

**UNITED STATES INTERNATIONAL TRADE COMMISSION
WASHINGTON, DC**

In the Matter of

**CERTAIN PHOTODYNAMIC
THERAPY SYSTEMS, COMPONENTS
THEREOF, AND PHARMACEUTICAL
PRODUCTS USED IN COMBINATION
WITH THE SAME**

Investigation No. 337-TA-_____

**VERIFIED COMPLAINT OF SUN PHARMACEUTICAL INDUSTRIES, INC.
UNDER SECTION 337 OF THE TARIFF ACT OF 1930, AS AMENDED**

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TABLE OF CONTENTS

	Page
I. INTRODUCTION	1
II. COMPLAINANT	3
III. PROPOSED RESPONDENTS.....	4
A. Proposed Respondent Biofrontera Inc.....	4
B. Proposed Respondent Biofrontera Pharma GmbH.....	5
C. Proposed Respondent Biofrontera Bioscience GmbH	8
D. Proposed Respondent Biofrontera AG	9
IV. THE TECHNOLOGY AND PRODUCTS AT ISSUE	11
A. The Technology At Issue	11
1. BLU-U® 4170 Device In Combination With Levulan® Prescription Medicine	12
2. BLU-U® 4170 Device Individually	13
3. BLU-U® 4170E Device Individually, And In Combination With Levulan® Prescription Medicine.....	14
B. The Products At Issue	17
V. THE ASSERTED PATENTS	18
A. The '028 Patent.....	18
1. Identification Of The Patent And Ownership	18
2. Non-Technical Description Of The Patented Invention	19
3. Foreign Counterparts To The '028 Patent	20
B. The '512 Patent.....	20
1. Identification Of The Patent And Ownership	20
2. Non-Technical Description Of The Patented Invention	21
3. Foreign Counterparts To The '512 Patent	21
VI. UNFAIR ACTS OF PROPOSED RESPONDENTS	22
A. Biofrontera Directly Infringes The Asserted Patents By Importing And Selling The	

Infringing BF-RhodoLED® XL Device.....	23
B. Biofrontera Indirectly Infringes The Asserted Patents	27
VII. SPECIFIC INSTANCES OF UNFAIR IMPORTATION AND SALE.....	30
A. Importation Of The BF-RhodoLED® XL Device.....	30
B. Importation Of The Ameluz® Prescription Medicine	37
VIII. CLASSIFICATION UNDER THE HARMONIZED TARIFF SCHEDULE	38
IX. LICENSEES	38
X. DOMESTIC INDUSTRY	39
A. Technical Prong.....	40
B. Economic Prong	40
XI. RELATED LITIGATION	42
XII. REQUESTED RELIEF	42

LIST OF EXHIBITS

Exhibit	Description
1	Certified Copy of U.S. Patent No. 11,446,512
2	Certified Assignment Records for U.S. Patent No. 11,446,512
3	Certified Copy of U.S. Patent No. 11,697,028
4	Certified Assignment Records for U.S. Patent No. 11,697,028
5	Sun Pharmaceutical FDA Premarket Notification 510(k) Submission
6	List of Foreign Counterparts to the Asserted Patents
7	Infringement Claim Chart for U.S. Patent No. 11,446,512
8	Infringement Claim Chart for U.S. Patent No. 11,697,028
9C	Confidential Domestic Industry Claim Chart for U.S. Patent No. 11,446,512
10C	Confidential Domestic Industry Claim Chart for U.S. Patent No. 11,697,028
11C	Confidential Sun Pharms. Indus., Inc., <i>Consolidated Financial Statements and Independent Auditors' Report for the Years Ended March 31, 2015 and 2014</i> (May 27, 2015).
12	Biofrontera Inc., <i>Form 10-K</i> (Mar. 15, 2024), https://www.sec.gov/Archives/edgar/data/1858685/000149315224010133/form10-k.htm .
13	Biofrontera Inc., <i>User Manual for RhodoLED® XL</i> (Nov. 2021), https://www.ameluz.com/fileadmin/AmeluzUSImages/05-pdf/Ameluz-Full-Prescribing-Information.pdf .
14	Del. Div. of Corps., <i>Entity Details: Biofrontera Inc.</i> (last visited on June 25, 2024)
15	Biofrontera Inc., <i>Contact</i> , https://www.biofrontera-us.com/contact (last visited June 25, 2024)
16	Biofrontera AG, Annual Report 2023 (Apr. 2022), https://investors.biofrontera-us.com/wp-content/uploads/2022/04/AnnualReport2021_BFRI.pdf .
17	Biofrontera Pharma GmbH <i>et al.</i> , <i>Second Amended and Restated License and Supply Agreement</i> (Feb. 19, 2024), https://www.sec.gov/Archives/edgar/data/1858685/000149315224007143/ex10-1.htm .)
18	Biofrontera Inc., <i>U.S. Board of Directors</i> , https://www.biofrontera-us.com/about-us/board-of-directors (last visited June 25, 2024)

Exhibit	Description
19	U.S. Securities and Exchange Commission Exhibit 99.1, <i>Biofrontera Inc. Names Founder and Executive Chairman Hermann Luebbert as Chief Executive Officer</i> (May 30, 2023), available at https://sec.gov/Archives/edgar/data/1858685/000149315223019402/ex99-1.htm
20	Biofrontera Inc., <i>Schedule 14A</i> (July 23, 2021), https://www.sec.gov/Archives/edgar/data/1858685/000149315222030999/formdef14a.htm .)
21	Biofrontera Inc. & Hermann Luebbert, <i>Amended Employee Agreement</i> , https://www.sec.gov/Archives/edgar/data/1858685/000149315221024281/ex10-11.htm (last visited June 25, 2024)
22	Biofrontera AG, <i>CEO Seeks Early Retirement from the Management Board</i> (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 .
23	Letter from James E. Dillard III, Acting Dir., FDA Div. of Gen. & Restorative Devices, to Samuel D. Swetland, Vice President, DUSA Pharms., Inc. Regul. Affs. & Compliance Guidelines (Dec. 3, 1999).
24	<i>SEC Form 10-K for DUSA Pharmaceuticals, Inc. for Fiscal Year Ended December 31, 2008</i> , at 1 (Mar. 11, 2009), https://www.sec.gov/Archives/edgar/data/879993/000095012309004456/y75261e10vk.htm
25	State of Delaware Certificate of Ownership and Merger Merging DUSA Pharmaceuticals, Inc. with Sun Pharmaceutical Industries, Inc., dated March 31, 2024
26	DUSA Pharms., Inc., <i>510(k) Summary</i> (Sept. 9, 2003), https://www.accessdata.fda.gov/cdrh_docs/pdf3/K031805.pdf .
27	Letter from Tanisha Hithe, Assistant Dir., FDA Div. of Gen. Surgery Devices, to Scott Lundahl, Sun Pharm. Indus., Inc., at 1 (June 13, 2024)
28	Sun Dermatology, <i>Operating Manual for BLU-U® Blue Light Photodynamic Therapy Illuminator Model 4170E</i> (Apr. 30, 2024).
29	Biofrontera Inc., <i>Highlights of Prescribing Information for Ameluz® 1</i> (May 2016), https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/208081s000lbl.pdf
30	Biofrontera AG, <i>Biofrontera AG Receives FDA-Approval of the Bf-Rhodoled® XL Lamp</i> (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)
31	Biofrontera, Inc., <i>2021 Annual Report</i> (Apr. 2022), https://investors.biofrontera-us.com/wp-content/uploads/2022/04/AnnualReport2021_BFRI.pdf .
32	Biofrontera Inc., <i>Highlights of Prescribing Information for Ameluz®</i> (Dec.

Exhibit	Description
	2021), https://www.ameluz.com/fileadmin/AmeluzUSImages/05-pdf/Ameluz-Full-Prescribing-Information.pdf .
33	Biofrontera, <i>Biofrontera Inc. to Sponsor the 2022 Fall Clinical Dermatology Conference</i> , BioPharm Catalyst (Oct. 18, 2022), https://www.biopharmcatalyst.com/company/BFRI/news/97248 .
34	Regina (Orsogna) Arnone, LinkedIn, https://www.linkedin.com/posts/regina-orsogna-arnone-2346997_scale2024-biofrontera-pdt-activity-7198081811854303235-m8A3 (last visited June 25, 2024).
35	Biofrontera Pamphlet, <i>Meet RhodoLED® XL Lamp</i>
36	Biofrontera Inc., <i>Contact Us</i> , https://us.ameluz.com/hcp/contact?utm_source=Updated_XL_Journal_Ad&utm_medium=JAAD_June_2024&utm_campaign=Brand_Awareness+ (last visited June 25, 2024).
37	Import Genius, <i>Importation Records from May 18, 2024</i> (annotated), https://app.importgenius.com/shipment-detail/mZDKzQOL6R1yxpPrj7MXBPMbvlWAdrkq8jBN/AKeERomoQr9jJZnJovkvy9Pv7DWBYqpaxzdg/us/import?view=consignee (last visited June 24, 2024.)
38	Biofrontera Inc., <i>Form 10-Q</i> (May 15, 2024), https://app.quotemedia.com/data/downloadFiling?webmasterId=104270&ref=318324277&type=HTML&symbol=BFRI&cdn=92e847b6f0046ec05e3552364eb03d43&companyName=Biofrontera+Inc.&formType=10-Q&formDescription=General+form
39	Biofrontera Inc., <i>Ameluz® Outer Packaging</i> (May 2024), https://dailymed.nlm.nih.gov/dailymed/getFile.cfm?setid=650daa9f-aeec-49ce-95b9-5fa20b988afd&type=pdf .
40	HTS Classifications 9018.20.90 and 9018.90.80
41C	Confidential Domestic Industry Declaration of Zvi Albert (Sun Pharms. Indus., Inc.)
42C	Confidential Scott Lundahl Declaration
43C	Confidential Photograph of BLU-U® 4170E Blue Light Photodynamic Therapy Illuminator
44C	Confidential Photograph of BLU-U® 4170E Blue Light Photodynamic Therapy Illuminator
45	DUSA Pharms., Inc., <i>Levulan® Kerastick® Label</i> (Dec. 3, 1999), https://www.accessdata.fda.gov/drugsatfda_docs/label/1999/209651bl.pdf .
46	Summary of Sun Pharmaceutical FDA 510(k) for BLU-U® Blue Light Photodynamic Therapy Illuminator Model 4170E
47	ImportGenius, <i>Importation Records from June 24, 2024</i> (annotated), https://app.importgenius.com/shipment-

Exhibit	Description
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48C	Confidential Photograph of BLU-U® 4170E Blue Light Photodynamic Therapy Illuminator
49C	Confidential Photograph of BLU-U® 4170E Blue Light Photodynamic Therapy Illuminator
50C	Confidential Photograph of BLU-U® 4170E Blue Light Photodynamic Therapy Illuminator
51C	Confidential Photograph of BLU-U® 4170E Blue Light Photodynamic Therapy Illuminator
52C	Confidential DUSA Pharmaceuticals Device Test Procedure, Five Panel BLU-U Power and Uniformity Test Procedure (DTP6-047 Rev A)
53C	Confidential Sun Pharma Five Panel BLU-U Power and Uniformity Test Form, Aug. 9, 2023
54C	Confidential Photograph of BLU-U® 4170E Blue Light Photodynamic Therapy Illuminator
55C	Confidential Photograph of BLU-U® 4170E Blue Light Photodynamic Therapy Illuminator
56C	Confidential Detailed Description of the Device for Model 4170D (Current and Proposed Device)
57	Ameluz Marketing (https://us.ameluz.com/)
58	Biofrontera Inc., <i>Biofrontera Announces the Launch of a New, FDA-Approved Red Light Source, the RhodoLED® XL Lamp</i> , https://investors.biofrontera-us.com/full-news/?qm-storyId=5287383329078091
59C	Confidential Caraco Pharmaceutical Laboratories, Ltd. and Subsidiaries Consolidated Financial Statements and Independent Auditors' Report, Fiscal Year Ending March 31, 2014 and 2013

APPENDICES

Appendix	Description
A	Certified Copy of the prosecution history of U.S. Patent No. 11,446,512
B	Technical references cited in the prosecution history of U.S. Patent No. 11,446,512
C	Certified Copy of the prosecution history of U.S. Patent No. 11,697,028
D	Technical references cited in the prosecution history of U.S. Patent No. 11,697,028
E	Certified Copy of the prosecution history of U.S. Patent Application No. 62/241,902

I. INTRODUCTION

1. Complainant Sun Pharmaceutical Industries, Inc. (“Sun Pharma” or “Complainant”) files this Complaint pursuant to Section 337 of the Tariff Act of 1930, 19 U.S.C. § 1337 (“Section 337”) and requests that the United States International Trade Commission (“the Commission”) commence an investigation based on the unlawful importation into the United States, the sale for importation, and/or the sale within the United States after importation of certain photodynamic therapy systems, components thereof, and pharmaceutical products used in combination with the same (the “Accused Products”), including the BF-RhodoLED® XL (alternatively, the “RhodoLED® XL”) device, individually and in combination with the Ameluz® prescription medicine.

2. The Proposed Respondents are 1) Biofrontera AG, 2) Biofrontera Bioscience GmbH, 3) Biofrontera Pharma GmbH (collectively, the “Biofrontera Foreign Entities”), and 4) Biofrontera Inc. (with the Biofrontera Foreign Entities, “Biofrontera” or “Respondents”). Respondents have engaged in unfair acts in violation of Section 337 through and in connection with the unlicensed importation into the United States, sale for importation, and/or sale within the United States after importation of certain photodynamic therapy systems, components thereof, and pharmaceutical products used in combination with the same that infringe at least one claim of U.S. Patent No. 11,697,028 (the “’028 Patent”) and/or U.S. Patent No. 11,446,512 (the “’512 Patent”) (collectively, the “Asserted Patents”), either literally and/or under the doctrine of equivalents. The ’028 and ’512 Patents are valid and enforceable United States patents owned by Sun Pharma.

3. Sun Pharma asserts that Biofrontera directly infringes, contributorily infringes, and/or induces the infringement of at least the following claims (“Asserted Claims”) of the Asserted Patents, with independent claims in bold underline:

Asserted Patent Nos.	Asserted Claims
11,697,028	<u>1</u> , 2, 4, <u>5</u> , 6, <u>16</u> , 17, 19, <u>20</u> , and <u>21</u>
11,446,512	<u>1</u> -3, 5, <u>8</u> , and <u>20</u>

Further discovery may reveal that Biofrontera infringes additional claims. Sun Pharma reserves the right to seek leave to amend the Complaint to assert additional claims.

4. Certified copies of the Asserted Patents are attached as Exhibits 1 and 3. Certified copies of the Asserted Patents’ prosecution histories are included as Appendices A and C. Certified copies of the Asserted Patents’ assignment records are attached as Exhibits 2 and 4.¹

5. As required by Section 337(a)(2) and defined by Section 337(a)(3), an industry in the United States exists relating to articles protected by the Asserted Patents or alternatively such industries relating to articles protected by the Asserted Patents are in the process of being established.

6. Sun Pharma seeks relief from the Commission in the form of a permanent limited exclusion order, pursuant to Section 337(d), excluding from entry into the United States Biofrontera’s photodynamic therapy systems, components thereof, and pharmaceutical products used in combination with the same that infringe one or more claims of the Asserted Patents, imported by, or on behalf of, Respondents or any affiliated companies, parents, subsidiaries, licensees, and/or other related business entities, including successors or assigns. Sun Pharma does not seek to exclude Biofrontera’s accused pharmaceutical products that Biofrontera certifies are not being imported or sold for use with Biofrontera’s accused photodynamic therapy treatments.

¹ Certified versions of Reel/Frame No. 067550/0174 (Ex. 2), and Reel/Frame Nos. 067409/0242 and 067409/0615 (Ex. 4) are not yet available from the United States Patent and Trademark Office (“USPTO”). Complainant’s counsel will file a supplement to the Complaint under separate cover upon receipt of the certified versions from the USPTO.

7. Complainants also seek a permanent cease and desist order, pursuant to Section 337(f), directing Respondents to immediately cease and desist from 1) importing, 2) marketing, 3) advertising, 4) demonstrating, 5) warehousing inventory for distribution, 6) distributing, 7) offering for sale, 8) selling, or 9) using in the United States photodynamic therapy systems, components thereof, and pharmaceutical products used in combination with the same that infringe one or more claims of the Asserted Patents, and aiding or abetting any other entity from doing the same.

8. Sun Pharma further seeks any other relief that the Commission deems proper, including, but not limited to, a bond, for the 60-day Presidential review period pursuant to Section 337(j).

II. COMPLAINANT

9. Complainant Sun Pharmaceutical Industries, Inc. is a corporation organized under the laws of Delaware, having its principal place of business at Independence Way, Princeton, NJ 08540.

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

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

12. Sun Pharma's latest BLU-U® Blue Light Photodynamic Therapy Illuminator device—the BLU-U Model 4170E—individually and/or used in combination with the Levulan®

Kerastick® prescription medicine (the “Domestic Industry Products”) practices one or more claims of the Asserted Patents.

13. Sun Pharma has made and continues to make significant and substantial investments in facilities, equipment, labor, and research and development related to the design, development, manufacture, sales, marketing, and support of the Domestic Industry Products in the United States.

III. PROPOSED RESPONDENTS

A. Proposed Respondent Biofrontera Inc.

14. On information and belief, proposed Respondent Biofrontera Inc. is involved in the importation of the Accused Products into the United States and/or sale of the Accused Products after importation in the United States. 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. (*See* Ex. 14, Del. Div. of Corps., *Entity Details: Biofrontera Inc.* (last visited on June 25, 2024); Ex. 15, Biofrontera Inc., *Contact*, <https://www.biofrontera-us.com/contact> (last visited on June 25, 2024).)

15. On information and belief, Biofrontera Inc. is the United States “commercial arm” of the “Biofrontera Group” (described below). (Ex. 16, Biofrontera AG, Annual Report 2023 (Apr. 2022), https://investors.biofrontera-us.com/wp-content/uploads/2022/04/AnnualReport2021_BFRI.pdf, at 2.) Biofrontera Inc. was established in March 2015 as a “wholly owned U.S. subsidiary of Biofrontera AG.” (Ex. 12, Biofrontera Inc., *Form 10-K*, at 4 (Mar. 15, 2024), <https://www.sec.gov/Archives/edgar/data/1858685/000149315224010133/form10-k.htm>.)

16. 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.”

(Ex. 16, at 1.) “Sales with Biofrontera Inc. account for 69% of the [Biofrontera] Group’s total sales.” (Ex. 16, at 67.)

B. Proposed Respondent Biofrontera Pharma GmbH

17. On information and belief, Proposed Respondent Biofrontera Pharma GmbH is sufficiently involved with the design, manufacture, sale, and importation of the Accused Products, such that it is an importer for purposes of Section 337. On information and belief, Biofrontera Pharma GmbH also sells for importation, and/or is involved in sales within the United States after importation, of the Accused Products.

18. 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. (Ex. 16, at 43.) Biofrontera Pharma GmbH is a wholly owned subsidiary of Biofrontera AG. (Ex. 16, at 1.)

19. 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.” (Ex. 16, at 1.) Biofrontera Pharma GmbH also holds some of the Biofrontera Group’s patents. (Ex. 16, at 9.)

20. 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 device 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 ES60601-1 (2005) + AMD 1 (2012)“, „IEC 60601-1-6:2013“	

(Ex. 13, Biofrontera Inc., User Manual for RhodoLED® XL (Nov. 2021), <https://www.ameluz.com/fileadmin/AmeluzUSImages/05-pdf/Ameluz-Full-Prescribing-Information.pdf>, Fig. 21; *see also* Ex. 16 at 1 (stating that the “PDT-lamp series,” which includes the BF-RhodoLED® XL, are “manufactured at Biofrontera’s headquarter in Leverkusen, Germany.”).)

21. On information and belief, Biofrontera Pharma GmbH took actions purposefully directed to the United States by entering a license agreement with Biofrontera Inc. to import and sell the Accused Products. (Ex. 17, Biofrontera Pharma GmbH *et al.*, *Second Amended and Restated License and Supply Agreement* (Feb. 19, 2024), <https://www.sec.gov/Archives/edgar/data/1858685/000149315224007143/ex10-1.htm>.)

22. On information and belief, Biofrontera Pharma GmbH restricts Biofrontera Inc.’s ability to sell the Accused Products without Biofrontera Pharma GmbH’s permission. On

information and belief, Biofrontera Pharma GmbH is “the sole supplier” of the BF-RhodoLED® XL device and Ameluz® prescription medicine to Biofrontera Inc. (Ex. 17, Sec. 5.1.)

23. On information and belief, Biofrontera Pharma GmbH alone controls the volume of Accused Products that enter the United States, 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.” (Ex. 17, Sec. 5.3.) Proposed Respondent 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.” (Ex. 17, Sec. 2.1(b).)

24. On information and belief, Biofrontera Pharma GmbH and proposed respondent Biofrontera Bioscience GmbH (discussed below) 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. (Ex. 17, 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. (Ex. 17, Sec. 10.1.)

25. 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®.” (Ex. 17, Sec. 5.3.)

C. Proposed Respondent Biofrontera Bioscience GmbH

26. On information and belief, proposed Respondent Biofrontera Bioscience GmbH is sufficiently involved with the design, manufacture, and importation of the Accused Products, such that it is an importer for purposes of Section 337. On information and belief, Biofrontera Bioscience GmbH also sells the Accused Products for importation into the United States.

27. Biofrontera Bioscience GmbH is a wholly owned subsidiary of Biofrontera AG. (Ex. 16, at 1.) 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.” (Ex. 16, 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. (Ex. 16, at 9.)

28. On information and belief, Biofrontera Bioscience GmbH knows the imported products are manufactured abroad and imported into the United States, because Biofrontera Bioscience GmbH took actions purposefully directed to the United States by entering a license agreement with Biofrontera Inc. to import and sell the Accused Products. (Ex. 17.) 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. (Ex. 17, 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. (Ex. 17, Sec. 10.1.)

D. Proposed Respondent Biofrontera AG

29. On information and belief, Proposed Respondent Biofrontera AG is sufficiently involved with the design, manufacture, and importation of the Accused Products, such that it is an importer for purposes of Section 337. On information and belief, Biofrontera AG also sells for importation into the United States the Accused Products.

30. 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. (Ex. 16, at 43.)

31. Biofrontera AG refers to itself and each of the Proposed Respondents, Biofrontera Bioscience GmbH and Biofrontera Pharma GmbH, as the “Biofrontera Group.”² (See Ex. 16, at 1 (“As of 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.”).)

32. 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, Proposed Respondent Biofrontera Inc. On information and belief, Biofrontera AG took

² Biofrontera Development GmbH and Biofrontera Neuroscience GmbH are also members of the Biofrontera Group but are not parties to this action.

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.” (Ex. 12 at 4).

33. 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 shares as of April 2024. (Ex. 16, 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®.” (Ex. 12, 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 depends to a large extent on the sales success of Biofrontera Inc. on the US market.” (Ex. 16, at XII.) Biofrontera Inc. “acquires Ameluz® and the PDT lamps BF-RhodoLED® and RhodoLED® XL from Biofrontera AG.” (Ex. 16, at 2.)

34. 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.” (Ex. 16, at 2.)

35. 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 Ex. 18, Biofrontera Inc., *U.S. Board of Directors*, <https://www.biofrontera-us.com/about-us/board-of-directors> (last visited 6-25-2024); Ex. 19, 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>; Ex. 20, 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. (Ex. 21, Biofrontera Inc. & Hermann Lübbert, *Amended Employee Agreement*, Pt. 1, <https://www.sec.gov/Archives/edgar/data/1858685/000149315221024281/ex10-11.htm> (last visited 06-25-2024).) 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.” (Ex. 22, 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. (Ex. 19.)

IV. THE TECHNOLOGY AND PRODUCTS AT ISSUE

A. The Technology At Issue

36. Photodynamic therapy (“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.

37. Sun Pharma’s PDT treatment began in 1991 when pioneering research and development in the novel field of photodynamic therapy treatment was conducted for the treatment

of dermatological conditions.³ Among its many product offerings, Sun Pharma now develops, designs, manufactures, and markets products for PDT treatment, which consists of: a) BLU-U® Blue Light Photodynamic Therapy Illuminator Model 4170 device (“BLU-U®,” “BLU-U® 4170,” or “BLU-U® 4170D”⁴); b) Levulan® prescription medicine; and c) BLU-U® Blue Light Photodynamic Therapy Illuminator Model 4170E device (“BLU-U® 4170E”).

38. 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.

1. BLU-U® 4170 Device In Combination With Levulan® Prescription Medicine

39. Sun Pharma received the first approval from the U.S. Food & Drug Administration (“FDA”) in December 1999 to use its PDT device, the BLU-U® 4170 device, in combination with a photosensitizer prescription medicine with 5-aminolevulinic acid (“ALA”), namely Levulan® prescription medicine, to treat non-hyperkeratotic actinic keratosis (“AK”) of the face or scalp. (Ex. 23, Letter from James E. Dillard III, Acting Dir., FDA Div. of Gen. & Restorative Devices, to Samuel D. Swetland, Vice President, DUSA Pharms., Inc. Regul. Affs. & Compliance Guidelines (Dec. 3, 1999).) Shortly thereafter, in September 2000, Sun Pharma launched the Levulan® prescription medicine in combination with targeted light delivery from the BLU-U® 4170 device.

³ 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. (Ex. 59C, at F-27.) On March 1, 2013, Sun Pharmaceutical Industries, Inc. merged into Caraco. (Ex. 59C, at F-30.) On April 1, 2014, Caraco changed its name to Sun Pharmaceutical Industries, Inc. (Ex. 11C, at F-7.) On March 31, 2024, DUSA merged with Sun Pharma, leaving Sun Pharma remaining as the surviving corporation. (Ex. 25.)

⁴ BLU-U® 4170 device ships as three separated components that must be assembled on site. Therefore, when Unique Device Identification (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. (See Ex. 56C, at 2.)

(Ex. 24, *SEC Form 10-K for DUSA Pharmaceuticals, Inc. for Fiscal Year Ended December 31, 2008*, at 1 (Mar. 11, 2009), <https://www.sec.gov/Archives/edgar/data/879993/000095012309004456/y75261e10vk.htm>.)

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



2. BLU-U® 4170 Device Individually

41. 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. (Ex. 26, *DUSA Pharms., Inc., 510(k) Summary*, at 107 (Sept. 9, 2003), https://www.accessdata.fda.gov/cdrh_docs/pdf3/K031805.pdf.)

42. 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. Sun Pharma continued to devote significant resources to the research and development of its PDT treatment.

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

43. 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 the BLU-U® 4170 device. 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.

44. On May 13, 2024, Sun Pharma submitted a Special Premarket Notification seeking FDA clearance for the BLU-U® 4170E device. (Ex. 5.) In its submission, Sun Pharma stated that its BLU-U® 4170 device (also known as the BLU-U® Model 4170D device) is the predicate device for the BLU-U® 4170E device:

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.

(Ex. 46 (annotated).)

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

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

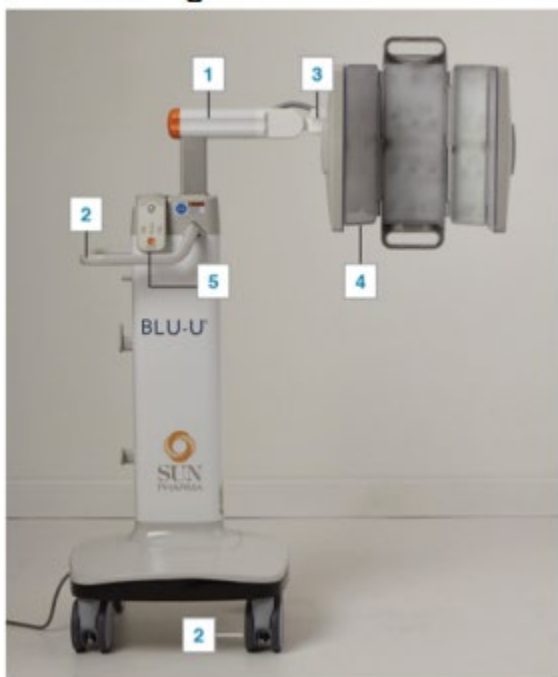
(Ex. 27, Letter from Tanisha Hithe, Assistant Dir., FDA Div. of Gen. Surgery Devices, to Scott Lundahl, Sun Pharm. Indus., Inc., at 1 (June 13, 2024) (annotated).)

46. The BLU-U® Model 4170E device is generally indicated to treat dermatological indications and specifically indicated to treat moderate inflammatory acne vulgaris. The BLU-U® Model 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 actinic keratoses (“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. (Ex. 28, Sun Dermatology, *Operating Manual for BLU-U® Blue Light Photodynamic Therapy Illuminator Model 4170E*, at 4 (Apr. 30, 2024).)

47. 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 device 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 five individual LED

panels connected by hinges. The panels are covered by a protective shield and the center panel directs cooling airflow to the patient to improve comfort during the treatment. It is mounted on a floor-stand, which permits rapid positioning as well as adjustment for patient height. The control panel / user interface is also affixed to the floor stand.

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.

(Ex. 28 at 7.)

48. Sun Pharma employees, and contractors working on its behalf, engage in research, design, development, engineering, product support, manufacturing support, testing, regulatory compliance, and medical support activities related to the BLU-U® 4170E device in the United States. To perform this work, Sun Pharma has invested significant domestic labor, capital, facilities, and equipment.

B. The Products At Issue

49. Pursuant to 19 C.F.R. §§ 210.10(b)(1) and 210.12(a)(12), Sun Pharma's clear statement in plain English of the category of products accused is as follows: The products at issue

are illuminators for photodynamic therapy with light sources on at least five panels, assembled or disassembled, replacement parts, and 5-aminolevulinic acid used in combination with the illuminators for photodynamic therapy.

50. As described further below and in the attached claim charts (Exhibits 7 and 8), at least Biofrontera's BF-RhodoLED® XL device individually and/or in combination with Biofrontera's Ameluz® prescription medicine infringes one or more claims of the '028 and/or '512 Patents. On information and belief, the BF-RhodoLED® XL device and Ameluz® prescription medicine are caused to be manufactured overseas by Biofrontera or one of its affiliates and then imported into the United States after manufacture abroad to be sold to consumers for use in the United States. Discovery may reveal that additional Biofrontera products infringe the Asserted Patents.

V. THE ASSERTED PATENTS

A. The '028 Patent

1. Identification Of The Patent And Ownership

51. The '028 Patent is entitled "Adjustable Illuminator for Photodynamic Therapy and Diagnosis" and duly and legally issued on July 11, 2023. The '028 Patent issued from U.S. Application No. 17/942,353, filed on September 12, 2022. The '028 Patent will expire on October 13, 2036. The '028 Patent discloses a system and method for photodynamic therapy and diagnosis of skin diseases.

52. Sun Pharma is the owner, by valid assignment, of the entire right, title, and interest in and to the '028 Patent. Prior to issuance, the '028 Patent inventors assigned all right, title, and interest in U.S. Patent Application Serial No. 17/942,353 to DUSA Pharmaceutical, Inc. ("DUSA"). This assignment is recorded at the United States Patent and Trademark Office ("USPTO") at Reel/Frame 067409/0242. (Ex. 4, Certified Assignment Records for U.S. Patent

No. 11,697,028.) Effective March 31, 2024, DUSA merged with Sun Pharma and assigned all right, title, and interest in the '028 Patent to Sun Pharma. This assignment is recorded at the USPTO at Reel/Frame 067409/0615. (Ex. 4.) The '028 Patent is valid, enforceable, and is currently in full force and effect.

53. In accordance with Rule 210.12(c) of the Commission's Rules of Practice and Procedure and the Commission's Temporary Change to the Filing Procedures dated March 19, 2020, this Complaint is accompanied by Appendices C and D containing (i) an electronic copy of the prosecution history of the '028 Patent, and (ii) an electronic copy of each reference mentioned in that prosecution history, respectively.

2. Non-Technical Description Of The Patented Invention

54. In non-technical terms, the '028 Patent relates to an adjustable illumination device and method for photodynamic therapy to treat and/or diagnose several types of ailments in or near the skin or other tissues, such as those in a body cavity. The patent describes a system for photodynamically diagnosing or treating a patient comprising an illuminator comprising five panels connected by hinged structures with light sources disposed on surfaces of the five panels wherein one of the five panels is positioned as a center panel configured to face the treatment surface, and two or more of the five panels being configured to be angled relative to the center panel. The light sources are configured to uniformly illuminate the treatment surface. Claim 5 describes a method for photodynamically diagnosing or treating a patient using the illuminator in conjunction with administering 5-aminolevulinic acid (ALA) to the patient.

55. The foregoing non-technical description of the patented technology is not intended to limit, define, or otherwise affect the scope of the claims of the '028 Patent. Additionally, the foregoing non-technical description should not be understood as defining or construing any term, phrase, or limitation recited in any claim of the '028 Patent.

3. Foreign Counterparts To The '028 Patent

56. The following foreign patent(s) and/or patent application(s) correspond to the '028 Patent: WO 2017/066270 (Inactive); EP 3,362,145 (Issued); ES 2,860,807 (Issued); PL 3,362,145 (Issued); EP 3,851,161 (Pending); AU 2018/250595 (Inactive); WO 2018/191356 (Inactive); CA 3,057,840 (Pending); JP 7,382,832 (Issued); JP 2023/146114 (Pending); AU 2023/285927 (Pending); DE 3,362,145 (Issued); FR 3,362,145 (Issued); GB 3,362,145 (Issued); IT 3,362,145 (Issued); and RO 3,362,145 (Issued). Sun Pharma is unaware of other foreign counterparts or foreign counterpart applications corresponding to the '028 Patent that have been issued, abandoned, denied, withdrawn, or which remain pending. (*See* Ex. 6, List of Foreign Counterparts to U.S. Patent Nos. 11,446,512 and 11,697,028.)

B. The '512 Patent

1. Identification Of The Patent And Ownership

57. The '512 Patent is entitled "Adjustable Illuminator for Photodynamic Therapy and Diagnosis" and duly and legally issued on September 20, 2022. The '512 Patent issued from U.S. Patent Application Serial No. 16/791,004, filed on February 14, 2020. The '512 Patent will expire on January 17, 2037. The '512 Patent discloses a system and method for photodynamic therapy and diagnosis of skin diseases.

58. Sun Pharma is the owner, by valid assignment, of the entire right, title, and interest in and to the '512 Patent. Prior to issuance, the '512 Patent inventors assigned all right, title, and interest in U.S. Patent Application Serial No. 16/791,004 to DUSA. This assignment is recorded at the USPTO at Reel/Frame 057030/0028. (*See* Ex. 2, Certified Assignment Records for U.S. Patent No. 11,446,512.) Effective March 31, 2024, DUSA merged with Sun Pharma and assigned all right, title, and interest in U.S. Patent No. 11,446,512 to Sun Pharma. This assignment is recorded at the USPTO at Reel/Frame 067550/0174. (*See* Ex. 2.) The '512 Patent is valid, enforceable, and is currently in full force and effect.

59. In accordance with Rule 210.12(c) of the Commission's Rules of Practice and Procedure and the Commission's Temporary Change to the Filing Procedures dated March 19, 2020, this Complaint is accompanied by Appendices A and B containing (i) an electronic copy of the prosecution history of the '512 Patent, and (ii) an electronic copy of each reference mentioned in that prosecution history, respectively.

2. Non-Technical Description Of The Patented Invention

60. In non-technical terms, the '512 Patent relates to an adjustable illumination device and method for photodynamic therapy to treat and/or diagnose several types of ailments in or near the skin or other tissues, such as those in a body cavity. The patent describes a system for photodynamically diagnosing or treating a patient comprising an illuminator comprising five panels connected by nested hinges with light sources disposed on surfaces of the five panels wherein one of the five panels is positioned as a center panel configured to face the treatment surface, and two or more of the five panels being configured to be angled relative to the center panel. The light sources are configured to uniformly illuminate the treatment surface. Claim 8 describes a method for photodynamically diagnosing or treating a patient using the illuminator in conjunction with administering 5-aminolevulinic acid (ALA) to the patient.

61. The foregoing non-technical description of the patented technology is not intended to limit, define, or otherwise affect the scope of the claims of the '512 Patent. Additionally, the foregoing non-technical description should not be understood as defining or construing any term, phrase, or limitation recited in any claim of the '512 Patent.

3. Foreign Counterparts To The '512 Patent

62. The following foreign patent(s) and/or patent application(s) correspond to the '028 Patent: WO 2017/066270 (Inactive); EP 3,362,145 (Issued); ES 2,860,807 (Issued); PL 3,362,145 (Issued); EP 3,851,161 (Pending); AU 2018/250595 (Inactive); WO 2018/191356 (Inactive); CA

3,057,840 (Pending); JP 7,382,832 (Issued); JP 2023/146114 (Pending); AU 2023/285927 (Pending); DE 3,362,145 (Issued); FR 3,362,145 (Issued); GB 3,362,145 (Issued); IT 3,362,145 (Issued); and RO 3,362,145 (Issued). Sun Pharma is unaware of other foreign counterparts or foreign counterpart applications corresponding to the '512 Patent that have been issued, abandoned, denied, withdrawn, or which remain pending. (*See* Ex. 6.)

VI. UNFAIR ACTS OF PROPOSED RESPONDENTS

63. Biofrontera's Accused Products directly infringe (literally and/or under the doctrine of equivalents), contributorily infringe, and/or induce the infringement of at least the Asserted Claims. (*See supra* Pts. I & III; *infra* Pt. VII.) Discovery may reveal that Biofrontera infringes additional claims of the Asserted Patents.

64. On information and belief, Biofrontera manufactures, assembles, packages and tests, and/or purchases the Accused Products outside the United States, specifically, at least in Germany. (Ex. 13, Fig. 21; *see also* Ex. 16, at 1 (stating that the "PDT-lamp series" which includes the BF-RhodoLED® XL device, are "manufactured at Biofrontera's headquarter in Leverkusen, Germany.")) Biofrontera then import into the United States, sell for importation, and/or sell within the United States after importation, the Accused Products. Each Proposed Respondent's activities related to the importation of Accused Products into the United States, sale of Accused Products for importation, and/or sale of Accused Products within the United States after importation are described above. (*See supra* Pt. III.)

65. Respondents have violated Section 337 by importing into the United States, selling for importation, and/or selling in the United States after importation products infringing the Asserted Claims of the Asserted Patents. By way of example, claim charts attached as Exhibits 7 and 8 demonstrate how the BF-RhodoLED® XL device, an exemplary Accused Product,

individually or in combination with Biofrontera's Ameluz® prescription medicine, infringes the Asserted Claims. Those exhibits are also representative of infringement by other Accused Products. Further discovery may reveal additional infringing Biofrontera products.

66. Biofrontera had actual notice of the '028 Patent by no later than the filing date of the *inter partes* review filed by Biofrontera AG. *Biofrontera AG v. DUSA Pharms., Inc.*, No. IPR2024-00874 (P.T.A.B. Apr. 30, 2024). Biofrontera had actual notice of the '512 Patent by no later than the filing of this Complaint.

A. Biofrontera Directly Infringes The Asserted Patents By Importing And Selling The Infringing BF-RhodoLED® XL Device

67. Biofrontera directly infringes the Asserted Patents by importing into the United States, selling for importation, and/or selling the Accused Products in the United States after importation. For example, Biofrontera's operating manual submitted to the FDA describes at least a device that infringes claim 1 of the '028 Patent and claim 1 of the '512 Patent. (*See* Ex. 13; *see also* Ex. 7 (Infringement Claim Chart for U.S. Patent No. 11,446,512); Ex. 8 (Infringement Claim Chart for U.S. Patent No. 11,697,028).) Biofrontera infringes the Asserted Patents either directly and/or through the doctrine of equivalents. (*See* Ex. 7; Ex. 8.)

68. Biofrontera entered the PDT treatment space decades after Sun Pharma's start. In fact, Biofrontera hired over twenty employees from Sun Pharma who took at least 600 Sun Pharma documents. *DUSA Pharms., Inc. v. Biofrontera Inc.*, Case No. 1:18-cv-10568-RGS, Dkt. No. 123 (D. Mass. 2018). In December 2018, the Federal District Court for the District of Massachusetts found that Biofrontera was in possession of Sun Pharma documents that contained "confidential and proprietary information" and enjoined Biofrontera from "making use of or disseminating DUSA's sales and financial information, customer lists and customer target lists, training and

marketing materials, standard operating procedures, technical information, and unpublished clinical data, and any derivations thereof.” *Id.*

69. In July 2015, Biofrontera applied for FDA approval to market its first PDT device, the BF-RhodoLED® device, 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:

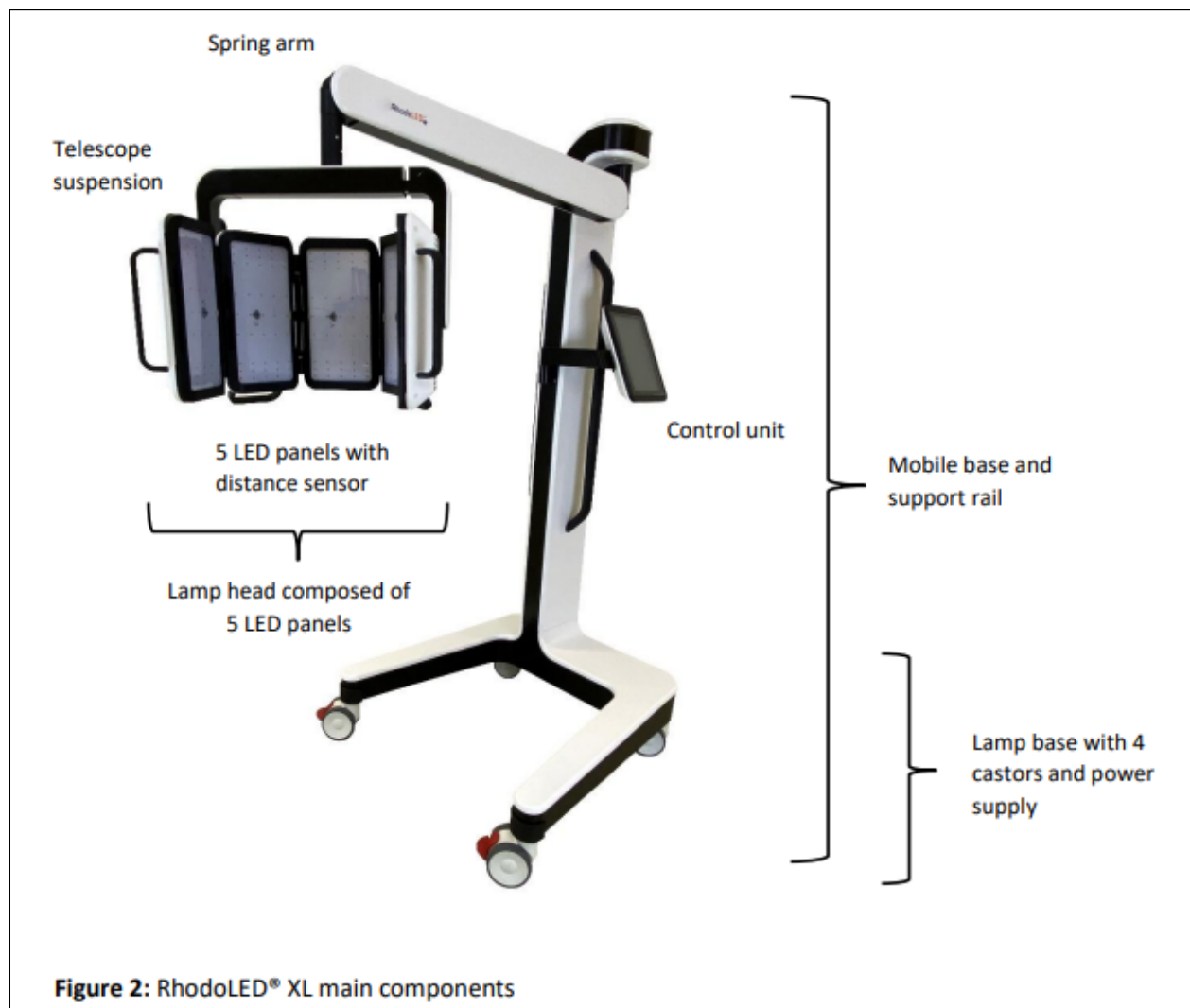
-----INDICATIONS AND USAGE-----
AMELUZ gel, a porphyrin precursor, in combination with photodynamic therapy using BF-RhodoLED lamp, is indicated for the lesion-directed and field-directed treatment of actinic keratoses of mild-to-moderate severity on the face and scalp (1).

(Ex. 29, Biofrontera Inc., *Highlights of Prescribing Information for Ameluz®*, at 1 (May 2016), https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/208081s000lbl.pdf.)

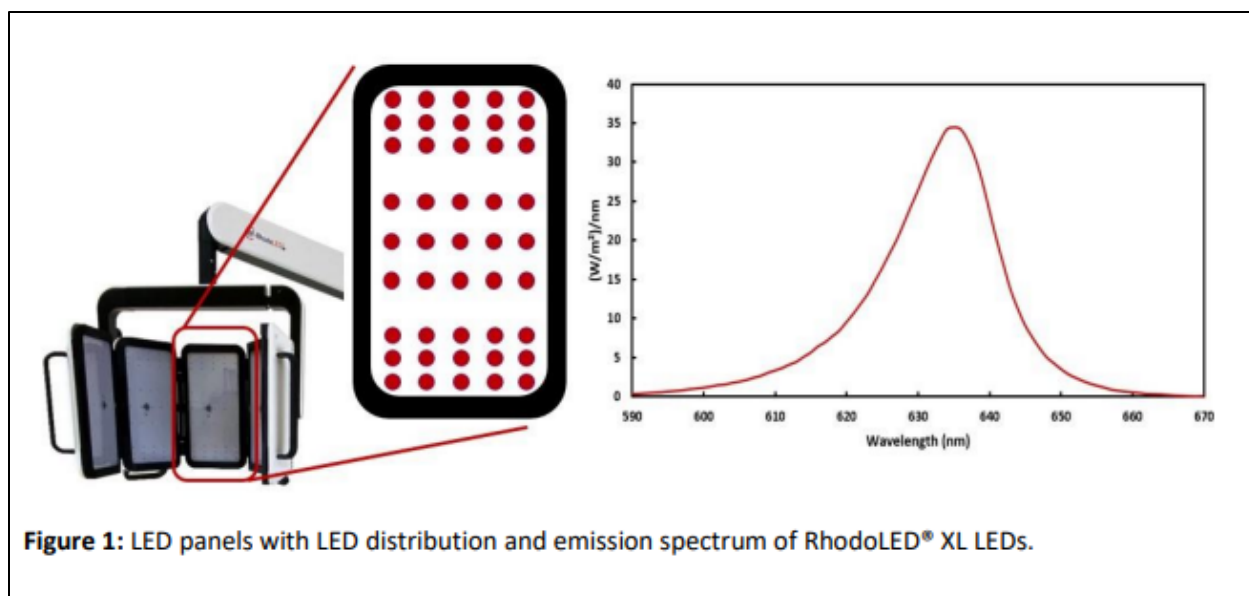
70. On October 22, 2021, the FDA approved a new Biofrontera device, the BF-RhodoLED® XL device, “in combination with Ameluz® for the treatment of mild and moderate actinic keratoses on the face and scalp.” (Ex. 30, Biofrontera AG, *Biofrontera AG Receives FDA-Approval of the BF-RhodoLED® XL Lamp* (Oct. 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 Ex. 30.)

71. 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.” (Ex. 13, at 9.) Figure 2 from the BF-RhodoLED® XL User Manual depicts the main components:



(Ex. 13, 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.” (Ex. 13, Sec. 4.1.) According to Biofrontera, “[t]he 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.”



(Ex. 13, Sec. 4.1.)

72. 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.

(Ex. 13, 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.

(Ex. 13, 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.

(Ex. 13, Sec. 3.)

73. 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 ®.” (Ex. 12, at 5; *see also* Ex. 31, Biofrontera, Inc., *2021 Annual Report*, at 7 (Apr. 2022), 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.”).)

B. Biofrontera Indirectly Infringes The Asserted Patents

74. Biofrontera actively induces others, such as its distributors and customers (none of which are licensed by Sun Pharma), to use and purchase the Accused Products such that others directly infringe the Asserted Claims of the Asserted Patents. 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.

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.

(Ex. 13, at 2.)

75. 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 and claim 8 of the ’512 Patent: “[a] method of photodynamically diagnosing or treating a patient.” (See ’028 Patent; ’512 Patent; Ex. 32, Biofrontera Inc., *Highlights of Prescribing Information for Ameluz®* (Dec. 2021), <https://www.ameluz.com/fileadmin/AmeluzUSImages/05-pdf/Ameluz-Full-Prescribing-Information.pdf>; see also Ex. 8; Ex. 7.) Claim 5 of the ’028 Patent and claim 8 of the ’512 Patent include “administering 5-aminolevulinic acid (ALA) to the patient,” and Biofrontera’s Amaluz® prescription medicine (which contains ALA) is used in conjunction with the BF-RhodoLED® XL device. (See ’028 Patent; ’512 Patent; Ex. 13, at 2 (“Our drug Amaluz® and medical device RhodoLED® XL have been approved in combination for photodynamic therapy.”); Ex. 32, Sec. 11 (showing that Ameluz® prescription medicine contains ALA); see also Ex. 8, element 5[a]; Ex. 7, element 8[a]; *supra* para. 76 (explaining how the BF-RhodoLED® XL User Manual instructs a user to use the BF-RhodoLED® XL device with the Ameluz® prescription medicine).)

76. In addition, claim 5 of the ’028 Patent and claim 8 of the ’512 Patent include “positioning an illuminator proximate to the patient,” and Biofrontera’s User Manual directs that the BF-RhodoLED® XL device’s illuminator should be positioned near the patient. (See ’028 Patent; ’512 Patent; see, e.g., Ex. 13, Fig. 13 (showing illuminator positioned near the patient’s

head); *see also* Ex. 8, element 5[b]; Ex. 7, element 8[b].) Finally, claim 5 of the '028 Patent and claim 8 of the '512 Patent include “uniformly illuminating a treatment surface of the patient with light sources disposed on the five panels of the illuminator,” and Biofrontera’s User Manual directs that BF-RhodoLED® XL device’s five panels uniformly illuminate the patent’s treatment area. (*See* '028 Patent, '512 Patent; Ex. 13, 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.*, Ex. 13, Fig. 13 (illuminating the treatment area of the patient’s face); *see also* Ex. 8, element 5[c]; Ex. 7, element 8[c].) Thus, Biofrontera actively induces patients and doctors to use the BF-RhodoLED® XL device in an infringing manner.

77. 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.*, Ex. 34, Regina (Orsogna) Arnone, LinkedIn, https://www.linkedin.com/posts/regina-orsogna-arnone-2346997_scale2024-biofrontera-pdt-activity-7198081811854303235-m8A3 (last visited June 25, 2024).)

78. Biofrontera also contributorily infringes certain Asserted Claims through importing into the United States, selling for importation, and/or selling within the United States after importation 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 Asserted Patents, 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. (Ex. 13, at 2; *see also supra* para. 76 (User Manual explaining that the BF-RhodoLED® XL device is used exclusively in combination with the Ameluz® prescription medicine).)

VII. SPECIFIC INSTANCES OF UNFAIR IMPORTATION AND SALE

A. Importation Of The BF-RhodoLED® XL Device

79. Biofrontera’s BF-RhodoLED® XL device is manufactured abroad in Leverkusen Germany by Biofrontera Pharma GmbH, 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 ES60601-1 (2005) + AMD 1 (2012)“, „IEC 60601-1-6:2013“	

(Ex. 13, Fig. 21; *see also* Ex. 16, at 1 (stating that the “PDT-lamp series” which includes the BF-RhodoLED® XL device, are “manufactured at Biofrontera’s headquarter in Leverkusen, Germany.”).)

80. Biofrontera has stated that it developed BF-RhodoLED® XL device for use only in the United States:

Both RhodoLED® lamps emit light with a wavelength of approx. 635 nm via their LEDs. Light at this wavelength, which is optimal for illumination in PDT with ALA or methyl ALA containing drugs, emits red light, but is still below the warming infrared range. The RhodoLED® lamp series combines controlled and constant light output in the desired wavelength with simple and clear operability and energy efficiency. Light energy and fan power can be changed during PDT treatment to respond to treatment-related pain. The BF-RhodoLED® can be distributed throughout the EU, UK, Switzerland as well as the USA. The use of the RhodoLED® XL is currently only planned for the US market.

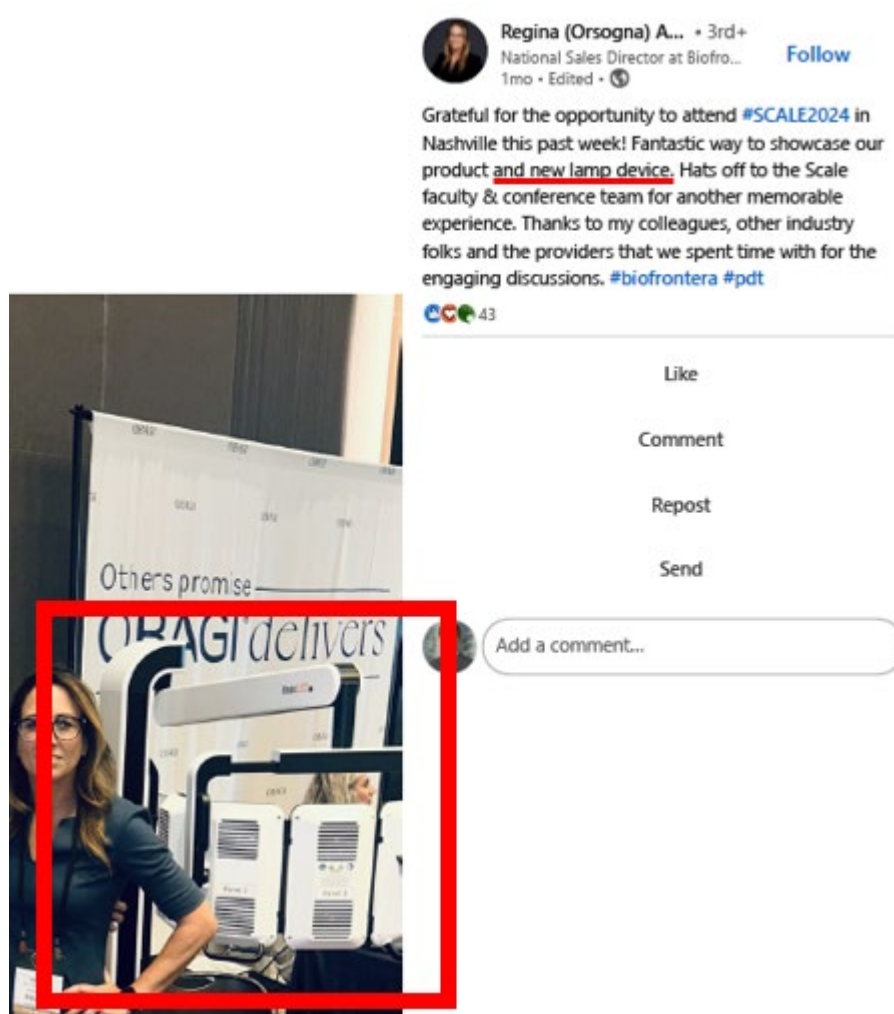
(Ex. 16, at 3.)

81. According to Biofrontera Inc., the BF-RhodoLED® XL device is available in the second quarter of 2024:

Under the Ameluz LSA, we hold the exclusive license to sell Ameluz® and the RhodoLED® lamp series comprising the RhodoLED® and the new, more advanced RhodoLED® XL (available in the second quarter of 2024) in the United States for all indications currently approved by the FDA as well as all future FDA-approved indications identified under the Ameluz LSA.

(Ex. 12, at 6.)

82. As part of its commercialization efforts, Biofrontera exhibited its BF-RhodoLED® XL device in the United States. For example, in May 2024, Biofrontera hosted a booth at the Music City Symposium for Cosmetic Advances & Laser Education (“SCALE”) in Nashville, TN, where Biofrontera showcased the BF-RhodoLED® XL device:



(Ex. 34 (annotations added).) The exhibition occurred after Biofrontera secured FDA approval for the BF-RhodoLED® XL device.

83. On information and belief, the BF-RhodoLED® XL device is currently being sold in the United States. For example, on information and belief, at least by June 12, 2024, Biofrontera had distributed pamphlets for doctors to lease the BF-RhodoLED® XL device:



(Ex. 35, Biofrontera Pamphlet, *Meet RhodoLED® XL Lamp*.) The pamphlet's QR code leads to an informational contact page hosted by Biofrontera:

CONTACT US

For your patients and your practice

Schedule a photodynamic therapy consult to find out how integrating AMELUZ® (aminolevulinic acid HCl) topical gel, 10% and BF-RhodoLED® into your practice can benefit your patients with AK.

 Call us at 1-844-4AMELUZ (1-844-426-3589)

 Or email us at info@bflnc.com

(Ex. 36, Biofrontera Inc., *Contact Us*, https://us.ameluz.com/hcp/contact?utm_source=Updated__XL_Journal_Ad&utm_medium=JAAD_June_2024&utm_campaign=Brand_Awareness+ (last visited June 25, 2024).)

84. Since the beginning of 2024, Biofrontera imported the BF-RhodoLED® XL device at least two times, namely on May 18 and June 9, 2024. The units were shipped from Belgium and arrived in the United States through Savannah, GA.

Contact info		
Type	Name	Address
IMPORTER	CARDINAL HEALTH SPS	501 MASON RD SUITE 200 LAVERGNE TN 37086 US
NOTIFY PARTY	-NOT AVAILABLE-	-NOT AVAILABLE-
SHIPPER	BIOFRONTERA PHARMA GMBH	HEMMEL RATHER STRASSE 201 LEVERKUSEN DE

Product details	
Container no.	Description area
TEMU8469242	BF-RHODOLED XL- RED LIGHT ILLUMINATION DEVICECUSTOMS TARIFF NUMBER 9018.90.80 00

Transit details	
Transit name	Transit value
Carrier	DSVF
Ship Registered In	SINGAPORE
Vessel	MAERSK MAKUTU
Voyage	417W
US Port	Savannah, Georgia
Foreign Port	Antwerp
Country of Origin	Belgium
Place of Receipt	ANTWERPEN
Bill of Lading	DSVFBSL0060116
Arrival Date	2024-05-18
Quantity	28 PKG
Container Count	1
Weight (LB / KG)	6468.00 / 2940.00
CBM	0 CM
House vs Master	H
Master Bill of Lading	MEDUAX792529

(Ex. 37, ImportGenius, *Importation Records from May 18, 2024* (annotated),

<https://app.importgenius.com/shipment-detail/mZDKzQOL6R1yxpPrj7MXBPMbvl>

WAdrkq8jBN/gyYQZk6Axp2E4BV0GJM9ydP1lemOGWoq3bj/us/import?view=consignee (last visited June 24, 2024).)

Contact info		
Type	Name	Address
IMPORTER	CARDINAL HEALTH SPS	501 MASON RD SUITE 200 LAVERGNE TN 37086 US
NOTIFY PARTY	-NOT AVAILABLE-	-NOT AVAILABLE-
SHIPPER	BIOFRONTERA PHARMA GMBH	HEMMELRATHER STRASSE 201 LEVERKUSEN DE

Product details	
Container no.	Description area
MSDU7632391	BF-RHODOLED XL- RED LIGHT ILLUMINATION DEVICECUSTOMS TARIFF NUMBER 9018.90.80 00

Transit details	
Transit name	Transit value
Carrier	DSVF
Ship Registered In	FRANCE
Vessel	MAERSK GARONNE
Voyage	420W
US Port	Savannah, Georgia
Foreign Port	Antwerp
Country of Origin	Belgium
Place of Receipt	ANTWERPEN
Bill of Lading	DSVFBSL0060495
Arrival Date	2024-06-09
Quantity	28 PKG

(Ex. 47, Import Genius, *Importation Records from June 9, 2024* (annotated), <https://app.importgenius.com/shipment-detail/mZDKzQOL6R1yxpPrj7MXBPMbvl>

WAdrkq8jBN/AKeERomoQr9jJZnJovkvy9Pv7DWBYYqpaxzdg/us/import?view=consignee (last visited June 24, 2024).)

85. On June 24, 2024, Biofrontera Inc. announced that it had “launched the commercial distribution of the RhodoLED XL on June 10, 2024, shipping the first three machines within 1 week of launch.” (Ex. 58, Biofrontera Inc., *Biofrontera Announces the Launch of a New, FDA-Approved Red Light Source, the RhodoLED® XL Lamp* (June 24, 2024), <https://investors.biofrontera-us.com/full-news/?qm-storyId=5287383329078091> (last visited June 25, 2024).)

B. Importation Of The Ameluz® Prescription Medicine

86. On information and belief, Biofrontera has imported into the United States, sold for importation, and/or sold within the United States after importation Ameluz® prescription medicine. Biofrontera Inc. has an exclusive license and supply agreement to sell Ameluz® prescription medicine in the United States, and in its Form 10-Q for the quarterly period ending March 31, 2024, Biofrontera, Inc. stated that it is currently selling Ameluz® prescription medicine in the United States and holds inventories of Ameluz® prescription medicine:

Our principal licensed product is Ameluz®, which is a prescription drug approved for use in combination with the RhodoLED® lamp series, for PDT (when used together, “Ameluz® PDT”). In the United States, the PDT treatment is used for the lesion-directed and field-directed treatment of actinic keratoses of mild-to-moderate severity on the face and scalp. We are currently selling Ameluz® for this indication in the U.S. under an exclusive license and supply agreement (the “Ameluz LSA”) with the Ameluz Licensor.

(Ex. 38, Biofrontera Inc., *Form 10-Q*, Sec. 1 (May 15, 2024),

7. Inventories

Inventories are comprised of Ameluz®, the BF-RhodoLED® lamps and immaterial amounts of Xepi® finished products.

(Ex. 38, Sec. 7.)

87. Ameluz® prescription medicine is manufactured in Switzerland and distributed in the United States by Biofrontera Inc.:

Outer Packaging, single Carton
NDC 70621-101-10
Ameluz® Rx Only
(aminolevulinic acid HCl) topical gel, 10%
Use contents within 3 months after opening. Discard after: __/__/__.
Store refrigerated 2°-8°C (36°-46°F), excursions permitted to 15°-30°C (59°-86°F).
Keep out of the sight and reach of children.
See package insert for dosage information. Net Wt. 2 g
Distributed By: Biofrontera Inc.
120 Presidential Way, Suite 330
Woburn, MA 01801
Product of Switzerland
For Topical Use Only with BF-RhodoLED® or RhodoLED® XL lamp
Healthcare Professionals Only
Ingredients: Each gram of Ameluz Gel contains 100 mg of the active ingredient, aminolevulinic acid hydrochloride (equivalent to 78 mg of aminolevulinic acid) and the following inactive ingredients: xanthan gum, soybean phosphatidylcholine, polysorbate 80, medium-chain triglyceride, isopropyl alcohol, dibasic sodium phosphate, monobasic sodium phosphate, sodium benzoate and purified water

(Ex. 39, Biofrontera Inc., *Ameluz® Outer Packaging*, at 2–3 (May 2024), <https://dailymed.nlm.nih.gov/dailymed/getFile.cfm?setid=650daa9f-aeec-49ce-95b9-5fa20b988afd&type=pdf>.)

VIII. CLASSIFICATION UNDER THE HARMONIZED TARIFF SCHEDULE

88. The Accused Products fall within at least the following headings of the Harmonized Tariff Schedule (“HTS”) of the United States: 2922.50.25 and 9018.90.80. (*See* Ex. 40, Excerpts from Harmonized Tariff Schedule of the United States Revision 3 (2024).) The identified HTS numbers are intended to be for illustration only and are not exhaustive of the products accused of infringement in this Complaint. The HTS numbers are not intended to limit the scope of the Investigation.

IX. LICENSEES

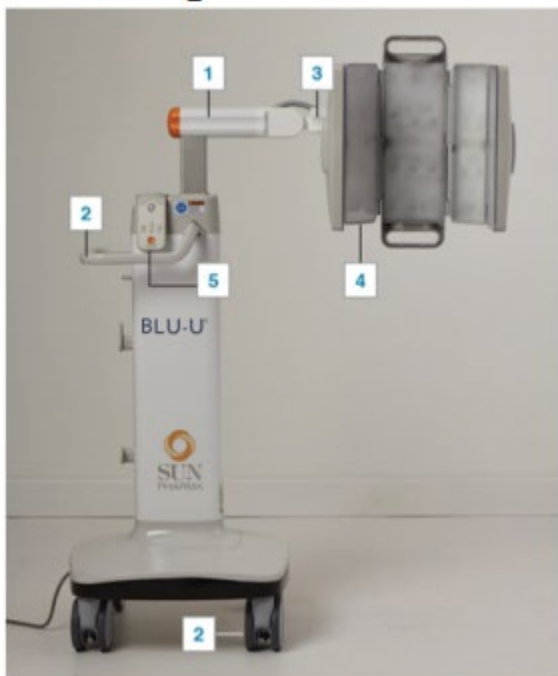
89. There are no licenses of the ’028 or ’512 Patents to any party.

X. DOMESTIC INDUSTRY

90. As required by Section 337(a)(2) and defined by Section 337(a)(3), a domestic industry exists in the United States in connection with articles covered by the Asserted Patents.

91. As described below and in the accompanying confidential declarations of Messrs. Zvi Albert and Scott Lundahl, Exhibits 41C and 42C, as well as in Confidential Exhibits 9C and 10C, Sun Pharma researches, manufactures, designs, markets, and develops in the United States the Domestic Industry Products, including the BLU-U® 4170E device, individually and in combination with Levulan® prescription medicine. Photographs of the Domestic Industry Products are included 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.

(Ex. 28 at 7.)

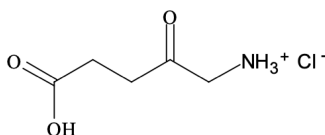
**LEVULAN® KERASTICK™ (aminolevulinic acid HCl) for Topical Solution, 20%
For Topical Use Only
Not for Ophthalmic Use**

DESCRIPTION

LEVULAN® KERASTICK™ (aminolevulinic acid HCl) for Topical Solution, 20%, contains the hydrochloride salt of 5-aminolevulinic acid (ALA), an endogenous 5-carbon aminoketone.

Aminolevulinic acid HCl (ALA HCl) is a white to off-white, odorless crystalline solid that is very soluble in water, slightly soluble in methanol and ethanol, and practically insoluble in chloroform, hexane and mineral oil.

The chemical name for ALA HCl is 5-amino-4-oxopentanoic acid hydrochloride (MW = 167.59). The structural formula is represented below:



(Ex. 45 at 1.)

A. Technical Prong

92. Sun Pharma's Domestic Industry Products, which include the BLU-U® 4170E device individually or in combination with Levulan® prescription medicine, practice one or more claims of the Asserted Patents. Claim charts demonstrating how the Domestic Industry Products are covered by an exemplary claim of each of the Asserted Patents and thus satisfy the technical prong of the domestic industry requirement under Section 337(a)(2), are attached as Confidential Exhibits 9C and 10C. Sun Pharma may further demonstrate satisfaction of the technical prong of the domestic industry requirement through other claims of the Asserted Patents.

B. Economic Prong

93. As defined under 19 U.S.C. §§ 1337(a)(3)(A), (B), and/or (C), there is a domestic industry comprising significant investments Sun Pharma made and/or plans to make and activities Sun Pharma has undertaken and/or plans to undertake in the United States relating to products protected by one or more claims of the Asserted Patents. These investments and activities include research and development, manufacturing, testing, and engineering for the Sun Pharma domestic

industry products. Specific, non-limiting examples of Sun Pharma's investments and activities related to the Asserted Patents are set forth in the confidential declarations of Messrs. Zvi Albert and Scott Lundahl at Confidential Exhibits 41C and 42C.

94. Sun Pharma employs a significant number of employees in its U.S. facilities in Billerica, MA and Princeton, NJ. These employees devote substantial personnel-hours toward the research and development, testing, engineering, and manufacturing of the Sun Pharma Domestic Industry Products. The confidential declarations of Messrs. Zvi Albert and Scott Lundahl set forth details regarding the investments it has made in these U.S. employees. (*See Confidential Ex. 41C; Confidential Ex. 42C.*)

95. Sun Pharma also invests capital toward manufacturing and research and development for products protected by the Asserted Patents. The confidential declarations of Messrs. Zvi Albert and Scott Lundahl at Confidential Exhibits 41C and 42C provide additional details regarding Sun Pharma's capital investments.

96. In addition, Sun Pharma has made substantial investments in plant and equipment in the United States. Sun Pharma owns a facility in Billerica, MA that house activities for research and development, manufacturing, testing, and engineering of the Sun Pharma Domestic Industry Products. The confidential declarations of Messrs. Zvi Albert and Scott Lundahl at Confidential Exhibits 41C and 42C include further non-limiting examples of Sun Pharma's investments in this category.

97. To the extent it is determined that a domestic industry does not currently exist, Sun Pharma is in the process of establishing a domestic industry with respect to the Asserted Patents because it is actively continuing to engage in the steps leading to the exploitation of its intellectual property rights, and there is a significant likelihood that an industry will be established in the

United States in the future. Further non-limiting examples regarding the active steps taken by Sun Pharma to establish a domestic industry are included in the confidential declaration of Messrs. Zvi Albert and Scott Lundahl at Confidential Exhibits 41C and 42C.

98. Sun Pharma's investments and expenditures related to the products protected by the Asserted Patents are significant and substantial at least because: (1) the Domestic Industry Products are manufactured in the United States, (2) all research and development activities related to the BLU-U® 4170E device take place in the United States, and (3) Sun Pharma's investments and expenditures related to the Domestic Industry Products are increasing year-over-year. Sun Pharma's domestic expenditures are necessary for development, approval, and commercialization of the Domestic Industry Products. Moreover, Sun Pharma's domestic activities add substantial value to the Domestic Industry Products. Further non-limiting examples regarding the aforementioned are included in the confidential declaration of Messrs. Zvi Albert and Scott Lundahl at Confidential Exhibits 41C and 42C.

XI. RELATED LITIGATION

99. In April 2024, Biofrontera AG filed an *inter partes* review against the '028 Patent. *Biofrontera AG v. DUSA Pharms., Inc.*, No. IPR2024-00874 (P.T.A.B. Apr. 30, 2024).

100. On June 25, 2024, Sun Pharma filed a patent litigation action against Biofrontera in the United States District Court for the District of Massachusetts, asserting the Asserted Patents. *Sun Pharmaceutical Industries, Inc. v. Biofrontera Bioscience GmbH, et al*, Civil Action No. 24-cv-11637, (D. Mass. 2024).

XII. REQUESTED RELIEF

101. WHEREFORE, by reason of the foregoing, Sun Pharma requests that the United States International Trade Commission:

(a) Institute an immediate investigation, pursuant to Section 337 of the Tariff Act of

1930, as amended, 19 U.S.C. § 1337, with respect to violations of Section 337 based on Respondents' unlawful 1) importation into the United States, 2) sale for importation into the United States, 3) sale within the United States after importation, and/or 4) use within the United States after importation, of certain photodynamic therapy systems, components thereof, and pharmaceutical products used in combination with the same that infringe one or more claims of United States Patent Nos. 11,697,028 and 11,446,512;

(b) Schedule and conduct a hearing on the unlawful acts and, following the hearing, determine that there has been a violation of Section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337;

(c) Issue a permanent, limited exclusion order, pursuant to Section 337(d) of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337(d), excluding from entry into the United States all of Biofrontera's photodynamic therapy systems, components thereof, and, subject to certification, pharmaceutical products used in combination with the same that infringe one or more claims of United States Patent Nos. 11,697,028 and 11,446,512, imported by, or on behalf of, Respondents or any affiliated companies, parents, subsidiaries, licensees, and/or other related business entities, including successors or assigns;

(d) Issue permanent cease and desist orders, pursuant to Section 337(f) of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337(f), directing each Respondent to cease and desist from the importation, marketing, advertising, demonstrating, warehousing inventory for distribution, sale, and use of Biofrontera's photodynamic therapy systems, components thereof, and pharmaceutical products used in combination with

the same, that infringe one or more claims of United States Patent Nos. 11,697,028 and 11,446,512, and aiding or abetting any other entity from doing the same;

(e) Impose a bond upon each Respondent to the extent it continues to import infringing articles during the 60-day-Presidential review period per 19 U.S.C. § 1337(j); and

(f) Grant such other and further relief as the Commission deems just and proper based on the facts determined by the investigation and the authority of the Commission.

Dated: June 25, 2024

Respectfully submitted,

/s/ Betty Chen

Betty Chen

Kurt Fredrickson

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Counsel for Sun Pharmaceutical Industries, Inc.