UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DUSA PHARMACEUTICALS, INC. Plaintiff v. BIOFRONTERA INC., BIOFRONTERA BIOSCIENCE GMBH, BIOFRONTERA PHARMA GMBH, BIOFRONTERA DEVELOPMENT GMBH, BIOFRONTERA NEUROSCIENCE GMBH, AND BIOFRONTERA AG, Defendants.	Civil Action No. _____ **JURY TRIAL DEMANDED**

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff DUSA Pharmaceuticals, Inc., ("DUSA") brings this complaint for patent infringement against Defendants Biofrontera Inc., Biofrontera Bioscience GmbH, Biofrontera Pharma GmbH, Biofrontera Development GmbH, Biofrontera Neuroscience GmbH, and Biofrontera AG (collectively, "Biofrontera" or "Defendants") and alleges as follows:

NATURE OF ACTION

1. This is an action for patent infringement under 35 U.S.C. § 271, *et. seq.*, by DUSA against Defendants for infringement of United States Patent Nos. 9,723,991 and 8,216,289 (the "Patents-in-Suit") by making, using, offering to sell, and selling BF-RhodoLED.

PARTIES

2. Plaintiff DUSA Pharmaceuticals, Inc., is a company organized and existing under the laws of New Jersey, with a principal place of business at 25 Upton Drive, Wilmington, MA 01887.

3. DUSA is a fully integrated specialty pharmaceutical company focused primarily on the development and marketing of its innovative technology for use in light-based skin therapy.

4. Upon information and belief, Biofrontera Inc., Biofrontera Bioscience GmbH, Biofrontera Pharma GmbH, Biofrontera Development GmbH, and Biofrontera Neuroscience GmbH, are each wholly owned subsidiaries of Biofrontera AG.

5. Upon information and belief, Biofrontera AG has a direct majority of the voting rights or another means of exercising control of each of its five wholly owned subsidiaries, namely Biofrontera Inc., Biofrontera Bioscience GmbH, Biofrontera Pharma GmbH, Biofrontera Development GmbH, and Biofrontera Neuroscience GmbH.

6. Upon information and belief, Biofrontera AG refers to itself and each of its five wholly owned subsidiaries—Biofrontera Inc., Biofrontera Bioscience GmbH, Biofrontera Pharma GmbH, Biofrontera Development GmbH, and Biofrontera Neuroscience GmbH—as the "Biofrontera Group."

7. Defendant Biofrontera AG is a corporation organized and existing under the laws of Germany, with a principal place of business at Hemmelrather Weg 201, 51377 in Leverkusen, Germany.

8. Defendant 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 in Leverkusen, Germany. Upon information and belief, Biofrontera Bioscience GmbH undertakes the research and development tasks for the Biofrontera Group.

9. Defendant 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. Upon information and belief, based on a license agreement with Biofrontera Bioscience GmbH, Biofrontera Pharma GmbH is responsible for the manufacturing and further licensing and marketing of the Biofrontera Group's products, including BF-RhodoLED.

10. Defendant Biofrontera Development 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. Upon information and belief, Biofrontera Development GmbH was established as a wholly owned subsidiary of Biofrontera AG in December 2012 and engages in activities to further

pursue development of Biofrontera products that cannot be sufficiently financed within the framework of normal business development.

11. Upon information and belief, Defendant Biofrontera Neuroscience 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. Upon information and belief, Biofrontera Neuroscience GmbH was established as a wholly owned subsidiary of Biofrontera AG in December 2012 and engages in activities to further pursue development of Biofrontera products that cannot be sufficiently financed within the framework of normal business development.

12. Defendant Biofrontera Inc. is a corporation organized and existing under the laws of Delaware, with a principal a place of business at 201 Edgewater Dr., Wakefield, MA 01880. Upon information and belief, Biofrontera Inc. was established in March 2015 and conducts business in the United States, marketing and selling Biofrontera's products for use in treating actinic keratosis and other non-melanoma skin cancer, including BF-RhodoLED.

JURISDICTION AND VENUE

13. This Court has subject matter jurisdiction over this action under 28 U.S.C. §§ 1331 and 1338(a).

14. This Court has personal jurisdiction over Defendants because, *inter alia*, upon information and belief, Defendants continuously, systematically, and

purposefully conduct business within this District, including but not limited to making, using, selling, offering to sell, and/or importing the BF-RhodoLED product line.

15. Defendants have purposefully availed themselves of the privileges and benefits of the laws of the state of Massachusetts by conducting their business in the United States through their office in Wakefield, Massachusetts.

16. This Court has jurisdiction over this action against the Defendants because the subject matter of this action satisfies the requirements of 35 U.S.C. § 299(a) in that (1) it arises, at least in part, out of the same transaction, occurrence, or series of transactions or occurrences relating to the making, using, importing into the United States, offering for sale, and/or selling of accused products or use of methods that infringe the Patents-in-Suit, and (2) questions of fact common to the Defendants will arise in the action.

17. Venue is proper in this district pursuant to at least 28 U.S.C. §§ 1391(b), (c), and 1400(b) because Defendants have, on information and belief, committed acts of infringement in this District and have a regular and established place of business at 201 Edgewater Dr., Wakefield, MA 01880.

THE ASSERTED PATENTS

The ’991 Patent

18. On August 8, 2017, the United States Patent and Trademark Office (“USPTO”) duly and legally issued United States Patent No. 9,723,991 (“the ’991 Patent”), entitled “Illuminator for Photodynamic Therapy.” The ’991 Patent has a priority date of May 1, 1998. A true and correct copy of the ’991 Patent is attached hereto as Exhibit 1.

19. DUSA Pharmaceuticals, Inc., is the assignee of the entire rights, title, and interest in and to the ’991 Patent. DUSA has the right to sue and recover damages for infringement of the ’991 Patent.

The ’289 Patent

20. On July 10, 2012, the USPTO duly and legally issued United States Patent No. 8,216,289 (“the ’289 Patent”), entitled “Illuminator for Photodynamic Therapy.” The ’289 Patent has a priority date of May 1, 1998. A true and correct copy of the ’289 Patent is attached hereto as Exhibit 2.

21. DUSA Pharmaceuticals, Inc., is the assignee of the entire rights, title, and interest in and to the ’289 Patent. DUSA has the right to sue and recover damages for infringement of the ’289 Patent.

FACTUAL BACKGROUND

22. Without limitation, the Patents-in-Suit concern a method for "photodynamic therapy" (or "PDT") and equipment for PDT. DUSA pioneered photodynamic therapy, and in 1998, DUSA submitted a New Drug Application to the Food and Drug Administration (FDA) for approval of this novel therapy. (Ex. 3, FDA Approval Letter, available at www.accessdata.fda.gov, accessed Mar. 21, 2018.)

23. In general, photodynamic therapy is a type of treatment that combines drugs with light sources to treat disease conditions. PDT includes a drug known as a "photosensitizer." Photosensitizers are light-sensitive molecules that have the capability of transferring light energy to surrounding structures. Photosensitizers can either be exogenous or endogenous. Exogenous photosensitizers are pre-formed at the time of administration whereas endogenous photosensitizers are synthesized by the body's cells in response to the application of a pre-cursor or pro-drug. Aminolevulinic acid (or "ALA") is one such pro-drug that, when applied to the skin, causes the photosensitizer protoporphyrin IX to be produced within specific cells. Photosensitizers are selective in terms of target cells versus healthy cells, and selectively accumulate in the tissue being diagnosed or treated. The photosensitizing

properties of the drug are then activated by exposure to a light source of certain wavelengths and intensities in the presence of oxygen.

24. At the molecular level, energy from the light source activates the photosensitizing property of the drug. The activated drug transfers energy to an intracellular oxygen molecule. This transfer of energy converts oxygen molecules into an energized form known as a "singlet oxygen." These excited singlet oxygen molecules then destroy or alter the targeted photosensitized cells while at the same time causing only mild and reversible damage to other tissues in the treatment area.

25. DUSA's research and development over the past two decades has focused on PDT. Particularly, effective treatment required a light output which was uniform in intensity and color—a requirement that was more difficult to achieve when the illuminated surface was contoured, or non-flat.

26. DUSA was the first in the industry to present ALA PDT for treatment of actinic keratosis of the face and scalp to the FDA. DUSA worked with the FDA to develop safe and effective light power and spectrum specifications to achieve optimal uniformity of treatment. Uniformity of power and spectrum is critical for this PDT, and DUSA was the pioneer in establishing effective and efficient parameters of treatment.

27. In December 1999, the FDA approved this novel therapy, which permitted the treatment of patients with Levulan® for topical solution in PDT using

DUSA's BLU-U® illuminator. (Ex. 3, FDA Approval Letter, available at www.accessdata.fda.gov, accessed Mar. 21, 2018.)

28. Levulan®, otherwise known as an aminolevulinic acid HCl (or "ALA HCl"), is a small molecule easily absorbed whether delivered topically, orally, or intravenously. Levulan® is converted through a cell-based process into a photosensitizer. The combination of Levulan® and targeted light delivery provides a highly selective form of PDT.

29. Shortly thereafter in September 2000, DUSA launched Levulan® for topical solution in PDT and with its BLU-U® illuminator for the treatment of non-hyperkeratotic actinic keratosis, or AKs, of the face or scalp. AKs are precancerous skin lesions caused by chronic sun exposure that can develop over time into a form of skin cancer called squamous cell carcinoma. PDT with the BLU-U® illuminator is additionally effective for the treatment of various other skin conditions, even without use of the Levulan® topical solution. In September 2003, the FDA further approved the use of BLU-U® without Levulan® PDT for the treatment of moderate inflammatory acne vulgaris and general dermatological conditions.

30. Over the course of nearly two decades, DUSA established itself as the leader in PDT therapy with its Levulan® with BLU-U® illuminator treatment. This widespread recognition and use came after many years of devoting significant resources to research and development, conducting numerous clinical studies and

clinical trials, and applying for and receiving numerous patents to protect its innovations—including the two patents at issue here.

31. The Patents-in-Suit protect the innovation reflected in DUSA's BLU-U® illuminator. These patents grew out of the need to improve the customized light source, or "illuminator," used in PDT based on the recognition that the success and effectiveness of Levulan® PDT is based, in part, on the delivery of light at an appropriate wavelength, intensity, and uniformity to a contoured surface.

32. Today, in 2018, DUSA continues to offer its revolutionary Levulan® PDT therapy to patients with dermatological conditions across North America. An estimated 58 million Americans are affected by actinic keratosis.

The Accused Products

33. Defendants make, use, sell, offer for sale, and/or import products, under the Biofrontera brand, for use in PDT treatment. These products include, but are not limited to, the BF-RhodoLED line of illuminator products.

34. Defendants describe BF-RhodoLED to be "an LED lamp emitting red light at a wavelength of 635 nm." Defendants describe BF-RhodoLED as "provid[ing] high energy efficiency plus controlled and constant light emission at the desired wavelength for the use in photodynamic therapy with the photosensitizer Ameluz® (aminolevulinic acid hydrochloride) gel, 10%." Defendants further state this "combination was FDA approved for lesion-directed and field-directed

treatment of actinic keratoses (AKs) of mild-to-moderate severity on the face and scalp." (Ex. 4, www.biofrontera.us.com/bf-rhodoled/, accessed Mar. 15, 2018.)

35. Defendants describe their PDT technology as "very targeted and can be implemented effectively." The "photosensitising gel is applied to the affected skin area and covered with a dressing" and "[t]he dressing is removed after about three hours and the patient is then treated for approximately ten minutes with cold red light, for instance with the BF-Rhodo-LED® lamp." (Ex. 5, Biofrontera 2016 Annual Report, at 7.)

36. On information and belief, Defendants commercially launched the BF-RhodoLED product line in the United States at least as early as October 2016. (Ex. 5, Biofrontera 2016 Annual Report at 3.)

37. Defendants acknowledge in public statements by Biofrontera CEO, Herman Lübbert, that "Biofrontera's main competitor in the U.S. is DUSA Pharmaceuticals," and that "DUSA manufactures Levulan Kerastick and Blu-U PDT, a similar combination of a topical cream [*sic*] and a phototherapy device." (Ex. 6, MedCityNews Article, Oct. 31, 2016.) Defendants acknowledge DUSA's Levulan® PDT used with the BLU-U® illuminator as a competitor product, stating "Biofrontera also drew on the experience of DUSA Pharmaceuticals Inc. with a competitor product already sold and distributed in the USA, Levulan Kerastick®" in describing their launch in the U.S. market of their Ameluz® PDT using the BF-

RhodoLED product. (Ex. 5, Biofrontera Annual Report 2016, at 34.) Industry analysts also report that "Biofrontera Group anticipates that Ameluz® in combination with BF-RhodoLED® will compete in the United States with currently marketed Levulan® Kerastick in combination with the lamp BLU-U®." (Ex. 7, Van Leeuwenhoeck Research Notes: Biofrontera, at 9.)

38. Defendants report that Biofrontera is actively promoting, marketing, and expanding their sales operations for their PDT technology in the United States that uses the BF-RhodoLED device. (Ex. 8, Biofrontera News Release, June 23, 2016.) Defendants state that "[m]arketing in the USA is occurring through the company's own subsidiary, Biofrontera Inc., which was founded for this purpose in March 2015." (Ex. 5, Biofrontera Annual Report 2016, at 34.) Defendants further state that "[v]ery qualified and experienced local staff were hired for important key positions in the USA, with hiring continuing." (Ex. 5, Biofrontera Annual Report 2016, at 34.)

39. Upon information and belief, "Biofrontera managed to hire the top sales persons with excellent customer networks from its competitor DUSA as well as oher [*sic*] dermatology companies." (Ex. 7, Van Leeuwenhoeck Research Notes: Biofrontera, at 5-6.) For example, upon information and belief, Dr. Michael Milane, the former Director of Medical Affairs for DUSA from 2011-2015 and former Senior Executive Director of Medical Affairs of DUSA's parent company Sun

Pharmaceuticals in 2015, left in 2016 to join Defendants. Upon information and belief, Dr. Milane is currently the Chief Medical Officer at Biofrontera Pharma GmbH.

40. Industry analysts report that "[t]he availability of topical PDT therapies for the treatment of AK and BCC has now become well established with the availability of DUSA's (now SUN Pharma's) Levulan® (only in the US) and Galderma's Metvix® (only in Europe)." (Ex. 7, Van Leeuwenhoeck Research Notes: Biofrontera, at 12.)

41. Defendants state that Biofrontera's "BF-RhodoLED® has been developed for use in photodynamic therapy in combination with Ameluz® (aminolevulinic acid hydrochloride) gel, 10%, for topical use" and that "[t]here is no approval for any other use or combination of use." (Ex. 9, www.biofrontera.us.com/using-bf-rhodoled/, accessed Mar. 15, 2018.)

42. Industry analysts report that "[a]s [Defendants'] drug and lamp are approved as a combined product in the USA, the speed of market penetration in the USA will depend in particular on how quickly the BF-RhodoLED® PDT lamp is positioned on the market." (Ex. 7, Van Leeuwenhoeck Research Notes: Biofrontera, at 16.)

43. Defendants provide instructions to users of their BF-RhodoLED for PDT for its use in conjunction with corresponding operating instructions on

Defendants' public website accessible in the United States, including in this district. (Ex. 9, www.biofrontera.us.com/using-bf-rhodoled/, accessed Mar. 15, 2018.)

44. Defendants instruct that, when "illuminat[ing] the treatment area with the BF-RhodoLED® lamp . . . [c]alibration by the operator is not needed." (Ex. 10, www.biofrontera.us.com/red-light-pdt, accessed Mar. 15, 2018.)

45. Defendants advise users that "[t]he light-field of the LED lamp consists of a total of 128 LEDs and lenses (arranged in a rectangle), which emit a uniform, bundled, visible red light with an average wavelength of approximately 635 +/- 9 nm." (Ex. 11, Biofrontera Print User Manual, at 11; Ex. 12, Excerpts of Biofrontera Online User Manual, at Section 4.1.)

46. Defendants further instruct users that "[i]t is imperative that a distance of 5 to 8 cm from the patient must be observed during treatment, otherwise the light dosage on the skin will deviate from the desired 37 J/cm^2." (Ex. 11, Biofrontera Print User Manual, at 8.)

COUNT I: PATENT INFRINGEMENT OF U.S. PATENT NO. 9,723,991

47. DUSA incorporates by reference paragraphs 1-46 as if fully set forth herein.

48. Upon information and belief, Biofrontera has directly infringed and continues to directly infringe at least Claim 1 of the '991 Patent under 35 U.S.C. § 271(a) literally or under the doctrine of equivalents, by making, using, offering for

sale, selling, and/or importing in the United States its PDT technology, including its BF-RhodoLED product.

49. As one, non-limiting example, Claim 1 of the '991 Patent states as follows:

> 1. An illuminator for diagnosing or treating a patient, comprising:
>
> a plurality of light sources configurable in a spaced relationship to a patient to treat or diagnose a dermatological condition,
>
> a controller, connected to the plurality of light sources, to control the light sources,
>
> wherein the light sources are configured and controlled to provide a uniform output of light to the patient to treat or diagnose a dermatological condition,
>
> the light sources being configured and controlled such that uniform output of light is provided when measured at distances of 2" and 4".

50. Each of the elements of Claim 1 is present in the BF-RhodoLED product.

51. The BF-RhodoLED product is an illuminator for treating a patient. For example, Defendants publicly describe the BF-RhodoLED product as "***a lamp for photodynamic therapy (PDT)*** with ***LEDs emitting red light***." (Ex. 13, *www.biofrontera.com/en/products-pipeline/products/rhodoled.html*, accessed Mar. 20, 2018.)

52. The BF-RhodoLED product has a plurality of light sources configurable in a spaced relationship to a patient to treat a dermatological condition.

For example, Defendants' user manual describes "[t]he light-field of the LED lamp consists of a total of 128 LEDs and lenses" in the BF-RhodoLED product, thereby demonstrating the presence of a plurality of light sources. (Ex. 11, Biofrontera Print User Manual, at 11; Ex. 4, www.biofrontera.us.com/bf-rhodoled/, accessed Mar. 15, 2018.)

53. The BF-RhodoLED product has a controller, connected to the plurality of light sources, to control the light sources. For example, the BF-RhodoLED product provides a remote control device that applies control to the light sources. According to the user manual, "[t]he lamp has a modern operating concept with a colour display and an integrated, capacitive touch screen. ***The use of a touch screen and customisable software buttons facilitates an intuitive and easy operation of the lamp***." (Ex. 11, Biofrontera Print User Manual, at 26.)

54. The BF-RhodoLED product has light sources that are configured and controlled to provide a uniform output of light to the patient to treat or diagnose a dermatological condition. For example, the BF-RhodoLED product is also designed to emit "a ***uniform, bundled, visible red light***." (Ex. 11, Biofrontera Print User Manual, at 11.) Additionally, when "illuminat[ing] the treatment area with the BF-RhodoLED® lamp . . . [c]alibration by the operator is not needed." (Ex. 10, www.biofrontera.us.com/red-light-pdt, accessed Mar. 15, 2018.)

55. The BF-RhodoLED product has light sources being configured and controlled such that uniform output of light is provided when measured at distances of 2" and 4". For example, the BF-RhodoLED product is designed to have such a uniform output at 2" to 4," as demonstrated by the user manual's statements that "***[i]t is imperative that a distance of 5 to 8 cm*** from the patient ***must be observed during treatment***, ***otherwise the light dosage on the skin will deviate*** from the desired [value]," and that "[u]sing the handle on the lamp head, ***position the lamp head at a distance of 5 to 8 cm from the area of skin to be treated***." (Ex. 11, Biofrontera Print User Manual, at 8, 25.)

56. As a result of Defendants' direct infringement of the '991 Patent, DUSA 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 DUSA would have made but for Biofrontera's infringing acts.

57. Defendants identify DUSA as their competitor in the United States market in their public statements. (Ex. 5, Biofrontera Annual Report 2016, at 34.) Defendants also acknowledge 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." (Ex. 5, Biofrontera Annual Report 2016, at 42.) Defendants state

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." (Ex. 5, Biofrontera Annual Report 2016, at 42.) Market analyst reports openly acknowledge DUSA's Levulan® therapy, as well as its approval and listing in the FDA Orange Book. (Ex. 14, Biofrontera FinnCap Report, Aug. 27, 2013, at 10.) The FDA Orange Book lists the '289 patent for Levulan®. The '289 Patent and the '991 Patent are continuations of the same patent, and share the same specification and effective filing date. Upon information and belief, Defendants monitor the patents of DUSA and have known about the '991 Patent at least since it issued on August 8, 2017, and knew or were willfully blind to the fact that their actions constituted infringement of at least Claim 1 of the '991 Patent. Defendants continue to infringe the '991 Patent despite such knowledge and their knowledge as of the filing and/or service of this Complaint.

58. Despite Defendants' knowledge of and notice of the '991 Patent and their ongoing infringement, Defendants continue to manufacture, use, sell, offer for sale, and/or import the accused BF-RhodoLED product in a manner that infringes the '991 Patent. Defendants lack a justifiable belief that they do not infringe the '991 Patent, or that the '991 Patent is invalid, and have acted recklessly in their

infringing activity, justifying an increase in the damages to be awarded to DUSA up to three times the amount found or assessed, in accordance with 35 U.S.C. § 284.

59. At least Defendants' willful infringement of the '991 Patent renders this case an exceptional case, justifying an award to DUSA of its reasonable attorneys' fees, in accordance with 35 U.S.C. § 285.

60. Upon information and belief, Defendants have also induced and continue to induce infringement of at least Claim 1 of the '991 Patent pursuant to 35 U.S.C. § 271(b), by actively and knowingly inducing, directing, causing, and encouraging others, including, but not limited to, their customers and/or end users, to make, use, sell, and/or offer to sell in the United States the BF-RhodoLED product.

61. Upon information and belief, Defendants' customers and/or end users have directly infringed and are directly infringing at least Claim 1 of the '991 Patent. Defendants have actively encouraged, educated, and instructed their customers and/or end users to use the BF-RhodoLED product for PDT treatment of actinic keratosis, and therefore Defendants have knowingly induced their customers and/or end users to directly infringe the '991 Patent. Defendants have acted and continue to act with the specific intent to encourage such infringement by customers and/or end users, and knowing that the induced acts by these customers and/or end users constitute infringement of the '991 Patent. Defendants' inducement includes, for

example, providing operational instructions, user manuals, online instructions, technical specifications, demonstrations, training, and other forms of support and instructions that induce their customers and/or end users to directly infringe the '991 Patent. (Ex. 9, http://www.biofrontera.us.com/using-bf-rhodoled/, accessed Mar. 15, 2018.)

62. Upon information and belief, Defendants have also contributed and continue to contribute to infringement of at least Claim 1 of the '991 Patent pursuant to 35 U.S.C. § 271(c), by offering to sell, selling, and/or importing into the United States their BF-RhodoLED product to their customers and/or end users for use in the practicing of at least Claim 1 of the '991 Patent, where the BF-RhodoLED product constitutes a material part of the patented invention, and where Defendants know that the BF-RhodoLED product is especially made and adapted for use in infringing the '991 Patent, and where such BF-RhodoLED product is not a staple article or commodity of commerce suitable for noninfringing use. (Ex. 4, www.biofrontera.us.com/bf-rhodoled/, accessed Mar. 15, 2018.) Further, upon information and belief, Defendants have knowledge of the activities of their customers and/or end users that infringe the '991 Patent by their use of the BF-RhodoLED product to treat dermatological conditions in a patient in the United States. Defendants also have knowledge that the only approved use of BF-RhodoLED that is offered for sale and sold in the United States is for use in PDT to

treat actinic keratosis, thereby establishing their knowledge of no substantial noninfringing use of the accused product. (Ex. 10, http://www.biofrontera.us.com/red-light-pdt/, accessed Mar. 15, 2018.)

63. Defendants have actual knowledge of the ’991 Patent at least as of service of this Complaint. Upon information and belief, Defendants also have pre-suit knowledge of the ’991 Patent at least based on their monitoring of DUSA’s Levulan® and BLU-U® therapy as a competitive product, based on their patent department’s regular review of “the current patent situation” on behalf of Biofrontera, based on a significant number of former DUSA employees who had knowledge of DUSA’s patented Levulan® and BLU-U® therapy and who have since worked at Biofrontera, marketing and promoting Biofrontera’s infringing product—including but not limited to Dr. Milane, and based on a series of meetings that took place in January 2008 in Leverkusen, Germany, in which an inventor of the Patents-in-Suit discussed DUSA’s PDT technology, including illuminator technology, with employees at Biofrontera.

64. Defendants have committed the foregoing infringing activities without a license from DUSA to the ’991 Patent.

65. Defendant’s infringement of the ’991 Patent has caused and will continue to cause irreparable injury to DUSA. Unless the Court enjoins such infringing acts, DUSA will continue to suffer additional irreparable injury.

COUNT II: PATENT INFRINGEMENT OF U.S. PATENT NO. 8,216,289

66. DUSA incorporates by reference paragraphs 1-46 as if fully set forth herein.

67. Upon information and belief, Biofrontera has directly infringed and continues to directly infringe at least Claim 1 of the '289 Patent under 35 U.S.C. § 271(a) literally or under the doctrine of equivalents, by making, using, offering for sale, selling, and/or importing in the United States its PDT technology, including its BF-RhodoLED product.

68. As one, non-limiting example, Claim 1 of the '289 Patent states as follows:

> 1. A method of photodynamically diagnosing or treating a patient, comprising:
>
> illuminating the patient with an illuminator whose measured output over an active emitting area is at least 60% of the measured maximum over all operation distances.

69. Each of these elements of Claim 1 is present in the BF-RhodoLED product.

70. The treatment of a patient using the BF-RhodoLED product is a method of photodynamically treating a patient. For example, Defendants publicly describe the BF-RhodoLED product as "***a lamp for photodynamic therapy (PDT)*** with ***LEDs emitting red light***." (Ex. 13, *www.biofrontera.com/en/products-pipeline/products/rhodoled.html*, accessed Mar. 15, 2018.)

71. The treatment of a patient using the BF-RhodoLED product includes the step of illuminating the patient with an illuminator whose measured output over an active emitting area is at least 60% of the measured maximum over all operation distances. For example, the BF-RhodoLED product is also designed to emit "a ***uniform, bundled, visible red light***." (Ex. 11, Biofrontera Print User Manual, at 11.) Further, upon information and belief, the BF-RhodoLED product's uniform output, when measured over an active emitting area, will reach values of at least 60% of the measured maximum over all operation distances. (Ex. 12, Excerpts of Biofrontera Online User Manual, at Section 4.1.)

72. As a result of Defendants' direct infringement of the '289 Patent, DUSA 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 DUSA would have made but for Biofrontera's infringing acts.

73. Defendants identify DUSA as their competitor in the United States market in their public statements. (Ex. 5, Biofrontera Annual Report 2016, at 34.) Defendants also acknowledge 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." (Ex. 5, Biofrontera Annual Report 2016, at 42.) Defendants state

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." (Ex. 5, Biofrontera Annual Report 2016, at 42.) Market analyst reports openly acknowledge DUSA's Levulan® therapy, as well as its approval and listing in the FDA Orange Book. (Ex. 14, Biofrontera FinnCap Report, Aug. 27, 2013, at 10.) The FDA Orange Book lists the '289 Patent for Levulan®. Upon information and belief, Defendants monitor the patents of DUSA and have known about the '289 Patent at least since it issued on July 10, 2012, and knew or were willfully blind to the fact that their actions constituted infringement of at least Claim 1 of the '289 Patent. Defendants continue to infringe the '289 Patent despite such knowledge and their knowledge as of the filing and/or service of this Complaint.

74. Despite Defendants' knowledge of and notice of the '289 Patent and their ongoing infringement, Defendants continue to manufacture, use, sell, offer for sale, and/or import the accused BF-RhodoLED product in a manner that infringes the '289 Patent. Defendants lack a justifiable belief that they do not infringe the '289 Patent, or that the '289 Patent is invalid, and have acted recklessly in their infringing activity, justifying an increase in the damages to be awarded to DUSA up to three times the amount found or assessed, in accordance with 35 U.S.C. § 284.

75. At least Defendants' willful infringement of the '289 Patent renders this case an exceptional case, justifying an award to DUSA of its reasonable attorneys' fees, in accordance with 35 U.S.C. § 285.

76. Upon information and belief, Defendants have also induced and continue to induce infringement of at least Claim 1 of the '289 Patent pursuant to 35 U.S.C. § 271(b), by actively and knowingly inducing, directing, causing, and encouraging others, including, but not limited to, their customers and/or end users, to make, use, sell, and/or offer to sell in the United States the BF-RhodoLED product.

77. Upon information and belief, Defendants' customers and/or end users have directly infringed and are directly infringing at least Claim 1 of the '289 Patent. Defendants have actively encouraged, educated, and instructed their customers and/or end users to use the BF-RhodoLED product for PDT treatment of actinic keratosis, and therefore Defendants have knowingly induced their customers and/or end users to directly infringe the '289 Patent. Defendants have acted and continue to act with the specific intent to encourage such infringement by customers and/or end users, and knowing that the induced acts by these customers and/or end users constitute infringement of the '289 Patent. Defendants' inducement includes, for example, providing operational instructions, user manuals, online instructions, technical specifications, demonstrations, training, and other forms of support and

instructions that induce their customers and/or end users to directly infringe the ’289 Patent. (Ex. 9, http://www.biofrontera.us.com/using-bf-rhodoled/, accessed Mar. 15, 2018.)

78. Upon information and belief, Defendants have also contributed and continue to contribute to infringement of at least Claim 1 of the ’289 Patent pursuant to 35 U.S.C. § 271(c), by offering to sell, selling, and/or importing into the United States their BF-RhodoLED product to their customers and/or end users for use in the practicing of at least Claim 1 of the ’289 Patent, where the BF-RhodoLED product constitutes a material part of the patented invention, and where Defendants know that the BF-RhodoLED product is especially made and adapted for use in infringing the ’289 Patent, and where such BF-RhodoLED product is not a staple article or commodity of commerce suitable for noninfringing use. Further, upon information and belief, Defendants have knowledge of the activities of their customers and/or end users that infringe the ’289 Patent by their use of the BF-RhodoLED product to treat dermatological conditions in a patient in the United States. Defendants also have knowledge that the only approved use of BF-RhodoLED that is offered for sale and sold in the United States is for use in PDT to treat actinic keratosis, thereby establishing their knowledge of no substantial noninfringing use of the accused product. (Ex. 10, http://www.biofrontera.us.com/red-light-pdt/, accessed Mar. 15, 2018.)

79. Defendants have actual knowledge of the ’289 Patent at least as of service of this Complaint. Upon information and belief, Defendants also have pre-suit knowledge of the ’289 Patent at least based on their monitoring of DUSA’s Levulan® and BLU-U® therapy as a competitive product, based on the listing of this patent for Levulan® in the FDA Orange Book, based on their patent department’s regular review of “the current patent situation” on behalf of Biofrontera, based on a significant number of former DUSA employees who had knowledge of DUSA’s patented Levulan® and BLU-U® therapy and who have since worked at Biofrontera, marketing and promoting Biofrontera’s infringing product—including but not limited to Dr. Milane, and based on a series of meetings that took place in January 2008 in Leverkusen, Germany, in which an inventor of the Patents-in-Suit discussed DUSA’s PDT technology, including illuminator technology, with employees at Biofrontera.

80. Defendants have committed the foregoing infringing activities without a license from DUSA to the ’289 Patent.

81. Defendant’s infringement of the ’289 Patent has caused and will continue to cause irreparable injury to DUSA. Unless the Court enjoins such infringing acts, DUSA will continue to suffer additional irreparable injury.

JURY DEMAND

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

PRAYER FOR RELIEF

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

(a) a finding that Defendants have infringed one or more claims of the Patents in-Suit 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 Patents-in-Suit has been and is willful;

(c) equitable relief under 35 U.S.C. § 283, including, but not limited to, an injunction that enjoins Defendants and any of their officers, agents, employees, assigns, representatives, privies, successors, and those acting in concert or participation with them from infringing, contributing to, and/or inducing infringement of the Patents-in-Suit;

(d) an award of damages sufficient to compensate DUSA for infringement of the Patents-in-Suit by Defendants through the date of judgment, including DUSA's lost profits, together with prejudgment interest under 35 U.S.C. § 284;

(e) entry of an order compelling Defendants to compensate DUSA for any ongoing and/or future infringement of the Patents-in-Suit, 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 and awarding DUSA its reasonable attorney fees, costs, and expenses;

(h) an accounting of Defendants' infringing activities through trial and judgment; and

(i) such other relief that the Court deems just and proper.

Dated: March 23, 2018

Respectfully submitted,

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