UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

v.

SUN PHARMACEUTICAL INDUSTRIES, INC.
Patent Owner

Case IPR2025-00287

U.S. Patent No. 11,446,512

DECLARATION OF HEATHER J. ROBERTS, M.D., FAAD

TABLE OF CONTENTS

Page

I. INTRODUCTION 1

II. BASES FOR OPINIONS 1

III. INFORMATION CONSIDERED 2

IV. EDUCATION AND EXPERIENCE 2

V. OVERVIEW OF THE '512 PATENT 5

VI. USE OF SUN PHARMA'S BLU-U® MODEL 4170 9

VII. BIOFRONTERA'S PHOTOTHERAPY DEVICES 14

VIII. DR. EHRENREICH'S DECLARATION 17

I. INTRODUCTION

1. I, Heather J Roberts, MD, FAAD submit this declaration in support of Patent Owner's Preliminary Response in *Inter Partes* Review Proceeding No. IPR2025-00287 of U.S. Patent No. 11,446,512 ("the '512 Patent").

2. I have been retained as an expert in this matter on behalf of Sun Pharmaceutical Industries, Inc. ("Sun Pharma").

3. I make this declaration based upon my personal knowledge. I am over eighteen years of age, and I am competent to testify as to the matters set forth herein if I am called upon to do so.

4. I am being compensated at my standard hourly rate of $900.00 per hour. My compensation is not dependent on the outcome of, or any issue in relation to, the above-captioned IPR2025-00287. I have no interest in either party.

II. BASES FOR OPINIONS

5. I have considered the documents and other materials listed below in Section III in view of my specialized knowledge provided by my education, training, research, and experience, as summarized in Section IV and described in detail in my CV, which is provided as Ex. 2016. My analysis of those materials, combined with the specialized knowledge that I have obtained over the course of my education and career, form the bases for my opinions in this declaration.

III. INFORMATION CONSIDERED

6. In forming the opinions set forth in this declaration, I have relied upon my experience and knowledge in the field of dermatology, as well as my review of certain documents in this matter, including:

- U.S. Patent No. 11,446,512 (Ex. 1001);
- Information regarding the BLU-U® from https://www.levulanhcp.com/;
- Gold, M. Therapeutic and Aesthetic Uses of Photodynamic Therapy Part two of a five-part series: Lasers and Light Treatments for Acne Vulgaris Promising Therapies, *J. Clin. Aesthet. Dermatol.*, 2008; 1(3)28-34. (Ex. 1023);
- Declaration of Michael Ehrenreich, MD (Ex. 1016);
- Information regarding the RhodoLED® XL and RhodoLED®; and
- all other exhibits cited herein.

IV. EDUCATION AND EXPERIENCE

7. As demonstrated by my professional experience described in my curriculum vitae (Ex. 2016) and the summary of my qualifications below, I have significant scientific and technological experience in dermatology. I have first-hand knowledge of the state of the art of dermatology since at least 1997.

8. I earned my B.A. in Biochemistry with highest honors from Rutgers University – Cook College in 1985. In 1989, I earned my M.D. degree from the

University of California, Irvine. At UC Irvine, I was a member of the Alpha Omega Honor Society, the national medical honor society.

9. After medical school, I completed my residency in Internal Medicine at Cedars-Sinai Medical Center in Los Angeles, California in 1993. I completed my residency in Dermatology at the USC Keck School of Medicine in 1997.

10. Following my residency, I served on the hospital faculty at USC in the dermatology clinic until 1998. I returned to USC as a Clinical Associate Professor of Dermatology in 2005 and maintained the position through 2016. During this time, I taught both laser surgery and dermatologic surgery techniques to residents and medical students.

11. From 1997-2005, I served as a volunteer clinical faculty member at Cedars-Sinai Medical Center, teaching in the general dermatology clinic for Internal Medicine residents and medical students. I was a staff dermatologist in the wound care center at Cedars-Sinai Medical Center in 2000.

12. In 2001, I founded my own practice, Heather J Roberts, MD, A Medical Corporation in dermatology. In my office, we treat patients for a wide variety of skin conditions including acne and actinic keratosis. We offer light therapies, including photodynamic therapy (PDT), in addition to many other dermatologic treatments and procedures.

13. I was the principal investigator in an FDA-approved study to treat acne with the Omnilight Laser. I have over 20 years of experience with light-based technologies, including PDT.

14. I am a Fellow of the American Academy of Dermatology and prior fellow of the American Society of Dermatologic Surgery. As a Fellow of the American Society of Dermatologic Surgery, I volunteered in the SCORES program, which was dedicated to repairing injuries for female victims of spousal abuse. I am also a founding board member for the Sun Safety for Kids program in California which strives to advance public awareness of the importance of lifelong skin cancer prevention behaviors.

15. I am a member of the California Society of Dermatology and Dermatologic Surgery and the Los Angeles Metropolitan Dermatologic Society. I am certified by the American Board of Dermatology.

16. Throughout my career, I have received numerous honors and awards, including Leading Physician of the World (awarded by the International Association of Dermatologists in 2017), Super Doctors Southern California (nominated by my peers and awarded by Los Angeles Magazine from 2016-2025), and America's Top Dermatologists (awarded by Consumers Research Council of America). I have been featured on Lifetime's "Speaking of Women's Health," as well as other media outlets.

17. Accordingly, I am an expert in the field of dermatology and have been since at least 1997.

V. OVERVIEW OF THE '512 PATENT

18. The '512 Patent is titled "ADJUSTABLE ILLUMINATOR FOR PHOTODYNAMIC THERAPY AND DIAGNOSIS." Ex. 1001 ('512 Patent), Cover.

19. I understand that the '512 Patent was filed on February 14, 2020, and claims priority to several earlier applications, the earliest of which, U.S. Provisional Application No. 62/241,902, was filed on October 15, 2015. Ex. 1001 ('512 Patent), Cover, p. 2.

20. The '512 Patent is assigned on its face to DUSA Pharmaceuticals, Inc. Ex. 1001 ('512 Patent), Cover. I understand that DUSA Pharmaceuticals, Inc. merged with Sun Pharmaceutical Industries, Inc. ("Sun Pharma") in 2024.

21. I have reviewed the specification and figures of the '512 Patent.

22. The '512 Patent discloses "[a]n adjustable illuminator for photodynamically diagnosing or treating a surface." Ex. 1001 ('512 Patent), Abstract. The '512 Patent states that "[t]he invention relates generally to an adjustable illuminator that provides a uniform distribution of visible light in a number of configurations and is suitable for use in photodynamic therapy and diagnosis." Ex. 1001 ('512 Patent), 1:17-20.

23. The ’512 Patent states that “some forms of treatment involving PDT, such as the use of ALA to treat actinic keratosis, require specific and highly uniform intensity and color of light to achieve effectiveness.” Ex. 1001 (’512 Patent), 2:29-31. The ’512 Patent further states that “[t]he optical dead space that can occur at or near the hinges of conventional adjustable illuminators reduces the uniformity of the light along the treatment area, thereby reducing the effectiveness of PDT.” Ex. 1001 (’512 Patent), 2:39-42. The ’512 Patent discloses that it is an object of the present invention to “reduce or eliminate these dead spaces and provide for a more uniform light distribution in an adjustable illuminator designed for PDT or PD of a variety of targeted areas.” Ex. 1001 (’512 Patent), 2:50-54.

24. The ’512 Patent describes a system for photodynamically diagnosing or treating a patient with an illuminator that has five panels connected by hinges with light sources (LEDs) on the surfaces of the five panels. Ex. 1001 (’512 Patent), 2:63–3:19.

25. FIG. 4 of the ’512 Patent “shows a perspective view of the illuminator having the main body of FIGS. 1A-1B mounted to a stand.” Ex. 1001 (’512 Patent), 3:33-34.

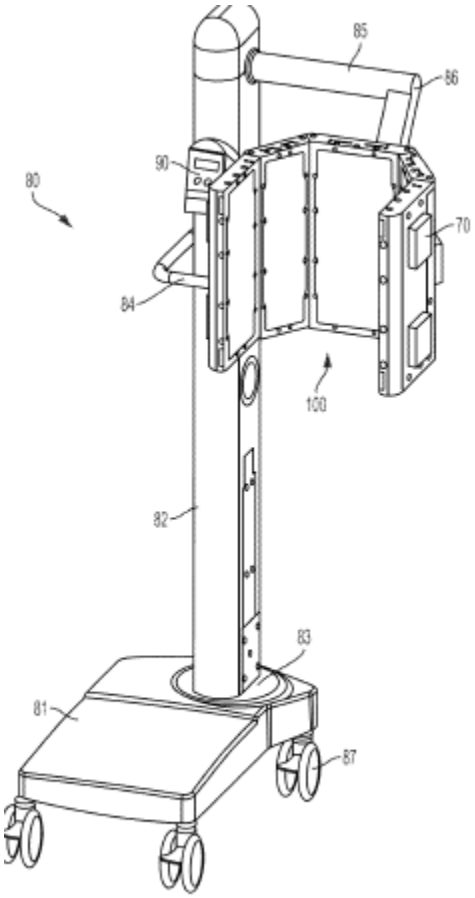


FIG. 4

Ex. 1001 (’512 Patent), FIG. 4.

26. The ’512 Patent discloses “[a]n example in which the LED arrays 60 may be individually configured is shown in FIG. 5.” Ex. 1001 (’512 Patent), 6:22-23, FIG. 5.

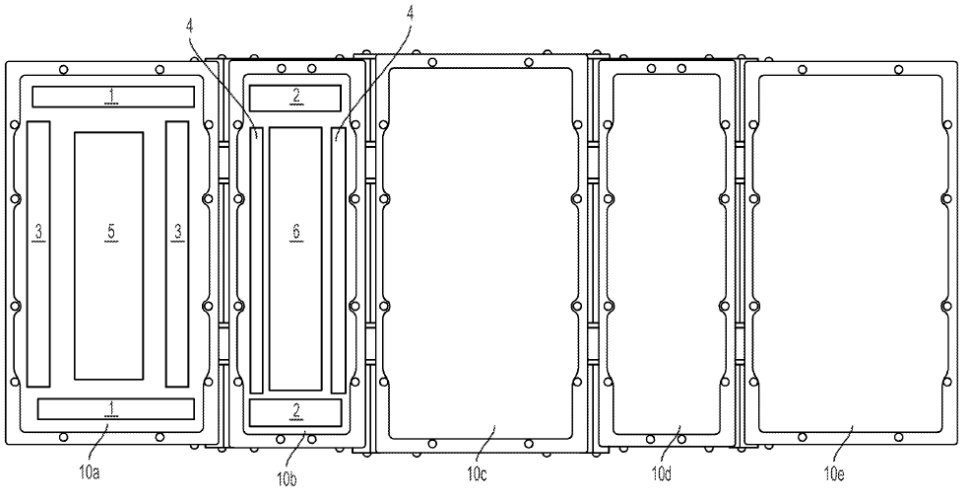


FIG. 5

Ex. 1001 ('512 Patent), FIG. 5.

27. The '512 Patent explains that "the LED arrays 60 are divided into three general areas, which may be described as 'addressable strings.' Areas 1, 3, and 5 correspond to an addressable string configuration that may be included in the wider panels 10*a*, 10*c*, and 10*e*, while areas 2, 4, and 6 correspond to an addressable string configuration that may be included in the narrower panels 10*b* and 10*d*." Ex. 1001 ('512 Patent), 6:23-29, FIG. 5. "The current to each area is adjusted in order to adjust the intensity of light emitting from each of the areas. For example, a higher current may be supplied to areas 1 and 2 than the current supplied to areas 3 and 4 such that areas 1 and 2 emit a higher intensity of light than areas 3 and 4. Similarly, a higher current may be supplied to areas 3 and 4 than the current supplied to areas 5 and 6." Ex. 1001 ('512 Patent), 6:30-36, FIG. 5.

VI. USE OF SUN PHARMA'S BLU-U® MODEL 4170

28. I have used Sun Pharma's BLU-U® blue light photodynamic therapy illuminator Model 4170 device ("BLU-U") in my dermatology practice.

29. The BLU-U device is shown below.



Ex. 2018 (https://www.levulanhcp.com/how-to-use (screenshot from "Apply LUVULAN KERASTICK" video)), 5. The BLU-U device has U-shaped light sources (fluorescent tubes), which provide uniform light to the treatment surface of a patient. The BLU-U light sources emit a specific wavelength of blue light. The BLU-U light sources work by using PDT to activate a photosensitizing agent on the

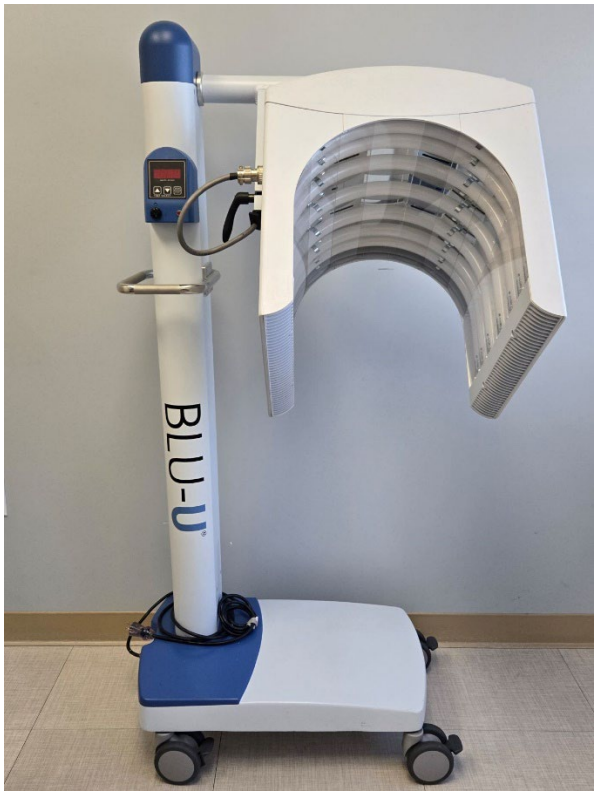
skin, which then destroys targeted cells. Ex. 2019 (https://www.levulanhcp.com/how-it-works).

30. As I state on my website, "PDT is a special treatment performed with a topical photosensitizing agent called Levulan (ALA) and a BLU-U visible light source. PDT has the unique ability to reverse sun damage and stimulate the development of healthy new skin." Ex. 2023 (https://drheatherroberts.com/procedures-and-treatments/photodynamic-therapy-pdt-for-skin-cancer/), 2.

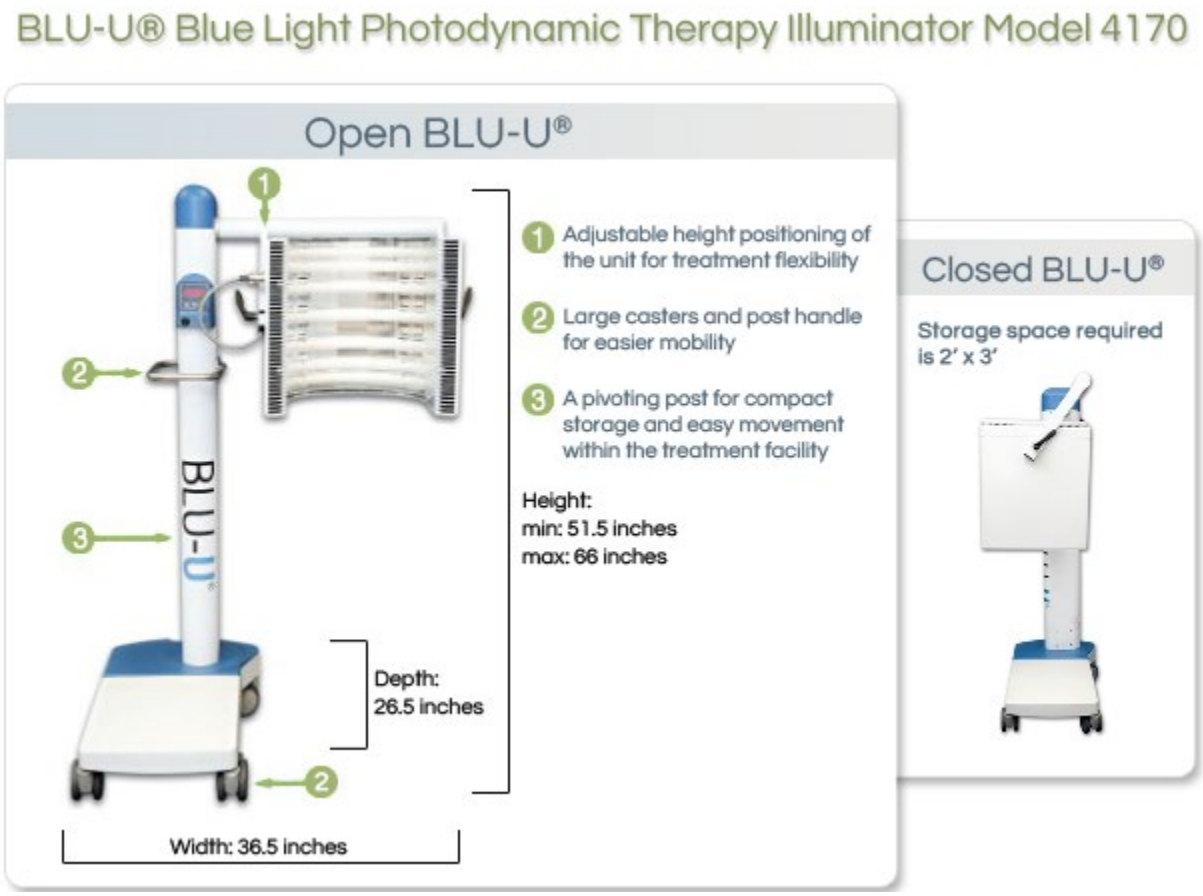
31. Sun Pharma's website explains that the BLU-U device is used in combination with LEVULAN® KERASTICK® for photodynamic therapy (PDT) to treat actinic keratoses (AKs). The LEVULAN® KERASTICK® contains 20% aminolevulinic acid HCl that penetrates to the root of AK lesions. BLU-U delivers light and activates protoporphyrin IX, causing cell death. Ex. 2020 (https://www.levulanhcp.com/treatment-landscape). Sun Pharma's website further states BLU-U is "[t]he only PDT indicated for the treatment of minimally to moderately thick actinic keratoses of the face or scalp, or actinic keratosis of the upper extremities." Ex. 2017 (https://www.levulanhcp.com/).

32. In addition, Sun Pharma's website states that "BLU-U covers an active working area of 214 square inches—14 times larger than the red light of other PDT treatments." Ex. 2020 (https://www.levulanhcp.com/treatment-landscape), 2.

33. I first purchased a BLU-U for my practice in 2004. I have continued to use the BLU-U in my offices for 20 years. Between 2004 and 2024, I have conducted approximately 2,400 treatments using the BLU-U, for example, to treat actinic keratoses and acne. The BLU-U device that I currently have in my office is shown below.



34. As shown below, the lighting head of BLU-U has "[a]djustable height positioning" and can be rotated to provide "treatment flexibility" to a desired area.



Ex. 2024 (https://www.mydrugrep.com/mobile-campaigns/Levulan_V13a_01a/space_requirements.html).

35. I have used BLU-U to treat patients with actinic keratoses and acne on the face, neck, hands, arms, chest, and back. For example, the pictures below illustrate examples of the positioning of BLU-U for the face, head, and arms.



Ex. 2018, p.2 (https://www.levulanhcp.com/how-to-use).

36. When treating patients' faces or necks, I have positioned them in the "U" of the device as shown above. When treating patients' arms or hands, I position the device over their extremities. When treating patients' chests or backs, I have had the patient turn to the right so the "U" of the device wraps halfway around their chest and back. Then, I have turned them to the left so the "U" of the device wraps around the other half of their chest and back.

37. I have obtained clinically effective results using BLU-U on patients' faces, necks, hands, arms, chests, and backs. I have seen improvement in AK lesions and acne, in line with results published by other dermatologists. For example, Goldman et al reported the BLU-U's "*effectiveness in inflammatory acne vulgaris lesions* in 12 patients. Lesion counts performed two weeks after the final treatment showed a *40-percent reduction in papular acne lesions, a 65-percent reduction in pustular acne lesions, and a 62-percent reduction in comedonal acne lesions*. A second study compared this blue light system to topical 1% clindamycin use. This study showed that the *blue light therapy was more effective than the topical clindamycin in reducing inflammatory acne vulgaris lesions*." Ex. 1023 (Gold), 29, 33 (emphasis added); Fig. 3.

38. As another example, "Taub reported her experience with short-contact, full-face therapy utilizing blue light sources (ClearLight or Blu-U) or an IPL with

RF (Aurora®, Syneron, Yokneam, Israel). Eighteen patients were evaluated. The patients received 2 to 4 treatments over a 4- to 8-week time period. Improvement was noted at four months following the last treatment. *Of the 18 patients, 11 showed 50-percent improvement, and five had greater than 75-percent improvement*." Ex. 1023, (Gold), 32-33 (emphasis added).

39. Consistent with my own positive experience with the BLU-U device over the last 20 years, I understand that BLU-U is the "#1-prescribed photodynamic therapy," according to Sun Pharma's website. Ex. 2017 (https://www.levulanhcp.com/). As reported by Sun Pharma, "LEVULAN KERASTICK + BLU-U has been the most trusted and reliable photodynamic therapy [PDT] for more than two decades." Ex. 2019 (https://www.levulanhcp.com/how-it-works).

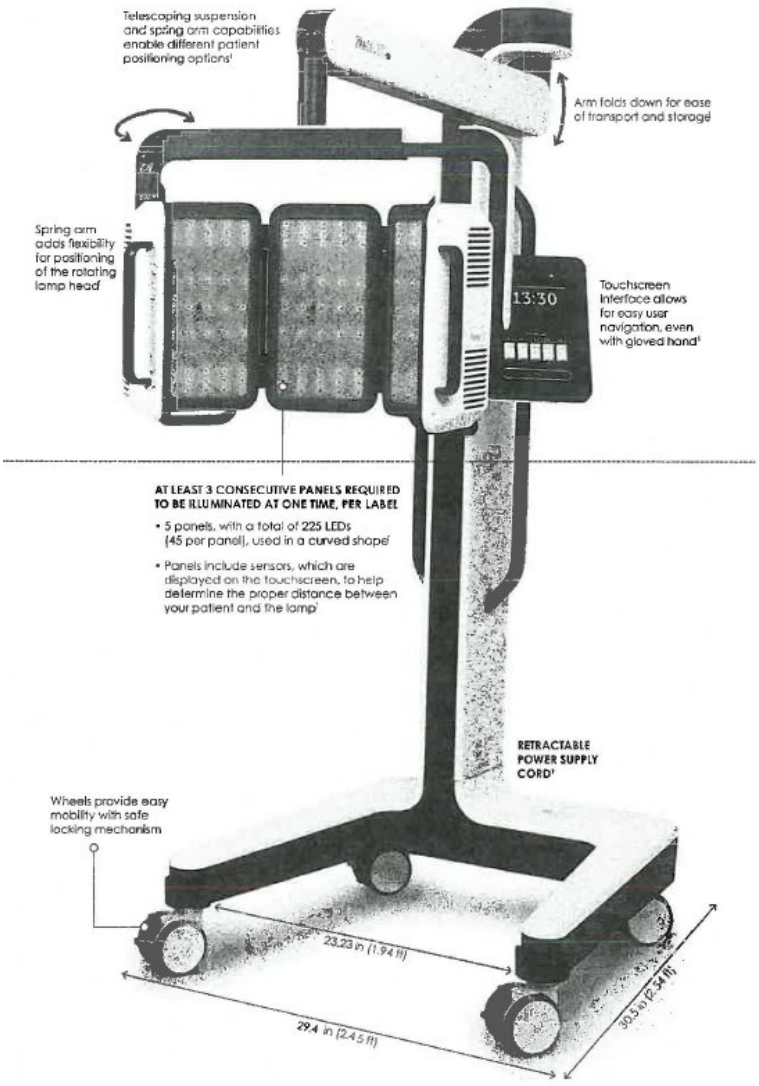
VII. BIOFRONTERA'S PHOTOTHERAPY DEVICES

40. I understand that Biofrontera sells a RhodoLED® PDT device for treatment of actinic keratoses with AMELUZ®, shown below.



Ex. 2056, 2; https://us.ameluz.com/hcp/activate-with-rhodoled-lamp/. I understand that Biofrontera's RhodoLED® device retails for $7,500.

41. I understand that Biofrontera more recently introduced the RhodoLED® XL PDT device for treatment of actinic keratoses in combination with AMELUZ®, shown below.



Ex. 2042, 3; https://us.ameluz.com/hcp/activate-with-rhodoled-lamp/. I understand that the current market price for the RhodoLED® XL is $18,500.

42. PDT devices, like the RhodoLED® XL, are large expenditures for dermatology practices. In my opinion, an interested dermatology practice would not purchase a more expensive PDT device unless there were clear and significant benefits to the more expensive device over the older device.

VIII. DR. EHRENREICH'S DECLARATION

43. I have reviewed Dr. Ehrenreich's declaration (Ex. 1016). I understand that Dr. Ehrenreich is the medical director of his practice, SOMA Skin & Laser. Dr. Ehrenreich states that he treats patients for a variety of skin conditions, including AK and acne, using Sun Pharma's BLU-U device. Ex. 1016, ¶¶9, 12, 40, 42; Ex. 2025 (https://somalaser.com/dr-michael-ehrenreich-md-millburn-dermatologist/); Ex. 2026 (https://somalaser.com/blu-for-acne/); Ex. 2027 (https://somalaser.com/photodynamic-therapy/); Ex. 2028 (https://somalaser.com/photodynamic-therapy-for-actinic-keratoses-and-skin-cancer/).

44. Dr. Ehrenreich complains about "problems" with the use of U-shaped fluorescent lights in PDT. Ex. 1016, ¶¶67-69. However, I note that Dr. Ehrenreich states that "uniformity of light is important," and "*the 'U' shape provides the desired irradiance and irradiance uniformity for Scalp and facial irradiation, and thus ensures that the proper visible light dosage is applied to all target areas during PDT*." Ex. 1016, ¶64 (emphasis added).

45. Dr. Ehrenreich also argues that BLU-U "makes it hard to treat hands, arms, and necks and upper chests," stating that positioning the patient and device to "make the patient comfortable" "is not ideal" because "[i]t is sometimes awkward

and uncomfortable for the patient and it can make setting and controlling the distance between the light and the treatment area difficult." Ex. 1016, ¶¶43, 72. I disagree.

46. As I explained above in Section VI, I have used BLU-U effectively to treat patients' faces, necks, hands, arms, chests, and backs. To treat these areas on the patient, I simply position the device and the patient appropriately. In fact, Sun Pharma's website provides an instructional video for positioning a patient's face, neck, hands, scalp, and arms in BLU-U, as shown below.





Ex. 2018 (https://www.levulanhcp.com/how-to-use (screenshot from "Position BLU-U" video")). I note that Dr. Ehrenreich's website links to Sun Pharma's

(DUSA Pharmaceuticals) website, which explains the positioning for treatment with BLU-U.

- Levulan Patient Education Video (for Actinic Keratoses)
- DUSA Pharmaceuticals Website (maker of Levulan Kerastick)

Ex. 2027 (https://somalaser.com/photodynamic-therapy/).

47. According to Sun Pharma's website, BLU-U is the only PDT indicated for treatment of minimally to moderately thick actinic keratoses of the face or scalp or actinic keratosis of the upper extremities. Ex. 2017 (https://www.levulanhcp.com/). In addition, Sun Pharma's website provides efficacy information for treating AK lesions on the upper extremities consistent with the positive results I have seen in my patients. Ex. 2021 (https://www.levulanhcp.com/efficacy) ("31% of patients had 100% clearance of AK lesions on the upper extremities"), ("42% of upper-extremity patients who were clear at 12 weeks did not have a recurrent lesion in the 12-month follow-up period"). Sun Pharma's patient brochure shows the following results after 2 treatments with the Levulan Kerastick and BLU-U.



Ex. 2022 (https://www.levulanhcp.com/assets/pdf/levulan-patient-brochure.pdf), 11-12.

48. Additionally, Dr. Ehrenreich advertises BLU-U on his website for acne and actinic keratosis, ***despite*** the alleged "problems" he describes in his declaration. Ex. 2026 (https://somalaser.com/blu-for-acne/); Ex. 2027 (https://somalaser.com/photodynamic-therapy/); Ex. 2028 (https://somalaser.com/photodynamic-therapy-for-actinic-keratoses-and-skin-cancer/). For example, Dr. Ehrenreich's website states that "Photodynamic Therapy (PDT) is an *innovative, non-invasive treatment* that has become a *powerful tool in dermatology*." Ex. 2029, (https://somalaser.com/photodynamic-therapy-for-skin-

conditions/) (emphasis added). In addition, Dr. Ehrenreich's website states that "[a]t SOMA Skin & Laser we use the BLU-U blue light. The resulting damage to the pre-cancerous or cancerous cells causes their destruction, and *results in a decreased risk of future actinic keratoses and skin cancer*." Ex. 2028 (https://somalaser.com/photodynamic-therapy-for-actinic-keratoses-and-skin-cancer/) (emphasis added). Dr. Ehrenreich's website also states that "*BLU-U is a unique blue light* that kills the acne-causing *P. acnes* bacteria in your skin." Ex. 2026 (https://somalaser.com/blu-for-acne/) (emphasis added). Dr. Ehrenreich recommends and shows using the BLU-U device for acne.

What Is BLU-U For Acne?

Blue light is an innovative treatment for moderate acne. If you have moderate acne and are uncomfortable taking antibiotics or are unhappy with your current topical treatment results, BLU-U blue light therapy – using light without drugs or antibiotics – may be for you. BLU-U is a unique blue light that kills the acne-causing *P. acnes* bacteria in your skin. During each treatment, you sit with your face close to the blue light for approximately 17 minutes. The treatment is repeated once or twice weekly for about six weeks. After several weeks, the blue light can help control your acne.



Ex. 2026 (https://somalaser.com/blu-for-acne/). Regarding actinic keratosis, Dr. Ehrenreich's website further states that "Photodynamic therapy is also *effective for large areas*." Ex. 2030 (https://somalaser.com/skin-conditions/actinic-keratosis/) (emphasis added). Notably, Dr. Ehrenreich's website ***does not mention any of his alleged "problems" with the BLU-U device***.

49. Moreover, while Dr. Ehrenreich alleges "problems" with the BLU-U device, he does not provide any solutions to the problems. Ex. 1016, ¶¶42-45, 67-74. He argues that his own experience "provides motivation to make modifications" and "to make [] a more effective and convenient device that would more effectively position the light source relative to the patient treatment area." Ex. 1016, ¶73. However, Dr. Ehrenreich does not suggest or provide any evidence regarding what those modifications would be.

I hereby declare that all statements made herein of my knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

5/7/2025
Date

Heather Roberts, M.D., FAAD