

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SUN PHARMACEUTICAL INDUSTRIES, INC.,
Petitioner,
v.

BIOFRONTERA INC.,¹
Patent Owner.

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

PATENT OWNER'S BRIEF ON DISCRETIONARY DENIAL

¹ Petitioner incorrectly identifies the patent owner as Biofrontera Bioscience GMBH. However, Biofrontera Bioscience GMBH assigned all interest in U.S. Patent No. 12,280,146 to Biofrontera Inc. *See* Reel/Frame 73509/0006 recorded on Nov. 5, 2025 (available at <https://assignmentcenter.uspto.gov/search/patent>).

TABLE OF CONTENTS

I.	INTRODUCTION	1
II.	PETITION FAILS TO NAME ALL REAL PARTIES-IN-INTEREST	2
III.	PETITION SHOULD BE DENIED AS PATENT OWNER HAS SETTLED EXPECTATIONS VIA U.S.-BASED INVESTMENTS RELATED TO THE '146 PATENT	5
IV.	CONCLUSION.....	8

PATENT OWNER'S EXHIBIT LIST

Exhibit No.	Description
2001	Declaration of Brian Larivee in support of being a provisionally recognized PTAB attorney
2002	Press Release, <i>Sun Pharma Announces Jeremy Allen as Vice President, Corporate Affairs for North America</i> (published October 22, 2025)
2003	Press Release, <i>Sun Pharma Announces the Availability of UNLOXCYT™ (cosibelimab-ipdl) for Advanced Cutaneous Squamous Cell Carcinoma (aCSCC)</i> (published January 15, 2026)
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 Beauroyre, 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)

Exhibit No.	Description
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
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

Patent Owner, Biofrontera Inc. (“Patent Owner” or “Biofrontera”), respectfully requests that the Director exercise his discretion to deny the Petition for post-grant review filed by Sun Pharmaceutical Industries, Inc. (“Petitioner”) challenging U.S. Patent No. 12,280,146 (the ’146 patent).

First, the Petition failed to comply with the statutory requirement to identify “all real parties in interest” because it does not name other entities publicly identified in its financial reports as having an interest in this proceeding, including at least its parent company. Notably, the Petitioner failed to provide this information despite the Petition being filed months after the Director issued a memorandum emphasizing the Office’s renewed enforcement of this requirement. *See* Memorandum on Interim Processes for PTAB Workload Management (October 28, 2025) (reinstating prior Office guidance on identification of real parties in interest).

Second, 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. PETITION 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 only identifies Petitioner itself, Sun Pharmaceutical Industries, Inc., as a real party-in-interest. Pet. at 1. Yet Petitioner overlooks the scope of the test for real party-in-interest, which requires at least its parent to be named (and perhaps other related entities to Petitioner).

The Federal Circuit has held that the test for real party-in-interest in an IPR “demands a flexible approach...an eye toward determining whether the non-party is 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). There is little doubt that Sun Pharmaceutical Industries Ltd. (“SPIL”), Petitioner’s India based parent company, should have been named as a real party-in-interest in the Petition.

First, SPIL owns 100% of Petitioner and consolidates Petitioner’s financial statements with its own:

a) List of entities included in the consolidated financial statements is as under:				
		Country of Incorporation	Effective ownership for the year ended	
			As at March 31, 2025	As at March 31, 2024
Parent Company				
Sun Pharmaceutical Industries Limited				
. . .				
20	Sun Pharmaceutical Industries, Inc.	United States of America	100.00%	100.00%

Ex. 2013 at 260. Given this relationship with Petitioner, SPIL would be “a clear beneficiary that has a preexisting, established relationship with the petitioner.” *Applications in Internet Time*, 897 F.3d at 1351. In addition, Petitioner’s financial statements are further 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. In total, SPIL lists 130 entities from which it consolidates financial information, including Petitioner. *Id.* at 260-263.

Further illustrating the level of control SPIL has over Petitioner is the fact that Petitioner issues press releases in the name of SPIL and vice versa. For instance, a press release dated October 22, 2025, uses letterhead for “Sun Pharmaceutical Industries Inc. [Petitioner]” but states in the body of the press release that it is issued by “Sun Pharmaceutical Industries Limited [SPIL]” to announce a new “Vice President, Corporate Affairs for North America.” Ex. 2002 at 1. Similarly, a press release dated January 16, 2026, issued on SPIL letterhead identifies yet another SPIL subsidiary, Checkpoint Therapeutics, Inc., as having certain “trademark rights”

while bearing a copyright indication in the name of Petitioner. *See* Ex. 2003 at 1 (letterhead for “Sun Pharmaceutical Industries Limited [SPIL]”) and 4 (“© 2026 Sun Pharmaceutical Industries, Inc. [Petitioner] All rights reserved. UNLOXCYT and UNLOXCYT SUPPORT are trademarks of Checkpoint Therapeutics, Inc.”).

The common interests and intermingling of Petitioner, its parent SPIL, and other related subsidiaries in financial records and press releases call into question Petitioner’s failure to properly identify all real parties-in-interest. It is Petitioner’s burden to establish that it properly named all real parties-in-interest for this PGR. *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.”); *see also Aruze Gaming Macau, Ltd. v. MGT Gaming, Inc.*, Case IPR2014-01288, Paper 13 at 12 (PTAB Feb. 20, 2015) (“if a nonparty can influence a petitioner’s actions in a proceeding before the Board, to the degree that would be expected from a formal copetitioner, that nonparty should be considered a[] [real party-in-interest] to the proceeding.”); and *Radware, Inc. v. F5 Networks, Inc.*, IPR2017-01249, Paper 10 at 7 (PTAB Oct. 23, 2017) (unnamed party can be considered an RPI where “an actual measure of control or opportunity to control the filing of and participation in an IPR might reasonably be expected”).

Therefore, the Petition fails to identify all the real-parties-in-interest in accordance with the Director's October 28, 2025 memo and the Petition should be denied.

III. 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 and market for products encompassed by the '146 Patent. 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 Dec. 18, 2025 press release); Ex. 2006 (Patent Owner 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 its \$11 million investment to transfer these assets to a U.S.-based company, clinical studies to further the development of Ameluz[®] are also being run 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, conducting phase 1 trials costs 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 US-based business that controls and runs its clinical trials in the US. Presently, its only commercial pharmaceutical product is Ameluz[®], which is approved 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 (“Overview” and “Our Strategy” sections). At the end of 2025, Biofrontera had 92 employees, with over 80% of those employees located in the US. *Id.* at 5 (“Employees”). 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 US. Its efforts have since resulted in one new label expansion to cover up to three tubes for treatment, two clinical trials ongoing, 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 in use in the US 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—is for Biofrontera’s personnel-related costs. *Id.* Thus, although Biofrontera is a relatively small company, the majority of its employees are in the US and a significant part of its focus and spending is on US clinical research and development.

IV. CONCLUSION

The Petition fails to meet the requirement that it name all real parties-in-interest. In addition, Patent Owner has made substantial U.S.-based investments related to the '146 Patent. These reasons support discretionary denial of this Petition. Lastly

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

Dated: March 27, 2026

Respectfully submitted,

/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 March 27, 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

SunPharmaPGRService@desmaraisllp.com

/James P. Murphy /
James P. Murphy
Reg. No. 55,474
Polsinelli PC
1000 Louisiana Street
Suite 6400
Houston, Texas 77002