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-_____

COMPLAINANT'S INITIAL STATEMENT REGARDING THE PUBLIC INTEREST

Complainant Sun Pharmaceutical Industries, Inc. ("Sun Pharma" or "Complainant"), hereby submits this Statement Regarding the Public Interest in compliance with Commission Rule 210.8, 19 C.F.R. § 210.8, for remedial orders sought against Respondents Biofrontera AG, Bioscience GmbH, Biofrontera Pharma GmbH, Biofrontera Inc. (collectively, "Biofrontera" or "Respondents").

I. INTRODUCTION

Over the past three decades in the United States, Sun Pharma (which acquired DUSA Pharmaceuticals, Inc. in 2012) revolutionized photodynamic therapy ("PDT") treatments for certain dermatological conditions. Sun Pharma's revolutionary PDT treatment includes the use of Levulan®, a unique prescription medicine that utilizes 5-aminolevulinic acid ("ALA") to target affected tissues. Sun Pharma's innovative device—the BLU-U®—uses light to activate Levulan® for treatment of skin conditions. Sun Pharma received the first approval from the FDA in December 1999 to use the BLU-U® in combination with Levulan® to treat actinic keratosis ("AK") of the face and scalp. Sun Pharma continues to spend significant resources to further improve its PDT products, including to develop the next generation of BLU-U®, which is BLU-U® 4170E. Sun Pharma has protected its innovative technology through numerous patents, including U.S. Patent

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No. 11,697,028 (the "'028 Patent") and U.S. Patent No. 11,446,512 (the "'512 Patent").

Pursuant to Section 337(d), Sun Pharma seeks relief from the Commission in the form of a permanent limited exclusion order, excluding from entry into the U.S. certain photodynamic therapy systems, components thereof, and pharmaceutical products used in combination with the same, that infringe one or more claims of the '028 and '512 Patents. This includes the BF-RhodoLED® XL device, individually and in combination with the Ameluz® prescription medicine. Sun Pharma also seeks a permanent cease and desist order, pursuant to Section 337(f), directing Respondents to immediately cease and desist from importing, marketing, advertising, demonstrating, warehousing inventory for distribution, distributing, offering for sale, selling, or using in the United States the same products.

II. USE OF ARTICLES POTENTIALLY SUBJECT TO REMEDIAL ORDERS IN THE UNITED STATES

In late 2016, Biofrontera hired over 20+ employees from Sun Pharma who took at least 600 Sun Pharma documents. *See DUSA Pharmaceuticals, Inc. v. Biofrontera Inc. et al*, Case No. 1:18-cv-10568-RGS, Dkt. No. 123 (D. Mass. 2018). Biofrontera launched BF-RhodoLED®, "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 (AKs) of mild-to-moderate severity on the face and scalp." (https://www.ameluz.com/fileadmin/AmeluzUSImages/05-pdf/Ameluz-Full-Prescribing-Information.pdf, at 6.).

In 2021, Biofrontera announced a new PDT device that contains five panels, the BF-RhodoLED® XL device, for the same indication as the BF-RhodoLED®. (*Id*. at 5.) The BF-RhodoLED® XL device is manufactured in Europe, imported into the United States, showcased at conferences in the United States, launched commercially in the United States, and infringes the '028 and '512 Patents. *See id.* Fig. 21.

According to Biofrontera, though the device was approved in 2021, its commercial launch was delayed until 2024. (*See* Biofrontera Inc., *2023 10-K*, available at https://investors.biofrontera-us.com/wp-content/uploads/2024/05/Form10-K.pdf, at 6 (noting the RhodoLED® XL is "available in the second quarter of 2024"), 20 ("Our efforts to commercialize a new lamp (the 'RhodoLED ® XL') that was approved by the FDA on October 21, 2021 have been delayed due to supply chain matters.").) Respondents intend to sell the infringing BF-RhodoLED® XL only in the United States. (*See* Biofrontera AG *Annual Report 2023* available at https://www.biofrontera.com/fileadmin/files/PDFs/Financial_Reports/2023/20240429_AR_2023_EN.pdf, at 3 ("The use of the RhodoLED® XL is currently only planned for the US market.").)

III. THE REQUESTED REMEDIAL ORDERS WOULD NOT HAVE ANY SIGNIFICANT ADVERSE EFFECT ON PUBLIC HEALTH, SAFETY, OR WELFARE CONDITIONS IN THE UNITED STATES

Sun Pharma's requested remedial orders will not raise public health, safety, or welfare concerns. ***First***, Sun Pharma's BLU-U® Model 4170 device has been commercially available to the public in the United States for many years and is indicated for "use in Photodynamic Therapy with Levulan Kerastick (aminolevulinic acid HCl) for Topical Solution, 20% for the treatment of non-hyperkeratotic actinic keratoses of the face or scalp." (https://www.accessdata.fda.gov/cdrh_docs/pdf/P990019A.pdf). Sun Pharma's BLU-U® Model 4170 device is an established and recognized leader in PDT treatments—indeed, Levulan® and BLU-U® are the "#1-prescribed photodynamic therapy." *See* https://www.levulanhcp.com & n.1. Sun Pharma would be able to quickly and fully replace the infringing products in the event an exclusion order takes effect, without escalating prices based on the exclusion.

Second, Respondents' own BF-RhodoLED® device is ***not*** at issue in this Investigation and is currently commercially available to the public in the United States, for lesion-directed and field-directed treatment of actinic keratoses (AKs) of mild-to-moderate severity on the face and scalp. Indeed, as noted above, Respondents' commercialization of the BF-RhodoLED® XL device began only in the second quarter of 2024, and the device is not yet currently in widespread commercial use. Therefore, the majority of the relevant patient population is currently using Sun Pharma's BLU-U® or Biofrontera Inc.'s BF-RhodoLED®, and can continue doing so going forward.

Third, Sun Pharma received FDA approval for the next-generation BLU-U® device, Model 4170E, on June 13, 2024. The new device has the same indications as the prior BLU-U® devices and maintains at least the same optical performance, but features five movable panels. Thus, the Model 4170E is another product available for the relevant population.

Fourth, there is strong public interest in protecting Sun Pharma's patent rights. *See, e.g., Certain Baseband Processor Chips and Chipsets,* Inv. No. 337-TA-543, Comm'n Op. at 136-37 (June 19, 2007). Sun Pharma and its many scientists have spent decades working hard to research and develop its unique technology to aid those suffering from certain skin conditions. The patents reflect their innovations and warrant protection.

Given the available options for the relevant patient population, the requested remedial orders would not have any significant adverse effect on public health, safety, or welfare conditions.

IV. THE REQUESTED REMEDIAL ORDERS WOULD NOT HAVE ANY SIGNIFICANT ADVERSE EFFECT ON COMPETITIVE CONDITIONS IN THE UNITED STATES ECONOMY OR THE PRODUCTION OF LIKE OR DIRECTLY COMPETITIVE ARTICLES IN THE UNITED STATES

No public interest concerns exist when the market contains an adequate supply of substitute products for those subject to a remedial order. *Certain Lens-Fitted Film Packages*, Inv. No. 337-TA-406, Comm'n. Op. at 18 (June 28, 1999). In addition to Sun Pharma's capacity to replace the

volume of articles subject to the requested remedial orders, as discussed above, Biofrontera Inc. informed investors that the delay associated with a full commercial launch of the BF-RhodoLED® XL device did not have a significant impact on that company's total revenues in part because they "have Rhod[o]LED lamps on hand and on order." (*See* Biofrontera Inc., *2023 10-K*, available at https://investors.biofrontera-us.com/wp-content/uploads/2024/05/Form10-K.pdf, at 49.) Because BF-RhodoLED® XL is not widely available—as only three units have been shipped to customers since launch—the proposed exclusion would retain the status quo and would not impact conditions in the US. (*See* https://investors.biofrontera-us.com/full-news/?qm-storyId=5287383329078091.)

V. THE REQUESTED REMEDIAL ORDERS WOULD NOT HAVE A SIGNIFICANT NEGATIVE IMPACT ON CONSUMERS IN THE UNITED STATES

If Respondents' infringing products are excluded from the U.S., there will be no interruption in available PDT treatments because the proposed remedial orders will have no effect on the devices used in treatment in current patient populations. Importantly, the remedial order would foster new and non-infringing innovations that would benefit the patient population. And Respondents cannot claim that a consumer choice justifies continued importation of infringing products as "the mere constriction of choice cannot be a sufficient basis" for denying relief. *See Certain Personal Data & Mobile Commc'n Devices & Related Software,* Inv. No. 337-TA-710, Comm'n Op. at 69 (Dec. 29, 2011).

VI. CONCLUSION

Issuing a permanent limited exclusion order and a cease and desist order in this Investigation against Respondents' infringing products will have no significant adverse effects on the public health, safety, or welfare in the U.S., competitive conditions in the U.S. economy, the production of like or competitive articles in the U.S., and the availability of such products and related services to consumers.

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Respectfully submitted,

/s/ Betty Chen

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