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*Attorneys for Plaintiff Sun Pharmaceutical
Industries, Inc.*

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

SUN PHARMACEUTICAL INDUSTRIES,
INC.

Plaintiff,

v.

BIOFRONTERA BIOSCIENCE GMBH,
BIOFRONTERA PHARMA GMBH,
BIOFRONTERA AG, and BIOFRONTERA
INC.

Defendants.

Civil Action No. _____

**SUN PHARMACEUTICAL
INDUSTRIES, INC.'S COMPLAINT FOR
PATENT INFRINGEMENT**

JURY TRIAL DEMANDED

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Sun Pharmaceutical Industries, Inc. (“Sun Pharma” or “Plaintiff”) hereby files this Complaint against Defendants Biofrontera Bioscience GmbH; Biofrontera Pharma GmbH; Biofrontera AG (collectively, the “Biofrontera Foreign Entities”); and Biofrontera Inc. (with the Biofrontera Foreign Entities, “Biofrontera” or “Defendants”); and alleges as follows:

I. NATURE OF ACTION

1. Sun Pharma brings this action for patent infringement under 35 U.S.C. § 271 against Defendants for infringing U.S. Patent Nos. 11,446,512 (the “’512 Patent”) and 11,697,028 (the “’028 Patent”) (collectively, the “Asserted Patents”) by making, using, importing, offering to sell, and selling certain photodynamic therapy (“PDT”) treatments, such as the BF-RhodoLED® XL (alternatively, the “RhodoLED® XL”) device, individually and in combination with Ameluz® prescription medicine (collectively, the “Accused Products”).

II. THE PARTIES

A. Plaintiff Sun Pharma

2. Sun Pharma is a corporation organized under the laws of Delaware, having its principal place of business at 2 Independence Way, Princeton, NJ 08540.

3. Sun Pharma is the assignee and sole owner of the Asserted Patents.

4. Among its many product offerings, Sun Pharma designs, markets, and sells photodynamic therapy systems, including BLU-U® Blue Light Photodynamic Therapy Illuminator devices, as well as pharmaceutical products, including the Levulan® prescription medicine, used in combination with BLU-U® Blue Light Photodynamic Therapy Illuminator devices.

B. Defendant Biofrontera Inc.

5. On information and belief, Defendant Biofrontera Inc. uses, offers to sell, and/or sells the Accused Products within the United States and/or imports into the United States the Accused Products.

6. Biofrontera Inc. is a corporation organized and existing under the laws of Delaware, with a principal place of business at 120 Presidential Way, Suite 300, Woburn, MA 01801.

7. On information and belief, Biofrontera Inc. is the United States “commercial arm” of the “Biofrontera Group” (described below). Biofrontera AG, *Annual Report 2023*, at 2 (Apr. 29, 2024) [hereinafter “AG Annual Report”], https://www.biofrontera.com/fileadmin/files/PDFs/Financial_Reports/2023/20240429_AR_2023_EN.pdf. Biofrontera Inc. was established in March 2015 as a “wholly owned subsidiary of Biofrontera AG.” Biofrontera Inc., *Form 10-K*, at 4 (Mar. 15, 2024) [hereinafter “Biofrontera Inc. 10-K”], <https://www.sec.gov/Archives/edgar/data/1858685/000149315224010133/form10-k.htm>.

8. On information and belief, Biofrontera Inc. pays a license fee to Biofrontera AG “structured as a tiered system. This pricing mechanism entails charging 50% of sales for volumes up to USD 30 million, as well as 40% for all sales between USD 30 million and USD 50 million.” AG Annual Report, at 1. “Sales with Biofrontera Inc. account for 69% of the [Biofrontera] Group’s total sales.” AG Annual Report, at 67.

C. Defendant Biofrontera Pharma GmbH

9. On information and belief, Defendant Biofrontera Pharma GmbH uses, offers to sell, and/or sells the Accused Products within the United States and/or imports into the United States the Accused Products.

10. Biofrontera Pharma GmbH is a corporation organized and existing under the laws of Germany, with a principal place of business at Hemmelrather Weg 201, 51377 Leverkusen,

Germany. Biofrontera Pharma GmbH is a “wholly owned subsidiary” of Biofrontera AG. AG Annual Report, at 1.

11. Biofrontera Pharma GmbH is a member of the Biofrontera Group and is “the holder of the CE certificate of BF-RhodoLED®” and “bears the responsibility for the production, further licensing and marketing of Biofrontera Group’s approved products.” AG Annual Report, at 1. Biofrontera Pharma GmbH also holds some of the Biofrontera Group’s patents. AG Annual Report, at 9.

12. On information and belief, Biofrontera Pharma GmbH knows the Accused Products are manufactured abroad and imported into the United States. Biofrontera Pharma GmbH manufactures Biofrontera’s BF-RhodoLED® XL abroad in Leverkusen Germany, as reflected by the device’s label:

Manufacturer	Biofrontera Pharma GmbH Hemmelrather Weg 201 51377, Leverkusen Germany www.biofrontera.com	Product	RhodoLED XL Medical Device Class III ME Equipment Class I
Protection Class	IP20	Order No	BF-LED-XL
Power Supply	XP-Power GSP750PS48-EF 100-120 VAC / 60 Hz Power Input: 750 VA	Serial-No	LEDXLUS-000-000
Weight	Ca. 75 kg	Date of Manufacture	yyyy/mm/dd
UDI	(01)4260308240164 (21)LEDXLUS-000-000 (11)yyyy-mm-dd	  	
			
MEDICAL - GENERAL MEDICAL EQUIPMENT AS TO ELECTRICAL SHOCK, FIRE, AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH „ANSI/AAMI E560601-1 (2005) + AMD 1 (2012)“, „IEC 60601-1-6:2013“			

Biofrontera Inc., *User Manual for RhodoLED® XL*, Fig. 21 (Nov. 2021) [hereinafter “BF-RhodoLED® XL User Manual”], <https://www.ameluz.com/fileadmin/AmeluzUSImages/05->

pdf/Ameluz-Full-Prescribing-Information.pdf; *see also* AG Annual Report, at 1 (stating that the “PDT-lamp series,” which includes the BF-RhodoLED® XL, are “manufactured at Biofrontera’s headquarter in Leverkusen, Germany.”).

13. On information and belief, Biofrontera Pharma GmbH took actions purposefully directed to the United States by entering into a license agreement with Biofrontera Inc. to import and sell the Accused Products. Biofrontera Pharma GmbH *et al.*, *Second Amended and Restated License and Supply Agreement*, at 1 (Feb. 19, 2024) [hereinafter “Supply Agreement”], <https://www.sec.gov/Archives/edgar/data/1858685/000149315224007143/ex10-1.htm>. On information and belief, Biofrontera Pharma GmbH is “the sole supplier” of the RhodoLED® XL device and Ameluz® prescription medicine to Biofrontera Inc. Supply Agreement, Sec. 5.1.

14. On information and belief, Biofrontera Pharma GmbH controls the volume of Accused Products that enter the United States, at least through forecasts and orders sent to Biofrontera Inc. Biofrontera Pharma GmbH “will organize the shipment” for the BF-RhodoLED® XL device “from the sites of manufacturing to the destination provided in [Biofrontera Inc.]’s order and be responsible for import into the USA.” Supply Agreement, Sec. 5.3. Biofrontera Inc. must “comply with branding guidance developed by [Biofrontera Pharma GmbH] and to provide to [Biofrontera Pharma GmbH] for its review copies of any advertising materials, websites and any other items, materials and media showing any of the Trademarks . . .” Supply Agreement, Sec. 2.1(b).

15. On information and belief, Biofrontera Pharma GmbH and Defendant Biofrontera Bioscience GmbH (discussed below) are “responsible for obtaining and maintaining the rights to all [U.S. Food & Drug Administration (“FDA”)] Approvals and any amendments or supplements required” for Biofrontera Inc. to sell or distribute Ameluz® prescription medicine in the United

States. Supply Agreement, Sec. 10.1. Likewise, on information and belief, Biofrontera Pharma GmbH and Biofrontera Bioscience GmbH are “responsible for obtaining and maintaining all FDA Approvals and any amendments or supplements required in order for [Biofrontera Pharma GmbH] to manufacture or have manufactured” the BF-RhodoLED® XL device and the Ameluz® prescription medicine. Supply Agreement, Sec. 10.1.

16. On information and belief, Biofrontera Pharma GmbH requires Biofrontera Inc. to handle importation formalities, such as fees, import clearance, and duties: “Incoterms used for shipment of PRODUCTS from Pharma to INC shall be CFR for Ameluz ® and DDP for BF RhodoLED®.” Supply Agreement, Sec. 5.3.

D. Defendant Biofrontera Bioscience GmbH

17. On information and belief, Biofrontera Bioscience GmbH uses, offers to sell, and/or sells the Accused Products within the United States and/or imports into the United States the Accused Products.

18. Biofrontera Bioscience GmbH is a corporation organized and existing under the laws of Germany, with a principal place of business at Hemmelrather Weg 201, 51377 Leverkusen, Germany. Biofrontera Bioscience GmbH is a wholly owned subsidiary of Biofrontera AG. AG Annual Report, at 1.

19. Biofrontera Bioscience GmbH “carries out research and development tasks as well as all regulatory functions for the Biofrontera Group and holds the patents and approvals for Ameluz® as well as BF-RhodoLED® and RhodoLED® XL.” AG Annual Report, at 1; *see also id.* at 7 (“All research and development activities of the Biofrontera Group relating to . . . Ameluz® are carried out by Biofrontera Bioscience GmbH, which is responsible for pharmaceutical development, conducting preclinical and clinical studies, and for granting, maintaining, and

extending the drug approvals.”). Biofrontera Bioscience GmbH also holds some of the Biofrontera Group’s patents. AG Annual Report, at 9.

20. On information and belief, Biofrontera Bioscience GmbH knows the imported products are manufactured abroad and imported into the United States, at least because Biofrontera Bioscience GmbH took actions purposefully directed to the United States by entering into a license agreement with Biofrontera Inc. to import and sell the Accused Products. Biofrontera Bioscience GmbH and Biofrontera Pharma GmbH are “responsible for obtaining and maintaining the rights to all FDA Approvals and any amendments or supplements required” for Biofrontera Inc. to sell or distribute Ameluz® prescription medicine in the United States. Supply Agreement, Sec. 10.1. Likewise, on information and belief, Biofrontera Bioscience GmbH and Biofrontera Pharma GmbH are “responsible for obtaining and maintaining all FDA Approvals and any amendments or supplements required in order for [Biofrontera Pharma GmbH] to manufacture or have manufactured” the BF-RhodoLED® XL device and the Ameluz® prescription medicine. Supply Agreement, Sec. 10.1.

E. Defendant Biofrontera AG

21. On information and belief, Defendant Biofrontera AG uses, offers to sell, and/or sells the Accused Products within the United States and/or imports into the United States the Accused Products.

22. Biofrontera AG is a German corporation organized under the laws of Germany, having a principal place of business at Hemmelrather Weg 201, 51377, Leverkusen, Germany.

23. Biofrontera AG refers to itself and each of Biofrontera Bioscience GmbH and Biofrontera Pharma GmbH as the “Biofrontera Group.”¹ See AG Annual Report, at 1 (“As of

¹ Biofrontera Development GmbH and Biofrontera Neuroscience GmbH are also members of the Biofrontera Group but are not parties to this action.

December 31, 2023, the Biofrontera Group . . . consists of a parent company, Biofrontera AG and four wholly owned subsidiaries in Germany. . . . Biofrontera Bioscience GmbH, Biofrontera Pharma GmbH, Biofrontera Development GmbH and Biofrontera Neuroscience GmbH are located at the parent company’s headquarters in Leverkusen, Germany.”).

24. On information and belief, Biofrontera AG controls importation of the Accused Products, and/or sells the Accused Products for importation into the United States, through its U.S. partner, Biofrontera Inc. On information and belief, Biofrontera AG took actions purposefully directed to the United States by its influence and oversight of Biofrontera Inc., which was founded as a “wholly owned subsidiary” of Biofrontera AG. Biofrontera Inc. 10-K, at 4.

25. Though Biofrontera Inc. had its initial public offering in October 2021, Biofrontera AG retains a significant stake in Biofrontera Inc., owning approximately 8% of Biofrontera Inc.’s “Common Stock” as of April 2024. AG Annual Report, at XII. Biofrontera AG commands “significant control” over Biofrontera Inc., both as a “significant stockholder” and through Biofrontera AG’s “control of the manufacture, clinical development and regulatory approval of Ameluz®.” Biofrontera Inc. 10-K, at 25. Similarly, Biofrontera AG has formed a “community of fate” with Biofrontera Inc., such that “[t]he economic success of Biofrontera AG in the future will continue to depend to a large extent on the sales success of Biofrontera Inc. on the US market.” AG Annual Report, at XII. Biofrontera Inc. “acquires Ameluz® and the PDT lamps BF-RhodoLED® and RhodoLED® XL from Biofrontera AG.” AG Annual Report, at 2.

26. On information and belief, Biofrontera AG knows the Accused Products are manufactured abroad and imported into the United States. Biofrontera AG notes its commitment to U.S. sales of the Accused Products by “maintaining the FDA approval, manufacturing the

products, providing a pharmacovigilance database and conducting previously defined clinical trials.” AG Annual Report, at 2.

27. Consistent with Biofrontera AG’s commanding control over Biofrontera Inc., the same senior officers rotate between the companies. For example, Hermann Lübbert founded the Biofrontera Group and served both as Biofrontera AG’s CEO and as managing director for all of Biofrontera AG’s subsidiaries. See Biofrontera Inc., *U.S. Board of Directors*, <https://www.biofrontera-us.com/about-us/board-of-directors>; Biofrontera, *Biofrontera Inc. Names Founder and Executive Chairman Hermann Luebbert as Chief Executive Officer* (May 30, 2023), <https://sec.gov/Archives/edgar/data/1858685/000149315223019402/ex99-1.htm>; Biofrontera Inc., *Schedule 14A*, at 7 (July 23, 2021), <https://www.sec.gov/Archives/edgar/data/1858685/000149315222030999/formdef14a.htm>.

When Biofrontera Inc. had its initial public offering in October 2021, Dr. Lübbert agreed to serve as Biofrontera Inc.’s Executive Chair for 30% of his time, while maintaining his role as CEO of Biofrontera AG. Biofrontera Inc. & Hermann Luebbert, *Amended Employee Agreement*, Pt. 1, <https://www.sec.gov/Archives/edgar/data/1858685/000149315221024281/ex10-11.htm>. On November 10, 2021, Dr. Lübbert resigned as CEO of Biofrontera AG but “confirmed that he will continue to remain available to the Biofrontera Group, particularly through his obligations as Executive Chairman of Biofrontera Inc.” Biofrontera AG, *CEO Seeks Early Retirement from the Management Board* (Nov. 10, 2021), https://www.biofrontera.com/en/investors/financial-announcements?tx_news_pi1%5Baction%5D=detail&tx_news_pi1%5Bcontroller%5D=News&tx_news_pi1%5Bnews%5D=248&cHash=e3440509f2be7e3e8ca0f1af40f188ca. In May of 2023, Dr. Lübbert was appointed CEO of Biofrontera Inc. while retaining his position as Biofrontera Inc.’s Chairman.

III. THE ASSERTED PATENTS

A. The '512 Patent

28. On September 20, 2022, the United States Patent and Trademark Office (“USPTO”) duly and legally issued the '512 Patent, titled “Adjustable Illuminator for Photodynamic Therapy and Diagnosis.” A true and correct certified copy of the '512 Patent is attached hereto as Exhibit 1.

29. Sun Pharma is the assignee of the entire rights, title, and interest in and to the '512 Patent. Sun Pharma has the right to sue and recover damages for infringement of the '512 Patent.

B. The '028 Patent

30. On July 11, 2023, the USPTO duly and legally issued the '028 Patent, entitled “Adjustable Illuminator for Photodynamic Therapy and Diagnosis.” A true and correct certified copy of the '028 Patent is attached hereto as Exhibit 2.

31. Sun Pharma is the assignee of the entire rights, title, and interest in and to the '028 Patent. Sun Pharma has the right to sue and recover damages for infringement of the '028 Patent.

IV. JURISDICTION AND VENUE

A. Jurisdiction

32. Sun Pharma incorporates by reference paragraphs 1–34 as if fully set forth herein.

33. This action arises under the patent laws of the United States, including 35 U.S.C. §§ 271, et seq. The jurisdiction of this Court over the subject matter of this action is proper under 28 U.S.C. §§ 1331 and 1338(a).

34. Personal jurisdiction exists over Biofrontera Inc. because Biofrontera Inc. conducts business in and has committed acts of patent infringement in Massachusetts. Personal jurisdiction also exists over Biofrontera Inc. because its affiliations with Massachusetts are continuous and

systematic, as Biofrontera Inc.'s principal place of business is located at 120 Presidential Way, Suite 300, Woburn, MA 01801.

35. On information and belief, acting in concert with the other Defendants, each of the Biofrontera Foreign Entities have purposefully directed the manufacturing, marketing, offers for sale, sale, importation, and distribution of the Accused Products, knowing that it will be sold and used in the United States, in the Commonwealth of Massachusetts, and in this District. Each of the Biofrontera Foreign Entities has made the product available for sale in the United States, in the Commonwealth of Massachusetts, and in this District, through an established distribution chain. On information and belief, each of the Biofrontera Foreign Entities will derive substantial revenue from the sale of the Accused Products in the United States, in the Commonwealth of Massachusetts, and in this District. Accordingly, each of the Biofrontera Foreign Entities has established minimum contacts within Massachusetts and this District, and purposefully availed itself of the benefits of Massachusetts and this District, and the exercise of personal jurisdiction over the Biofrontera Foreign Entities would not offend traditional notions of fair play and substantial justice. In addition, or in the alternative, this Court has personal jurisdiction over the Biofrontera Foreign Entities pursuant to Federal Rule of Civil Procedure 4(k)(2).

36. Thus, Defendants are subject to this Court's general and specific jurisdiction pursuant to due process and/or the Massachusetts Long Arm Statute, due at least to Defendants' substantial business in Massachusetts and in this District, including through its past and ongoing infringing activities. Defendants regularly do and solicit business herein, and/or because Defendants have engaged in persistent conduct and/or has derived substantial revenues from goods and services provided in Massachusetts and in this District.

B. Venue

37. Sun Pharma incorporates by reference paragraphs 1–40 as if fully set forth herein.

38. Venue is proper in this District under 28 U.S.C. § 1400(b) with respect to Biofrontera Inc. because Biofrontera Inc. has committed acts of infringement in this District and Biofrontera Inc. has a regular and established place of business, at least at 120 Presidential Way, Suite 300, Woburn, MA 01801.

39. Venue is proper in this District under 28 U.S.C. § 1391(c) because the Biofrontera Foreign Entities do not reside in the United States and thus may be sued in any judicial district.

V. FACTUAL BACKGROUND

40. PDT describes a type of treatment where a “photosensitizer” prescription medicine is exposed to light sources to treat diseases, particularly dermatological conditions. PDT treatment is generally a two-step process: first, the application of a drug known as a “photosensitizer,” or a pre-cursor of this type of drug; and second, the activation of the drug by controlled exposure to a selective light source.

41. Sun Pharma’s PDT treatment began in 1991 when pioneering research and development in the novel field of PDT treatment was conducted for the treatment of dermatological conditions.² Among its many product offerings, Sun Pharma now develops, designs, manufactures, and markets products for PDT treatment, which consists of a) the BLU-U® Blue Light Photodynamic Therapy Illuminator Model 4170 (“BLU-U®,” “BLU-U® 4170,”

² DUSA Pharmaceutical, Inc. (“DUSA”), a New Jersey corporation, began this work. In November 2012, Sun Pharmaceutical Industries, Inc. acquired DUSA for a cash value of over \$230 million. Sun Pharmaceutical Industries, Inc. purchased DUSA via Caraco Pharmaceuticals Laboratories, Ltd. (“Caraco”) through Caraco Acquisition Co., which was merged into DUSA. On March 1, 2013, Sun Pharmaceutical Industries, Inc. merged into Caraco. On April 1, 2014, Caraco changed its name to Sun Pharmaceutical Industries, Inc. On March 31, 2024, DUSA merged with Sun Pharma, leaving Sun Pharma remaining as the surviving corporation.

or “BLU-U® 4170D”³) device, b) Levulan® prescription medicine, and c) the BLU-U® Blue Light Photodynamic Therapy Illuminator Model 4170E (“BLU-U® 4170E”) device.

42. Sun Pharma has expended tremendous amounts of time, labor, and resources in the United States over the past three decades to develop these safe and effective PDT treatments.

A. Sun Pharma’s BLU-U® 4170 In Combination With Levulan® Prescription Medicine

43. Sun Pharma received the first approval from the FDA in December 1999 to use its PDT device, the BLU-U® 4170, in combination with a photosensitizer prescription medicine with 5-aminolevulinic acid (“ALA”), namely Levulan®, to treat non-hyperkeratotic actinic keratosis (“AK”) of the face or scalp. Shortly thereafter, in September 2000, Sun Pharma launched the Levulan® prescription medicine in combination with targeted light delivery from the BLU-U® 4170 device.

44. The Levulan® prescription medicine is currently manufactured in Billerica, Massachusetts at Sun Pharma facility. A picture reflecting the exterior of the Billerica, Massachusetts factory is below:

³ The BLU-U® 4170 device ships as three separated components that must be assembled on site. Therefore, when Unique Device Indication (UDI) labeling became required, it was necessary to change the model number to create unique identifiers for each component, where Model 4170D referred to the assembled device. Model 4170 and Model 4170D are therefore the same device.



B. BLU-U® 4170 Individually

45. In September 2003, Sun Pharma received FDA approval for the use of the BLU-U® 4170 device for the treatment of moderate inflammatory acne vulgaris and general dermatological conditions, for standalone use even without Levulan® prescription medicine.

46. Over the course of nearly two decades, Sun Pharma established itself as the leader in PDT treatment with its Levulan® prescription medicine and BLU-U® 4170 device.

C. BLU-U® 4170E Individually, And In Combination With Levulan® Prescription Medicine

47. For more than eight years, Sun Pharma has been working on the development of its BLU-U® 4170E device, which is the next generation of BLU-U® 4170. The BLU-U 4170E device contains technology that was built upon technology, research and development, and innovations of the BLU-U® 4170 device. The BLU-U® 4170E device has the same spectral output, mode of operation, treatment area, and general operating principles as well as the same intended use, and the same general and specific indications for use as the BLU-U® 4170 device.

48. On May 13, 2024, Sun Pharma submitted a Special Premarket Notification seeking FDA clearance for the BLU-U® 4170E device. In its submission, Sun Pharma stated that its BLU-U® 4170 (also known as BLU-U® Model 4170D) is the predicate device for the BLU-U® 4170E:

510(k) SUMMARY	
Applicant & Submitter:	Sun Pharmaceutical Industries, Inc.
Address:	29 Dunahm Rd. Billerica, MA 01821
Phone:	781-867-1230
Contact Person:	Scott Lundahl
Preparation Date:	May 13th, 2024
Device Submitted:	BLU-U® Blue Light Photodynamic Therapy Illuminator Model 4170E
Proprietary Name:	BLU-U® Blue Light Photodynamic Therapy Illuminator
Common Name:	Blue Light Therapy Device
Classification Name:	Laser surgical instrument for use in General and Plastic Surgery and in Dermatology. Product Code GEX
Predicate Device:	BLU-U® Blue Light Photodynamic Therapy Illuminator Model 4170D
Device Description:	The BLU-U® 4170E is a compact light source that delivers a uniform distribution of blue light to the body with a spectral output at a peak wavelength of 417 nm. The principle parts of the system include the light unit and floor stand with timer.
Intended Use:	The BLU-U® Model 4170E Blue Light Photodynamic Therapy Illuminator is intended to provide phototherapeutic light to the body. The BLU-U® 4170E is generally indicated to treat dermatological indications. The BLU-U® 4170E is specifically indicated to treat moderate inflammatory acne vulgaris.
Performance Data:	The BLU-U® Model 4170E Blue Light Photodynamic Therapy Illuminator has the same spectral output, mode of operation, treatment area, and general operating principles as well as the same intended use, the same general and specific indications for use as the predicate device. A data base search has been performed to evaluate any adverse effects of the device that is currently marketed and none have been found.

49. On June 13, 2024, the FDA approved Sun Pharma's 510(k) submission, finding that the BLU-U 4170E is "substantially equivalent" to the BLU-U® 4170:

Re: K241358

Trade/Device Name: BLU-U® Blue Light Photodynamic Therapy Illuminator, Model 4170E

Regulation Number: 21 CFR 878.4810

Regulation Name: Laser Surgical Instrument For Use In General And Plastic Surgery And In Dermatology

Regulatory Class: Class II

Product Code: GEX

Dated: May 13, 2024

Received: May 14, 2024

Dear Scott Lundahl:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database

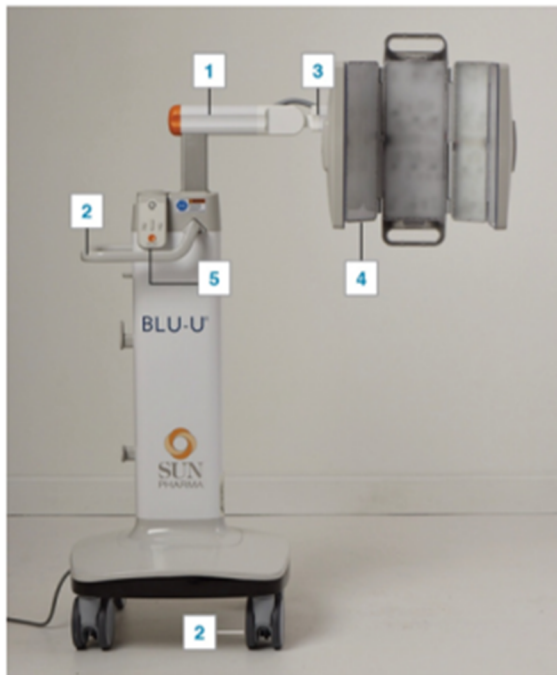
50. The BLU-U® 4170E device is generally indicated to treat dermatological indications and specifically indicated to treat moderate inflammatory acne vulgaris. The BLU-U® 4170E device, in combination with the Levulan® Kerastick® (aminolevulinic acid HCl) for Topical Solution, 20% prescription medicine, is indicated for the treatment of minimally to moderately thick AK of the face, scalp or upper extremities. And the BLU-U® 4170E device alone, without Levulan® Kerastick® prescription medicine, is indicated to treat moderate inflammatory acne vulgaris.

51. The approved “Indication for Use” for the BLU-U® 4170E device is intended to provide phototherapeutic light to the body. In particular, the BLU-U® 4170E is an illumination device designed to provide a uniform distribution of blue light to areas of the patient’s face, scalp or upper extremities for the use stated above. It is comprised of 5 individual LED panels connected by hinges. The panels are covered by a protective shield, the center panel directs cooling airflow to the patient to improve comfort during the treatment. It is mounted on a floor-stand (Base),

which permits rapid positioning as well as adjustment for patient height. The control panel / user interface is also affixed to the floor stand.

52. An exemplary image of the BLU-U® 4170E device can be found below:

Product Diagram:



①	Adjustable height positioning of the unit for treatment flexibility.
②	Large locking casters and post handle for easier mobility.
③	A pivoting arm for compact storage and easy movement within the treatment facility.
④	Five Panel LED treatment array.
⑤	Control Panel / User Interface.

53. The BLU-U® 4170E device has head panels attached to each other via hinge assemblies, as reflected in the exemplary annotated image below:



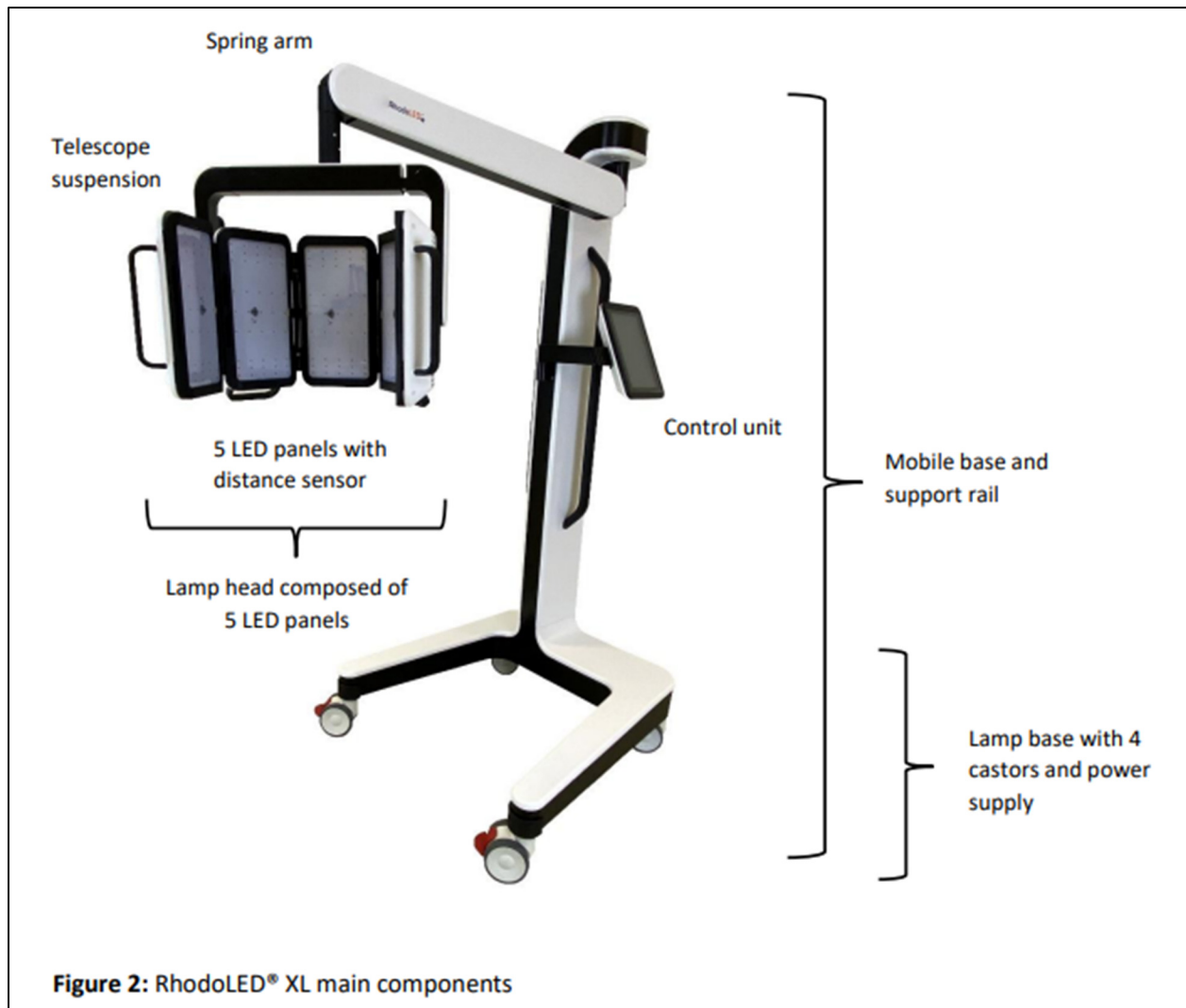
D. Biofrontera's Products

54. Biofrontera is also in the PDT treatment space. Biofrontera's products include the Accused Products, such as the BF-RhodoLED XL® devices, individually and in combination with Ameluz® prescription medicine.

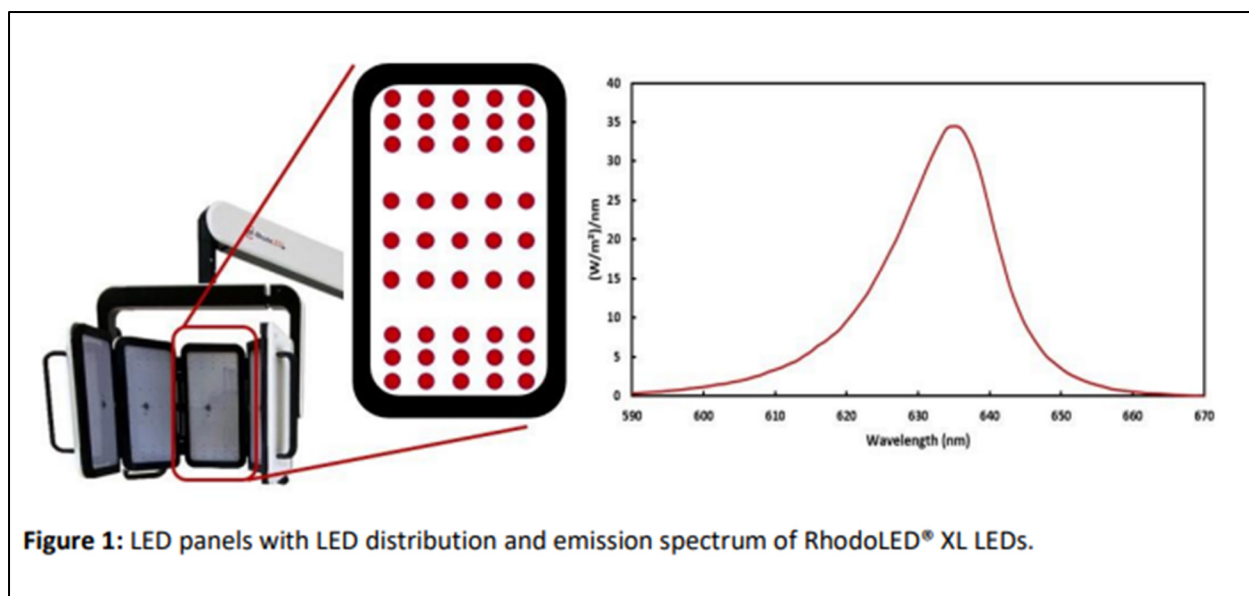
55. In July 2015, Biofrontera applied for FDA approval to market its first PDT device, the BF-RhodoLED®, together with a photosensitizer prescription medicine, Ameluz® (its name for ALA). The FDA granted approval to Biofrontera for PDT treatment of mild to moderate AK on the face and scalp using Ameluz® prescription medicine and the BF-RhodoLED® device. On October 22, 2021, the FDA approved a new Biofrontera device, the BF-RhodoLED® XL, “in

combination with Ameluz® for the treatment of mild and moderate actinic keratoses on the face and scalp.” Biofrontera AG, *Biofrontera AG Receives FDA-Approval of the BF-RhodoLED® XL Lamp* (Oct. 22, 2021), <https://www.biofrontera.com/en/investors/financial-announcements/ad-hoc-news/pta-adhoc-biofrontera-ag-biofrontera-ag-receives-fda-approval-of-the-bf-rhodoledr-xl-lamp>. Biofrontera claims that the BF-RhodoLED® XL device “enables the illumination of larger areas, enabling the simultaneous treatment of several actinic keratoses distant from each other.” *See id.*

56. Biofrontera describes the accused BF-RhodoLED® XL device as a “red-light emitting LED lamp, comprised of three main components, the lamp head, an easily adjustable spring arm, and the mobile base with castors for smooth transport.” BF-RhodoLED® XL User Manual, at 8. Figure 2 from the BF-RhodoLED® XL User Manual depicts the main components:



BF-RhodoLED® XL User Manual, Fig. 2. Biofrontera explains that “RhodoLED® XL has 45 LEDs per panel with a total of 5 panels (225 LEDs), which emit a uniform, visible red light.” BF-RhodoLED® XL User Manual, Sec. 4.1. According to Biofrontera, “The LEDs are distributed on each panel in a specific way (*see* Figure 1), such that they are more densely packed towards the upper and lower edges than in the center region of each panel. This distribution optimizes the homogeneity of illumination over the treated skin.”



BF-RhodoLED® XL User Manual, Sec. 4.1.

57. The User Manual also instructs that the BF-RhodoLED® XL device is to be used in combination with administering Ameluz® prescription medicine to the patient.

Our drug Ameluz® and medical device RhodoLED® XL have been approved in combination for photodynamic therapy; the only approved use of our lamp is in combination with Ameluz® gel. This user manual provides important RhodoLED® XL product details, precautions and warnings, and operating instructions. For Ameluz®, please use its US prescribing information. The Ameluz® prescribing information includes information on how to use the gel along with contraindications, warnings and precautions and dosage and administration.

Thorough reading and use of both this user manual and the Ameluz® USPI is required prior to treatment.

BF-RhodoLED® XL User Manual, at 2.

1 Intended Use

RhodoLED® XL is a red light-emitting LED lamp, which is used exclusively in combination with Ameluz® gel for lesion-directed and field-directed treatment of actinic keratoses of mild-to-moderate severity on the face and scalp.

BF-RhodoLED® XL User Manual, Sec. 1.

3 Warnings and Precautions



The RhodoLED® XL has been developed for use in photodynamic therapy in combination with Ameluz® gel (excitation wavelength 635 nm). Any other use or combination of use is prohibited.

BF-RhodoLED® XL User Manual, Sec. 3.

58. According to Biofrontera, its main competitor for PDT treatment is Sun Pharma and its Levulan® prescription medicine and BLU-U® devices: “Our primary competitor in the PDT space is Levulan® and the associated light, Blu-U®.” Biofrontera Inc. 10-K, at 5; *see also* Biofrontera, Inc., *2021 Annual Report*, at 7 (Apr. 2022) [hereinafter “Inc. Annual Report”], https://investors.biofrontera-us.com/wp-content/uploads/2022/04/AnnualReport2021_BFRI.pdf (“The primary competing PDT drug in the United States is Levulan®, which has been approved for the treatment of minimally to moderately thick actinic keratoses of the face or scalp in combination with PDT with a blue light source since 1999.”).

VI. COUNT I: INFRINGEMENT OF THE ’512 PATENT

59. Sun Pharma incorporates by reference paragraphs 1–63 as if fully set forth herein.

60. The ’512 Patent is valid and enforceable.

61. On information and belief, Defendants have directly infringed and continue to directly infringe one or more claims of the ’512 Patent under 35 U.S.C. § 271(a), literally and/or under the doctrine of equivalents, by making, using, offering for sale, selling, and/or importing in the United States PDT treatment technology embodied in the Accused Products, including its BF-RhodoLED® XL device, individually and in combination with Ameluz® prescription medicine.

62. For example, as reflected in the exemplary chart attached as Exhibit 3, Defendants infringe at least exemplary claim 1 of the ’512 Patent by making, using, selling, offering for sale, and/or importing into the United States the Accused Products.

63. As a result of Defendants' direct infringement of the '512 Patent, Sun Pharma has suffered, and continues to suffer, damages in an amount not yet determined, of at least a reasonable royalty and/or lost profits due to loss of sales, profits, and potential sales that Sun Pharma would have made but for Defendants infringing acts.

64. Biofrontera publicly identifies Sun Pharma as its competitor in the United States market. Biofrontera Inc. 10-K, at 5 ("Our primary competitor in the PDT space is Levulan® and the associated light, Blu-U®."); *see also* Inc. Annual Report, at 7 ("The primary competing PDT drug in the United States is Levulan®, which has been approved for the treatment of minimally to moderately thick actinic keratoses of the face or scalp in combination with PDT with a blue light source since 1999.").

65. Biofrontera also acknowledges that "claims regarding Biofrontera's potential infringement of patents . . . may hinder or completely prevent the development or manufacturing of certain products, and may obligate us to pay damages or royalties to third parties." Biofrontera AG, *Annual Report 2017*, at 40 (2017), https://www.biofrontera.com/fileadmin/files/PDFs/Financial_Reports/2017/Annual%20report%202017.pdf. Biofrontera states that their "patent department regularly reviews the current patent situation, in cooperation with the relevant operational departments, and monitors possible patent infringement attempts, so that it can take suitable legal steps if necessary." *Id.*

66. On information and belief, Biofrontera monitors Sun Pharma's patents and has known about the '512 Patent at least since it issued on September 20, 2022, and Biofrontera knew or was willfully blind that its actions constituted infringement of at least claim 1 of the '512 Patent. Biofrontera continues to infringe the '512 Patent despite such knowledge and its knowledge as of the filing and/or service of this Complaint.

67. Despite Defendants' knowledge of and notice of the '512 Patent and its ongoing infringement, Defendants continues to manufacture, use, sell, offer for sale, and/or import the Accused Products, including the BF-RhodoLED® XL device, individually and in combination with Ameluz® prescription medicine, in a manner that infringes the '512 Patent. On information and belief, Defendants lacks a justifiable belief that they do not infringe the '512 Patent, or that the '512 Patent is invalid, and have acted recklessly in their infringing activity, justifying an increase in the damages to be awarded to Sun Pharma up to three times the amount found or assessed, in accordance with § 284.

68. At least Defendants' willful infringement of the '512 Patent renders this case an exceptional case, justifying an award to Sun Pharma of its reasonable attorneys' fees, in accordance with § 285.

69. On information and belief, Defendants actively induce others, such as their distributors and customers (none of which are licensed by Sun Pharma), to use and purchase the Accused Products such that others directly infringe '512 Patent. For example, Biofrontera provides its distributors and customers with materials and instructions on operating the Accused Products, and Biofrontera has the specific intent and knowledge that these materials and instructions direct, teach, or assist others in infringing the Asserted Patents.

70. For example, Biofrontera's operating manual submitted to the FDA describes at least how to perform the method of claim 8 of the '512 Patent: "[a] method of photodynamically diagnosing or treating a patient." *See* '512 Patent; Ameluz® Prescribing Information, Biofrontera Inc., *Highlights of Prescribing Information for Ameluz®* (Dec. 2021) [hereinafter "Ameluz® Prescribing Information"], <https://www.ameluz.com/fileadmin/AmeluzUSImages/05-pdf/Ameluz-Full-Prescribing-Information.pdf>; *see also* Ex. 3 ('512 Patent claim chart.) Claim 8

of the '512 Patent includes “administering 5-aminolevulinic acid (ALA) to the patient,” and Biofrontera’s Ameluz® prescription medicine (which contains ALA) is used in conjunction with the BF-RhodoLED® XL device. *See* BF-RhodoLED® XL User Manual, at 2 (“Our drug Ameluz® and medical device RhodoLED® XL have been approved in combination for photodynamic therapy.”); Ameluz® Prescribing Information, Sec. 11 (showing that Ameluz contains ALA); *see also* Ex. 3, element 8[a] ('512 Patent claim chart); *supra* Count I (explaining how the BF-RhodoLED® XL user manual instructs a user to use the BF-RhodoLED® XL device with the Ameluz® prescription medicine).)

71. In addition, claim 8 of the '512 Patent includes “positioning an illuminator proximate to the patient,” and Biofrontera’s operating manual directs that the BF-RhodoLED® XL’s illuminator should be positioned near the patient. *See* '512 Patent; *see, e.g.*, BF-RhodoLED® XL User Manual, Fig. 13 (showing illuminator positioned near the patient’s head); *see also* Ex. 3, element 8[b] ('512 Patent claim chart). Finally, claim 8 of the '512 Patent includes “uniformly illuminating a treatment surface of the patient with light sources disposed on the at least five panels of the illuminator,” and Biofrontera’s operating manual directs that BF-RhodoLED® XL’s five panels uniformly illuminate the patient’s treatment area. *See* '512 Patent; BF-RhodoLED® XL User Manual, Sec. 4.1 (“RhodoLED® XL has 45 LEDs per panel with a total of 5 panels . . . which emit a uniform, visible red light.”); *see, e.g.*, BF-RhodoLED® XL User Manual, Fig. 13 (illuminating the treatment area of the patient’s face); *see also* Ex. 3, element 8[c] ('512 Patent claim chart). Thus, Biofrontera actively induces patients and doctors to use the BF-RhodoLED® XL device in an infringing manner.

72. Other active steps by Biofrontera include encouraging, advertising (including internet websites), promoting, and instructing others to use and/or how to use Accused Products.

For example, Biofrontera advertises its PDT treatment. *See, e.g.,* Regina (Orsogna) Arnone, LinkedIn [hereinafter “Arnone LinkedIn Post”], https://www.linkedin.com/posts/regina-orsogna-arnone-2346997_scale2024-biofrontera-pdt-activity-7198081811854303235-m8A3?utm_source=share&utm_medium=member_desktop (displaying the BF-RhodoLED® XL at a dermatology conference).

73. Defendants also contributorily infringe certain Asserted Claims through importing into the United States components of the Accused Products that constitute a material part of the Asserted Claims, knowing the same to be especially made or especially adapted for use in an infringement of the ’512 Patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use. For example, certain components of the BF-RhodoLED® XL device are specifically designed for use, individually and in combination with the administration of ALA to a patient, which constitutes infringement of the Asserted Claims. Components of the Asserted Products do not have any substantial noninfringing uses. For example, Biofrontera instructs users that “the only approved use of our lamp is in combination with Ameluz® gel,” referring to their ALA prescription medicine. BF-RhodoLED® XL User Manual, at 2.

74. Defendants have committed the foregoing infringing activities without a license from Sun Pharma to the ’512 Patent.

75. Defendants’ infringement of the ’512 Patent has caused and will continue to cause irreparable injury to Sun Pharma. Unless the Court enjoins such infringing acts, Sun Pharma will continue to suffer additional irreparable injury.

VII. COUNT II: INFRINGEMENT OF THE ’028 PATENT

76. Sun Pharma incorporates by reference paragraphs 1–80 as if fully set forth herein.

77. The ’028 Patent is valid and enforceable.

78. On information and belief, Defendants have directly infringed and continue to directly infringe at least claim 1 of the '028 Patent under 35 U.S.C. § 271(a), literally and/or under the doctrine of equivalents, by making, using, offering for sale, selling, and/or importing in the United States PDT treatment technology embodied in the Accused Products, including its BF-RhodoLED® XL device, individually and in combination with Ameluz® prescription medicine.

79. For example, as reflected in the exemplary chart attached as Exhibit 4, Defendants infringe at least exemplary claim 1 of the '028 Patent by making, using, selling, offering for sale, and/or importing into the United States the Accused Products.

80. As a result of Defendants' direct infringement of the '028 Patent, Sun Pharma has suffered, and continues to suffer, damages in an amount not yet determined, of at least a reasonable royalty and/or lost profits due to loss of sales, profits, and potential sales that Sun Pharma would have made but for Defendants' infringing acts.

81. Biofrontera publicly identifies Sun Pharma as its competitor in the United States market. Biofrontera Inc. 10-K, at 5 ("Our primary competitor in the PDT space is Levulan® and the associated light, Blu-U®."); *see also* Inc. Annual Report, at 7 ("The primary competing PDT drug in the United States is Levulan®, which has been approved for the treatment of minimally to moderately thick actinic keratoses of the face or scalp in combination with PDT with a blue light source since 1999.").

82. Biofrontera also acknowledges that "claims regarding Biofrontera's potential infringement of patents . . . may hinder or completely prevent the development or manufacturing of certain products, and may obligate us to pay damages or royalties to third parties." Biofrontera AG, *Annual Report 2017*, at 40 (2017), https://www.biofrontera.com/fileadmin/files/PDFs/Financial_Reports/2017/Annual%20report%2

02017.pdf. Biofrontera states that their “patent department regularly reviews the current patent situation, in cooperation with the relevant operational departments, and monitors possible patent infringement attempts, so that it can take suitable legal steps if necessary.” *Id.*

83. On information and belief, Biofrontera monitors Sun Pharma’s patents, and at least as of Biofrontera’s filed *inter partes* review of the ’028 Patent, *see Biofrontera AG v. DUSA Pharmaceuticals, Inc.*, No. IPR2024-00874 (P.T.A.B. Apr. 30, 2024), Biofrontera knew or was willfully blind that its actions constituted infringement of at least claim 1 of the ’028 Patent. Biofrontera continues to infringe the ’028 Patent despite such knowledge and its knowledge as of the filing of this Complaint.

84. Despite Defendants’ knowledge of and notice of the ’028 Patent and its ongoing infringement, Defendants continues to manufacture, use, sell, offer for sale, and/or import the Accused Products, including the BF-RhodoLED® XL device, individually and in combination with Ameluz® prescription medicine, in a manner that infringes the ’028 Patent. On information and belief, Defendants lack a justifiable belief that they do not infringe the ’028 Patent, or that the ’028 Patent is invalid, and have acted recklessly in its infringing activity, justifying an increase in the damages to be awarded to Sun Pharma up to three times the amount found or assessed, in accordance with § 284.

85. At least Defendants’ willful infringement of the ’028 Patent renders this case an exceptional case, justifying an award to Sun Pharma of its reasonable attorneys’ fees, in accordance with § 285.

86. On information and belief, Defendants actively induces others, such as their distributors and customers (none of which are licensed by Sun Pharma), to use and purchase the Accused Products such that others directly infringe the ’028 Patent. For example, Biofrontera

provides its distributors and customers with materials and instructions on operating the Accused Products, and Biofrontera has the specific intent and knowledge that these materials and instructions direct, teach, or assist others in infringing the '028 Patent.

87. For example, Biofrontera's operating manual submitted to the FDA describes at least how to perform the method of claim 5 of the '028 Patent: "[a] method of photodynamically diagnosing or treating a patient." *See* '028 Patent; Ameluz® Prescribing Information; *see also* Ex. 4 ('028 Patent claim chart.) Claim 5 of the '028 Patent includes "administering 5-aminolevulinic acid (ALA) to the patient," and Biofrontera's Ameluz® prescription medicine (which contains ALA) is used in conjunction with the BF-RhodoLED® XL device. *See* '028 Patent; BF-RhodoLED® XL User Manual, at 2 ("Our drug Ameluz® and medical device RhodoLED® XL have been approved in combination for photodynamic therapy."); Ameluz® Prescribing Information, Sec. 11 (showing that Ameluz contains ALA); *see also* Ex. 4, element 5[a] ('028 Patent claim chart); *supra* Count II (explaining how the BF-RhodoLED® XL user manual instructs a user to use the BF-RhodoLED® XL device with the Ameluz® prescription medicine).

88. In addition, claim 5 of the '028 Patent includes "positioning an illuminator proximate to the patient," and Biofrontera's operating manual directs that the BF-RhodoLED® XL's illuminator should be positioned near the patient. *See* '028 Patent; *see, e.g.*, BF-RhodoLED® XL User Manual, Fig. 13 (showing illuminator positioned near the patient's head); *see also* Ex. 4, element 5[b] ('028 Patent claim chart). Finally, claim 5 of the '028 Patent includes "uniformly illuminating a treatment surface of the patient with light sources disposed on the five panels of the illuminator," and Biofrontera's operating manual directs that BF-RhodoLED® XL's five panels uniformly illuminate the patient's treatment area. *See* '028 Patent; BF-RhodoLED® XL User Manual, Sec. 4.1 ("RhodoLED® XL has 45 LEDs per panel with a total of 5 panels . . . which emit

a uniform, visible red light.”); *see, e.g.*, BF-RhodoLED® XL User Manual, Fig. 13 (illuminating the treatment area of the patient’s face); *see also* Ex. 4, element 5[c] (’028 Patent claim chart). Thus, Biofrontera actively induces patients and doctors to use the BF-RhodoLED® XL device in an infringing manner.

89. Other active steps by Biofrontera include encouraging, advertising (including internet websites), promoting, and instructing others to use and/or how to use Accused Products. For example, Biofrontera advertises its PDT treatment. *See, e.g.*, Arnone LinkedIn Post (displaying the BF-RhodoLED® XL at a dermatology conference).

90. Defendants also contributorily infringe certain Asserted Claims through importing into the United States components of the Accused Products that constitute a material part of the Asserted Claims, knowing the same to be especially made or especially adapted for use in an infringement of the ’028 Patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use. For example, certain components of the BF-RhodoLED® XL device are specifically designed for use, individually and in combination with the administration of ALA to a patient, which constitutes infringement of the Asserted Claims. Components of the Asserted Products do not have any substantial noninfringing uses. For example, Biofrontera instructs users that “the only approved use of our lamp is in combination with Ameluz® gel,” referring to their ALA prescription medicine. BF-RhodoLED® XL User Manual, at 2.

91. Defendants have committed the foregoing infringing activities without a license from Sun Pharma to the ’028 Patent.

92. Defendants’ infringement of the ’028 Patent has caused and will continue to cause irreparable injury to Sun Pharma. Unless the Court enjoins such infringing acts, Sun Pharma will continue to suffer additional irreparable injury.

VIII. JURY DEMAND

Pursuant to Federal Rule of Civil Procedure 38(b), Sun Pharma hereby demands a trial by jury of all issues so triable.

IX. PRAYER FOR RELIEF

WHEREFORE, Sun Pharma respectfully requests that the Court enter judgment in Sun Pharma's favor against Defendants, and provide Sun Pharma the following relief:

- a. a finding that Defendants have infringed one or more claims of the Asserted Patents under 35 U.S.C. §§ 271(a), (b), and/or (c), and a final judgment incorporating the same;
- b. a finding that Defendants' infringement of the Asserted Patents has been and is willful;
- c. equitable relief under 35 U.S.C. § 283 or otherwise in accordance with principles of equity, including a permanent and preliminary injunction that enjoins Defendants and any of its 1) officers, 2) agents, 3) employees, 4) assigns, 5) representatives, 6) privies, 7) successors, 8) affiliates, and 9) those acting in concert or participation with Defendants, from infringing, inducing, or contributing to infringement of the Asserted Patents;
- d. an award of damages sufficient to compensate Sun Pharma for Defendants' infringement of the Asserted Patents through the date of judgment, including reasonable royalties and/or Sun Pharma's lost profits, together with prejudgment interest under 35 U.S.C. § 284;
- e. an entry of an order compelling Defendants to compensate Sun Pharma for any ongoing and/or future infringement of the Asserted Patents, in an amount and under terms appropriate under the circumstances, and payment of any supplemental

damages as appropriate and post-judgment interest after the date of judgment under 35 U.S.C. § 284;

- f. a declaration or order finding that Defendants' infringement is willful and/or an order increasing damages under 35 U.S.C. § 284;
- g. a judgment holding that this is an exceptional case under 35 U.S.C. § 285 or otherwise in accordance with statute or principles of equity, and awarding Sun Pharma its reasonable attorney fees, costs, and expenses;
- h. an accounting of Defendants' infringing and improper activities through trial and judgment; and
- i. such other relief that the Court deems just and proper.

Dated: June 25, 2024

By: /s/ Brian D. Matty

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