

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

DECLARATION OF EDWARD GIMMI, PH.D.

I, Edward Gimmi, declare as follows:

1. I am the Associate Vice President, Brand Patent Strategy and Portfolio Management for Sun Pharmaceutical Industries, Inc. (“SPI Inc.”). I am employed by SPI Inc.

Sun Pharmaceutical Industries Inc. Overview

2. SPI Inc. is a corporation organized and existing under the laws of Delaware. SPI Inc. maintains its business operations in Princeton, New Jersey, USA. Exhibit 1030 (DUSA Pharmaceuticals, Inc. and Sun Pharmaceutical Industries, Inc. Merger Documents).

3. SPI Inc.’s CEO, Richard Ascroft, maintains his office in Princeton, New Jersey. SPI Inc.’s executive leaders include Mr. Ascroft; Reem Malki, Executive Vice President and Chief Quality Officer; Sridhar Shankar, Senior Vice President and Head of Global Product and Innovation; and Erik Zwicker, Senior Vice President and General Counsel. In addition, Frank Righetti, Vice President and Business Unit Head of Cutaneous Oncology, leads the teams responsible for Levulan® Kerastick® at SPI Inc. Ms. Malki, Mr. Shankar, Mr. Zwicker, and Mr. Righetti are all located in the United States. Exhibits 1031 (<https://sunpharma.com/usa/about-us/>), 1038 (<https://www.linkedin.com/in/frank-righetti-a4369127/>).

4. SPI Inc. is an indirect wholly-owned subsidiary of Sun Pharmaceutical Industries, Ltd. (“SPI Ltd.”).

5. SPI Inc. maintains a separate legal department from SPI Ltd. For example, 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.

SPI Inc.’s Business Operations

6. SPI Inc. is a corporation engaged in the business of, *inter alia*, manufacturing, distributing, marketing, and selling pharmaceutical formulations covering a broad spectrum of chronic and acute therapies, including photodynamic therapy (“PDT”).

7. My understanding is that on March 31, 2024, DUSA Pharmaceuticals, Inc. (“DUSA”) merged into SPI Inc. *See* Exhibit 1030 (DUSA Pharmaceuticals, Inc. and Sun Pharmaceutical Industries, Inc. Merger Documents). DUSA, which no longer exists as an entity, was the first in the industry to present aminolevulinic acid (“ALA”) for PDT to the FDA for the treatment of actinic keratosis of the face and scalp. SPI Ltd. was not involved with the merger of DUSA and SPI Inc.

8. In 1999, the FDA approved the use of ALA, under the name Levulan® Kerastick®, in combination with DUSA’s BLU-U® illuminator for the treatment of

non-hyperkeratotic actinic keratosis of the face and scalp. The FDA has since approved the Levulan® Kerastick® and BLU-U® combination therapy for additional indications.

9. My understanding is that Abhay Gandhi, who was the President and Chief Executive Officer of SPI Inc. in 2024, signed the merger documents. Exhibit 1030 (DUSA Pharmaceuticals, Inc. and Sun Pharmaceutical Industries, Inc. Merger Documents).

10. SPI Inc. currently has three PDT products: (1) Levulan® Kerastick®, which is the pharmaceutical composition containing ALA that competes with Biofrontera's Ameluz®, (2) the BLU-U® 4170D Blue Light Photodynamic Therapy Illuminator, and (3) the BLU-U® 4170E Blue Light Photodynamic Therapy Illuminator ("PDT Products").

11. U.S. revenue for the PDT Products is earned by SPI Inc. My understanding is that SPI Inc. spends millions of dollars per year on PDT-related expenses in the United States, amounting to eight figures annually.

12. As part of its business, SPI Inc. prepares and files Abbreviated New Drug Applications ("ANDAs") and New Drug Applications ("NDAs"). SPI Ltd. has not prepared or filed ANDAs or NDAs related to PDT.

13. My understanding is that DUSA (now SPI Inc.) prepared and filed NDA No. N020965, which is directed to Levulan® Kerastick®. DUSA (now SPI

Inc.) paid all fees associated with the filing of NDA No. N020965. The individuals who prepared and filed NDA No. N020965 are/were employed by DUSA (now SPI Inc.). *See* Exhibits 1032 (NDA No. N020965 Levulan® Kerastick® Administrative Documents), 1033 (NDA No. N020965 Levulan® Kerastick® Label).

14. My understanding is that DUSA (now SPI Inc.) prepared and filed PMA No. P990019, which is directed to the BLU-U® Blue Light Photodynamic Therapy Illuminator. DUSA (now SPI Inc.) prepared and filed 510(k) No. K031805, which is directed to the BLU-U® 4170D Blue Light Photodynamic Therapy Illuminator. My understanding is that DUSA (now SPI Inc.) paid all fees associated with the filing of PMA No. P990019 and 510(k) No. K031805. The individuals who prepared and filed PMA No. P990019 and 510(k) No. K031805 are/were employed by DUSA (now SPI Inc.). *See* Exhibits 1034 (PMA No. P990019 BLU-U® Approval Letter), 1035 (PMA No. P990019 BLU-U® Safety and Effectiveness Data), 1036 (510(k) No. K031805 BLU-U® 4170D Summary).

15. My understanding is that DUSA (now SPI Inc.) prepared and filed 510(k) No. K241358, which is directed to the BLU-U® 4170E Blue Light Photodynamic Therapy Illuminator. SPI Inc. paid all fees associated with the filing of 510(k) No. K241358. The individuals who prepared and filed 510(k) No. K241358 are/were employed by DUSA (now SPI Inc.). *See* Exhibit 1037 (510(k) No. K241358 BLU-U® 4170E Statement).

SPI Inc.'s Involvement With The Instant Petition

16. SPI Inc. and its in-house counsels in the United States were—and are—the sole corporate entities ultimately responsible for directing and funding the preparation and filing of the petition for post-grant review of U.S. Patent No. 12,280,146.

17. SPI Inc. was—and is—the only entity financially responsible for the Petition filing and associated legal expenses.

18. Other than SPI Inc., neither SPI Ltd. nor any of the other entities listed in Exhibit 2013 provided funding or other compensation for the preparation or filing of the Petition for this PGR proceeding.

19. In-house counsel employed by SPI Inc. selected and hired outside counsel for this PGR proceeding.

20. 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. SPI Inc.'s billing department keeps invoice payment for the instant Petition accurate.

21. Levulan® Kerastick®, which competes with Biofrontera's Ameluz®, is not owned by, manufactured by, or marketed by SPI Ltd. SPI Inc. owns, manufactures, and markets Levulan® Kerastick®.

Other Sun Pharma Entities

22. SPI Ltd. is a parent company to numerous other companies, such as SP New Milford Parent LLC, SP Housatonic LLC, SP Housatonic II LLC, SP Housatonic III LLC, and Checkpoint Therapeutics, Inc.

23. My understanding is that Sun Pharma New Milford Parent LLC, SP Housatonic LLC, SP Housatonic II LLC, and SP Housatonic III LLC are holding companies. My understanding is that, prior to its acquisition by SPI Ltd., Checkpoint Therapeutics, Inc. developed immunotherapies for patients with solid tumor cancers, such as Unloxcyt™, an anti-PD-L1 treatment for metastatic or locally advanced cutaneous squamous cell carcinoma. Exhibit 2013 (Sun Pharmaceuticals Industries Ltd. Annual Report for 2024-2025), 7.

24. My understanding is that, following their inception as affiliates of SPI Ltd., none of the aforementioned entities currently have any full-time employees.

25. I am not employed by Sun Pharma New Milford Parent LLC, SP Housatonic LLC, SP Housatonic II LLC, SP Housatonic III LLC, or Checkpoint Therapeutics, Inc.

26. Sun Pharma New Milford Parent LLC, SP Housatonic LLC, SP Housatonic II LLC, SP Housatonic III LLC, and Checkpoint Therapeutics, Inc. were not involved with the merger of DUSA and SPI Inc.

27. My understanding is that none of the aforementioned entities in Paragraph 22 are engaged in the business of manufacturing, distributing, marketing, and selling pharmaceutical formulations used with PDT.

28. None of the aforementioned entities in Paragraph 22 had, or will have, any involvement or input into this instant proceeding.

29. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under § 1001 of Title 18 of the United States Code.

April 27, 2026

Date



Edward Gimmi, Ph.D.