodoLED and RhodoLED® XL. Biofrontera’s revenue, therefore, is heavily dependent on sales of Ameluz®. *See* Ex. 2012 at 4-5. At the end of 2025, Biofrontera had 92 employees, with over 80% of those employees located in the U.S. *Id.* at 5. As Biofrontera explains in its 10-K, core aspects of its strategy depend on conducting clinical research to create new label indications and extensions. *See Id.* at 4-5 (“Our Strategy”). Beginning on June 1, 2024, Biofrontera assumed control of all clinical trials relating to Ameluz® in the U.S. Its efforts have since resulted in one new label expansion covering treatment with up to three tubes, two ongoing clinical trials, and three clinical trials in the planning stages. *Id.* at 6. Of note, following a Phase III clinical trial, the FDA has accepted Biofrontera’s filing to use Ameluz® for the treatment of superficial basal cell carcinoma (“sBCC”) and set a Prescription Drug User Fee Act (“PDUFA”) date of September 28, 2026. *Id.* at 6. Importantly, the FDA approved the formulation of Ameluz® covered by this patent in 2024, and this formulation is used in U.S. production of Ameluz®, including for clinical trials. *See Id.* at 6. Over the 2025 fiscal year, Biofrontera’s R&D spending increased by nearly 80 percent, to \$3.7 million. *Id.* at 40. The plurality of that spending—over \$1.5 million—was for Biofrontera’s personnel-related costs. *Id.* Thus, although Biofrontera is a relatively small company, the majority of its employees are in the

U.S. and a significant part of its focus and spending is on U.S. clinical research and development.

V. CONCLUSION

The Petition unjustly adds new substantive arguments to the second petition to address holes that Patent Owner pointed out in the first petition. This second petition also still fails to meet the requirement that it name all real parties in interest given its failure to name beneficiaries that have a preexisting, established relationship with Petitioner. Lastly, Patent Owner has made substantial U.S.-based investments related to the '146 Patent. These reasons support discretionary denial of this Petition.

Therefore, the Director should discretionarily deny institution of this IPR.

Respectfully submitted,

Dated: September 21, 2026

/James P. Murphy/
James P. Murphy
Reg. No. 55,474
Polsinelli PC

1000 Louisiana Street
Suite 6400
Houston, Texas 77002

Brian Larivee
pro hac vice
Polsinelli PC
One International Place
100 Oliver St.
Suite 3900
Boston, Massachusetts 02110

Kendall Gurule
Reg. No. 77,605
Polsinelli PC
1401 I St NW Suite 800
Washington, DC 20005

CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. §§ 42.6(e)(4)(i) *et seq.* and 42.105(b), the undersigned certifies that on September 21, 2026, complete copies of the foregoing document, including all supporting exhibits, are being served via email on the following counsel of record for Petitioner:

Yung-Hoon Ha
yha@desmaraisllp.com

Bridget P. Belcher
bbelcher@desmaraisllp.com

SunPharmaIPRService@desmaraisllp.com

/Ericka Murray/
Ericka Murray
Polsinelli PC
1000 Louisiana Street
Suite 6400
Houston, Texas 77002