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. 1:18-cv-10568-RGS **JURY TRIAL DEMANDED** (Leave to file granted 10/30/18)

SECOND AMENDED COMPLAINT

For their Second Amended Complaint against Defendants Biofrontera Inc., Biofrontera Bioscience GmbH, Biofrontera Pharma GmbH, and Biofrontera AG (collectively, "Biofrontera" or "Defendants"), Plaintiff DUSA Pharmaceuticals, Inc., ("DUSA"), by their attorneys, 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.

2. This action also concerns misappropriation of trade secrets under common law and statutory law, tortious interference with contractual relations, and deceptive and unfair trade practices.

PARTIES

3. 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.

4. 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.

5. 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.

6. 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.

7. 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."

8. 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.

9. 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.

10. 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.

11. 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.

12. Upon information and belief, 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.[1]

13. 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

[1] The parties have separately dismissed without prejudice Biofrontera Development GmbH and Biofrontera Neuroscience GmbH pursuant to the terms set forth in the Stipulation Regarding the German Biofrontera Entity Defendants filed on June 22, 2018 (Dkt. No. 35).

and selling Biofrontera's products for use in treating actinic keratosis and other non-melanoma skin cancer, including BF-RhodoLED.

JURISDICTION AND VENUE

14. This Court has subject matter jurisdiction over Plaintiff's asserted patent claims under 28 U.S.C. §§ 1331 and 1338(a).

15. This Court has subject matter jurisdiction over Plaintiff's asserted Defend Trade Secrets Act claim under 18 U.S.C. § 1836(c).

16. This Court has supplemental jurisdiction over Plaintiffs' asserted state law claims under 28 U.S.C. 1367(a), because they form part of the same case or controversy under Article III of the United States Constitution.

17. 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.

18. 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.

19. 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.

20. 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

21. 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.

22. 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

23. 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.

24. 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

DUSA'S Historical Innovation and Contributions to PDT

25. 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.)

26. 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.

27. 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.

28. 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.

29. 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.

30. 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.)

31. 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.

32. 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.

33. 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.

34. 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.

35. 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

36. 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.

37. 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.)

38. 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.)

39. 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.)

40. 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, MedCity News 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.)

41. 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.)

42. 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 was the Chief Medical Officer at Biofrontera Pharma GmbH through April 2018.

43. 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.)

44. 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.)

45. 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.)

46. 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.)

47. 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.)

48. 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.)

49. 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.)

DUSA's Confidential Information and/or Trade Secrets

50. DUSA's success in the marketplace relies not only on its novel technologies, but also on its ability to successfully offer for sale and market its products and services to clients. This, in turn, depends on DUSA's ability to identify clients for its products and to cultivate relationships with them.

51. DUSA invests and has invested a significant amount of money and time to develop a marketing strategy and business intelligence for its products, including Levulan® and the BLU-U® illuminator. The marketing strategy and business intelligence includes information relating to the identity of DUSA's customers, DUSA's customer relationships and account history (including purchase volume and frequency), the marketing channels used by DUSA, strategic current and future business decisions, next-generation product development details, unpublished results of clinical trials, plans for formulations and modification of devices, and training programs (collectively "Confidential Information").

52. DUSA deems this Confidential Information to be trade secret and proprietary DUSA information, and DUSA protects these trade secrets and takes significant steps to maintain its confidentiality.

53. The Confidential Information is extremely valuable to DUSA and would be extremely valuable to competitors in the industry.

DUSA's Policy and Efforts to Maintain the Secrecy of its Confidential Information

54. At all times, DUSA goes to great efforts to maintain the secrecy of its Confidential Information.

55. For example, DUSA's employees sign non-disclosure agreements agreeing not to use or disclose DUSA's Confidential Information to any other entity.

56. DUSA undertakes additional efforts to secure its Confidential Information. For example, in addition to physical restrictions in accessing DUSA's premises, in which employees must enter specific pin codes to gain access, DUSA's premises is monitored by video surveillance. Furthermore, DUSA employs company-wide multi-step security protocols that include passwords and credentials before providing its own employees with access to DUSA's Confidential Information, which even when used, only provide employees with information limited to certain subject matters.

57. Additionally, DUSA's Confidential Information, including its successful marketing scheme, is not available for purchase on the market. Nor would

DUSA place this Confidential Information into the market: this information has enabled DUSA to succeed for decades where others, including its competitors, have failed.

Biofrontera's Misappropriation of DUSA's Confidential Information

58. Upon information and belief, recognizing the value of DUSA's Confidential Information, especially as it relates to marketing and DUSA's customers, Biofrontera sought to obtain DUSA's Confidential Information.

59. 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.)

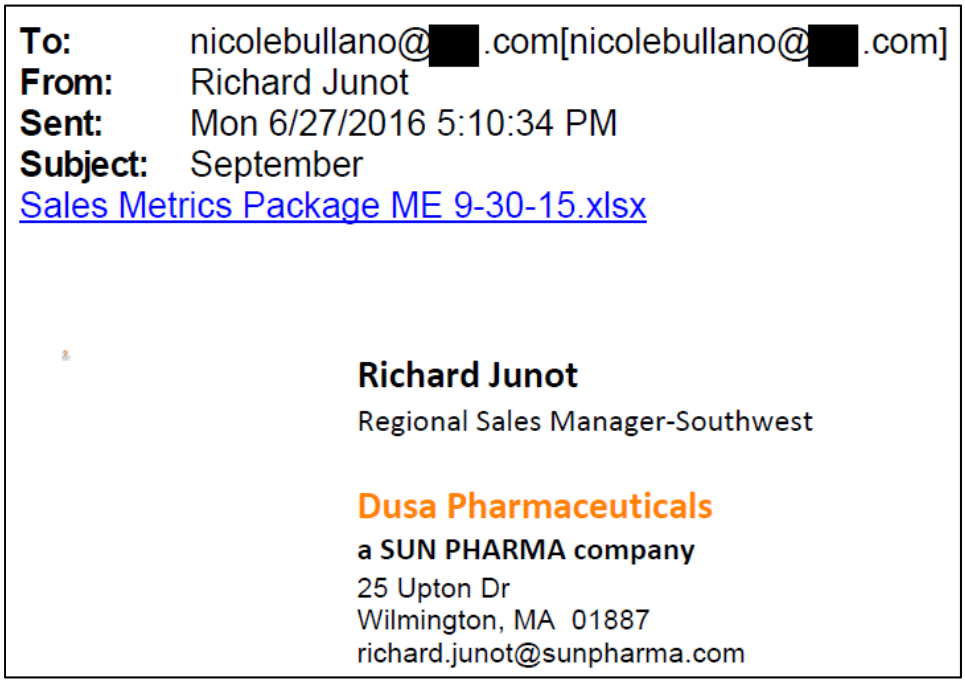
60. Upon information and belief, Richard Junot, the former sales manager for DUSA from 2006-2016, left in July 2016 to join Defendants. Upon information and belief, Mr. Junot is currently a Regional Sales Manager at Biofrontera Inc. Mr. Junot, as a former sales manager at DUSA and by virtue of his job responsibilities at DUSA, had access to and knowledge of DUSA's Confidential Information before leaving for Biofrontera. In and around the month before his departure, Mr. Junot emailed to his personal email account from DUSA sensitive 2011-2015 sales information of DUSA's Levulan® Kerastick and BLU-U® products:

To: sealedjarhead@[redacted].com[sealedjarhead@[redacted].com]
From: Richard Junot
Sent: Fri 5/27/2016 5:52:22 PM
Subject: stuff
Copy of Sales Metrics Package ME 12-31-11.xls
Copy of Sales Metric Pkge ME 12-31-12.xls
Sales Metric Pkge ME 3-31-14.xls
Sales Metrics Package ME 3-31-15.xlsx

Richard Junot
Regional Sales Manager-Southwest

Dusa Pharmaceuticals
a SUN PHARMA company
25 Upton Dr
Wilmington, MA 01887
richard.junot@sunpharma.com

61. In the days immediately preceding his departure, Mr. Junot emailed to a non-DUSA email recipient sensitive sales information of DUSA's Levulan® Kerastick and BLU-U products from 2015:



To: nicolebullano@[redacted].com[nicolebullano@[redacted].com]
From: Richard Junot
Sent: Mon 6/27/2016 5:10:34 PM
Subject: September
Sales Metrics Package ME 9-30-15.xlsx

Richard Junot
Regional Sales Manager-Southwest

Dusa Pharmaceuticals
a SUN PHARMA company
25 Upton Dr
Wilmington, MA 01887
richard.junot@sunpharma.com

62. Upon information and belief, Jon Lyons, the former Medical Science Liaison for DUSA from May to July 2016, left in July 2016 to join Defendants. Upon information and belief, Dr. Lyons is currently a Senior Medical Science Liaison at Biofrontera Inc. Mr. Lyons, as a former Medical Science Liaison and by virtue of his job responsibilities at DUSA, had access to and knowledge of DUSA's Confidential Information before leaving for Biofrontera. Further, upon information and belief, in the last month of his employment at DUSA, Mr. Lyons connected USB devices to his work computer several times in the weeks leading up to his departure from DUSA, including at least USB devices: "SanDisk Cruzer Glide," internal serial number 200548574007F0324D2F, last connected 4/18/2016 at 9:03 AM; General USB Device, internal serial number 070163E2E6122450, last connected 6/2/2016 at 6:35 AM; Generic USB Device, internal serial number 070163E4EEE5D705, last connected 7/21/2016 at 9:52 PM and assigned drive letter "E"; and WD My Passport 259F USB Device, internal serial number 575846314535353 54A594C48, last connected 7/13/2016 at 8:58 AM. Upon information and belief, Mr. Lyons transferred information from his DUSA work computer and/or from DUSA's information systems to USB devices, including DUSA's Confidential Information.

63. Along with Mr. Junot and Dr. Lyons, Biofrontera also procured trade secret information from former DUSA employees comprising the key home office functionality of DUSA, including employees from DUSA's sales, finance, medical,

marketing, quality control, and internal infrastructure divisions. These former DUSA employees include Jon Lyons, former Medical Science Liaison; Jeff Holm, former Director of Training; Bryan Rose, former Director of Managed Markets; Erica Monaco, former Director of Finance; Alison Trainor, former Payroll Analyst; and Darrell Lowman, former Director of Quality Control.

64. In addition to these employees, Biofrontera further engaged in significant misappropriation of Confidential Information through the hiring of DUSA's sales force throughout the United States. Upon information and belief, other employees that Biofrontera hired from DUSA include Bert McCarley, a former DUSA Senior Territory Representative who became a Senior Territory Manager for Biofrontera Pharma GmbH; Dare Lacopo, a former Senior Territory Sales Manager for DUSA who became a Senior Territory Sales Manager for Biofrontera Pharma GmbH; Holly Hendrix Smith, a former Senior Territory Manager for DUSA who joined Biofrontera's sales team for the accused products, and Nicole Bullano Giles, a former Senior Territory Manager and Regional Sales Trainer for DUSA who became a Senior Territory Sales Manager at Biofrontera Pharma GmbH. Upon information and belief, Bert McCarley still holds his position at Biofrontera Pharma GmbH.

65. Upon information and belief, Bert McCarley, the former DUSA Senior Territory Representative from November 2009 to December 2016, left in December

2016 to join Defendants. Upon information and belief, Mr. McCarley is currently a Senior Territory Manager at Biofrontera Pharma GmbH. Mr. McCarley, as a former senior territory representative at DUSA and by virtue of his job responsibilities at DUSA, had access to and knowledge of DUSA's Confidential Information before leaving for Biofrontera. Upon information and belief, in June 2016 several months before Mr. McCarley left DUSA to join Defendants, Mr. McCarley forwarded an email from his DUSA email account to his personal email account attaching DUSA's physician target list for sales related to DUSA's patented device:

Submit Time: 6/3/2016 09:40:37
From: CN=Bert McCarley/OU=Sales/OU=WILMINGTON/O=SPIINC
To: bertmccarley@[redacted].com
Cc:
Subject: Fw: Physician Target List

SUN PHARMA

Bert Mccarley

Senior Territory Manager

Dusa Pharmaceuticals
a SUN PHARMA company

25 Upton Dr
Wilmington, MA 01887
bert.mccarley@sunpharma.com

66. Further, upon information and belief, in May 2016 several months before Mr. McCarley left DUSA to join Defendants, Mr. McCarley sent an email

from his DUSA email account to his personal email account attaching sales metrics information related to DUSA products such as Levulan®:

Submit Time: 5/18/2016 10:20:07
From: CN=Bert McCarley/OU=Sales/OU=WILMINGTON/O=SPIINC
To: bertmccarley@[redacted].com
Cc:
Subject: Fw: Corrected BP

Bert Mccarley
Senior Territory Manager
Dusa Pharmaceuticals
a SUN PHARMA company
25 Upton Dr
Wilmington, MA 01887
bert.mccarley@sunpharma.com

Attached are the fixed BP.
TM BP 2016 - [redacted] v2.xlsmTM BP 2016 - [redacted] v2.xlsmTM BP 2016 - [redacted] v2.xlsmTM BP 2016 - [redacted] v2.xlsmTM BP 2016 - [redacted] v2.xlsmTM BP 2016 - [redacted] v2.xlsmTM BP 2016 - [redacted] v2.xlsmTM BP 2016 - [redacted] v2.xlsmTM BP 2016 - [redacted] v2.xlsmTM BP 2016 - [redacted] v2.xlsmIAM BP 2016 - [redacted] v2.xlsmIAM BP 2016 - [redacted] v2.xlsmTM BP 2016 - [redacted] v2.xlsmTM BP 2016 - [redacted] v2.xlsmTM BP 2016 - [redacted] v2.xlsmTM BP 2016 - [redacted] v2.xlsmTM BP 2016 - [redacted] v2.xlsm

67. Upon information and belief, Holly Hendrix Smith, the former DUSA Senior Territory Manager, left in July 2016 to join Defendants. Upon information and belief, Ms. Hendrix Smith joined Biofrontera in a sales role of the accused products. Ms. Hendrix Smith, as a former senior territory manager at DUSA and by virtue of her job responsibilities at DUSA, had access to and knowledge of DUSA's Confidential Information before leaving for Biofrontera. Upon information and

belief, in and around the month of her departure, Ms. Hendrix Smith sent emails from her DUSA email account to customers of DUSA promoting Biofrontera's accused product to DUSA's customers and providing her new Biofrontera contact information to DUSA's customers:

Submit Time: 7/1/2016 01:21:20
From: CN=Holly Hendrix/OU=SALES/OU=WILMINGTON/O=SPIINC
To: '[redacted]" <[redacted]@[redacted].org>@SPIL
Cc:
Subject: RE: Good Afternoon

Hi [redacted],

I wanted to follow up and see if you received the PDT hats I sent?

Also, tomorrow will be my last day at Dusa. However, I'll still be in dermatology sales working for Biofrontera and their recently FDA approved PDT combination therapy. The drug (Ameluz) and red light have been used in Europe for years and the drug will be available in September. It should also be less expensive than Levulan! My new email address will be: h.hendrix@biofrontera.com.

I look forward to working with you in the future!

Sincerely,

SUN PHARMA

Holly Hendrix - MBA

Senior Territory Manager
Southern California Territory
DUSA Pharmaceuticals, Inc.
a SUN PHARMA company

68. Upon information and belief, Dare Lacopo, the former DUSA Senior Territory Sales Manager from August 2009 to July 2016, left in July 2016 to join Defendants. Upon information and belief, Ms. Lacopo became a Senior Territory Sales Manager for Biofrontera Pharma GmbH. Ms. Lacopo, as a former senior territory sales manager at DUSA and by virtue of her job responsibilities at DUSA, had access to and knowledge of DUSA's Confidential Information before leaving

for Biofrontera. Upon information and belief, in and around the month of her departure, Ms. Lacopo sent an email from her DUSA email account to a customer of DUSA's informing the customer that Ms. Lacopo would be leaving DUSA to join Biofrontera but would still be the customer's representative at Biofrontera:

To: '[redacted]" [redacted]@[redacted].com>
Submit Time: 7/1/2016 20:18:20
From: CN=Dare Lacopo/OU=Sales/OU=WILMINGTON/O=SPIINC
Subject: Re: Levulan
Cc:

I will still be your rep with new company so will see you again soon!

Enjoy your vacation!

Dare

Dare S. Lacopo
Senior Territory Manager
Dallas/North Texas
DUSA pharmaceuticals, Inc
a SUN Pharma company

dare.lacopo@sunpharma.com

69. Upon information and belief, Biofrontera obtained through these employees the Confidential Information that has been critical to DUSA's success to date with regard to the marketing and sale of its patented invention and product, Levulan® and BLU-U®. DUSA's former employees had knowledge of DUSA's customer relationships and history, marketing strategy, and business intelligence that DUSA maintains as confidential.

70. For example, DUSA deems its customer account and history information to be highly sensitive competitive information.

71. DUSA maintains as confidential the identities of DUSA's customers as well as their account history, including information pertaining to the volume and frequency of their purchases, and DUSA does not organize this information in such a way as to permit anyone outside of DUSA to be able to determine the identities of key customers in the field. DUSA distributes Levulan® through unconventional distribution channels that differ from typical pharmaceutical distribution channels. For example, those involved in the distribution channels would not be able to determine all of the key customers to whom DUSA sells Levulan®. As such, it would have required a significant investment of time and resources for DUSA's competitors to discover these channels independently.

72. This is borne out by the history of companies that preceded Biofrontera, who had PDT therapies to treat actinic keratosis approved by the FDA, but ultimately failed in the marketplace because of their lack of key knowledge concerning the U.S. market. For example, DUSA's own first distribution partner, Berlex Laboratories, failed to effect a successful launch of the product for three years, necessitating DUSA's taking over of the marketing efforts and relaunching its own product. Photocure, another company that received FDA approval for PDT therapy using an ester of ALA, was on the marketplace for three years, but never successfully sold its

product in the U.S. market. Another company, Galderma, entered the market and tried to market a product similar to Levulan® and BLU-U®, but ultimately failed and ceased selling their product due to lack of knowledge of how to market the product.

73. After hiring away DUSA's key personnel, Biofrontera marketed its Ameluz and BF-RhodoLED products by targeting specific DUSA customers. Biofrontera knew exactly which customers to contact and knew the exact stick volume of Levulan® those customers were ordering. Biofrontera did not succeed on its own, but on the shoulders of DUSA and the unauthorized exploitation of DUSA's Confidential Information.

Biofrontera Group's U.S. Activities

74. Biofrontera Inc. was established in 2015. Upon information and belief, Biofrontera Inc.'s officers are comprised of Herman Lübbert, Thomas Schaffer, and Christoph Dünwald, and all three of these individuals are also officers of Biofrontera AG and Biofrontera Pharma GmbH. Upon information and belief, both Hermann Lübbert and Thomas Schaffer are named officers of Biofrontera Bioscience GmbH, Biofrontera Development GmbH, and Biofrontera Neuroscience GmbH.

75. In 2016, it was Biofrontera Bioscience GmbH—not Biofrontera Inc.—who sought and obtained FDA approval for BF-RhodoLED to be used in photodynamic therapy in combination with its drug, Ameluz.

76. It was also Biofrontera Pharma GmbH—not Biofrontera Inc.—that applied for and received U.S. trademark protection for Biofrontera's Ameluz and BF-RhodoLED.

77. Upon information and belief, employees of Biofrontera—not specific to Biofrontera Inc.—are engaged in the offer for sale, sale, and use of Biofrontera's products in the United States.

78. For example, upon information and belief, Biofrontera AG's CEO of U.S. Operations, Monica Tamborini, was in contact with Jon Lyons in 2016. Upon information and belief, former DUSA employee Jeff Holm is now Vice President of Sales and Marketing for Biofrontera AG. Upon information and belief, other U.S. sales managers who are employed by Biofrontera Pharma GmbH to offer for sale, sell, and use the accused products include Bert McCarley.

79. Upon information and belief, in addition to selling its own products, Biofrontera employees are actively encouraging and telling customers of DUSA's Levulan® and BLU-U® therapy that they may use BLU-U® with Biofrontera's Ameluz product—a use that is not authorized by DUSA or by the FDA—and inducing them to do so.

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

80. DUSA incorporates by reference paragraphs 1-79 as if fully set forth herein.

81. 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.

82. 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".

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

84. 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.)

85. 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.)

86. 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.)

87. 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.)

88. 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.)

89. 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.

90. 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.

91. 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.

92. 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.

93. 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.

94. 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.)

95. Each of the elements of Claim 1 is present in the BLU-U® product.

96. The BLU-U device is an illuminator for treating a patient.

97. The BLU-U® device has a plurality of light sources configurable in a spaced relationship to a patient to treat a dermatological condition.

98. The BLU-U® device has a controller, connected to the plurality of light sources, to control the light sources.

99. The BLU-U® device 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.

100. The BLU-U® device has light sources being configured and controlled such that uniform output of light is provided when measured at distances of 2" and 4".

101. Upon information and belief, sales representatives from Biofrontera regularly visit DUSA customers who own a BLU-U® device and leave samples of Ameluz, encouraging DUSA customers to use Ameluz with the BLU-U® device in place of Levulan®. Defendants have knowledge that the BLU-U® device is not approved for use with any drug other than Levulan®, and use of the BLU-U® device with Ameluz is a non-approved and unauthorized use of the technology that practices the '991 Patent.

102. 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.)

103. 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.

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

105. 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

106. DUSA incorporates by reference paragraphs 1-79 as if fully set forth herein.

107. 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.

108. 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.

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

110. 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.)

111. 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.)

112. 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.

113. 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.

114. 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.

115. 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.

116. 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.

117. 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.)

118. Each of the elements of Claim 1 is present in the BLU-U® product.

119. The treatment of a patient using the BLU-U® product is a method of photodynamically treating a patient.

120. The treatment of a patient using the BLU-U® 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.

121. Upon information and belief, sales representatives from Biofrontera regularly visit DUSA customers who own a BLU-U® device and leave samples of

Ameluz, encouraging DUSA customers to use Ameluz with the BLU-U® device in place of Levulan®. Defendants have knowledge that the BLU-U® device is not approved for use with any drug other than Levulan®, and use of the BLU-U® device with Ameluz is a non-approved and unauthorized use of the technology that practices the ’289 Patent.

122. 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.)

123. 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.

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

125. 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.

COUNT III: TRADE SECRET MISAPPROPRIATION UNDER THE DEFEND TRADE SECRETS ACT

126. DUSA incorporates by reference paragraphs 1-79 as if set forth fully herein.

127. DUSA takes steps to protect and preserve the secrecy of its Confidential Information as detailed above, including through non-disclosure agreements and technological protections including passwords and encryption. The Confidential Information was accumulated through years of industry experience and know-how and significant expenditure of resources.

128. All or a significant portion of DUSA's Confidential Information relates to BLU-U®, Levulan® and related products and services, which are used in, or intended for use in, interstate and foreign commerce. This includes Confidential Information related to DUSA's marketing strategies, customers, and prospective customers.

129. The Defend Trade Secrets Act provides a broad definition for "trade secrets," as "all forms and types of financial, business, scientific, technical, economic, or engineering information, including patterns, plans, compilations, program devices, formulas, designs, prototypes, methods, techniques, processes, procedures, programs, or codes, whether tangible or intangible, and whether or how stored, compiled, or memorialized physically, electronically, graphically,

photographically, or in writing." DUSA's Confidential Information constitutes trade secrets under the Defend Trade Secrets Act.

130. Upon information and belief, Biofrontera improperly acquired DUSA's Confidential Information by hiring away key employees who had access to the Confidential Information. Further, once the former DUSA employees joined various of the Defendant entities, Biofrontera improperly used that information to specifically target DUSA's customers in the market who Biofrontera knew were subscribers of Levulan® to market its own Ameluz product specifically as a replacement for Levulan®.

131. Biofrontera's improper acquisition and use of DUSA's Confidential Information constitutes trade secret misappropriation under 18 U.S.C. § 1836, *et seq*., the Defend Trade Secrets Act ("DTSA").

132. Biofrontera's misappropriation of DUSA's Confidential Information has caused and continues to cause harm and damages to DUSA in the form of lost profits and lost sales of Levulan® and BLU-U®, as well as the threat of future injury caused by Biofrontera's misappropriation. Unless the Court enjoins such improper acts, DUSA will continue to suffer additional irreparable injury.

133. At least Defendants' willful misappropriation of DUSA's Confidential Information renders this case an exceptional case, justifying an increase in the

damages to be awarded to DUSA up to two times the amount found or assessed and reasonable attorneys' fees, in accordance with 18 U.S.C. § 1836(b)(3)(C) and (D).

COUNT IV: TRADE SECRET MISAPPROPRIATION UNDER MASSACHUSETTS GENERAL LAWS CHAPTER 93 SECTION 42

134. DUSA incorporates by reference paragraphs 1-79 as if set forth fully herein.

135. DUSA's Confidential Information constitutes a trade secret under Massachusetts law, and all or a portion of the DUSA employees who Biofrontera hired away had access to this Confidential Information in their roles at DUSA.

136. These former DUSA employees learned DUSA's trade secrets in confidence and were under a contractual duty to neither use nor to disclose the trade secrets to third parties without DUSA's consent.

137. Upon information and belief, Biofrontera hired these former DUSA employees with knowledge that they possessed DUSA's Confidential Information, with knowledge that they were not permitted to disclose the Confidential Information to Biofrontera, and with intent to obtain the Confidential Information to use in marketing and selling Biofrontera's products.

138. Upon information and belief, Biofrontera improperly acquired DUSA's Confidential Information by hiring away key employees who had access to the Confidential Information. Further, once the former DUSA employees joined various of the Defendant entities, Biofrontera improperly used that information to

specifically target DUSA's customers in the market who Biofrontera knew were subscribers of Levulan® to market its own Ameluz product specifically as a replacement for Levulan®.

139. Biofrontera's improper acquisition and use of DUSA's Confidential Information constitutes trade secret misappropriation under Chapter 93, Section 42, of the Massachusetts General Laws. Upon information and belief, Biofrontera's improper acquisition and use of DUSA's Confidential Information was willful and malicious.

140. Biofrontera's misappropriation of DUSA's Confidential Information has caused and continues to cause harm (including irreparable harm) and damages to DUSA. Unless the Court enjoins such improper acts, DUSA will continue to suffer additional irreparable injury.

141. At least Defendants' misappropriation of DUSA's Confidential Information justifies an increase in the damages to be awarded to DUSA up to two times the amount found or assessed and reasonable attorneys' fees.

COUNT V: COMMON LAW MISAPPROPRIATION OF CONFIDENTIAL, PROPRIETARY, AND TRADE SECRET INFORMATION

142. DUSA incorporates by reference paragraphs 1-79 as if set forth fully herein.

143. DUSA owns Confidential Information as described above.

144. DUSA employees, including those that have been hired by Biofrontera, were exposed to and provided access to this Confidential Information in their roles as DUSA employees.

145. These employees are obligated to maintain the confidentiality and secrecy of this Confidential Information, and are prohibited from disclosing this Confidential Information to third parties, including competitors.

146. Upon information and belief, Biofrontera misappropriated the Confidential Information by hiring away DUSA employees, inducing the DUSA employees to disclose the Confidential Information to Biofrontera, and using the Confidential Information for its own benefit in selling and marketing its own products. Biofrontera acted without DUSA's permission or authorization. Upon information and belief, Biofrontera's improper acquisition and use of DUSA's Confidential Information was willful and malicious.

147. Biofrontera's misappropriation of DUSA's Confidential Information has caused harm (including irreparable harm) and damages to DUSA. Unless the Court enjoins such improper acts, DUSA will continue to suffer additional irreparable injury.

COUNT VI: TORTIOUS INTERFERENCE WITH CONTRACTUAL RELATIONS

148. DUSA incorporates by reference paragraphs 1-79 as if set forth fully herein.

149. DUSA had provisions in its employment agreements with its former employees specifically protecting its Confidential Information and/or trade secrets.

150. Upon information and belief, Biofrontera knew that the former DUSA employees had valid and enforceable provisions in their employment agreements with DUSA protecting DUSA's Confidential Information, including trade secrets, and knowingly induced the former DUSA employees to break those contracts.

151. Upon information and belief, Biofrontera improperly solicited the former DUSA employees to leave DUSA, knowing the employees had information protection provisions in their employment agreements, and obtained and used information such as customer information and business strategies and plans from the former DUSA employees.

152. Biofrontera used this information to target specific DUSA customers, using information improperly obtained from the former DUSA employees in violation of their information protection provisions, misleading customers into using DUSA's BLU-U® device in an unauthorized manner, such as with Biofrontera's Ameluz product.

153. DUSA further has provisions in its sales contracts with customers that have purchased a BLU-U® device from DUSA. These provisions specifically permit the use of BLU-U® for FDA-approved uses, such as use of Levulan® with BLU-U®. Upon information and belief, Defendants know or should have known

that customers that have purchased a BLU-U® device from DUSA can only use BLU-U® with FDA-approved uses, at least based on knowledge obtained from former DUSA sales employees working for Biofrontera. Defendants have knowledge that the BLU-U® device is not approved by the FDA for use with any drug other than Levulan®, and that the use of the BLU-U® device with Ameluz is a not approved by the FDA. Upon information and belief, sales representatives from Biofrontera regularly visit and/or contact DUSA customers who own a BLU-U® device and encourage DUSA customers to use Ameluz with the BLU-U® device in place of Levulan®. Thus, Biofrontera has and continues to encourage DUSA customers to breach their contracts by using the BLU-U® device with Ameluz.

154. DUSA was harmed by Biofrontera's actions in the form of lost profits and sales of DUSA's Levulan® and BLU-U® device, as well as the threat of future injury caused by Biofrontera's tortious interference. Unless the Court enjoins such improper acts, DUSA will continue to suffer additional irreparable injury.

155. At least Defendants' tortious interference justifies an increase in the damages to be awarded to DUSA up to three times the amount found or assessed and reasonable attorneys' fees.

COUNT VII: DECEPTIVE AND UNFAIR TRADE PRACTICES UNDER MASSACHUSETTS GENERAL LAWS CHAPTER 93A

156. DUSA incorporates by reference paragraphs 1-79 as if set forth fully herein.

157. In addition to the conduct described in Counts I through VI, above, Biofrontera has undertaken actions with the specific intent of causing competitive injury to DUSA and in the course of competition with DUSA. These actions constitute violations of Massachusetts General Laws Chapter 93A.

158. Biofrontera engaged in deceptive and unfair trade practices by, upon information and belief, targeting customers and potential customers from improperly acquired lists of DUSA's customers and potential customers, providing samples of Ameluz to those customers, and encouraging their use with the BLU-U® device instead of the FDA approved Levulan®.

159. DUSA further has provisions in its sales contracts with customers that have purchased a BLU-U® device from DUSA. These provisions specifically permit the use of BLU-U® for FDA-approved uses, such as use of Levulan® with BLU-U®. Upon information and belief, Defendants know or should have known that customers that have purchased a BLU-U® device from DUSA can only use BLU-U® with FDA-approved uses, at least based on knowledge obtained from former DUSA sales employees working for Biofrontera. Defendants have knowledge that the BLU-U® device is not approved by the FDA for use with any drug other than Levulan®, and that the use of the BLU-U® device with Ameluz is a not approved by the FDA. Upon information and belief, sales representatives from Biofrontera regularly visit and/or contact DUSA customers who own a BLU-U®

device and encourage DUSA customers to use Ameluz with the BLU-U® device in place of Levulan®. Thus, Biofrontera has and continues to engage in deceptive and unfair trade practices by encouraging DUSA customers to breach their contracts by using the BLU-U® device with Ameluz instead of Levulan®.

160. Biofrontera's conduct has been willful and malicious.

161. Upon information and belief, Biofrontera further engaged in deceptive and unfair trade practices by returning to those customers and urging them to sign papers stating that the Ameluz samples they gave them came from Medical Affairs.

162. Upon information and belief, Biofrontera's deceptive and unfair trade practices occurred primarily and substantially within Massachusetts, including because DUSA is a Massachusetts corporation, and Biofrontera does business in the United States through its entity located in Massachusetts. Further, Biofrontera's marketing activities are directed at DUSA customers in Massachusetts, in addition to elsewhere across the country.

163. DUSA was harmed due to Biofrontera's actions and suffered damages in the form of lost profits and sales of its FDA approved Levulan® product, as well as the threat of future injury caused by Biofrontera's tortious interference. Additionally, apart from the financial damage caused by targeting DUSA customers and soliciting their replacement of DUSA product with Biofrontera product, upon information and belief, Biofrontera is encouraging DUSA's customers to use

DUSA's BLU- U® device with Biofrontera's Ameluz product. DUSA has not tested its BLU-U® device with Biofrontera's Ameluz product and has no control over Ameluz's chemical contents, manufacturing, or quality control. Accordingly, DUSA cannot control or manage the potentially adverse effects one could experience from the untested combination of a BLU-U® device with Ameluz. Thus, Biofrontera is unfairly exposing DUSA to potential liability in connection with health or safety problems posed by the untested combination for which Biofrontera advocates.

164. Unless the Court enjoins such improper acts, DUSA will continue to suffer additional irreparable injury.

165. At least Defendants' deceptive and unfair trade practices justifies an increase in the damages to be awarded to DUSA up to three times the amount found or assessed and reasonable attorneys' fees.

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 and Defendants' misappropriation of trade secrets has been and is willful;

(c) a finding that Defendants have misappropriated trade secrets in violation of the Defend Trade Secrets Act, Massachusetts General Laws Chapter 93 Section 42, and common law;

(d) a finding that Defendants have committed tortious interference under Massachusetts state law;

(e) a finding that Defendants have engaged in deceptive and unfair trade practices under Massachusetts General Laws Chapter 93A;

(f) equitable relief under 35 U.S.C. § 283, Massachusetts General Laws Chapter 93A, or otherwise in accordance with principles of equity, including, but not limited to, an injunction and, where appropriate, a temporary restraining order 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; that enjoins and/or restrains Defendants from misappropriating DUSA's trade secrets; that enjoins

Defendants from committing tortious interference with DUSA; and that enjoins Defendants from engaging in deceptive and unfair trade practices;

(g) 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; for misappropriation of DUSA's trade secrets, including lost profits, together with prejudgment interest; for tortious interference with DUSA, including lost profits, together with prejudgment interest; and for its deceptive and unfair trade practices, including lost profits, together with prejudgment interest;

(h) 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; to compensate DUSA for any ongoing and/or future misappropriation of DUSA's trade secrets, 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; to compensate DUSA for any ongoing and/or future tortious interference with DUSA, 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; to compensate DUSA for any ongoing and/or future deceptive and unfair trade practices, 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;

(i) a declaration or order finding that Defendants' infringement is willful and/or an order increasing damages under 35 U.S.C. § 284;

(j) a declaration or order finding that Defendants' misappropriation of trade secrets is willful and/or an order increasing damages under 18 U.S.C. § 1836(b)(3)(C);

(k) a declaration or order increasing damages up to two times for Defendants' misappropriation of trade secrets under Massachusetts General Laws Chapter 93 Section 42;

(l) a declaration or order increasing damages up to three times for Defendants' tortious interference with DUSA;

(m) a declaration or order increasing damages up to three times for Defendants' deceptive and unfair trade practices against DUSA;

(n) a declaration or order awarding DUSA treble damages pursuant to Massachusetts General Laws Chapter 93A or other applicable law;

(o) a judgment holding that this is an exceptional case under 35 U.S.C. § 285, Massachusetts General Laws Chapter 93A § 11, 18 U.S.C. § 1836(b)(3)(D), or otherwise in accordance with statute or principles of equity, and awarding DUSA its reasonable attorney fees, costs, and expenses;

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

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

Dated: October 30, 2018

Respectfully submitted,

By: */s/ Kevin Su*

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Attorneys for Plaintiff DUSA Pharmaceuticals, Inc.

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing document has been served on all counsel of record via this Court's ECF system on October 30, 2018.

/s/ Kevin Su
Kevin Su