

**UNITED STATES INTERNATIONAL TRADE COMMISSION
WASHINGTON, D.C. 20436**

**Before the Honorable Bryan F. Moore
Administrative Law Judge**

In the Matter of

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

Investigation No. 337-TA-1411

**RESPONDENTS BIOFRONTERA AG, BIOFRONTERA BIOSCIENCE GMBH,
BIOFRONTERA PHARMA GMBH, AND BIOFRONTERA INC.'S
PRE-HEARING BRIEF**

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TABLE OF ABBREVIATIONS

Abbreviation	Meaning
CX-	Complainant's Exhibit
CX-xxxxC	Confidential Complainant's Exhibit
RX-	Respondents' Exhibit
RX-xxxxC	Confidential Respondents' Exhibit
JX-	Joint Exhibit
JX-xxxxC	Confidential Joint Exhibit
'512 Patent	U.S. Patent No. 11,446,512
'028 Patent	U.S. Patent No. 11,697,028
Asserted Patents	The '512 Patent and the '028 Patent
Complainant <i>or</i> Sun Pharma	Sun Pharmaceutical Industries, Inc.
Respondents <i>or</i> Biofrontera	Biofrontera Inc., Biofrontera Pharma GMBH, Biofrontera Bioscience GMBH, & Biofrontera AG
ITC	International Trade Commission
ID	Initial Determination
Comm'n Op	Commission Opinion
USPTAB or PTAB	United States Patent Trial and Appeal Board
USPTO <i>or</i> PTO	United States Patent and Trademark Office
IPR	<i>Inter Partes</i> Review
a POSA	A Person of Ordinary Skill in the Art at the time of the invention
R&D	Research and Development
Accused Products	Accused Products
DI Products	Domestic Industry Products
CMIB	Complainant's Initial Markman Brief
CMRB	Complainant's Reply Markman Brief
RMIB	Respondents' Initial Markman Brief
RMRB	Respondents' Reply Markman Brief
EDI	Economic Domestic Industry
TDI	Technical Domestic Industry
CDO	Cease and Desist Order
LEO	Limited Exclusion Order

Abbreviation	Meaning
DOE	Doctrine of Equivalents
Compl.	Complaint
Rog No.	Interrogatory No.
PDT	Photodynamic therapy
ALA	5-aminolevulinic acid
BLU-U®	BLU-U® 4170 or BLU-U® 4170D
Prior Art References	
Lundahl	U.S. Patent No. 6,223,071 to Lundahl, et al.
Larsen	U.S. Patent Publication No. 2005/0075703 to Larsen
Kennedy	U.S. Patent No. 5,079,262 to Kennedy, et al.
Hente	U.S. Patent Publication No. 2010/0118522 to Hente
Perutz	U.S. Patent No. 4,823,858 to Perutz
'902 prov.	U.S. Provisional Application No. 62/241,902

I. INTRODUCTION

Respondents Biofrontera Inc., Biofrontera Pharma GmbH, Biofrontera Bioscience GmbH, and Biofrontera AG (collectively, “Biofrontera” or “Respondents”) submit this pre-hearing brief pursuant to Order No. 6 (Sep. 3, 2024) (Procedural Schedule) and Order No. 2 (Aug. 1, 2024) (Ground Rules) in Investigation No. 337-TA-1411 brought by Complainant Sun Pharma, Inc. (“Complainant” or “Sun Pharma”).

Biofrontera and Sun Pharma compete in a growing, but small, portion of the market for the treatment of certain types of skin cancer with Photodynamic Therapy (“PDT”). PDT has been known in the art and used for decades. The Accused Product in this investigation is Biofrontera’s illuminator, or lamp, that is used in combination with a photosensitizer topical gel product in PDT treatment. This litigation, just one of several suits brought by Sun Pharma, one of the largest generic pharmaceutical companies in the world, is Sun’s latest attempt to litigate its much smaller competitor out of business. JX-0198 (Complaint), Exs. 11C, 41C; CX-0077C. Sun Pharma even rushed to file this complaint before it had a domestic industry product available to sell, and the lack of a domestic industry alone is sufficient to find no violation of Section 337. Moreover, Sun Pharma’s attempts to claim an additional two decades of exclusivity based on patents that the evidence will demonstrate are invalid and not infringed should be rejected.

The development of an improved photosensitizer for the treatment of skin cancers is key to understanding the subsidiary role of illuminators/lamps in the PDT treatment market. The Biofrontera Respondents were founded in 1997 by Dr. Hermann Luebbert and Dr. Montserrat Foguet. Dr. Luebbert and Dr. Foguet saw an opportunity to innovate and improve PDT and set Biofrontera on that path in two ways. First, Biofrontera in-licensed and then further developed a nanoemulsion with 5-aminolevulinic acid, or “ALA,” as its active ingredient, creating a shelf-stable and deeper penetrating formulation of ALA, which Biofrontera markets as Ameluz®. Biofrontera

launched Ameluz[®] in Europe in 2011. Second, Biofrontera paired Ameluz[®] with a new photodynamic illuminator using a single panel of LEDs emitting red light that it developed and sold as the RhodoLED[®]. The longer wavelength of red light from the RhodoLED[®] penetrates more deeply into the skin than, for instance, blue light, enabling for treatment of AKs that are deeper within the skin tissue.

After going through the process of obtaining FDA approval, Biofrontera launched Ameluz[®] in combination with the RhodoLED[®] in the U.S. in 2016 and received feedback from physicians that its single panel device could be expanded to cover a larger treatment surface. In light of that feedback, Biofrontera began working on a second LED-based illuminator that illuminated a larger area using the same wavelength and similar technology in 2017. Similar to other illuminators in the field, the RhodoLED[®] XL used LED panels connected by hinges to allow it to more easily accommodate, and more effectively illuminate, different shapes and sizes of heads as well as different parts of the anatomy (*e.g.*, chest, arms, back, etc.). In 2021, after development work and some pandemic delays, Biofrontera received FDA approval for the RhodoLED[®] XL in combination with Ameluz[®]. After resolving some post-pandemic supply chain issues and optimizing its design, Biofrontera launched the RhodoLED[®] XL in June 2024.

Beginning in 1999, Sun Pharma's predecessor in interest, DUSA Pharmaceuticals, Inc. ("DUSA"), began selling a pharmaceutical product called Levulan[®] in combination with a photodynamic illuminator called the BLU-U[®] 4170D for treatment of AKs. As Sun Pharma has acknowledged, the BLU-U[®] 4170D is covered by the claims of U.S. Patent No. 6,223,071 ("Lundahl"), which describes a blue light PDT illuminator that uses fluorescent lightbulbs arrayed in a fixed, U-shape form, with the lightbulbs arranged more closely together in the area that is closer to the top and bottom edges of the claimed illuminator. Lundahl explains that having the

lightbulbs closer together in the areas that are closer to a patient's forehead and chin when the PDT device is used to treat AKs on the face enables the device to provide a uniformity of light on the treatment surface when the device is placed within two to four inches from the treatment surface, which is effective for PDT.

Sun Pharma's investigation here arises from two patents related to (1) incorporating hinges in a multi-panel device to account for the well-known shortcomings of the previous BLU-U[®] design related to its inflexible design; and (2) changing the lightbulbs in its photodynamic illuminator disclosed in Lundahl from fluorescents to LEDs, which had become the market standard and was consistent with government recommendations at the time. In doing so, Sun Pharma is attempting to claim an additional two decades of exclusivity based on patents that the evidence will demonstrate are invalid and not infringed. The "Asserted Patents"—U.S. Patent Nos. 11,446,512 ("the '512 Patent") and 11,697,028 ("the '028 Patent")—recite systems and methods for photodynamically treating or diagnosing patients using a device with five adjustable panels and LED lights connected by hinges. In designing the claimed device, the named inventors simply tried to replicate the light output and treatment methods in the prior BLU-U[®] 4170D device as described in Lundahl, in an effort to bring the product to market through the simplest and cheapest route possible at FDA. Accordingly, many of the claimed output and method steps were directly incorporated from Lundahl.

The Asserted Patents are not infringed for several reasons. First, the claims were narrowed during prosecution to overcome a Section 112 rejection, with virtually all Asserted Claims requiring that the panels are connected by "[nested hinges/hinged structures] on inner side surfaces of adjacent panels." Sun Pharma's infringement position strains the meaning of both the limitations "*on*" and "*inner side surfaces*" beyond both the plain and ordinary meaning of the terms.

Biofrontera's RhodoLED[®] XL panels are not connected by hinges *on* inner side surfaces, but rather are connected by hinges that *extend through* the side surfaces of the panels where they are connected internally. Sun Pharma's claims also require use of "the at least five panels" / "the five panels" of the photodynamic illuminator. However, the label and user manual for Ameluz[®] and the RhodoLED[®] XL, respectively, require the use of only three panels; use of five panels is at a physician's discretion. Sun Pharma will be unable to demonstrate that the panels of RhodoLED[®] XL is positioned within approximately four inches of a patient's treatment surface or that the lights of the illuminator are "individually configurable," as those terms have been construed by the ALJ. Biofrontera thus neither directly infringes the Asserted Claims nor induces infringement of the Asserted Claims.

In addition to not being infringed, all Asserted Claims are invalid as obvious over the combination of U.S. Patent No. 6,223,071 ("Lundahl"), which incorporates U.S. Patent No. U.S. Pat. No. 5,079,262 ("Kennedy") by reference, and U.S. Patent Publication No. 2005/0075703 ("Larsen").¹ As discussed above, Lundahl, which claims the relevant features of Sun Pharma's legacy BLU-U[®] 4170D fixed U-shaped illuminator, expressly discloses many of the limitations set forth in the Asserted Claims, including the use of uniformity of light in PDT treatment, along with the relative spacing of light elements necessary to achieve such uniformity. Lundahl further teaches a treatment distance of two to four inches, use of blue and red light for PDT, and use of ALA in PDT the Lundahl device had shortcomings that would have been recognized by a person of ordinary skill in the art ("POSA") in the prior art timeframe. First, its fixed u-shape design

¹ The Patent Trial and Appeal Board has instituted an inter partes review ("IPR") of the '028 Patent on the grounds described in this prehearing brief. See IPR2024-01312. An IPR petition is pending an institution decision on the '512 Patent, which has claims very similar to those of the '028 Patent. IPR 2025-00287.

would not have accommodated treatment of different shapes and sizes of patients or body parts that also experience AKs. Certainly, the fixed u-shape could not have been used on the chest or backs of most patients, and treatment around the surfaces of smaller body parts, such as legs and arms, would not have been possible at the FDA-approved two to four inches. Second, the fluorescent bulbs used in Lundahl not only had shortcomings from the lack of depth in skin penetration based on the light wavelength produced, but fluorescent bulbs were becoming disfavored across the industry and by government regulatory agencies due to their toxic mercury content. At the same time, LEDs were not only becoming more economical, but they were becoming the preferred light element in the industry due to their higher efficiencies, smaller power requirements, lower heat generation, and better control of output characteristics of light. As a result, a POSA would have been motivated to replace the fluorescent bulbs in Lundahl with LEDs and to create a more flexible device to be used on a wide variety of treatment surface shapes and sizes.

With that motivation in mind, a POSA would have turned to Larsen, which teaches the use of a five-panel LED illuminator in conjunction with photosensitizers, including ALA, for PDT. Larsen specifically teaches the use of five panels in its illuminators, which it refers to as “applicators,” connected by hinges on the inner side surfaces of the applicators. Larsen also teaches use of a range of wavelengths, including the visible light ranges claimed by the Asserted Patents. Accordingly, Lundahl and Larsen together teach most of the claimed elements. To the extent that certain claim elements of the Asserted Patents are not disclosed by Lundahl and Larsen, other analogous prior art references, such as U.S. Publication No. 2010/0118522 (“Hente”) and U.S. Patent No. 4,823,858 (“Perutz”), provide clear disclosures of such elements. As summarized above and explained more fully below, a POSA would have been motivated to

combine the teachings of the prior art to arrive at the device and methods set forth in the Asserted Claims here. Moreover, a POSA would have had a reasonable expectation of success when implementing the distribution of light sources taught by Lundahl using Larsen's LED panels, particularly given the improved control of light output provided by LEDs, in comparison to fluorescent tubes

The Asserted Patents are also invalid under Section 112 for failing to enable or adequately describe a system or method for "photodynamically diagnosing ... a patient." The specification of the Asserted Patents is devoid of teaching or examples that would allow a POSA to diagnose patients without undue experimentation. Sun Pharma seems to acknowledge as much, hanging its hat on third party articles that it alleges would enable a POSA to piece together a way to practice the invention. In fact, Sun Pharma's cited articles just demonstrate the undue experimentation that would be necessary to practice the full scope of the claims. In any event, the thin disclosure and heavy reliance on third party art shows that the inventors themselves were not in possession of the concept of "photodynamically diagnosing ... a patient."

Finally, Sun Pharma's domestic industry arguments are lacking. As described above, practice of both the method claims and the system claims require a "treatment surface" of a patient. Yet, the evidence that the domestic industry product has been used to treat a patient is paper-thin. Indeed, the evidence that the technical prong has been met is based only on hearsay evidence from Sun Pharma's Scott Lundahl, who alleges that somewhere, at some point, some doctor has conducted photodynamic therapy using the Sun Pharma domestic industry product to treat some patient prior to the FDA approval or sale of the product. Sun Pharma's attempt to satisfy the economic prong requirement is based on minimal, stale, hypothetical, and insignificant expenses related to this single product that was not on sale as of the filing of the Complaint, and is still not

on sale today. The claimed expenses are insufficient to show that Sun Pharma has a domestic industry or a domestic industry in the process of being established.

The evidence will show that Biofrontera developed its RhodoLED[®] XL illuminator on its own and that Sun Pharma's Asserted Patents are simply not infringed. Moreover, the Asserted Patents are invalid as obvious, not enabled, and not adequately described. For these reasons, the Commission should find no violation of Section 337 and decline to issue Sun Pharma's requested remedial orders.

A. Procedural History

Sun Pharma filed the Complaint in this case on June 25, 2024, naming Biofrontera entities as Respondents. The Commission instituted the Investigation on July 26, 2024. 89 Fed. Reg. 62790 (Aug. 1, 2024). On August 19, 2024, the ALJ issued an Initial Determination setting a target date of February 2, 2026, and a Final Initial Determination date of October 1, 2025. *See* Order No. 5 (Sep. 16, 2024). The evidentiary hearing is scheduled to take place between June 30 and July 3, 2025. *Id*

The ALJ issued the procedural schedule on September 3, 2024. Order No. 6. The ALJ held a *Markman* hearing on November 21, 2024, and issued a *Markman* Order on March 4, 2025. Order No. 18 (March 4, 2025).

On May 6, 2025, Sun Pharma filed a Corrected Motion for Summary Determination, arguing that it has satisfied the economic prong of the domestic industry requirement. EDIS Doc. No. 850279. Biofrontera filed an opposition to Sun Pharma's Motion on May 16, 2025. EDIS Doc. No. 851468 The ALJ has not yet ruled on Sun Pharma's Motion.

B. The Parties

1. Complainant Sun Pharmaceutical Industries, Inc.

Complainant Sun Pharmaceutical Industries, Inc. is a pharmaceutical company organized under the laws of Delaware and has its principal place of business at Independence Way, Princeton, NJ, 08540. In November 2012 Sun Pharmaceutical Industries, Inc. purchased DUSA Pharmaceutical, Inc., the assignee of the Asserted Patents. JX-0198 (Complaint) ¶ 37. Sun Pharma sells three PDT treatment products, including the BLU-U[®] series of lamps and Levulan[®] prescription medicine. *Id.*; JX-0016C (Albert Dep. Tr.) 38:3-13; CX-0020C (Albert WS) Q/A 8.

2. Respondent Biofrontera Inc.

Respondent Biofrontera Inc. is a biopharmaceutical company organized under the laws of Delaware and located at Woburn Massachusetts. JX-0007C (Leffler Dep. Tr.) 67:2-6. Biofrontera Inc. is a highly innovative dermatology company in the field of dermatology, including photodynamic therapy and topical antibiotics. Biofrontera's goal is to advance patient care in collaboration with dermatologists. RX-1383 ("Products," Biofrontera website). Biofrontera Inc. accomplishes this goal through its FDA-approved combination treatment of its photodynamic illuminators, RhodoLED[®] or RhodoLED[®] XL, and Ameluz[®] for actinic keratoses. RX-1175 (Biofrontera Announces U.S. FDA Approval). Biofrontera Inc. is a separate, independent entity from Biofrontera AG. JX-0008C (Luebbert Dep. Tr.) 31:4-7; RX-0004C (Luebbert WS) Q/A 11. Biofrontera Inc. is an independent company that was spun out from Biofrontera AG in 2021. Biofrontera Inc. has a licensing agreement with Biofrontera AG to purchase and sell Ameluz[®] and the RhodoLED[®] series of lamps in the United States. JX-0007C, 25:20-26:13; RX-0003C (Leffler WS) Q/A 9.

3. Respondent Biofrontera AG

Respondent Biofrontera AG is a German pharmaceutical company organized under the laws of Germany and has a principal place of business at Hemmelrather Weg 201, 51377, Leverkusen, Germany. Biofrontera AG is an independent entity, separate from Biofrontera Inc.

JX-0008C, 31:4-7; RX-0004C, Q/A 11; JX-0011C (Foguet Dep. Tr. Vol. 1) 28:19-22; RX-0002C (Foguet WS) Q/A 26. Biofrontera AG sells the RhodoLED[®] XL lamps to Biofrontera Inc. *Id.* at 57:15-17.

4. Respondent Biofrontera Pharma GmbH

Respondent Biofrontera Pharma GmbH is a wholly owned subsidiary of Biofrontera AG. JX-0011C, 28:16-18; RX-0002C, Q/A 26. Biofrontera Pharma GmbH is responsible for the manufacture of the RhodoLED[®] XL for sale to Biofrontera Inc. JX-0008C, 35:2-6.

5. Respondent Biofrontera Bioscience GmbH

Respondent Biofrontera Bioscience GmbH is also a wholly owned German subsidiary of Biofrontera AG. JX-0011C, 28:16-18. Biofrontera Bioscience GmbH carries out research, development tasks and regulatory functions for the Biofrontera Group and holds the patents and FDA regulatory approvals for Ameluz[®] as well as BF-RhodoLED[®] series of lamps. *Id.* Biofrontera Bioscience GmbH is also the sole manufacturer Ameluz[®]. JX-0008C, 36:2-6.

C. Overview of the Technology

Phototherapy is the use of light—either ultraviolet, visible or infrared—for the treatment of disease. Today, phototherapy employing red or infrared light at low levels is commonly used to treat cold sores, reduce acne breakouts, and stimulate muscle recovery; while ultraviolet light is routinely used to treat skin disorders such as psoriasis and eczema, through a process called photobiomodulation. The prime targets of medicine, however, are pre-cancers and cancers of all types; and the cure rather than the mitigation of disease. To achieve these goals, the more potent *photodynamic therapy* (PDT) is utilized.

PDT is a subgroup of phototherapy that utilizes light to activate a photosensitive compound on or within the body to achieve a beneficial therapeutic effect. These photosensitive compounds are called photosensitizers, which upon local or systemic application to a patient, preferentially

accumulate in pre-cancerous and cancerous tissues. The photosensitizer molecules absorb light of the appropriate wavelength, inducing photocytotoxic reactions that lead to the destruction of the undesired cells. These reactions therefore occur only within the pathological tissues in the area of photosensitizer distribution and light illumination, thereby selectively destroying the precancerous or cancerous tissue. RX-1359 (Agostinis, P et al. Photodynamic Therapy of Cancer: An Update. CA Cancer J Clin.2011; 61(4): 250-281).

PDT has been known in the art and used for decades. PDT typically uses a light source with sufficient irradiance within a narrow wavelength band. While some lasers and PDT illuminators of the 1990s had the requisite power and wavelength tunability to precisely match photosensitizer absorption bands, their cost and size impeded progress in PDT. Fortunately, concurrent development of solid-state light-emitting diodes (LEDs) and laser diodes (or diode lasers) quite effectively removed this limitation. With low cost, long lifetimes and adequate power, LEDs became the obvious replacement for previous illumination sources, including fluorescent tubes. For PDT, LEDs with output wavelengths in the blue (~400-450 nm) and/or in the red (~600-690 nm) were rapidly designed to be relatively inexpensive, compact illumination sources for PDT. For instance, Sun Pharma's BLU-U® 4170D and BLU-U® 4170E emit light in the blue range at a 417nm wavelength. JX-0091C.6 (BLU-U® Blue Light Photodynamic Therapy Illuminator Model 4170E Operating Manual). Biofrontera's RhodoLED® and RhodoLED® XL emit light in the red range at a 635nm wavelength. JX-0072C.7 (RhodoLED® XL User Manual).

As PDT has progressed, newer topical photosensitizers using 5-aminolevulinic acid ("ALA"), such as Sun Pharma's Levulan® and Biofrontera's Ameluz®, have been utilized successfully for both the effective treatment of actinic keratosis (AKs) and off-label treatment of severe acne. AKs are scaly dermatological lesions caused by exposure to sun or ultraviolet light.

Left untreated, AKs may develop into skin cancer (specifically squamous cell carcinoma, or “SCC”). With AKs in particular, photodynamic therapy (“PDT”) operates by applying a pharmaceutical compound of photosensitizing acid—in the present case, 5-aminolevulinic acid, or “ALA”—to the treatment surface on a patient’s skin. After an incubation period, the patient’s treatment surface is illuminated by a carefully positioned photodynamic illuminator that deposits a predetermined dose of light energy on the treatment surface. ALA, which is converted to protoporphyrin IX (“PPIX”) in cells, releases reactive oxygen species that destroy the AK cells. For either application, the response of the AK or acne lesion depends on the uptake of the photosensitizer, the irradiance (in W/cm² or mW/cm², the rate at which energy is delivered per unit area of skin), and the wavelength of the light source. Assuming that the drug uptake by individual lesions is similar, uniform efficacy then depends on the uniformity of the irradiance and the wavelength on the skin’s surface.

The use of ALA and PDT in combination has been known for decades, and, for instance, was described in RX-1354.0005-6 (S. Silapunt et al., Topical and Light-based Treatments for Actinic Keratoses, Seminars in Cutaneous Medicine and Surgery, Vol 22, No 3 (2003)). When using PDT to treat AKs, topical ALA is applied to skin with AK lesions and subsequently covered with a dressing or bandage or saran wrap for an incubation period. For instance, Sun Pharma’s Levulan[®] label states it has an incubation period of 14-18 hours for the face or scalp and 3 hours for upper extremities, whereas Biofrontera’s Ameluz[®] label states it has an incubation period of 3 hours for all applications. See JX.0197C.3 (Levulan[®] label), JX-0074.4 (Ameluz[®] label). Light is then applied to the patient’s skin.

Once applied, ALA diffuses within the skin and accumulates in tumors and dysplastic cells, wherein it is converted into the endogenous photosensitizer protoporphyrin IX (PpIX). PpIX

absorbs light in the “400-700 nm wavelength, with maximal absorption at 410, 630, and 690 nm wavelengths, but corresponding decrease in light penetration into the skin from 6 mm at 630 nm to 1.5 mm at 410 nm.” RX-1354.0005-6. When light at these wavelengths is applied to the cells treated with ALA, oxygen dependent cytotoxic reactions occur that kill the treated cells that preferentially accumulate ALA and the reactive product PpIX. PpIX is then cleared from the cells over the course of 48 hours. *Id.*

Effective PDT is also dependent on achieving a sufficiently uniform irradiance emitted by the light source. Accordingly, the design of the light source itself plays an important role in treating AKs and other conditions with PDT. As an example, if a light source has a consistent intensity and wavelength output across its entire output surface, the resultant field of illumination necessarily decreases in brightness around the edges of the illuminated field. Because of this decrease in brightness, these edge areas receive a lower irradiance than the center of the illumination field. For a rectangular light source, a greater decrease in illumination occurs at the edges in the light’s narrow dimension. CX-1333C at 126:12-128:17 (Grove Dep. Tr.). To at least partially compensate for this non-uniform illumination, the lamp can be designed to be “brighter” (*i.e.*, to emit light at a greater intensity) near its edges in the narrow dimension than from its center (e.g., towards the edge closes to the chin and forehead when positioned near a face). For a single rectangular light source, this would mean increasing the intensity near the longer edge of the rectangle. But where a series of rectangular light sources are arranged with their longer edges side by side, this would mean increasing the intensity near the shorter edges of the light sources. *Id.* In either case, the area of the field of illumination having more uniform illumination would be significantly increased.

As another example, if a PDT lamp were to use horizontal fluorescent tubes, the spacing between tubes could be reduced near the top and bottom of the lamp, or extra tubes could be added to improve uniformity. For instance, Lundahl teaches:

The number of tubes used and the spacing between them were chosen to achieve desired uniformity and power output specifications. Optimum output distribution has been found to occur when seven tubes 10(1)–10(7) are placed in the chassis in a symmetric pattern with respect to opposite edges of the unit with the following approximate lateral spacing: 7 cm between the center tube 10(4) and each of the two tubes 10(3), 10(5) adjacent to the center tube 10(4); 5 cm between the tubes 10(3), 10(2) and 10(5), 10(6), i.e., the next pairs of tubes out from the center; and 3.5 cm between tubes 10(2), 10(1) and 10(6), 10(7).

RX-0065(Lundahl), 6:43-54. Similarly, if the lamp consists of a rectangular panel or panels of many LEDs, the number or density of LEDs could be increased near the upper and lower edges of the panel(s).

For illumination of the face specifically, a U-shaped collection of fluorescent tubes (like the DUSA BLU-U[®], described in Lundahl, or an array of hinged, rectangular panels with numerous LEDs such as Larsen can be utilized. See RX-0065 and RX-0099 (Larsen). Each approach requires appropriate placement of the individual light sources, either tubes or LEDs, to minimize the variation in irradiance on the face.

D. The Asserted Patents

1. The '512 Patent

i. Priority Dates

The '512 Patent claims priority to several earlier patent applications, the earliest of which, U.S. Provisional Application No. 62/241,902, was filed on October 15, 2015. '512 Patent, 1:8-13.

Sun Pharma has not asserted a priority date that would be earlier than October 15, 2015. RX-0006C, Q/A 59. Biofrontera does not concede that any claims of the '512 Patent should be

accorded this priority date. Even still, the references relied upon were all published well before October 15, 2015. RX-0006C, Q/A 87-88, 105-106, 117-118, 125-126, 134-135.

ii. *The '512 Patent's Specification*

The '512 Patent uses the acronyms "PDT" and "PD" for the terms "photodynamic therapy" and "photodynamic diagnosis" respectively. The '512 Patent further explains the general approach for PDT or PD. "[A] patient is first administered a photoactivatable agent or a precursor of a photoactivatable agent that accumulates in the tissue to be treated or diagnosed. The area in which the photoactivatable agent is administered is then exposed to visible light, which causes chemical and/or biological changes in the agent. These changes allow the agent to then selectively locate, destroy, or alter the target tissue while, at the same time, causing only mild and reversible damage to other tissues in the treatment area." JX-0001 ('512 Patent), 1:34-43.

The '512 Patent teaches that it is desirable for the power output to be uniform. "For effective treatment, it is desirable to have a power output that is uniform in intensity and color." JX-0001, 1:48-49.

The '512 Patent also teaches that adjusting the power input to certain areas of panels is one way to improve uniformity. "In order to even further reduce or eliminate optical dead spaces, it is preferable that the light sources on each of the panels are individually configurable to provide specific power output to certain areas of the light sources on the panels to compensate for decreased uniformity. For example, the power outputted to each individual diode in an array of light emitting diodes (LED) may be individually adjusted." JX-0001, 3:12-19.

The '512 Patent also teaches that light exposure will decrease with increased distance from the light source (*i.e.*, panel). "In addition, 'fall off' increases as the distance between the light source and the point on the surface increases." JX-0001, 6:6-8.

In order to compensate for intensity fall off and improve uniformity, the '512 Patent teaches changing the intensity of some LEDs to compensate for fall off. "In order to increase the uniformity of light exposure to the treatment area while maintaining a practical size of the illuminator, the LED arrays 60 may be individually configured to increase the intensity of light emitting from certain diodes to compensate for this fall-off effect." JX-0001, 6:16-21.

Specifically, the '512 Patent teaches increasing the intensity of light emitted from LEDs at the edges of panels. "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. Thus, a higher intensity of light is emitted overall from the edges, which may allow for a reduction in any fall-off effect." JX-0001, 6:30-38.

Exemplary embodiments of the '512 Patent are described as being able to achieve uniformities of 60% to 80%. "In one embodiment, the measured output over the active emitting area (over the entire active emitting area) is within 60% of the measured maximum (over the entire active emitting area) measured with a cosine response detector over all operation distances. More preferably, the measured output over the emitting area is within 70% of the measured maximum over a distance of two and four inches. Even more preferably, the measured output over the emitting area is within 80% of the measured maximum over a distance of two and four inches." JX-0001, 8:54-63.

iii. The '512 Patent's Prosecution History

Sun Pharma filed the '512 Patent on February 14, 2020, as application number 16/791,004. The '512 patent is a divisional application of Application No. 15/292,731, filed on October 13,

2016, now granted as U.S. Patent No. 10,589,122, which claims the benefit of priority to U.S. Provisional Application No. 62/241,902, filed October 15, 2015. JX-0001, 1:8-13.

In a non-final office action mailed on October 25, 2021, the USPTO rejected the claims as follows:

- (i) claims 1-20 under §112 as being indefinite for failing to particularly point out and distinctly claim the subject matter regarded as the invention, including claims 1 and 6 for the unclear claim limitation “nested hinges configured to reduce optical dead space” for failing to define the metes and bounds of the claims²;
- (ii) claims 1, 2, 6, 7, 13, 18, and 19 under §102 as being anticipated by U.S. Application Publication No. 2007/0283655 (Tobin);
- (ii) claims 1, 2, 5-7, and 18 under §102 as being anticipated by U.S. Application Publication No. 2005/0075703 (Larsen);
- (iii) claims 3-5 under §103 as being unpatentable over Tobin in view of U.S. Application Publication No. 2003/0216795 (Harth);
- (iv) claims 11, 12, and 14-17 under §103 as being unpatentable over Tobin in view of U.S. Application Publication No. 2013/0066404 (Tapper);
- (v) claims 3 and 4 under §103 as being unpatentable over Larsen in view of Harth;
- (vi) claims 11, 12, and 14-17 under §103 as being unpatentable over Larsen in view of Tapper; and
- (vii) claim 20 under §103 as being unpatentable over Larsen. Additionally, the disclosure was objected to for not indicating the present status of all applications referred to therein.

JX-0004, 551-560.

Sun Pharma filed a response on February 25, 2022, in which claims 1, 3, 6, and 18-20 were amended, claims 7-10 were cancelled, and claims 21-24 were newly added. JX-0004, 1638-1641. Additionally, paragraph [0001] of the specification was revised. JX-0004, 1637. The claims were amended as shown and described below:

² The USPTO rejected this unclear claim limitation because it was unknown what the optical space was compared to in order to have been “reduced”. Despite this rejection, and Sun Pharma’s subsequent amendment of claims 1 and 6 to remove this limitation, Sun Pharma has referenced “optical dead space” as related to the hinge structures in the present proceeding.

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions and listings of claims in the application:

1. (Currently Amended) A system for photodynamically diagnosing or treating a patient, comprising:
 - an illuminator comprising at least five panels connected by nested hinges on inner side surfaces of adjacent panels ~~configured to reduce optical dead space~~,
 - light sources disposed on surfaces of the at least five panels ~~a surface of the illuminator~~, the illuminator being configured to uniformly illuminate a treatment surface of the patient via the light sources,
 - one of the at least five panels positioned as a center panel configured to face the treatment surface, and two or more of the at least five panels being configured to be angled relative to the center panel,
 - wherein each of the at least five panels has two first edges and two second edges shorter than the two first edges, and the light sources are arranged such that a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges.

JX-0004, 1638.

Sun Pharma amended independent claim 1, directed to a system for photodynamically diagnosing or treating a patient, to include: (1) the “nested hinges” connecting the at least five panels of the illuminator being “on inner side surfaces of adjacent panels”; (2) the light sources being disposed on “surfaces of the at least five panels”; and (3) “wherein each of the at least five panels has two first edges and two second edges shorter than the two first edges, and the light sources are arranged such that a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges”. RX-0006C, Q/A 74. Additionally, Sun Pharma amended independent claim 1 to remove the limitation “configured to

reduce optical dead space” to overcome the Section 112 rejection that this limitation makes the metes and bounds of the claim unclear. JX-0004, 1643.

Sun Pharma amended independent claim 6, directed to a method of photodynamically diagnosing or treating a patient, to include the same limitations it amended in claim 1. Additionally, claim 6 was amended to include a method step of “administering 5-aminolevulinic acid (ALA) to the patient” as the first step of the claimed method. JX-0004. Further, Sun Pharma amended independent claim 6 to remove the unclear limitation “configured to reduce optical dead space,” similar to claim 1. JX-0004, 1638-1640.

Sun Pharma asserted that the added limitation of “wherein each of the at least five panels has two first edges and two second edges shorter than the two first edges, and the light sources are arranged such that a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges” overcame the §102 rejections over Tobin and Larsen. JX-0004, 1643-1644. Specifically, Sun Pharma argued that neither Tobin nor Larsen discloses or teaches an illuminator with light sources arranged so as to provide a higher intensity of light emitted proximate second edges of the panels, which are shorter than first edges of the panels, as compared to the intensity of light emitted not proximate the second edges. JX-0004, 1643-1644. Additionally, Sun Pharma’s response asserted that claims 1 and 6 as amended, and the claims depending therefrom, overcame the §103 rejections over Tobin and Larsen in view of Harth and Tapper. JX-0004, 1643-1644.

The USPTO mailed a notice of allowability on May 16, 2022, allowing claims 1-6 and 11-24. JX-0004. In the reasons for allowance, the examiner indicated that the art of record neither anticipates nor renders obvious two elements: (1) “nested hinges on inner side surfaces of adjacent panels” and (2) “wherein each of the at least five panels has two first edges and two second edges

shorter than the two first edges, and the light sources are arranged such that a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges” in combination with the rest of the claimed limitations set forth in the independent claim. JX-0004.

2. The '028 Patent

i. Priority Dates

Like the '512 Patent, the '028 Patent claims priority to several earlier patent applications, the earliest of which, U.S. Provisional Application No. 62/241,902, was filed on October 15, 2015, the same provisional application to which the '512 Patent claims priority. JX-0002 ('028 Patent), 1:8-15.

There is no assertion of a priority date that would be earlier than October 15, 2015. RX-0006C, Q/A 59. Biofrontera does not concede that any claims of the '028 Patent should be accorded this priority date. Even still, the references relied upon were all published well before October 15, 2015. RX-0006C, Q/A 87-88, 105-106, 117-118, 125-126, 134-135.

ii. The '028 Patent's Specification

The '028 Patent shares a specification with the '512 Patent and, in all material respects, the text and figures of the specification are identical. Order No. 18, 12, n. 4. For purposes of this briefing, we cite to the specification of the '512 Patent.

iii. The '028 Patent's Prosecution History

The '028 Patent is a continuation of, and shares much with, the '512 Patent's prosecution history. The '028 Patent was filed on September 12, 2022, as application number 17/942,353. The '028 patent is a continuation application of U.S. Application No. 16/791,004 ('004 Application), filed February 14, 2020, now granted as the '512 Patent. The '004 Application is a divisional application of U.S. Application No. 15/292,731, filed October 13, 2016, now granted as U.S. Pat.

No. 10,589,122, which claims the benefit of priority to U.S. Provisional Application No. 62/241,902, filed October 15, 2015. JX-0002, 1:8-15.

In a non-final office action mailed on November 18, 2022, the examiner rejected the claims as follows: (i) claim 2 under §112 as being indefinite for failing to particularly point out and distinctly claim the subject matter regarded as the invention by using the relative term “about” in reference to values of a range without defining the term in the claim or specification; (ii) claims 18 and 20-22 under §103 as being unpatentable over U.S. Pat. No. 7,033,381 (Larsen) in view of U.S. Application Publication No. 2006/0253175 (Fan); and (iii) claims 18 and 20-22 under §103 as being unpatentable over Fan. JX-0003, 129-133.

Additionally, the examiner objected to the disclosure for not indicating the present status of all applications referred to therein. Claims 1, 2, 4, 5, 7, 8, and 10-17 were rejected on the ground of nonstatutory double patenting as being unpatentable over claims (1 and 2), 3-5, (8 and 2), 3, 16, 19, 9, 12, 10, 11, 13, and 14 of the ’512 Patent. JX-0003, 134-135. Claims 3, 6, 9, and 19 were objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. JX-0003, 135.

Sun Pharma filed a response on February 16, 2023, in which claims 1, 2, 7, 18, and 20 were amended, claims 3, 6, and 19 were cancelled, and claims 23 and 24 were newly added. JX-0003, 438-442. Additionally, paragraph [0001] of the specification was revised. JX-0003, 437. The claims were amended as described below. Sun Pharma submitted a terminal disclaimer over the ’512 Patent with its response. JX-0003, 444.

Sun Pharma amended independent claim 1, directed to a system for photodynamically diagnosing or treating a patient, and independent claim 7, directed to a method of

photodynamically diagnosing or treating a patient, to narrow the description of the illuminator, amending from the illuminator “comprising at least five panels” to “comprising five panels”. JX-0003, 438-442.

Sun Pharma amended independent claim 18, directed to a system for photodynamically diagnosing or treating a patient, to narrow the description of the illuminator as specified above for claims 1 and 7. JX-0003, 438-442. Additionally, Sun Pharma amended claim 18 to include “each of the five panels having two first edges and two second edges shorter than the two first edges, the light sources arranged such that a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges”. JX-0003, 438-442.

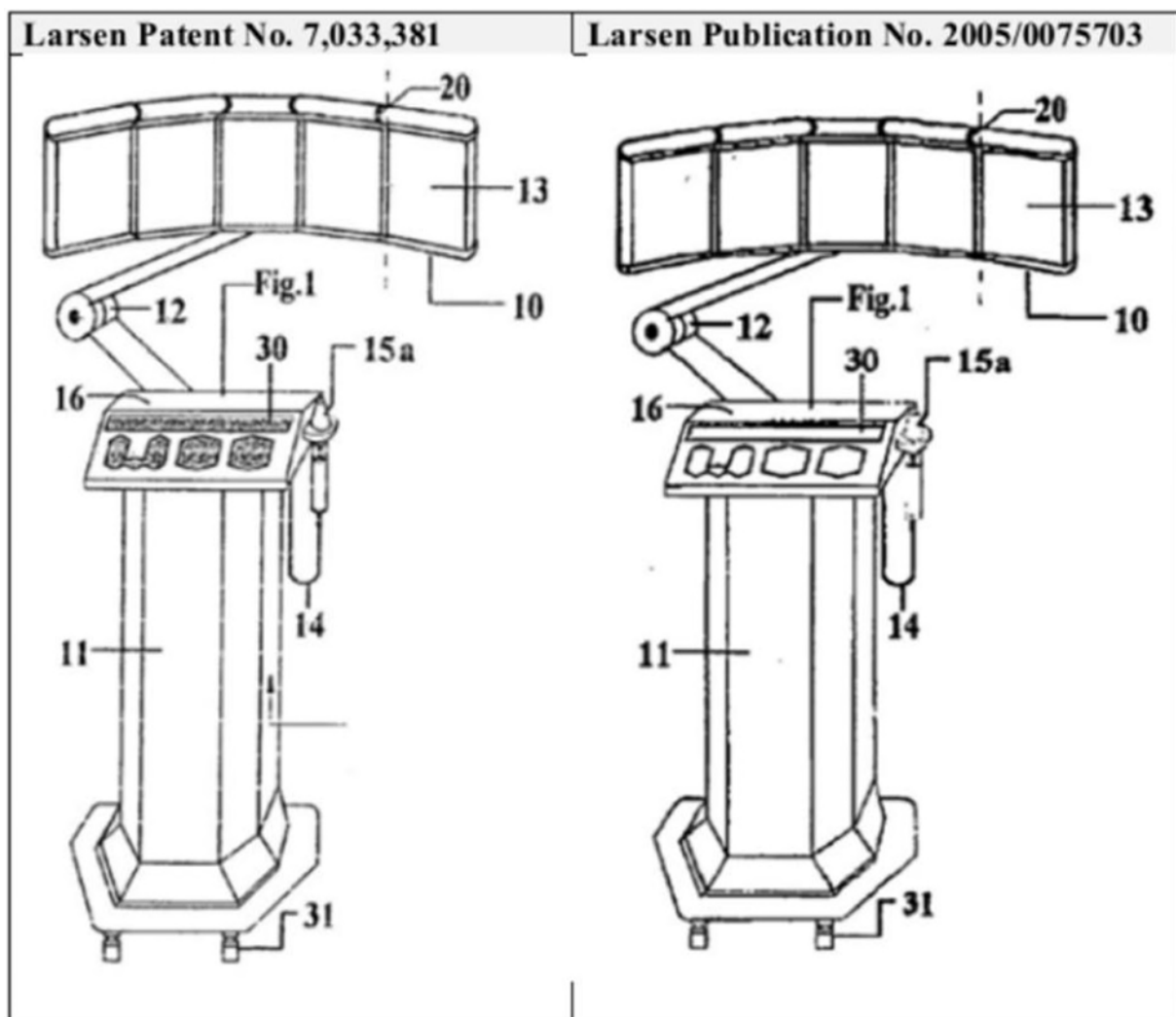
Sun Pharma’s response asserted that independent claim 18 was amended to recite subject matter relating to dependent claim 19, indicated as allowable, for claim 18, and the claims depending therefrom, to overcome the §103 rejections over Larsen and Fan. JX-0003, 444.

The USPTO mailed a notice of allowability on March 1, 2023, allowing claims 1, 2, 4, 5, 7-18, and 20-24. JX-0003, 446-453. In the reasons for allowance, the examiner indicated that the art of record neither anticipates nor renders obvious “wherein each of the five panels has two first edges and two second edges shorter than the two first edges, and the light sources are arranged such that a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges” in combination with the rest of the claimed limitations set forth in the independent claim. JX-0003, 452.

During prosecution of the ’028 Patent, the examiner cited a daughter patent of the Larsen reference (U.S. Patent No. 7,033,381) which included a figure 1 identical to that of the Larsen reference cited here. JX-0003, 130-131. The examiner found “Claims 18 and 20-22 are rejected under 35 U.S.C 103 as unpatentable over Larsen (U.S. Patent No. 7,033,381, cited by Applicant in

view of Fan et al. (U.S. 2006/0253175, cited by Applicant). Regarding claim 18, Larsen discloses a system for photodynamically diagnosing or treating a patient (see Abstract), comprising: a mobile base supported by at least four wheels 31 (see base shown in Figure 1 and wheels 31 shown and described in col. 5, lines 14-15, where although only two wheels are shown, it is inherent that there are at least two more wheels, for a total of 4, in order for the device to be stable); a pillar 11 perpendicular to the base (see Figure 1); a controller 16 disposed to be supported by the pillar (see Figure 1); and an illuminator connected at an end of the arm (shown by five interconnected panels 13 in Figure 1), the arm being hinged to allow adjustment of a position of the illuminator relative to the base (see Figures 1 and 3 which show the hinged arm and joints/hinges 25/26/27), the illuminator comprising at least five panels 13 connected by hinged structures 10 (see Figure 1 and col. 5, lines 44-47) to allow continuous illumination across the at least five panels, wherein the at least five panels are individually configurable to control illumination from each of the at least five panels (see col. 5, lines 19-22, which describes that the panels can be controlled individually), light sources 17 disposed on surfaces of the at least five panels, the illuminator being configured to uniformly illuminate a treatment surface of the patient via the light sources, the light sources being configured to output light uniformly during at least part of a time when the treatment surface is illuminated (see col. 6, lines 14-22, where the ‘constant effect’ described is considered the claimed ‘configured to uniformly illuminate.’ JX-0003, 130-131; RX-0006C, Q/A 78.

For reference, Fig. 1 of both Larsen references is reproduced below. As can be seen, the figures are identical. Both Larsen references share much of the same disclosure. RX-0006C, Q/A 252.



E. The Products at Issue

1. Biofrontera's Product

Biofrontera's RhodoLED[®] XL device is accused of infringing the Asserted Claims of the '512 and '028 Patents (the "Accused Product"), either on its own or in combination with Biofrontera's Ameluz[®] prescription medicine.

Ameluz[®], a topical gel with the active ingredient 5-aminolevulinic acid ("ALA"), is used with the RhodoLED[®] XL or its predecessor device, the BF-RhodoLED[®], for photodynamic therapy. JX-0194C.1 (Ameluz[®] Prescribing Information). Specifically, Ameluz[®] is a porphyrin precursor that when used in combination with the BF-RhodoLED[®] or RhodoLED[®] XL is indicated

for lesion-directed and field-directed treatment of actinic keratoses of mild-to-moderate severity on the face and scalp. JX-0194C.2, 6. Ameluz[®] first received approval in Europe in December 2011 and subsequently gained FDA approval in the United States in May 2016, initially for use with the BF-RhodoLED[®], Biofrontera's first generation photodynamic illuminator. RX-0002C, Q/A 14, 19.

Shortly afterwards, in September 2017, Biofrontera began developing the RhodoLED[®] XL, which is the latest advancement following the BF-RhodoLED[®], and it gained FDA approval for RhodoLED[®] XL in 2021. RX-0004C, Q/A 51, 67. Both generations of the illuminator are LED lamps that use red light, which penetrates the skin more deeply than blue light and reaches abnormal cells deeper in the epidermis. *Id.* at Q/A 36-37. There are several distinctions between the BF-RhodoLED[®] and the RhodoLED[®] XL, one being that the BF-RhodoLED[®] utilizes a single panel of LEDs, whereas the RhodoLED[®] XL features five panels. *Id.* at Q/A 58. Further, the arrangement of LEDs is slightly different on the panels of the respective lamps, as is the treatment distance, the power output, and the treatment time. *Id.* at Q/A 60. The five panels of the RhodoLED[®] XL enable simultaneous treatment of various areas of the face and scalp, though it is not uncommon to employ fewer panels (i.e., three panels) in practice. *Id.* at Q/A 66. The BF-RhodoLED[®] and the RhodoLED[®] XL are currently the only FDA-approved red light photodynamic illuminators approved for use with Ameluz[®] and the only red-light FDA-approved PDT illuminators. *Id.* at Q/A 130.

2. Domestic Industry Product

Sun Pharma alleged that its BLU-U[®] 4170E device individually, or in combination with Sun Pharma's Levulan[®] Kerastick, practices each of the Asserted Patents. RX-0013C (Jokerst Rpt.) ¶ 140; CX-0016C (Vander Veen WS) Q/A 27. The BLU-U[®] 4170E device is a lamp with five LED panels "designed to provide a uniform distribution of blue light to areas of the patient's

face, scalp or upper extremities.” CX-0355C (Model 4170E Operating Manual). The FDA approved the use of single-panel BLU-U® 4170D in combination with Levulan® for treatment of non-hyperkeratotic actinic keratosis (“AK”) of the face or scalp in December 1999. CX-1221 (FDA PMA Approval Letter, P990019A). As of the filing of the Complaint, Sun Pharma had received FDA approval to market the BLU-U® 4170E on its own, but not in combination with Levulan®. JX-0198, ¶ 45. On May 1, 2025, the FDA approved the BLU-U® 4170E for use in combination with Levulan®. CX-1343.1 (FDA Premarket Approval for BLU-U® Model 4170E).

II. JURISDICTION AND IMPORTATION

A. Subject Matter, Personal, and Statutory Jurisdiction

Section 337 confers subject matter jurisdiction on the Commission to investigate, and if appropriate, to provide a remedy for, unfair acts and unfair methods of competition in importation, the sale for importation, or the sale after importation of articles into the United States. *See* 19 U.S.C. §§ 1337(a)(1)(B)(i), (C), (a)(2). Biofrontera does not contest the subject matter jurisdiction of the Commission to adjudicate this Investigation and Biofrontera has submitted to the personal jurisdiction of the Commission through its participation in this Investigation. Furthermore, Biofrontera notes that, to the extent that “the terms ‘subject matter jurisdiction,’ ‘personal jurisdiction,’ and ‘in rem jurisdiction’ are not necessarily applicable to the Commission’s investigative authority under section 337” Biofrontera does not contest that the Commission has statutory authority to investigate Biofrontera’s alleged violation of section 337.

B. In Rem Jurisdiction and Importation

Biofrontera does not contest that the Commission has *in rem* jurisdiction over Biofrontera’s Accused Product. Biofrontera has entered a joint stipulation with Sun Pharma that it has imported into the United States the Accused Product identified in that stipulation. *See* Updated Joint Stipulation of Importation and Inventory at 2 (Jan. 2, 2024) (EDIS Doc. No. 840393). Therefore,

Biofrontera does not contest that the importation requirement has been satisfied in this Investigation as to the identified Accused Product.

III. CLAIM CONSTRUCTION

A. The Asserted Claims

Sun Pharma is asserting claims 1, 3, 5, 8, 17-18, and 20 of the '512 Patent and claims 1-2, 4, 16-17, 19-21 of the '028 Patent (collectively "Asserted Claims"). As of April 17, 2025, Sun Pharma is no longer asserting infringement of claims 5 and 6 of the '028 Patent, which were initially asserted against Biofrontera in this investigation. JX-0198, ¶ 3.

1. Asserted Claims of the '512 Patent

The Asserted Claims of the '512 Patent are reproduced below in their entirety:

1. A system for photodynamically diagnosing or treating a patient, comprising:

an illuminator comprising at least five panels connected by nested hinges on inner side surfaces of adjacent panels,

light sources disposed on surfaces of the at least five panels, the illuminator being configured to uniformly illuminate a treatment surface of the patient via the light sources,

one of the at least five panels positioned as a center panel configured to face the treatment surface, and two or more of the at least five panels being configured to be angled relative to the center panel,

wherein each of the at least five panels has two first edges and two second edges shorter than the two first edges, and the light sources are arranged such that a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges.

3. The system of claim 1, wherein the illuminator is configured to output red light at a dose of about 30 J/cm² to about 150 J/cm².

5. The system of claim 1, wherein a plurality of the light sources are configured to emit light having a wavelength in a range of 400 nm to 700 nm.

8. A method of photodynamically diagnosing or treating a patient, comprising: administering 5-aminolevulinic acid (ALA) to the patient;

positioning an illuminator proximate to the patient, the illuminator comprising at least five panels connected by nested hinges on inner side surfaces of adjacent panels; and

uniformly illuminating a treatment surface of the patient with light sources disposed on the at least five panels of the illuminator,

wherein each of the at least five panels has two first edges and two second edges shorter than the two first edges, and the light sources are arranged such that a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges.

17. The method of claim 8, wherein at least one panel includes a recess configured to receive a flange of one of the nested hinges.

18. The method of claim 17, wherein the recess is positioned at an inner side surface of the at least one panel.

20. A system for photodynamically diagnosing or treating a patient, comprising: an illuminator comprising at least five panels connected by nested hinges on inner side surfaces of adjacent panels, the nested hinges being configured so as to allow continuous illumination across the at least five panels, light sources disposed on surfaces of the at least five panels, the illuminator being configured to uniformly illuminate a treatment surface of the patient via the light sources,

one of the at least five panels positioned as a center panel configured to face the treatment surface, and two or more of the at least five panels being configured to be angled relative to the center panel,

wherein each of the at least five panels has two first edges and two second edges shorter than the two first edges, and the light sources are arranged such that a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges.

2. Asserted Claims of the '028 Patent

The Asserted Claims of the '028 Patent are reproduced below in their entirety:

1. A system for photodynamically diagnosing or treating a patient, comprising: an illuminator comprising five panels connected by hinged structures on inner side surfaces of adjacent panels; and

light sources disposed on surfaces of the five panels, the illuminator being configured to uniformly illuminate a treatment surface of the patient via the light sources,

one of the five panels being positioned as a center panel configured to face the treatment surface, and two or more of the five panels being configured to be angled relative to the center panel,

wherein the five panels are positioned to allow treatment within approximately four inches of the treatment surface, and

wherein each of the five panels has two first edges and two second edges shorter than the two first edges, and the light sources are arranged such that a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges.

2. The system of claim 1, wherein the illuminator is configured to output red light at a dose of 30 J/cm² to 150 J/cm².

4. The system of claim 1, wherein a plurality of the light sources are configured to emit light having a wavelength in a range of 400 nm to 700 nm.

16. A system for photodynamically diagnosing or treating a patient, comprising:
a mobile base supported by at least four wheels;

a pillar perpendicular to the base;

a controller disposed to be supported by the pillar;

an arm mounted to a top portion of the pillar; and

an illuminator connected at an end of the arm, the arm being hinged to allow adjustment of a position of the illuminator relative to the base, the illuminator comprising:

five panels connected by hinged structures to allow continuous illumination across the five panels, wherein the five panels are individually configurable to control illumination from each of the five panels,

light sources disposed on surfaces of the five panels, the illuminator being configured to uniformly illuminate a treatment surface of the patient via the light sources, the light sources being configured to output light uniformly during at least part of a time when the treatment surface is illuminated, each of the five panels having two first edges and two second edges shorter than the two first edges, the light sources arranged such that a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges, and

one or more fans mounted to at least one of the five panels.

17. The system of claim 16, wherein one of the five panels is positioned as a center panel configured to face the treatment surface, and two or more of the five panels are configured to be angled relative to the center panel.

19. The system of claim 16, wherein the light sources are configured to output red light during at least part of the time when the treatment surface is illuminated.

20. A system for photodynamically diagnosing or treating a patient, comprising:

an illuminator comprising five panels connected by hinged structures on inner side surfaces of adjacent panels, wherein the illuminator is configured to output light at a variable irradiance density during treatment; and

light sources disposed on surfaces of the five panels, the illuminator being configured to uniformly illuminate a treatment surface of the patient via the light sources,

one of the five panels being positioned as a center panel configured to face the treatment surface, and two or more of the five panels being configured to be angled relative to the center panel,

wherein the five panels are positioned to allow treatment within approximately four inches of the treatment surface, and

wherein each of the five panels has two first edges and two second edges shorter than the two first edges, and the light sources are arranged such that a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges.

21. A system for photodynamically diagnosing or treating a patient, comprising: an illuminator comprising five panels connected by hinged structures on inner side surfaces of adjacent panels; and

light sources disposed on surfaces of the five panels, the illuminator being configured to uniformly illuminate a treatment surface of the patient via the light sources,

one of the five panels being positioned as a center panel configured to face the treatment surface, and two or more of the five panels being configured to be angled relative to the center panel,

wherein the five panels are positioned to allow treatment within approximately four inches of the treatment surface,

wherein the five panels are individually configurable to control illumination from each of the five panels, and

wherein each of the five panels has two first edges and two second edges shorter than the two first edges, and the light sources are arranged such that a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges.

B. Claim Construction

During claim construction in this investigation, the parties agreed to the below constructions, which were adopted by the ALJ, and submitted briefing and supporting expert declarations as to the remaining disputed terms.

Claim Term	Relevant Claims	Parties' Agreed Construction
"uniformly illuminate a treatment surface"	'028 patent: claims 1, 16, 20, 21 '512 patent: claims 1, 2, 20	"irradiating light over the active emitting area such that the measured irradiance at a treatment surface of the patient is at least within 60% of the measured maximum"
"uniformly illuminating a treatment surface"	'512 patent: claim 8	"irradiating light over the active emitting area such that the measured irradiance at a treatment surface of the patent is at least within 60% of the measured maximum"

On November 31, 2024, a *Markman* hearing was held and on March 4, 2025, ALJ Moore issued his *Markman* Order. Order No. 18. Below are the disputed claim terms, the parties' respective constructions for each term, and ALJ Moore's constructions from the *Markman* Order:

Claim Term	Sun Pharma's Construction	Biofrontera's Construction	ALJ Moore's Construction
"a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not	"a higher intensity of light is emitted close to the second shorter edges compared to the intensity of light emitted not close	Indefinite.	"a higher intensity of light is emitted close to the second shorter edges compared to the intensity of light emitted not close to the second shorter edges"

proximate the second edges” ³	to the second shorter edges”		
“photodynamically diagnosing or treating a patient”	Preamble not limiting.	Preamble is limiting, plain and ordinary meaning.	Preamble is limiting.
“nested hinges” ⁴	Plain and ordinary meaning. “hinges that fit on inner side surfaces of adjacent panels”	Indefinite.	“hinges that fit on inner side surfaces of adjacent panels”
“recess”	Plain and ordinary meaning.	Plain and ordinary meaning. An indentation in a surface.	“indentation, small hollow, or cleft”
“the five panels are individually configurable to control illumination from each of the five panels” ⁵	Plain and ordinary meaning. The power output and/or light intensity of each panel can be individually controlled.	Indefinite.	Plain and ordinary meaning. “the power output and/or light intensity of each panel can be individually controlled.”
“within approximately four	Plain and ordinary meaning.	“less than or equal to four inches	“less than or equal to approximately four inches from the treatment surface” ⁶

³Biofrontera expressly reserves the right to assert that this claim term is indefinite on appeal and any related proceedings, and that Sun Pharma’s construction, which was adopted by ALJ Moore, is also indefinite.

⁴ Biofrontera expressly reserves the right to assert that this claim term is indefinite on appeal and any related proceedings, and that Sun Pharma’s construction, which was adopted by ALJ Moore, is also indefinite.

⁵ Biofrontera expressly reserves the right to assert that this claim term is indefinite on appeal and any related proceedings, and that Sun Pharma’s construction, which was adopted by ALJ Moore, is also indefinite.

⁶ Biofrontera expressly reserves the right to assert that this claim term is indefinite on appeal and any related proceedings, and that the adopted construction is also indefinite.

inches of the treatment surface”		from the treatment surface”	
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Id.

C. Person of Ordinary Skill in the Art

In the *Markman* Order, ALJ Moore adopted the following definition of a person of ordinary skill in the art (“POSA”):

A person of ordinary skill in the art would have a M.D. and/or a Ph.D. in an electrical engineering, optoelectronics, physics, optical sciences, optical engineering, or related scientific or engineering field, and at least one to two years of work or research experience in optical engineering, optics, optoelectronics, phototherapy, photodynamic therapy, or a related field.

Id. at 13.

Biofrontera relies on the expert opinions and testimony of Dr. Robert Grove, Ph.D, and Dr. Michael Ehrenreich, M.D. *See, e.g.*, RX-0006C (Grove Initial Witness Statement); RX-0007C (Ehrenreich Initial Witness Statement); RX-0009C (Grove Rebuttal Witness Statement); RX-0011C (Ehrenreich Rebuttal Witness Statement). Drs. Grove and Ehrenreich both qualify as a POSA under the definition adopted by ALJ Moore.

Dr. Grove has a Ph.D. in Instrumentation related to laser applications (i.e., optical sciences) and at least one to two years of experience in optical engineering, optics, optoelectronics, phototherapy and photodynamic therapy. Dr. Grove obtained his Ph.D. from MIT in 1975 and had substantial experience working in the fields of optical engineering, optics, optoelectronics, phototherapy and photodynamic therapy, and has been working in the field of photodynamic therapy since its inception, including at various companies focused on the development phototherapy devices, all before the priority date of the Asserted Patents. RX-1420.0006; *see also* RX-0006C, Q/A 7-12. Dr. Grove is qualified to testify about the device and engineering-related issues in this Investigation. RX-0006C, Q/A 23.

Dr. Ehrenreich has an M.D. and at least one to two years of experience with phototherapy and photodynamic therapy. Dr. Ehrenreich obtained his M.D. from Rutgers in 2006 and subsequently completed his residency in dermatology in 2010. RX-1419.0001. Dr. Ehrenreich also had substantial experience photodynamically treating patients before the priority date of the Asserted Patents, including at SOMA Skin and Laser, the dermatology practice he founded in 2010. RX-0007C, Q/A 11-14. Dr. Ehrenreich is qualified to testify about the medical and treatment issues in this Investigation. RX-0007C, Q/A 23.

IV. BIOFRONTERA DOES NOT INFRINGE THE ASSERTED CLAIMS OF THE '512 PATENT AND THE '028 PATENT

A. Legal Standards for Infringement

Sun Pharma bears the burden of proving infringement. *Certain Televisions, Remote Controls, & Components Thereof*, Inv. No. 337-TA-1263, Initial Determination (Pub. Version) at 29 (June 28, 2022) (citing *Enercon GmbH v. Int'l Trade Comm'n*, 151 F.3d 1376, 1384 (Fed. Cir. 1998)); *Spansion, Inc. v. Int'l Trade Comm'n*, 629 F.3d 1331, 1349 (Fed. Cir. 2010). “An infringement analysis entails two steps. The first step is determining the meaning and scope of the patent claims asserted to be infringed. The second step is comparing the properly construed claims to the device accused of infringing.” *Certain Televisions*, Inv. No. 337-TA-1263, Initial Determination at 28 (citation omitted); *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995), *aff'd*, 517 U.S. 370 (1996). The first step, claim construction, is a “matter of law.” *Markman*, 52 F.3d at 970–71. The second step, comparing the construed claims to the Accused Products, is a question of fact. *See, e.g., W.E. Hall Co. v. Atlanta Corrugating, LLC*, 370 F.3d 1343, 1350 (Fed. Cir. 2004). To prevail on its infringement claim, Complainant “must supply sufficient evidence to prove that the accused product or process contains, either literally or under the doctrine of equivalents, every limitation of the properly construed claim.” *Eli Lilly & Co. v.*

Hospira, Inc., 933 F.3d 1320, 1328 (Fed. Cir. 2019), cert. denied 141 S. Ct. 112 (2020) (citation omitted).

To prove literal infringement, Complainant must show that “every limitation in the claim is literally met by the accused device.” See *Enercon GmbH*, 151 F.3d at 1384; *Certain Plaintiff-Derived Recombinant Human Serum Albumins (“rHSA”) and Products Containing Same*, Inv. No. 337-TA-1238, Initial Determination (Pub. Version) at 34 (April 7, 2022) (citation omitted). “[F]ailure to meet a single limitation is sufficient to negate infringement of the claim.” *Laitram Corp. v. Rexnord, Inc.*, 939 F.2d 1533, 1535 (Fed. Cir. 1991).

To prove infringement under doctrine of equivalents, a complainant must show that the substitute element in the Accused Product “matches the function, way and result of the claimed element” and does not play a “role substantially different from the claimed element.” *Warner-Jenkinson Co., Inc. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 40 (1997) However, where a claim uses terms of approximation like “about” and “approximately,” the doctrine of equivalents is not available to further expand the scope of the claim. *Cohesive Techs., Inc. v. Waters Corp.*, 543 F.3d 1351, 1371–72 (Fed. Cir. 2008) (holding that claim containing the word “about” “already captured what would otherwise be equivalents within the literal scope of the claim.”); *Ortho-McNeil Pharm., Inc. v. Caraco Pharm. Lab’ys, Ltd.*, 476 F.3d 1321, 1328–29 (Fed. Cir. 2007) (holding that the doctrine of equivalents could be used to expand the word “about”).

Indirect infringement occurs when an alleged infringer actively induces or contributes to the infringement of a third party. 35 U.S.C. § 271(b)-(c); *Certain Digital Video Receivers, Broadband Gateways, & Related Hardware and Software Components*, Inv. No. 337-TA-1158, Initial Determination (Pub. Version) at 233 (July 28, 2020). To prove that Biofrontera indirectly infringes an asserted claim, Sun Pharma must show that there is predicate direct infringement.

Digital Video Receivers, Inv. No. 337-TA-1158, Initial Determination at 233; *Dynacore Holdings Corp. v. U.S. Philips Corp.*, 363 F.3d 1263, 1272 (Fed. Cir. 2004).

Induced infringement requires: (1) knowledge of the infringed patent; and (2) intentionally aiding and abetting a third party to infringe. 35 U.S.C. § 271(b); *Certain Dental and Orthodontic Scanners and Software*, Inv. No. 337-TA-1144, Initial Determination (Pub. Version) at 243 (April 30, 2020); *Global-Tech Appliances, Inc. v. SEB S.A.*, 563 U.S. 754, 766 (2011); *Warsaw Orthopedic, Inc. v. NuVasive, Inc.*, 824 F.3d 1344 (Fed. Cir. 2016). Specifically, a complainant must prove that: (1) there is underlying direct infringement of an asserted claim by a third party; (2) the respondent intended to cause the direct infringement; and (3) the respondent knew that the acts of the directly infringing party would constitute direct infringement of the asserted patent. *See, e.g., Power Integrations, Inc. v. Fairchild Semiconductor Int’l, Inc.*, 843 F.3d 1315, 1332 (Fed. Cir. 2016).

When a patent claims a method of treating a patient, pharmaceutical manufacturers generally do not directly infringe because they do not treat or otherwise administer their products to patients. *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1363 (Fed. Cir. 2003). Thus, to infringe a method of treatment claim, the complainant must prove that the respondent indirectly infringes, for example by inducing healthcare providers to treat patients according to the claims of the patent. *Id.*

“The accused infringer must have ‘knowingly aided and abetted’ direct infringement” and taken active steps to encourage, recommend, or promote infringement.” *Takeda Pharms. U.S.A., Inc. v. West-Ward Pharm. Corp.*, 785 F.3d 625, 630–31 (Fed. Cir. 2015) (quoting *Warner-Lambert*, 316 F.3d at 1363). “In order to support inducement liability, instructions may not merely describe an infringing mode; they must ‘evidence “intent to encourage infringement.”’” *H.*

Lundbeck A/S v. Lupin Ltd., 87 F.4th 1361, 1370 (Fed. Cir. 2023) (quoting *Takeda*, 785 F.3d at 631) (emphasis omitted); *see also Warner-Lambert*, 316 F.3d at 1364 (“mere knowledge of possible infringement by others does not amount to inducement; specific intent and action to induce infringement must be proven.”).

Typically, the inducement analysis in cases involving pharmaceutical products and method of treatment claims involves considering what the accused infringer’s drug product label tells healthcare providers about how to treat patients using the drug product. *See, e.g., HZNP Medicines LLC v. Actavis Lab’ys UT, Inc.*, 940 F.3d 680, 685–86, 702 (Fed. Cir. 2019). However, the accused infringer’s drug product label and other relevant materials must “encourage, recommend, or promote” infringement of the asserted method of treatment claims to induce healthcare providers to directly infringe. *Takeda*, 785 F.3d at 631. A respondent does not induce infringement when a label “operates in an ‘if/then’ manner,” such that one of the treatment steps recited in the Asserted Claims of the patent is presented as an optional step on the accused drug product label. *HZNP*, 940 F.3d at 702. And where a label permits an infringing use, but does not encourage, recommend, or promote that use, a respondent does not induce infringement. *Acorda Therapeutics Inc. v. Apotex Inc.*, 2011 WL 4074116, *18 (D.N.J. 2011), *aff’d*, 476 Fed. Appx. 746 (Fed. Cir. 2012).

Finally, the inducement inquiry in drug product label cases is not a purely hypothetical exercise when the accused infringer is already marketing the Accused Product. *Amarin Pharma, Inc. v. Hikma Pharms. USA Inc.*, 104 F.4th 1370, 1379–80 (Fed. Cir. 2024). In those cases, the complainant must establish with evidence that a third party (*i.e.*, a healthcare provider) has directly infringed the Asserted Patents using the respondent’s Accused Product by following the guidance on the respondent’s drug product label or other relevant materials. *Id.* However, “[t]he mere

existence of direct infringement by physicians, while necessary to find liability for induced infringement, is not sufficient for inducement.” *Takeda*, 785 F.3d at 631.

B. All of the Asserted Claims of the ’512 Patent and Claims 1, 2, 4, 20, and 21 of the ’028 Patent Are Not Infringed Based on Absence of the Claimed Requirement for “Panels Connected by Nested Hinges (or Hinged Structures) On Inner Side Surfaces of Adjacent Panels.”

Independent claims 1, 8, and 20 of the ’512 Patent recite the limitation “panels connected by nested hinges on inner side surfaces of adjacent panels.” JX-0001, cls. 1, 8, and 20. The remainder of the Asserted Claims of the ’512 Patent – claims 3, 5, 17 and 18 – similarly require this limitation by virtue of their dependence from one of the independent claims. JX-0001, cls. 3, 5, 17, and 18. Accordingly, all of the Asserted Claims of the ’512 Patent require “panels connected by nested hinges on inner side surfaces of adjacent panels.” As noted above, “nested hinges on inner side surfaces of adjacent panels” has been construed to mean “hinges that fit on inner side surfaces of adjacent panels.” Order No. 18, 35. Accordingly, as construed, the claim term recites “panels connected by hinges that fit on inner side surfaces of adjacent panels.” None of the Asserted Claims of the ’512 Patent are infringed by Biofrontera at least because the RhodoLED® XL does not meet this limitation.

Independent claims 1, 20, and 21 of the ’028 Patent recite the limitation “panels connected by hinged structures on inner side surfaces of adjacent panels.” JX-0002, cls. 1, 20, and 21. Claims 2 and 4 of the ’028 Patent similarly require this limitation by virtue of their dependence from one of the independent claims. JX-0002, cls. 2 and 4. Accordingly, claims 1, 2, 4, 20, and 21 of the ’028 Patent require “panels connected by hinged structures on inner side surfaces of adjacent panels.” Claims 1, 2, 4, 20, and 21 of the ’028 Patent are not infringed by Biofrontera at least because the RhodoLED® XL does not meet this limitation.

Quite simply, the RhodoLED® XL does not contain “panels connected by hinges that fit **on** inner side surfaces of adjacent panels,” because the hinges of the RhodoLED® XL extend **through** inner side surfaces of adjacent panels to connect [REDACTED] within the interior of the panels. RX-0009C, Q/A 31.

The inner side surfaces refer to the exterior side surfaces of a panel between the front and the back of the panel. RX-0009C, Q/A 36. As Dr. Grove explains, these are the exterior surfaces of the panel that face the adjacent panel, RX-0009C, Q/A 36.

Inner Side Surfaces of the RhodoLED® XL

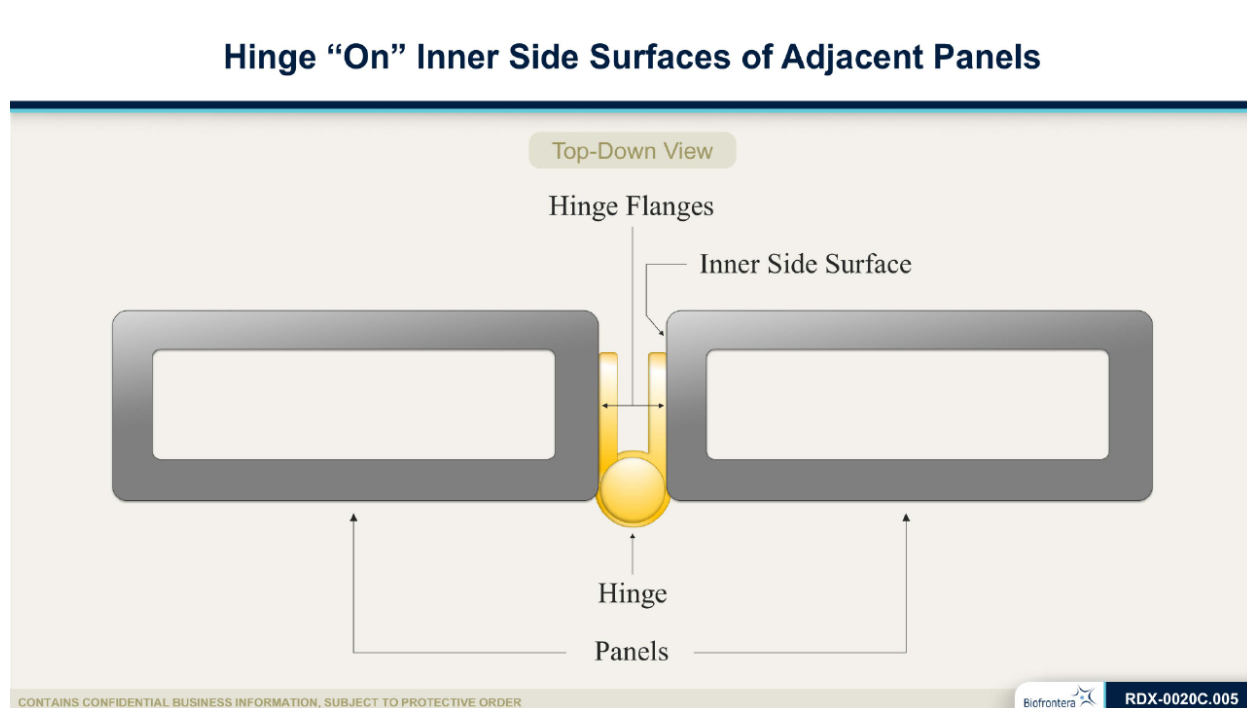


RDX-0020C.012.

The claim language requires that the recited hinges be “on” these inner side surfaces. JX-0001, cls. 1, 8, and 20. The term “on” is a term used in both the plain language of the claims, as well as in ALJ Moore’s construction. Order No. 18, 35. *See also Bicon, Inc. v. Straumann Co.*, 441 F.3d 945, 950 (Fed. Cir. 2006) (“Claims are interpreted with an eye toward giving effect to all terms in the claim.”). “On” is a preposition that has a meaning distinct from alternative prepositions such as “through,” “within,” “past,” “behind,” “into,” or similar. RX-0009C, Q/A 34. Specifically,

the term “on” means “in contact with and supported by the top surface of.” JX-0029.1; RX-0009C, Q/A 32.

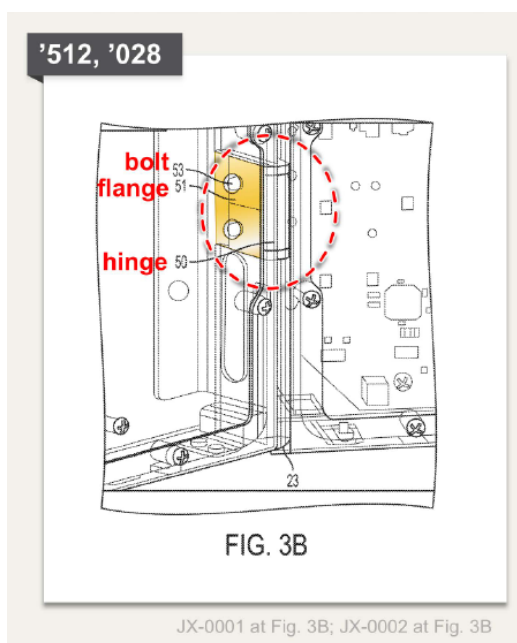
Accordingly, “hinges that fit on inner side surfaces of adjacent panels” (as required by the construction of “nested hinges” in the ’512 Patent) and “hinged structures on inner side surfaces of adjacent panels” (as recited in the aforementioned ’028 Patent claims) requires hinges that are in contact with and supported by the top or exterior of the inner side surfaces. RX-0009C, Q/A 33. As shown in the diagram below, such hinges would be laid flat against, and parallel to, the inner side surfaces of adjacent panels.



RDX-0020C.005.

In order to be supported by such surfaces and to effectively connect adjacent panels, such hinges may be – to use the words of the ’512 Patent – “mounted to the inner side surfaces of adjacent panels” JX-0001, 4:63-66. While Dr. Jokerst has argued that “the claim language is silent as to whether the hinge must be ‘mounted on or affixed to’ an inner side surface of adjacent

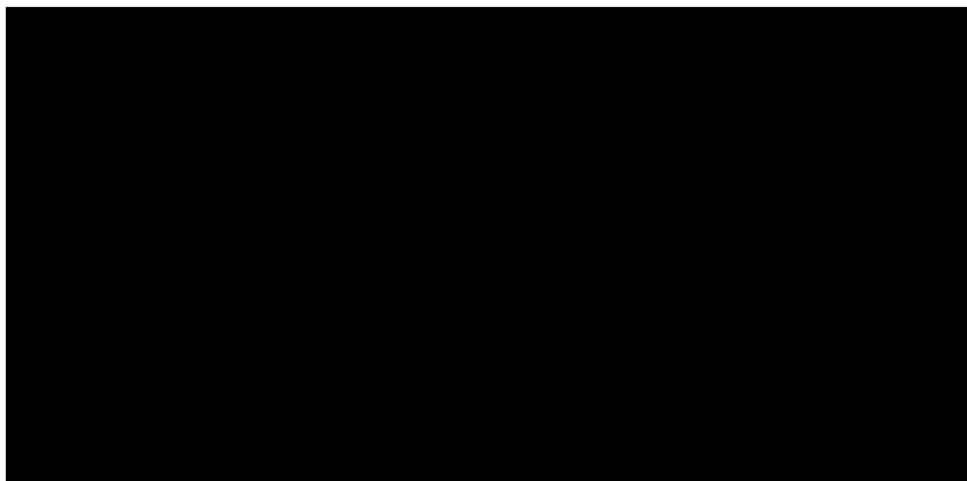
panel” (CX-0014C, Q/A 473), the specification of the Asserted Patents is not, and it logically follows that for panels to be “connected by hinges that fit on inner side surfaces,” the hinges would need to be affixed to those surfaces in some way. RX-0009C, Q/A 70. This is borne out by the hinge structures disclosed in the Asserted Patents and used in the BLU-U® 4170E. For example, FIG. 3B of the ’512 Patent shows hinges laid flat against inner side surfaces of adjacent panels, secured to those surfaces with bolts.



RDX-0020C.006 (excerpt).

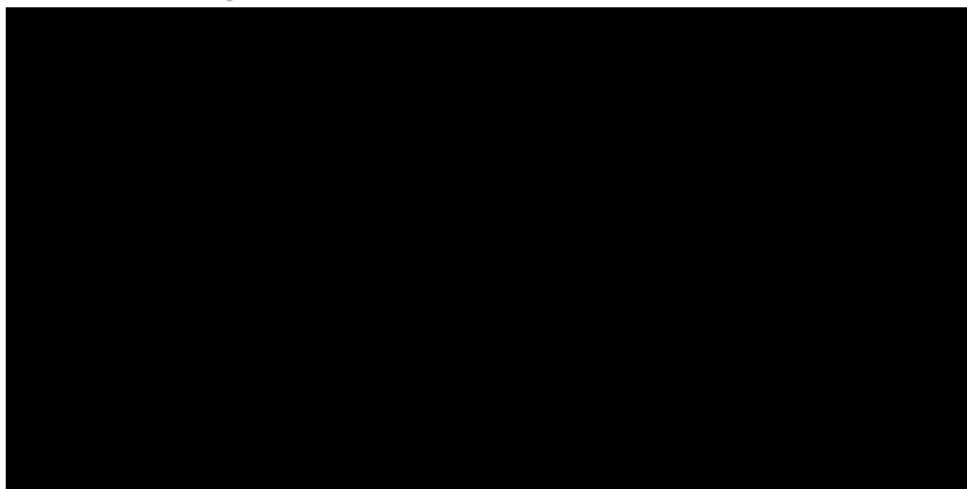
The BLU-U® 4170E also has the same hinge structure, with hinges laid flat against the inner side surfaces of adjacent panels and mounted to these surfaces via a bolt. RX-0009C, Q/A 41-44.

Hinges on Inner Side Surfaces in the BLU-U® 4170E



RDX-0020C.0007.

Hinges on Inner Side Surfaces in the BLU-U® 4170E

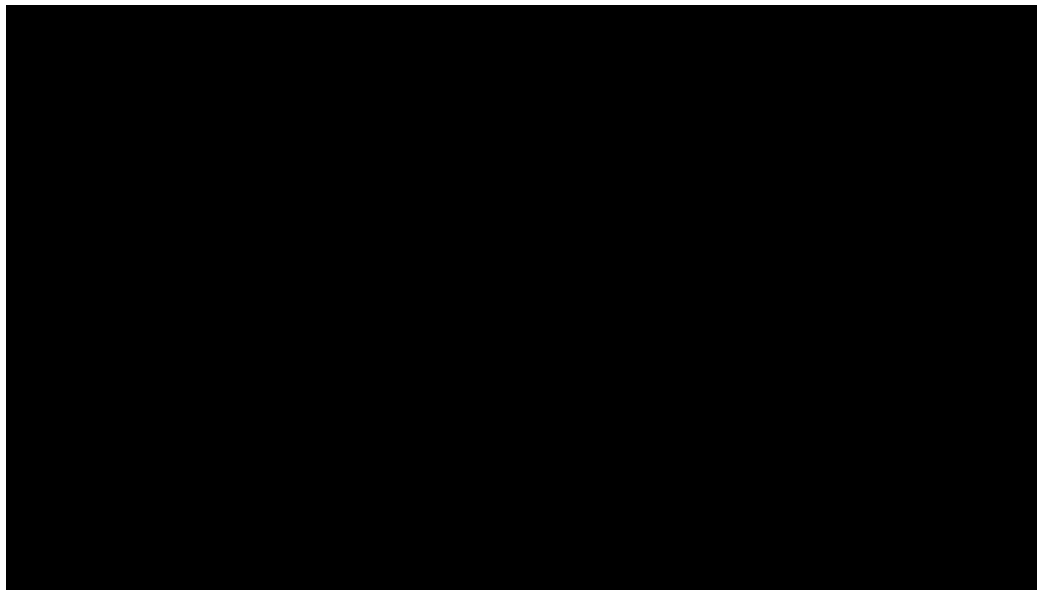


RDX-0020C.0008. Sun Pharma's expert, Dr. Jokerst, has confirmed that "each of the five panels of . . . the BLU-U® 4170E device are connected to at least one adjacent panel by one or more nested hinges on inner side surfaces of adjacent panels. The hinges that connect the five panels are 'nested' because they fit on inner side surfaces of the adjacent panels." CX-0014C, Q/A 99.

The RhodoLED® XL, on the other hand, has a very different hinge structure. Specifically, the panels of the RhodoLED® XL include two hinges, 

[REDACTED]

[REDACTED]” RX-0009C, Q/A 49. As explained by Dr. Grove, these hinges extend *through* openings in the inner side surfaces of adjacent panels to connect [REDACTED] within an interior compartment of the panels, as illustrated in the below diagram. RX-0009C, Q/A 31.



RDX-0020C.011.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

⁷ As used herein, the “front” side of the RhodoLED[®] XL (or other illuminator) refers to the light-emitting side and the “back” side refers to the opposing side, which does not emit light.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

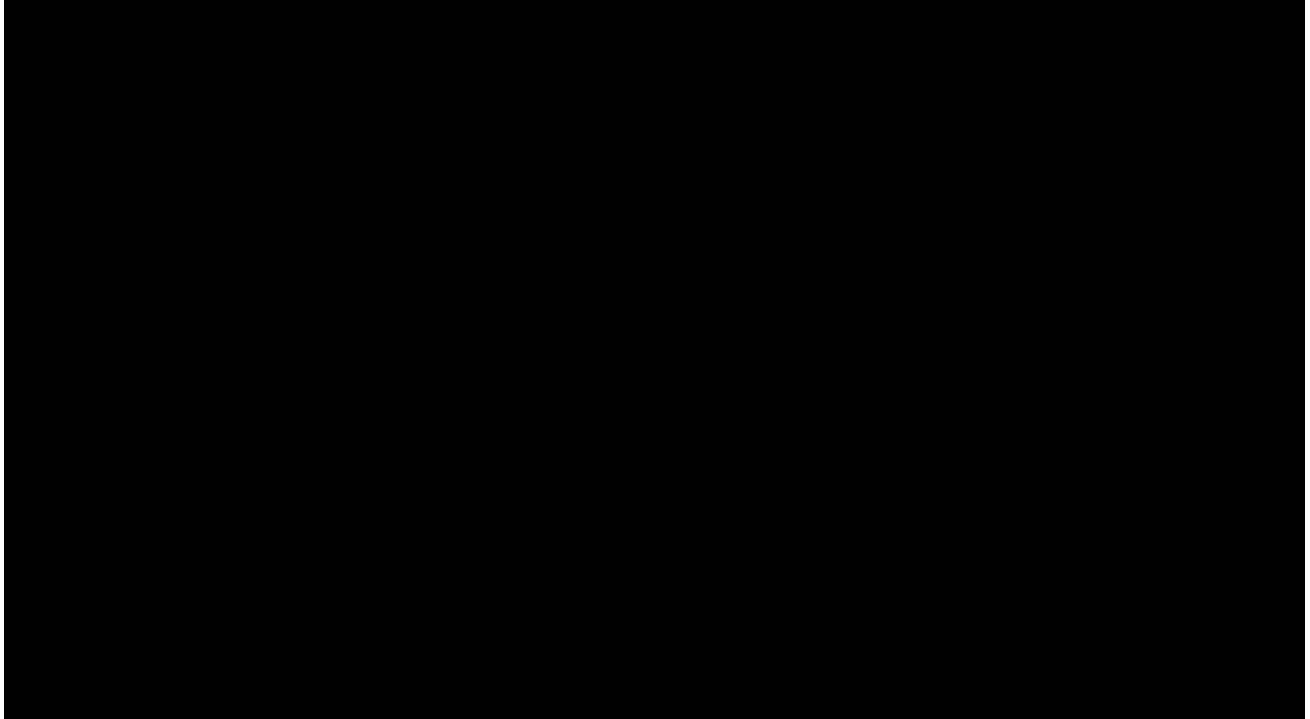
RDX-0020C.014.

[REDACTED]

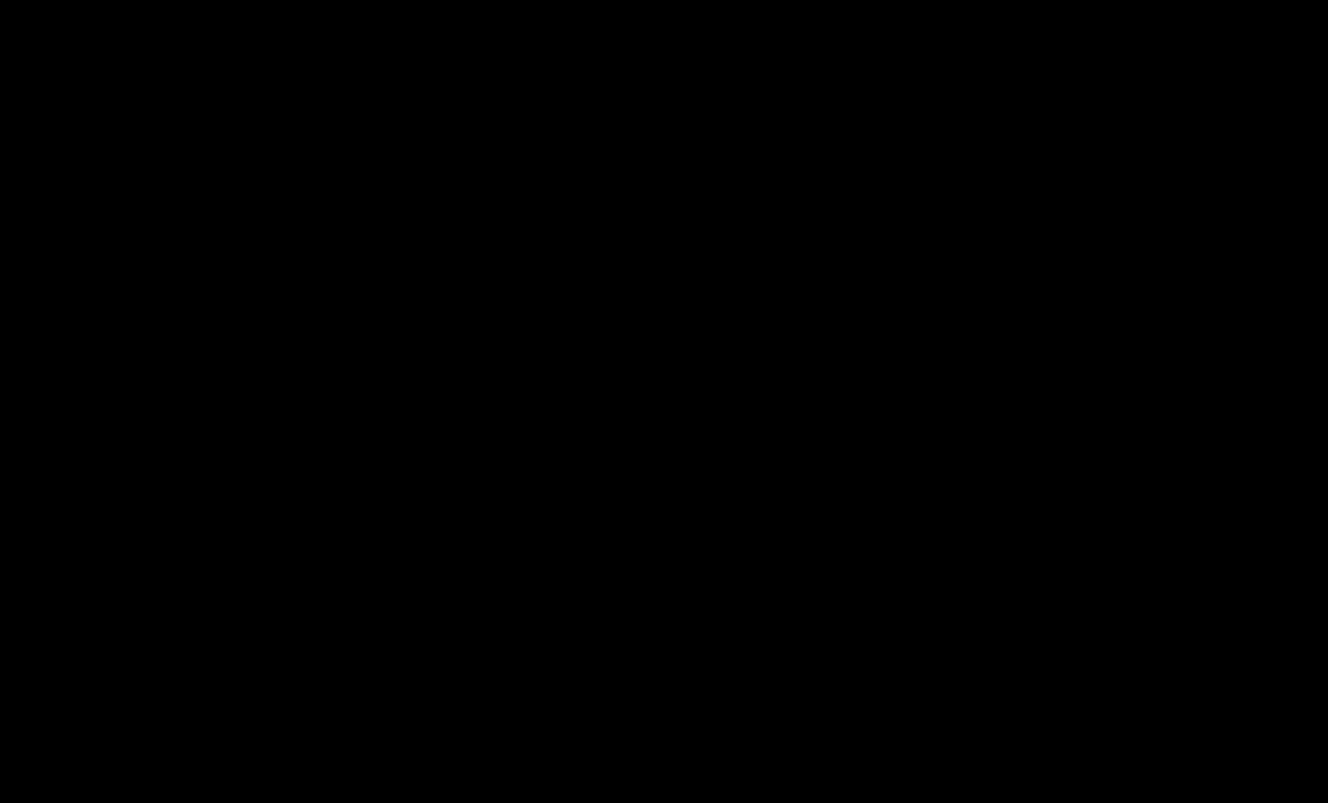
RDX-0020C.017.



Although [REDACTED] located within the interior of the panel, its tabs extend through openings in the inner side surfaces of the panel, as shown below. RX-0009C, Q/A 52-53.



RDX-0020C.013. The hinges of the RhodoLED[®] XL are laid flat on the front side of the tabs and the hinge flanges extend through openings on the inner side surfaces to bolted attachment points on the tabs located within the interior compartment of the panel, as depicted below. RX-0009C, Q/A 65.



Accordingly, the friction hinges of the RhodoLED[®] XL are not “**on** inner side surfaces of adjacent panels” because they extend **through** inner side surfaces of adjacent panels to **connection points inside of the panels**. RX-0009C, Q/A 66. Further, the fact that the friction hinges need to extend through the inner side surface to the interior of the panel means that the RhodoLED[®] XL panels are not connected by “hinges that fit on inner side surfaces of adjacent panels,” nor are they connected by “hinged structures on inner side surfaces of adjacent panels,” as required by the claims. RX-0009C, Q/A 67. Thus, Biofrontera’s RhodoLED[®] XL does not infringe any of the Asserted Claims.

Although Dr. Jokerst has testified that the friction hinges of the RhodoLED[®] XL **fit** on inner side surface because they “do not extend past the side surfaces to intrude on the front, back, top, or bottom of the panels” (CX-0014C, Q/A 472), this is both inaccurate and logically flawed. First, the frictions hinges *do* extend past the side surfaces – they extend through the side surfaces

[REDACTED]

to attachment points inside the panel compartment. RX-0009C, Q/A 65, 67. Second, just because hinges do not intrude on the front, back, top, or bottom of the panels does not necessarily mean that they fit on the inner side surfaces. RX-0009C, Q/A 68. For example, the hinges could extend into the interior of the panels (as they do) without reaching all the way to the front, back, top, or bottom of the panels. RX-0009C, Q/A 68.

Dr. Jokerst's assertion that the tabs [REDACTED] are part of the inner side surfaces of the panels (CX-0014C, Q/A 446-475), is similarly inaccurate. RX-0009C, Q/A 60. The tabs are not part of the inner side surfaces of the panels – they are part of the [REDACTED], which is a separate component. RX-0009C, Q/A 53, 60-61. The fact that portions of the [REDACTED] extend through holes in the inner side surfaces does not mean that these two separate components somehow merge into one. Further, even if the [REDACTED] could somehow be considered part of the panel surfaces (which it is not), the friction hinges are still disposed on and connected to the *front* surface of the planar support structure – not any side surface whatsoever. RX-0009C, Q/A 66.

Finally, while there may be some incidental contact between the friction hinge flanges and the opening in the inner side surface as the flanges extend into the panel (as alleged by Dr. Jokerst (CX-0014C, Q/A 470)), the claim language requires that the hinges be “on” – i.e., in contact with and supported by the top surface of – the inner side surfaces. RX-0009C, Q/A 69. But, the RhodoLED® XL hinge flanges are not supported by the inner side surfaces because their support comes from being bolted to the front surface of the hinge holders. RX-0009C, Q/A 69. Further, the claim language requires “panels *connected* by hinges.” Incidental contact does not constitute connection, as required by the claims.

[REDACTED]

With respect to the '028 Patent only, Dr. Jokerst has also asserted that [REDACTED] [REDACTED] of the RhodoLED® XL may satisfy the limitation of “panels connected by hinged structures *on* inner side surfaces of adjacent panels.” CX-0014C, Q/A 671. However, this is inaccurate for two reasons – (i) the [REDACTED]” Dr. Jokerst refers to are not hinges and (ii) [REDACTED] are not “on inner side surfaces of adjacent panels.” RX-0009C, Q/A 82, 84.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED].

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED].

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

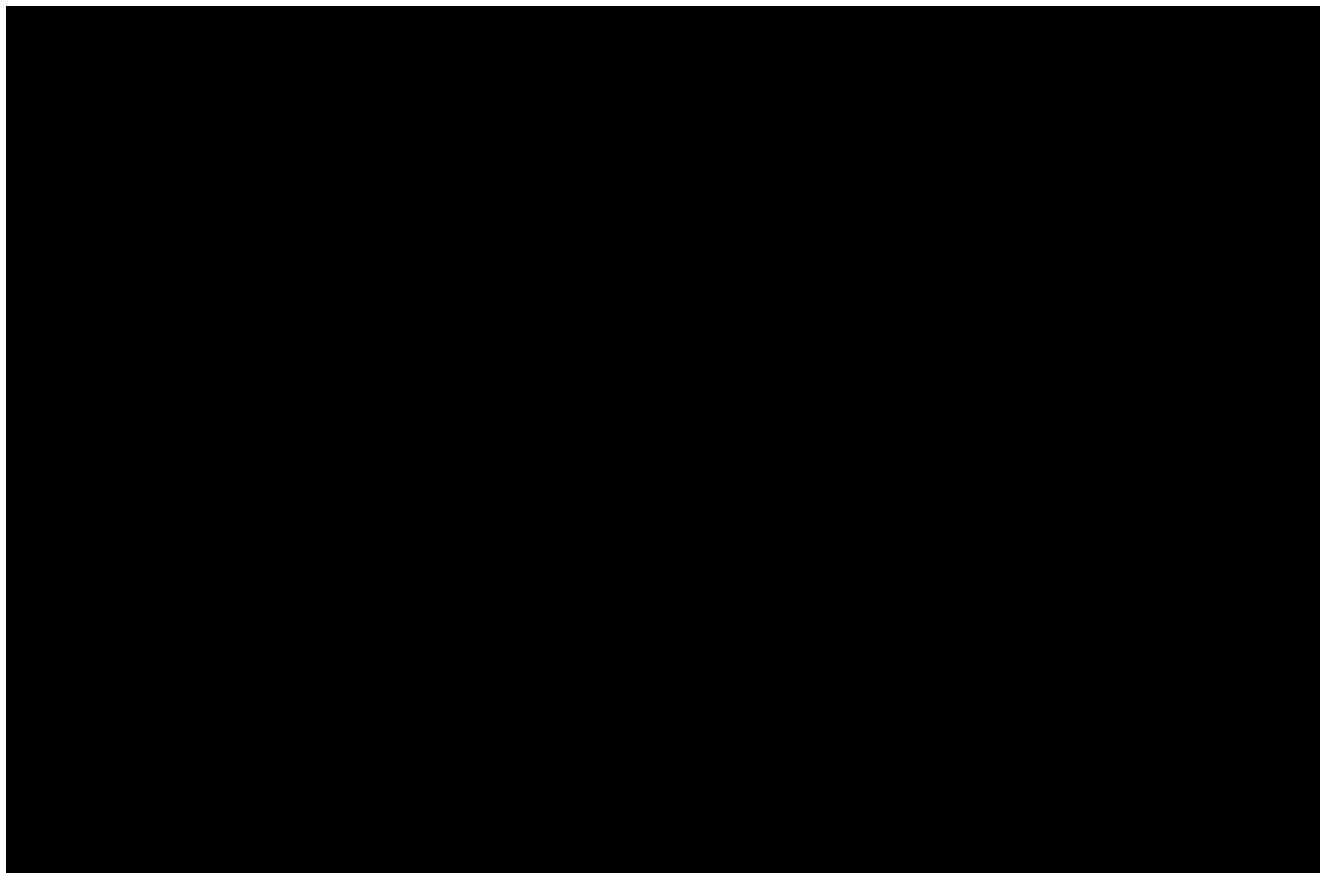
[REDACTED]

In contrast, the function of a hinge is to rotationally secure two or more objects – e.g., a hinge is used to rotationally secure a door to a door frame. RX-0009C, Q/A 20. Accordingly, hinges are load-bearing components that need to be able to bear the weight of the objects they secure together and have sufficient strength to withstand the mechanical forces resulting from the rotational movement of the objects. RX-0009C, Q/A 21. For example, the hinges that secure a door to a door frame also function to support and hold the door off the ground as it opens and closes and therefore must have sufficient strength to do so. RX-0009C, Q/A 21. A POSA would understand a hinged structure as having the same functional and structural requirements as a hinge. RX-0009C, Q/A 29, 79. This is even more so, given that the '028 Patent does not disclose “hinged

[REDACTED]

structures” in the specification, but only teaches “hinges” and “nested hinges,” e.g., hinges 50 depicted in FIGS. 3A-B.

The [REDACTED] do not have the structural strength to serve as hinges (or hinged structures) for the RhodoLED® XL panels. RX-0009C, Q/A 79. The RhodoLED® XL panels are very heavy. RX-0009C, Q/A 79. Additionally, the panels – and consequently, the hinges connecting them – are subject to substantial force when they are moved by a user. RX-0009C, Q/A 79. In contrast, the [REDACTED] is made of a thin, pliable plastic. RX-0009C, Q/A 79. In fact, this plastic is so thin that it readily bent when subjected to even minor torque, as shown in the image below from Dr. Grove’s personal inspection of the device. RX-0009C, Q/A 79.



RDX-0020C.021 (excerpt). Consequently, the [REDACTED] does not have nearly enough structural strength to serve as a hinge for the RhodoLED® XL panels. RX-0009C, Q/A 79. Rather, this function is served by the friction hinges. RX-0009C, Q/A 80. Without the friction hinges, the

[REDACTED]

[REDACTED] would not be able to support the panels on their own, without breaking or causing the entire panel assembly to come apart during normal use. RX-0009C, Q/A 80.

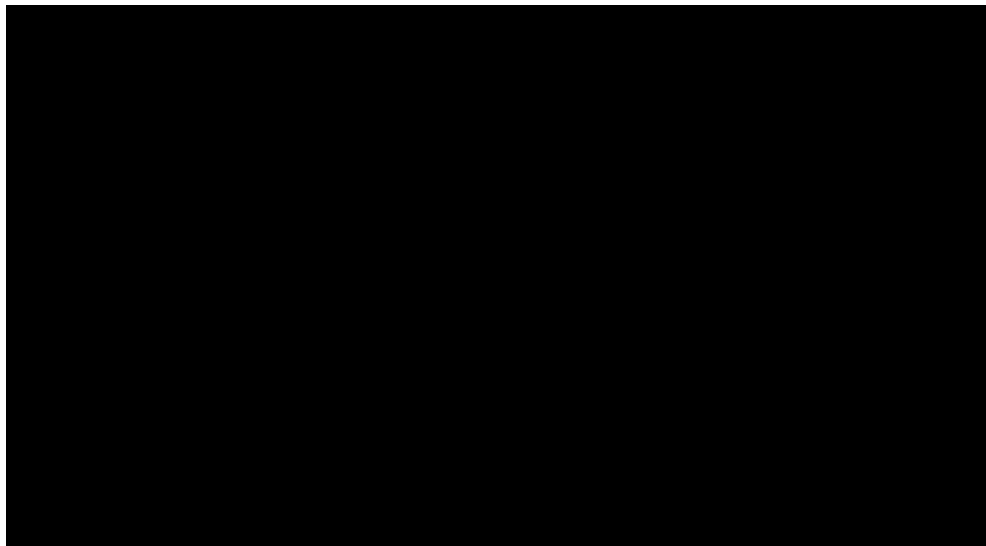
Although Dr. Jokerst alleges that the [REDACTED] are “hinged structures” because they are merely rotatable structures (CX-0014C, Q/A 671), this definition is so broad as to render the term meaningless, and ignores a POSA’s knowledge and understanding of how hinges work. For example, rotatable valves rotate to control the flow of fluid, yet the valve would not be a hinge because it is not designed to support and enable pivoting of two objects, but rather to control fluid flow. RX-0009C, Q/A 81. Similarly, a ceiling fan, a tire, or a steering wheel are all rotatable, but none of these would be considered to be hinges or hinged structures because none of them have the primary function of rotationally securing and supporting two objects. [REDACTED]

[REDACTED]

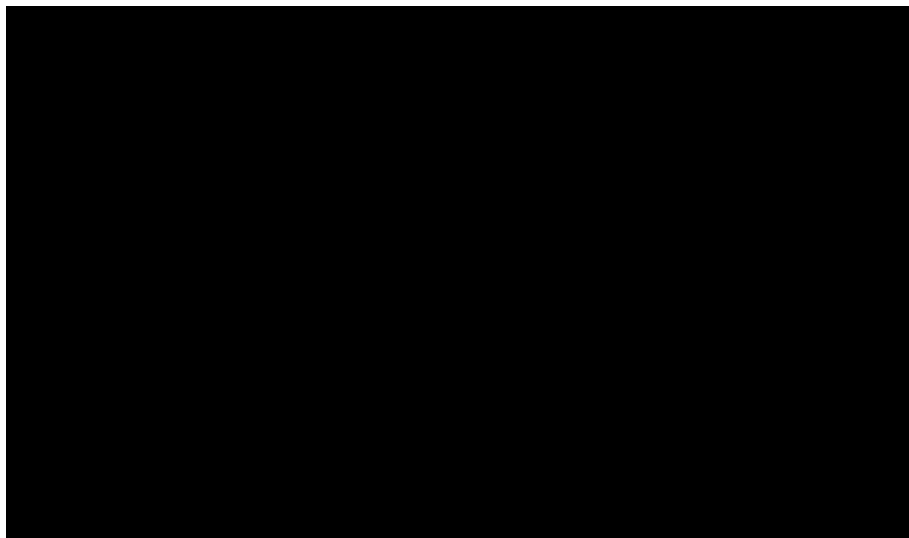
[REDACTED] RX-0009C, Q/A 76. Accordingly, the [REDACTED] are not hinges or hinged structures. RX-0009C, Q/A 81-83.

Additionally, the [REDACTED] are not **on** inner side surfaces of adjacent panels. RX-0009C, Q/A 81-83. As discussed in detail above, “**on** inner side surfaces of adjacent panels” requires that the object in question be in contact with and supported by the top surface of the inner sides of the panels – not that the object extend **through** an opening in the side surface. RX-0009C, Q/A 84. Like the friction hinges, the [REDACTED] extend through openings in the inner side surfaces of adjacent panels. RX-0009C, Q/A 84.

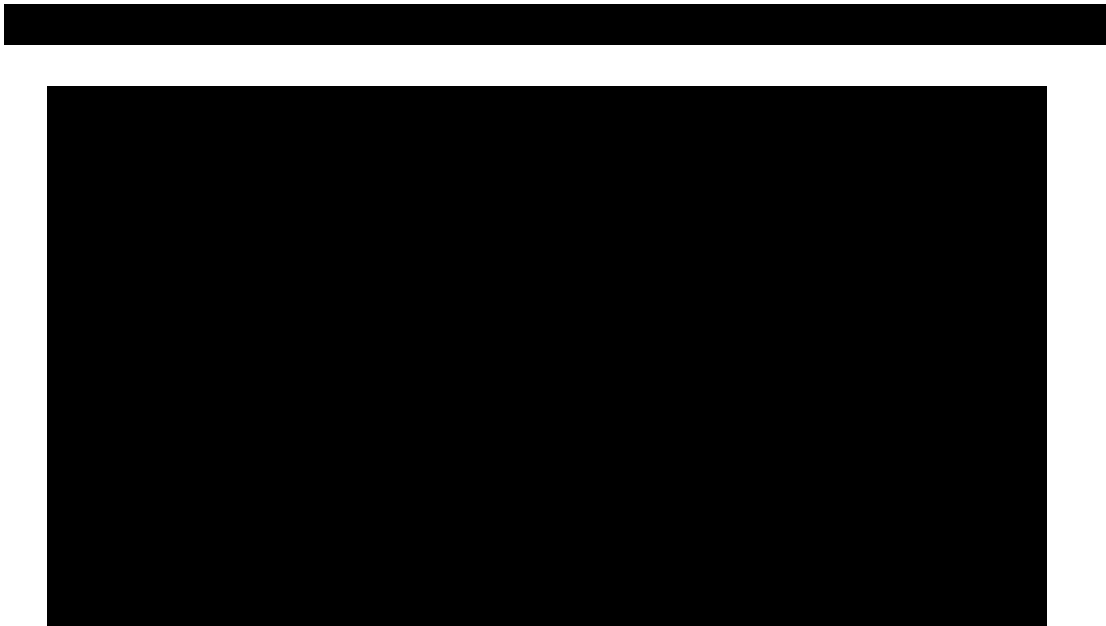
As Dr. Grove has illustrated below, the bracket and wire entry port of the [REDACTED] [REDACTED] e pass **through** an opening in the inner side surface of the panels to an attachment point within the internal compartment of the panel and not on an inner side surface.



RDX-0020.022. The openings *through* which the [REDACTED] extend can be seen in the back and front views below.



RDX-0020C.023.



RDX-0020C.024. Accordingly, the [REDACTED] are not “hinged structures on inner side surfaces of adjacent panels” because (i) they are not hinges, and (ii) they are not on inner side surfaces of adjacent panels. RX-0009C, Q/A 87.

Therefore, none of the Asserted Claims of the '512 Patent are literally infringed by Biofrontera at least because the RhodoLED[®] XL does not have “panels connected by hinges that fit on inner side surfaces of adjacent panels.” Similarly, claims 1, 2, 4, 20, and 21 of the '028 Patent are not infringed by Biofrontera at least because the RhodoLED[®] XL does not contain “panels connected hinged structures on inner side surfaces of adjacent panels”. RX-0009C, Q/A 89. Additionally, Sun Pharma has not asserted that RhodoLED[®] XL meets this limitation under the doctrine of equivalents, and, consequently, the Asserted Claims of the '512 Patent and claims 1, 2, 4, 20, and 21 of the '028 Patent are also not infringed under the doctrine of equivalents.⁸

C. Claims 17 and 18 of the '512 Patent are Not Infringed Based on the Claimed Requirement for “A Recess.”

Dependent claim 17 of the '512 Patent recites the limitation “recess configured to receive a flange of one of the nested hinges.” JX-0002, cl. 17. As noted above, “recess” has been construed

⁸ To the extent Sun Pharma elects to assert in the future that this limitation is met under the doctrine of equivalents, Biofrontera reserves the right to respond.

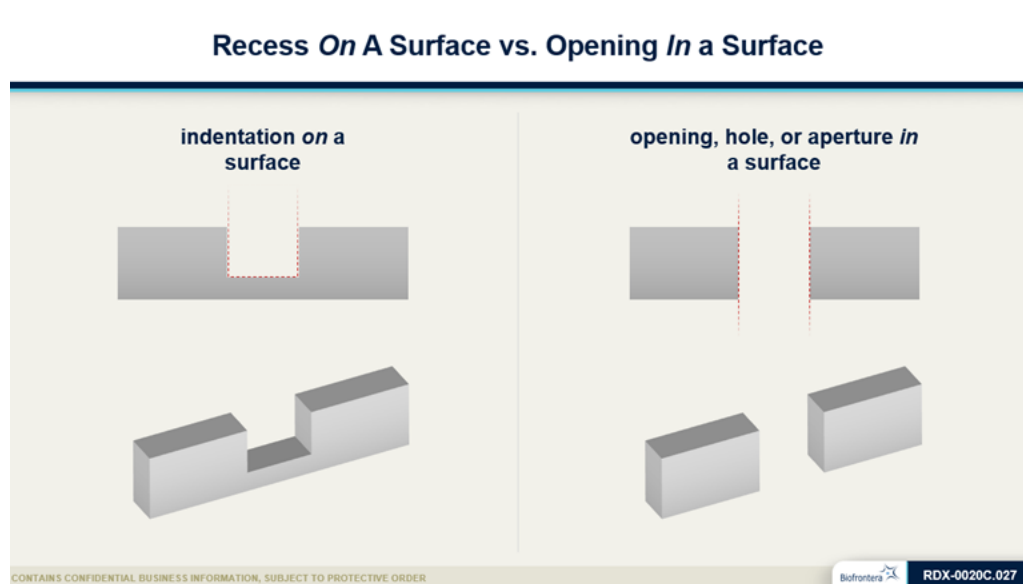
to mean “indentation, small hollow, or cleft” and “nested hinges on inner side surfaces of adjacent panels” has been construed to mean “hinges that fit on inner side surfaces of adjacent panels.” Markman Order, 35, 47. Accordingly, as construed, claim 17 collectively requires an “indentation, small hollow, or cleft configured to receive a flange of one of the hinges that fit on inner side surfaces of adjacent panels.”

Dependent claim 18 of the '512 Patent recites the limitation “the recess is positioned at an inner side surface of the at least one panel.” JX-0001, ('512 Patent) at cl. 18. In light of the claim construction of “recess,” claim 18 requires “the indentation, small hollow, or cleft is positioned at an inner side surface of the at least one panel.”

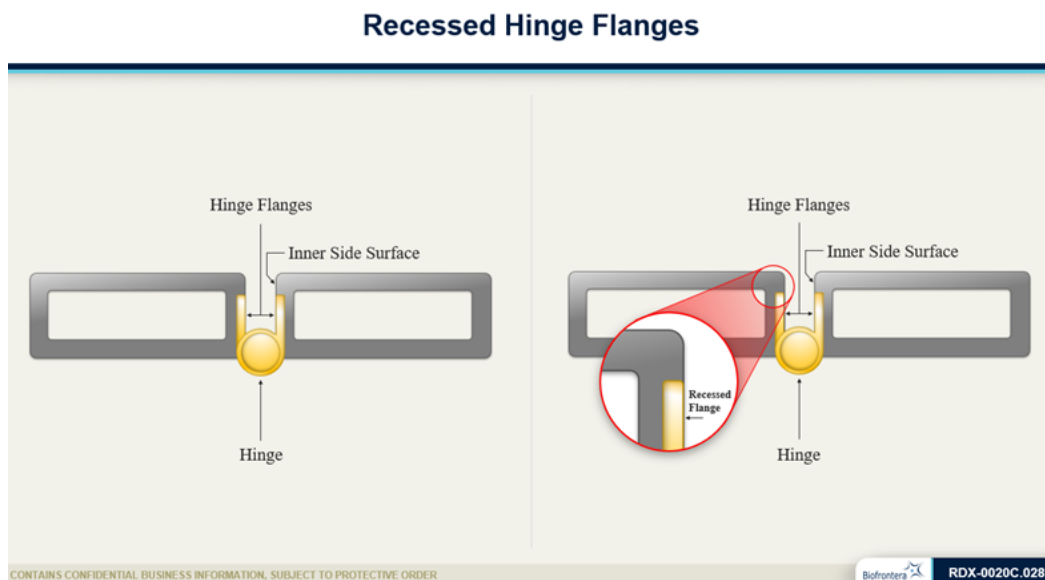
Claim 18 depends from claim 17, and both claims 17 and 18 depend from claim 8, which includes the limitation “panels connected by nested hinges on inner side surfaces of adjacent panels” (JX-0001, cl. 8) or, as construed, “panels connected by hinges that fit on inner side surfaces of adjacent panels.” Claims 17-18 of the '512 Patent are not infringed by Biofrontera at least because the RhodoLED® XL does not contain an indentation, small hollow, or cleft configured to receive a hinge flange **on** an inner side surface. RX-0009C, Q/A 102-103.

Via their dependency from claim 8, claims 17-18 require hinges that fit **on** an inner side surface – meaning that the “indentation, small hollow, or cleft” configured to receive the flange of this hinge must be on the same inner side surface. RX-0009C, Q/A 104. Within this context, an “indentation, small hollow, or cleft” must be formed on the continuous inner side surface, as opposed to extending through it. As explained in more detail by Dr. Grove, a POSA understands that panels that are connected by hinges that fit on inner side surfaces must also utilize hinges that attach or mount on the inner side surfaces, and that any indentation, small hollow, or cleft that is designed to receive these hinges must also be on the same inner side surface(s). RX-0009C, Q/A

103. Any other conclusion would be nonsensical. RX-0009C, Q/A 103. Within this context, an “indentation, small hollow, or cleft” must be formed on the continuous inner side surface, as opposed to extending through it. RX-0009C, Q/A 104. Accordingly, as Dr. Grove has illustrated below, within the context of the claims, an “indentation, small hollow, or cleft” cannot include a hole or an opening, as these are fundamentally different structural arrangements. RX-0009C, Q/A 103-104.



RDX-0020C.027. Accordingly, for a hinge flange to be received in a recess (i.e., an indentation, small hollow, or cleft) on an inner side surface of adjacent panels, the hinge flange must fit into an indentation, small hollow, or cleft in the continuous surface of the inner sides of adjacent panels, as Dr. Grove has illustrated in the diagram below. RX-0009C, Q/A 107.



RDX-0020C.028.

As previously explained in detail, the panels of the RhodoLED[®] XL do not include indentations, small hollows, or clefts on a continuous inner side surface – instead, they include an opening through which the hinge flanges extend for attachment to the tabs of [REDACTED], within the interior compartment of the RhodoLED[®] XL panels. RX-0009C, Q/A 107-108.

Accordingly, claims 17-18 of the '512 Patent are not literally infringed by Biofrontera at least because the RhodoLED[®] XL does not contain an indentation, small hollow, or cleft configured to receive a hinge flange **on** an inner side surface. RX-0009C, Q/A 108-109. Additionally, Sun Pharma has not asserted that RhodoLED[®] XL meets this limitation under the doctrine of equivalents, and, consequently, claims 17-18 are also not infringed under the doctrine of equivalents.⁹

⁹ To the extent Sun Pharma elects to assert in the future that this limitation is met under the doctrine of equivalents, Biofrontera reserves the right to respond.

D. Biofrontera Does Not Infringe the Asserted Method Claims Because They Require the Use of “Five Panels” to “Uniformly Illuminate a Treatment Surface of the Patient”

1. Biofrontera Does Not Directly Infringe the Asserted Method Claims of the '512 Patent

The Asserted Claims of the '512 patent include method claims 8, 17, and 18, which recite “[a] *method* of photodynamically diagnosing or treating a patient” using the claimed “illuminator” by performing certain treatment steps. '512 patent, claims 8, 17, and 18. For example, the asserted method claims of the '512 patent require the steps of:

- (1) Administering ALA to the patient;
- (2) Positioning the illuminator proximate to the patient; and
- (3) Uniformly illuminating a treatment surface of the patient with light sources disposed on the at least five panels of the illuminator.

RX-0011C, Q/A 61. As the Federal Circuit has explained, claims directed to a method that require the performance of certain steps can only be directly infringed by a party that performs each of the claimed steps. *Warner-Lambert*, 316 F.3d at 1363.

Here, because Biofrontera does not diagnose or treat patients according to the claimed method, Biofrontera does not directly infringe claims 8, 17, and 18 of the '512 patent. RX-0011C.0017-18, Q/A 61-64. Indeed, Sun Pharma's experts, Drs. Shmuylovich and Jokerst, only testified that Biofrontera induces healthcare providers to infringe the asserted method claims of the '512 patent, not that Biofrontera directly infringes these claims. CX-0009C, Q/A 132-134; CX-0010C, Q/A 591-593.

Thus, because Biofrontera does not perform the claimed steps of diagnosing or treating patients, including administering ALA to the patient, positioning an illuminator proximate a patient, and uniformly illuminating a treatment surface of the patient with light sources disposed on the at

least five panels of the illuminator, Biofrontera does not directly infringe method claims 8, 17, and 18 of the '512 patent.¹⁰

2. Biofrontera Does Not Indirectly Infringe the Asserted Method Claims of the '512 Patent

Sun Pharma and its experts have alleged that Biofrontera induces healthcare providers to infringe the asserted method claims of the '512 patent. *See, e.g.*, CX-0009C, Q/A 132-134; CX-0010C, Q/A 591-593. Because the asserted method claims require the performance of certain steps, Biofrontera must intend (*i.e.*, encourage, recommend, or promote) for healthcare providers to perform each of the steps required by these claims to induce infringement.¹¹ *See, e.g., Takeda*, 785 F.3d at 631 (pharmaceutical manufacturers must “encourage, recommend, or promote” an infringing use); *Vita-Mix Corp. v. Basic Holding, Inc.*, 581 F.3d 1317, 1328 (Fed.Cir.2006) (no direct or induced infringement when user manual did not evidence a specific intent to infringe even though device could be used in an infringing manner); *Acorda Therapeutics Inc. v. Apotex Inc.*, 2011 WL 4074116, *20 (C.A. No. 07-4937, D.N.J. Sept. 6, 2011) (finding no induced infringement and stating “[t]he label does not direct infringement, and while the information might allow people to infringe, the ultimate question is not whether some physicians may infringe the patent.”), *aff'd*, 476 Fed. Appx. 746 (Fed. Cir. 2012). In the instant case, to establish that Biofrontera has induced infringement of the method claims of the '512 Patent, Sun Pharma must prove that Biofrontera “encouraged, recommended, or promoted” use of the RhodoLED® XL in a manner that would

¹⁰ While Sun Pharma has not asserted that Biofrontera directly infringes the asserted method claims, Biofrontera reserves the right to respond, including at trial.

¹¹ Although there are two types of indirect infringement, induced infringement and contributory infringement, Sun Pharma and its experts have only asserted that Biofrontera induces infringement. While Sun Pharma has not asserted that Biofrontera contributorily infringes the Asserted Claims, Biofrontera reserves the right to respond, including at trial.

directly infringe all steps of the method claims. *Warner-Lambert*, 316 F.3d at 1363; *see also Takeda*, 785 F.3d at 631; *Amarin*, 104 F.4th at 1379-80.

Independent claim 8 of the '512 patent, from which claims 17 and 18 depend, requires several steps, including the steps of “positioning an illuminator proximate to the patient, the illuminator comprising at least five panels...and uniformly illuminating a treatment surface of the patient with light sources disposed on ***the at least five panels*** of the illuminator.” '512 patent, claims 8, 17, 18. Under the legal principle of antecedent basis, and consistent with the plain and ordinary meaning of this phrase, light sources disposed on all of “***the at least five panels***” must be used to “uniformly illuminate a treatment surface.” *Baldwin Graphic Sys., Inc. v. Siebert, Inc.*, 512 F.3d 1338, 1342-43 (Fed. Cir. 2008) (use of definite articles such as “the” and “said” are “anaphoric phrases, referring to the initial antecedent phrase”); *see also Warner-Lambert Co.*, 316 F.3d at 1356 (citations omitted). Consequently, the asserted method claims of the '512 patent require the use of at least five panels to uniformly illuminate the treatment surface of a patient. RX-0011C, Q/A 80-81. In other words, the use of *fewer* than five panels to uniformly illuminate the treatment surface of a patient would fall outside the scope of the asserted method claims of the '512 patent and would not infringe. *Id.*

The plain language meaning is supported by the specification, which clearly draws a distinction between the use of five or more panels on one hand, and the use of fewer than five panels on the other. *See, e.g.*, JX-0001, at 3:50-60 (describing where the light sources are separate from other components of the illuminator); 4:23-44 (describing properties of different subsets of the panels); 5:50-6:8 (explaining that the individual panels may be controlled to ensure uniform illumination); 7:53-57 (disclosing an embodiment where only three panels are used); *see also* RX-0011C, Q/A 82. Thus, when Sun Pharma intended to discuss the use of fewer than five panels, the

specification did so with clear language. RX-0011C, Q/A 82. But in the asserted method claims of the '512 patent, Sun Pharma deliberately drafted the claims to recite “uniformly illuminating a treatment surface” with “*the at least five panels.*” *Id.*

Additionally, the claims support this by expressly omitting any language that would indicate to a POSA that fewer than five panels may be used. RX-0011C, Q/A 83. Indeed, Sun Pharma now owns a new patent, U.S. Patent No. 12,290,700, which issued on May 6, 2025, that expressly claims the use of *fewer* than five panels as part of a method of treatment claim (reciting a step of illuminating with “a plurality of light sources,” encompassing two or more panels). RX-1432, cls.; RX-0011C, Q/A 84-87. Further, neither Dr. Jokerst nor Dr. Shmuylovich testified that the asserted method claims of the '512 patent encompass the use of fewer than five panels. *See, e.g.*, CX-0009C.31-32, 36-37; CX-0010C.85-94; *see also* RX-0011C, Q/A 88-89.

Accordingly, the claim phrase “uniformly illuminating a treatment surface of the patient with light sources disposed on the at least five panels of the illuminator,” as recited in the asserted method claims of the '512 patent, requires the use of at least five panels to illuminate the treatment surface. To prove that Biofrontera induces infringement of the asserted method claims of the '512 patent, Sun Pharma must prove that Biofrontera encourages, recommends, or promotes that healthcare providers should use all five panels of the RhodoLED[®] XL to photodynamically treat patients. As the evidence in this Investigation will show, Biofrontera does not induce healthcare providers to use all five panels of the RhodoLED[®] XL to photodynamically treat patients. As Dr. Ehrenreich testified, Biofrontera does not instruct healthcare providers to use *all five* panels of the RhodoLED[®] XL via the Ameluz[®] label or the RhodoLED[®] XL user manual. RX-0011C, Q/A 94. First, the Ameluz[®] label’s only “instruction” to healthcare professionals is to “[i]lluminate the treatment area.” JX-0074.4; RX-0011C, Q/A 97. To illuminate the treatment area, the label

“recommend[s]” the use of “3 adjacent panels,” but gives healthcare providers an option to use all five panels. JX-0074.4; RX-0011C, Q/A 95-98. In other words, the Ameluz[®] label instructs, or recommends, that healthcare providers should use three adjacent panels to treat patients, which does not amount to inducing healthcare providers to infringe the asserted method claims of the ’512 patent. RX-0011C, Q/A 95-98.

Indeed, the Ameluz[®] label does not even require the use of the RhodoLED[®] XL—it explains that the BF-RhodoLED[®] (consisting of a single panel) can be used and that “[l]arger areas can be illuminated in several steps.” JX-0074.4; RX-0011C, Q/A 97. Thus, the label is indifferent about how the treatment area is illuminated—it can be accomplished with either of two devices, the RhodoLED[®] XL or the BF-RhodoLED[®], and even if the RhodoLED[®] XL is selected, the label only requires the use of three adjacent panels, not all five. RX-0011C, Q/A 96-98.

Further, the fact that the Ameluz[®] label *allows* healthcare providers to use all five panels at their discretion does not mean Biofrontera induces infringement of the asserted method claims. *Takeda*, 785 F.3d at 631 (“The mere existence of direct infringement by physicians, while necessary to find liability for induced infringement, is not sufficient for inducement.”); *see also* *HZNP*, 940 F.3d at 702; *Accorda*, 2011 WL 4074116 at *18. For example, the Ameluz[®] label explains that:

RhodoLED XL has a curved configuration with an effective treatment area up to 23 x 29 cm. Position the lamp head of the RhodoLED XL 11-14 cm from the skin’s surface. This **usually allows** a full-face illumination **with the use of 5 panels**. The smallest **recommended number of panels to be used are 3 adjacent panels** (see chapter 8.4.6 of RhodoLED XL user manual).

JX-0074.4-5 (emphasis added); RX-0011C, Q/A 101. The phrase “usually allows” shows that “the use of 5 panels” is optional, whereas the use of “3 adjacent panels” is “recommended.” RX-0011C, Q/A 101.

Moreover, the RhodoLED[®] XL user manual, which is also included on the Ameluz[®] label at pages JX-0074.32-55, does not instruct healthcare providers to use all five panels. RX-0011C, Q/A 48. As Dr. Ehrenreich testified, the Ameluz[®] label tells healthcare providers to follow the instructions and warnings on the RhodoLED[®] XL user manual. RX-0011C, Q/A 104; JX-0074.1, JX-0074.4. Thus, healthcare providers would not read the Ameluz[®] label alone when treating patients with the RhodoLED[®] XL—they would understand that the RhodoLED[®] XL user manual must also be read in conjunction with the label to determine how the device should be used to treat patients. RX-0011C, Q/A 104-105; *see also id.* at RX-0011C, Q/A 48-50.

The RhodoLED[®] XL user manual reinforces that it is at the discretion of healthcare providers whether to use five panels or fewer, but that at least three adjacent panels must be used. RX-0011C, Q/A 104-105; *see also* JX-0086.16-17. For example, the RhodoLED[®] XL user manual includes “step-by-step instruction[s]” that should be followed during treatment, including “[s]electing active panels (see chapter 8.4.5)” (step 6) before initiating a patient treatment session. RX-0011C, Q/A 105-106; *see also* JX-0086.16-17. And chapter 8.4.6 of the RhodoLED[®] XL user manual explains that treatment can be accomplished using “three adjacent panels” depending on the patient’s “face and head size[.]” JX-0086.16; RX-0011C, Q/A 105-106. Thus, the RhodoLED[®] XL user manual’s step-by-step instructions clearly explain that healthcare providers should use at least three adjacent panels, and that they may choose to use all five panels. RX-0011C, Q/A 105-106.

Chapter 8.4.5 of the RhodoLED[®] XL user manual explains that “[t]he device has 5 LED panels,” and that each of the individual panels “can be deactivated via the software” reflected on the device’s touchscreen if desired. JX-0086.16. While “[a]ll panels are activated by default,” the user manual explains that each individual panel can be easily “deactivated” using the software. *Id.*; *see also* RX-0011C, Q/A 105-106. This demonstrates that Biofrontera has designed the

RhodoLED® XL in a way that allows healthcare providers to use their discretion when determining whether to use three or five panels to treat patients. RX-0011C, Q/A 107. Biofrontera does not *intend* (i.e., encourage, recommend, or promote) that healthcare providers use all five panels. *Id.* Instead, Biofrontera specifically designed the RhodoLED® XL device so that healthcare providers have the option of using three, four, or five panels, and can treat patients with the desired number of panels. *Id.*

Finally, the RhodoLED® XL user manual explains that “[i]f less than 5 panels are used for a treatment, ***it must be ensured that at least three adjacent panels are used.*** The treatment area is thereby reduced and reaches from the midline of the one outer panel to the other midline of the other outer panel.” JX-0086.17; RX-0011C, Q/A 108. This requirement that the healthcare provider must “ensure[] that at least three adjacent panels are used” is consistent with the label’s statement that “[t]he smallest recommended number of panels to be used are 3 adjacent panels (see chapter 8.4.6 of RhodoLED XL user manual).” JX-0086.17; JX-0074.4; RX-0011C, Q/A 108.

The evidence does not support that healthcare providers are prevented from using their discretion when using the RhodoLED® XL device. Rather, the Ameluz® label expressly states that Ameluz® is “indicated for the lesion-directed and field-directed treatment of [AK] of mild-to-moderate severity on the face and scalp.” JX-0074.1; RX-0011C, Q/A 47; RX-0011C, Q/A 169. Thus, Ameluz® in combination with the RhodoLED® XL device is indicated to treat both single AK lesions (i.e., lesion-directed therapy) as well as multiple AK lesions (i.e., field-directed therapy) on the face and scalp. JX-0074.1; RX-0011C, Q/A 47; RX-0011C, Q/A 169. A healthcare provider would understand that the coverage necessary for a treatment area can vary significantly depending on the number and type of AKs on a patient’s face and scalp. JX-0074.1; RX-0011C, Q/A 47; RX-0011C, Q/A 169.

For example, if a patient has a single (or relatively small number) of AK lesions that must be treated, the coverage area would be limited to only that specific area of the patient's face or scalp. RX-0011C, Q/A 47; RX-0011C, Q/A 169. In that scenario, the patient's AK lesion could be treated with fewer than five panels because the "coverage area" is quite small and there would be no need to illuminate the other areas that do not require any treatment. RX-0011C, Q/A 47; RX-0011C, Q/A 169. Indeed, in this scenario, a healthcare provider would understand that illuminating a patient's entire face and scalp (i.e., the unaffected areas of the face and scalp) would serve no therapeutic purpose. RX-0011C, Q/A 47; RX-0011C, Q/A 169. And if the necessary illumination could be achieved with only three panels, it would be desirable to deactivate the other two panels so that the patient and healthcare providers are not exposed to excess light and heat. RX-0011C, Q/A 47; RX-0011C, Q/A 169. Thus, a healthcare provider would actively try to minimize the illumination of the areas of a patient's face and scalp that do not require treatment—the easiest way to do that would be to use three panels instead of five, as supported by the evidence. RX-0011C, Q/A 47; RX-0011C, Q/A 169.

To reiterate, Biofrontera's intent is for healthcare providers to use at least three adjacent panels of the RhodoLED[®] XL, but healthcare providers are allowed to use all five panels when treating patients, and the evidence will show that Biofrontera designed the RhodoLED[®] XL device with that goal in mind. Indeed, Dr. Luebbert testified to exactly this point in his witness statement. RX-0004C, Q/A 102.

Likewise, deposition statements by Dr. Jon Lyons, an employee of Biofrontera, demonstrate that healthcare providers do not *need* to use all five panels because three panels *can* achieve a uniformity of light.¹² RX-0011C, Q/A 133.

Specifically, Dr. Lyons was asked about a document in which Biofrontera responded to certain questions from the FDA about the RhodoLED® XL. JX-0067C. Dr. Jokerst likewise relied on this document, among others, to testify that Biofrontera induces healthcare providers to use all five panels of the RhodoLED® XL to treat patients. CX-0010C.93. As Dr. Ehrenreich explained, these documents have no bearing on what Biofrontera tells *healthcare providers* about using the RhodoLED® XL to treat patients, and thus have limited, if any value, to the inducement issues in this case. RX-0011C, Q/A 131-133.

Regardless, Biofrontera explained to the FDA that:

Within the default configuration of the BF-RhodoLED XL lamp all panels are activated. However, it is correct that panels can be individually deactivated. ***This function was intended to allow healthcare providers to adapt the illumination surface to the requirements of the individual patient.***

JX-0067C.5; RX-0011C, Q/A 131-133. Thus, Biofrontera expressly represented to the FDA that patients can be treated using three panels, and that the use of all five panels is optional. JX-0067C.5; RX-0011C, Q/A 131-133.

Similarly, Drs. Shmuylovich and Jokerst relied on a number of marketing materials, other FDA-related documents, and research and development documents in support of their testimony that Biofrontera induces healthcare providers to use all five panels of the RhodoLED® XL to treat patients. *See, e.g.*, CX-0009C.23 (citing JX-0108C, JX-0085C); CX-0009C.25 (citing JX-0073C);

¹² When asked whether a response about Biofrontera's representation to the FDA indicates "that even if three of the RhodoLED XL panels are being used, there's still a uniformity of light," Dr. Lyon's answered "[t]hat's correct." JX-0009C, 47:16-48:11.

[REDACTED]

CX-0009C.35 (citing JX-0089C); CX-0009C.37 (citing JX-0105C); CX-0010C.92 (citing JX-0078C); CX-0010C.93 (citing JX-0067C). As Dr. Ehrenreich testified, while some of these documents have little, if any, relevance to what Biofrontera tells healthcare providers about using the RhodoLED[®] XL to treat patients, they all consistently explain that Biofrontera recommends, or intends, for healthcare providers to use at least three adjacent panels to treat patients, and that healthcare providers are allowed to use all five at their discretion. *See, e.g.*, RX-0011C, Q/A 114-133. Even Biofrontera’s marketing materials, including a video of Dr. Ted Lain demonstrating how healthcare providers may use the RhodoLED[®] XL device to treat patients, explain that while the RhodoLED[®] XL device has five panels, healthcare providers should use at least three panels, with the option to use five panels, to treat patients. *Id.*

Accordingly, Biofrontera does not encourage, recommend, or promote the use of all five panels of the RhodoLED[®] XL to “uniformly illuminate a treatment surface of the patient with light sources disposed on the at least five panels of the illuminator,” as required by the asserted method claims of the ’512 patent. As the evidence will show, Biofrontera does not induce healthcare providers to illuminate a treatment surface with all five of the RhodoLED[®] XL’s panels, and does not indirectly infringe method claims 8, 17, and 18 of the ’512 patent. Additionally, Sun Pharma has not asserted that RhodoLED[®] XL meets this limitation under the doctrine of equivalents, and, consequently, Biofrontera does not induce infringement of claims 8, 17, and 18 under the doctrine of equivalents.¹³

E. Biofrontera Does Not Infringe Claims 1, 2, 4, 20, and 21 of the ’028 Patent Because the “Within Approximately Four Inches” Limitation Is Not Met

¹³ To the extent Sun Pharma elects to assert in the future that this limitation is met under the doctrine of equivalents, Biofrontera reserves the right to respond.

Sun Pharma has not proven that all five panels of the RhodoLED[®] XL are positioned within approximately four inches of a patient's treatment surface, as required by claims 1, 2, 4, 20, and 21 of the '028 Patent. Asserted Claims 1, 2, 4, 20, and 21 of the '028 Patent recite "[a] system for photodynamically diagnosing or treating **a patient**," and include a requirement that "the five panels **are positioned to allow treatment** within approximately four inches of **the treatment surface**." '028 patent, claims 1, 2, 4, 20, and 21. As Sun Pharma's expert agrees, this limitation can only be infringed by a healthcare provider that performs the steps or actions recited in the Asserted Claims to **position** the RhodoLED[®] XL relative to a patient's treatment surface. RX-0011C, Q/A 139; RX-1379C (Jokerst Dep. Tr.), 176:1-177:14 ("this is a system for photodynamically diagnosing or treating, and so *this illuminator needs to be placed at distances that are consistent with photodynamically diagnosing or treating*."); RX-0013C (Jokerst Op. Rep.), ¶¶317, 797; RX-0996C.0389-390 (Complainant's Fourth Supplemental Interrogatory Responses dated December 4, 2024). Likewise, ALJ Moore's claim construction order explains with respect to these specific claims "refer to a 'treatment surface'" and "[b]y using these words, the claims specify that *the system is used for treating (or diagnosing) a patient*." Order No. 18, 29. Accordingly, because Biofrontera does not use the RhodoLED[®] XL to treat or diagnose patients and does not position "the five panels" of the RhodoLED[®] XL "within approximately four inches of the treatment surface" of a patient, Biofrontera does not directly infringe claims 1, 2, 4, 20, and 21 of the '028 Patent. RX-0011C, Q/A 139.

Further, Biofrontera does not induce healthcare providers to position "the five panels" of the RhodoLED[®] XL "within approximately four inches of the treatment surface" of a patient. RX-0011C, Q/A 137. As a starting point, the phrase "within approximately four inches of the treatment surface" was construed to mean "less than or equal to approximately four inches from the treatment

surface.” Order No. 18, 45. Thus, the scope of “less than or equal to approximately four inches,” specifically what numerical cutoff above 4.0 inches constitutes “approximately four inches,” is relevant to the inducement issues in this Investigation.

Sun Pharma’s expert, Dr. Jokerst, offered two alternative positions in her initial witness statement.¹⁴ CX-0010C, Q/A 728-729. *First*, Dr. Jokerst testified that “approximately” means plus-or-minus 10% based on her experience as an engineer, not based on anything in the specification of the Asserted Patents. *Id.* Under this theory, Dr. Jokerst testified that “approximately four inches” would encompass distances up to 4.4 inches. *Id.*

Second, Dr. Jokerst testified that “[t]o the extent the phrase ‘approximately four inches’ is informed by the technological context of the photodynamic illuminators ... ‘approximately’ refers to the expected variations in placing the illuminator’s panels in a curved orientation around the treatment surface, such as a face.” *Id.* Under this theory, Dr. Jokerst did not appear to offer a specific numerical value or cutoff above 4.0 inches. RX-0011C, Q/A 142.

Regardless, Dr. Ehrenreich testified that in the absence of specific guidance in the specification that “approximately” means plus-or-minus 10%, which is not disclosed anywhere in the specification of the Asserted Patents, he would interpret this phrase to refer to a *de minimus* increase in distance above 4.0 inches. RX-0011C, Q/A 152. Dr. Ehrenreich based his testimony on (1) the limited guidance the specification offers about what this phrase means and (2) his

¹⁴ As Dr. Ehrenreich explained, Dr. Jokerst did not expressly take either of these positions in her opening expert report. RX-0011C, Q/A 145-146; *see also* RX-0013C, ¶799. And while Dr. Shmuylovich initially offered opinions about whether Biofrontera infringes this claim limitation in his opening expert report, his initial witness statement does not include any testimony on these claims or this infringement issue. RX-0011C, Q/A 147-148; *see also* RX-0012C, ¶¶135-139. Indeed, under questioning at their depositions, Sun Pharma’s Dr. Jokerst and Dr. Shmuylovich offered different testimony about what this limitation means. *Compare* RX-1379C.0179-181 (Jokerst Dep. Tr.) with RX-1380C.0131-141(Shmuylovich Dep. Tr.).

experience as dermatologist. *Id.* For example, Dr. Ehrenreich explained that “healthcare providers that treat patients via PDT would understand that even small changes in the distance between a patient’s skin and the light source can affect the efficacy of the treatment.” *Id.* Accordingly, the evidence will show that the phrase “less than or equal to approximately four inches from the treatment surface” should encompass only a *de minimus* increase in distance above 4.0 inches, not a ten percent variation.

With those points in mind, Dr. Ehrenreich testified that Biofrontera does not practice this claim limitation for several reasons. *First*, the Ameluz[®] label and the RhodoLED[®] XL user manual explain that the RhodoLED[®] XL panels should be positioned “4.9 +/- 0.6 inches” from a patient’s treatment surface. *See, e.g.*, JX-0074.4; JX-0086.9-10, 18, 27; *see also, e.g.*, RX-0011C, Q/A 155-158. Because “4.9 +/- 0.6 inches” is more than a *de minimus* increase above 4.0 inches, Biofrontera does not induce healthcare providers to position the RhodoLED[®] XL’s panels “less than or equal to approximately four inches from the treatment surface.”

Second, Dr. Jokerst testified that a patient’s nose may be closer to one of the panels of the RhodoLED[®] XL than the rest of the patient’s face is to the panels. CX-0010C, Q/A 731. But as Dr. Ehrenreich explained: (1) that does not mean that Biofrontera encourages, recommends, or promotes that healthcare providers should position the RhodoLED[®] XL’s panels closer to a patient’s nose than the rest of their face; (2) the claims of the ’028 patent require that “*the five panels*” are positioned within approximately four inches of the patient’s treatment surface, but under Dr. Jokerst’s nose-theory, at most one of the five panels would be within that distance; and (3) neither Dr. Jokerst nor Sun Pharma has produced any evidence in this Investigation that shows that a patient was treated with the RhodoLED[®] XL device such that the panels were positioned

“less than or equal to approximately four inches from the treatment surface.” RX-0011C, Q/A 167-170.

Third, Dr. Jokerst cited a number of other documents related to Biofrontera’s research and development efforts and correspondence with the FDA. *See, e.g.*, JX-0166C; JX-0082C; *see also* CX-0010C.126-129. As Dr. Ehrenreich explained, these documents are not illustrative of what Biofrontera tells healthcare providers about how to use the RhodoLED® XL to treat patients. *See, e.g.*, RX-0011C, Q/A 166. Regardless, the evidence will show that these documents are consistent with the instructions and guidance on the Ameluz® label and the RhodoLED® XL user manual—they do not encourage, recommend, or promote positioning all five panels of the RhodoLED® XL “less than or equal to approximately four inches from the treatment surface.”

In addition, Drs. Luebbert and Foguet both testified that Biofrontera’s *intent* is for healthcare providers to position the RhodoLED® XL panels at a distance of 4.9 inches from a patient’s treatment surface. RX-0004C.0028-30; RX-0002C, Q/A 93-95. The evidence will show that the Ameluz® label and RhodoLED® XL user manual allow for a 0.6-inch variation from 4.9 inches to account for patient movement during treatment. *See, e.g.*, RX-0002C, Q/A 93-95.

Even assuming Dr. Jokerst’s theories about noses and hypothetical treatment distances of 4.3 inches or less are correct, *at most* they show that it is possible for healthcare providers to directly infringe this claim element. But the fact that direct infringement may occur, or even that it is permitted and has occurred under a drug product label or user manual, does *not* automatically mean that healthcare providers were induced to infringe. *Warner-Lambert*, 316 F.3d at 1364 (“mere knowledge of possible infringement by others does not amount to inducement; specific intent and action to induce infringement must be proven.”). *HZNP*, 940 F.3d at 685–86, 702; *Acorda Therapeutics*, 2011 WL 4074116 at *18. Absent specific evidence that this type of direct

infringement has occurred, or that Biofrontera has specifically instructed healthcare providers to use these treatment distances, Biofrontera does not infringe these claims.

Finally, for the first time in this Investigation, Dr. Jokerst alleged in her initial witness statement that “[t]o the extent Biofrontera is found not to infringe this claim element literally, it is my opinion that the stated treatment distance range for the RhodoLED[®] XL is the *equivalent* of the claimed treatment distance range of ‘within approximately four inches of the treatment surface’ under the construction of ‘less than or equal to approximately four inches from the treatment surface’ because both treatment distance ranges perform *the same function, in the same way, to achieve the same result.*” CX-0010C, Q/A 746. Dr. Jokerst did not opine in her opening expert report that Biofrontera infringes this claim element under the doctrine of equivalents. *See generally*, RX-0013C. Regardless, the Federal Circuit has made it clear that when a claim uses terms of approximation like “about” and “approximately,” the doctrine of equivalents is not available to further expand the scope of the claim. *Cohesive Techs., Inc. v. Waters Corp.*, 543 F.3d 1351, 1371–72 (Fed. Cir. 2008) (holding that claim containing the word “about” “already captured what would otherwise be equivalents within the literal scope of the claim.”); *Ortho-McNeil Pharm., Inc. v. Caraco Pharm. Lab’ys, Ltd.*, 476 F.3d 1321, 1328–29 (Fed. Cir. 2007) (holding that the doctrine of equivalents could be used to expand the word “about”). Accordingly, Sun Pharma may not attempt to broaden the scope of a claim term like “within *approximately* four inches” under the doctrine of equivalents to capture Biofrontera’s recommended treatment distance.

Accordingly, the evidence will show that Biofrontera does not infringe, directly or indirectly, literally or under the doctrine of equivalents, claims 1, 2, 4, 20, and 21 of the ’028 Patent.

F. Biofrontera Does Not Infringe Claims 16, 17, 19, and 21 of the ’028 Patent Because the “Individually Configurable” Limitation Is Not Met

Asserted systems claims 16, 17, 19, and 21 of the '028 Patent recite a requirement that “the five panels are individually configurable to control illumination from each of the five panels.” As ALJ Moore concluded, the preamble of all system claims is limiting, requiring that the system in question be “[a] system for ***photodynamically diagnosing or treating a patient***[.]” Reading these limitations in combination illustrates that configuring the illuminator must be done in connection with “photodynamically diagnosing or treating a patient.” This condition is simply not met by the RhodoLED® XL. Sun Pharma has offered several different theories as to how these limitations are allegedly infringed. But Sun Pharma’s allegations for this limitation conflict with the plain language of its claims and also fail because the accused manufacturing and maintenance steps are not part of “photodynamically diagnosing or treating a patient.”

As ALJ Moore held, the preamble of these claims “refer to a ‘treatment surface’” and “[b]y using these words, the claims specify that *the system is used for treating (or diagnosing) a patient.*” Order No. 18, 29. ALJ Moore further concluded that “the term ‘the five panels are individually configurable to control illumination from each of the five panels’ will be construed with its plain and ordinary meaning, which is ‘the power output and/or light intensity of each panel can be individually controlled.’” *Id.* at 40.

First, Sun Pharma argues, contrary to the language of its claims, that the claim limitation is met by turning individual panels off. *See* CX-0010C, Q/A 800. But the claims in question require that all five panels be used, stating “***light sources disposed on surfaces of the five panels***, the illuminator being configured to uniformly illuminate a treatment surface of the patient via ***the light sources...***” A plain reading of the italicized language shows that “light sources disposed on surfaces of the five panels” provides the antecedent basis for “the light sources” used later in the claim. As Dr. Ehrenreich testified, using light sources disposed on ***fewer than five panels*** does not

[REDACTED]

illuminate a treatment surface of the patient via the light sources disposed on surfaces of *the five panels*. RX-0011C, Q/A185. As Dr. Ehrenreich explained, this plain meaning of the claims is supported by Sun Pharma’s prosecution of U.S. Patent No. 12,290,700 (“’700 Patent”), a related patent deriving from the same parent applications and specification as the Asserted Patents. *See* RX-0011C, Q/A 84-87 (discussing RX-1432, U.S. Patent. No. 12,290,700). As the ’700 Patent demonstrates, if Sun Pharma wanted to claim use of fewer than all five patents, it knew how to do so. RX-1432.0021 (claiming “positioning two or more of the plurality of panels to be extended from the center panel such that the plurality of panels are positioned to allow treatment of the extremities of the patient”).

Second, adjustment of LEDs in a password protected [REDACTED] mode does not infringe.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]. *See, e.g.*, CX-0017C, Q/A 30-35, 40.

It is not possible for healthcare providers to adjust or control the “light intensity” of any of the panels of the RhodoLED® XL. Indeed, the [REDACTED] menu on the RhodoLED® XL, [REDACTED], is password protected and can only be accessed by Biofrontera employees. *See, e.g.*, JX-0118C.7; JX-0086.25; *See also, e.g.*, RX-0011C, Q/A 186-189; CX-0017C, Q/A 30-35, 40. As Dr. Foguet and Dr. Ehrenreich testified, healthcare providers would have no access to this [REDACTED] menu, and would not attempt to

access these settings or alter the intensity of the lights on the device under any circumstances. *See* RX-0002C, Q/A 76; RX-0011C, Q/A 190-191. Thus, configuring the LED intensity as part of the manufacturing process or [REDACTED]

[REDACTED] does not satisfy the Asserted Claims because it is not controlling the illumination as part of a system or method for photodynamically diagnosing or treating a patient. Under similar circumstances, the Federal Circuit has confirmed that software features that cannot be practiced by users will prevent a finding of infringement, even if some part of the system's code could be modified to operate in an infringing manner. *See Telemac Cellular Corp. v. Topp Telecom, Inc.*, 247 F.3d 1316 (2001) ("a device is capable of being modified to operate in an infringing manner is not sufficient, by itself, to support a finding of infringement"); *see also* U.S. Customs and Border Protection Ruling No. HQ H325116 at 30 (May 27, 2022).

Accordingly, the evidence will show that Biofrontera does not infringe, directly or indirectly, claims 16, 17, 19, and 21 of the '028 Patent.

V. THE ASSERTED CLAIMS OF THE '512 PATENT AND THE '028 PATENT ARE INVALID

A. The Asserted Claims Are Obvious Under 35 U.S.C. § 103

Claims 1, 2, 4, 16, 17, and 19-21 of the '028 Patent and claims 1, 3, 5, 8, 17-18, and 20 of the '512 Patent (collectively, the "Asserted Claims") are asserted by Sun Pharma in this Investigation. All of the Asserted Claims are invalid for obviousness over the prior art, as summarized in the chart below.

- **Claims 1, 2, 4, 16, 17, and 19-21 of the '028 Patent are invalid as obvious over Lundahl in view of Larsen.**
- **Claims 1, 3, 5, 8, and 20 of the '512 Patent are invalid as obvious over Lundahl in view of Larsen.**
- **Claims 1, 3, 5, 8, 17, 18, and 20 of the '512 Patent are invalid as obvious over Lundahl in view of Larsen further in view of Hente.**
- **Claims 17 and 18 of the '512 Patent are invalid as obvious over Lundahl in view of Larsen further in view of Hente, and further in view of Perutz**

RDX-0017C.006 (excerpt).

1. Legal Standards for Obviousness

Under 35 U.S.C. § 103, a patent claim is invalid “if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which said subject matter pertains.” 35 U.S.C. § 103. While the ultimate determination of whether an invention would have been obvious is a legal question, it is based on “underlying factual inquiries including: (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the claimed invention and the prior art; and (4) objective evidence of nonobviousness,” if any. *Eli Lilly and Co. v. Teva Pharms. USA, Inc.*, 619 F.3d 1329, 1336 (Fed. Cir. 2010). All four factors inform a conclusion of obviousness. *Apple Inc. v. Intl Trade Comm'n*, 725 F.3d 1356, 1365-66 (Fed. Cir. 2013).

If all elements of a claim are found in a combination of prior art references “the factfinder should further consider whether a person of ordinary skill in the art would be motivated to combine those references, and whether in making that combination, a person of ordinary skill would have

a reasonable expectation of success.” *Merck & Cie v. Gnosis S.p.A.*, 808 F.3d 829, 833 (Fed. Cir. 2015). In *KSR v. Teleflex*, the Supreme Court rejected a rigid approach to the obviousness inquiry and set out “an expansive and flexible approach” for evaluating obviousness. *KSR Int’l Co. v. Teleflex, Inc.*, 550 U. S. 398, 415 (2007). “Under the correct analysis, any need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed.” *Id.*, at 420. The *KSR* decision indicates that pressure to solve a known problem, the presence of a limited number of predictable solutions, and anticipated success are all relevant factors in determining whether an invention is obvious. *Id.*, at 421.

Where a problem is within the knowledge of one of ordinary skill in the art, it is irrelevant for purposes of determining obviousness that the relevant prior art does not disclose the problem. *See Cross Medical Prods., Inc. v. Medtronic Sofamor Danek Inc. and Medtronic Sofamor Danek USA, Inc.*, 424 F.3d 1293, 1323 (Fed. Cir. 2005). “When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense.” *KSR*, 550 U. S. at 421.

Evidence of a reasonable expectation of success may flow from the prior art references themselves, the knowledge of one of ordinary skill in the art, or the nature of the problem to be solved. *See Elekta Ltd. v. ZAP Surgical Sys., Inc.*, 81 F.4th 1368, 1376-77 (Fed. Cir. 2023). “An expectation of success need only be *reasonable*, not absolute.” *Pfizer Inc. v. Sanofi Pasteur Inc.*, 94 F.4th 1341, 1352 (Fed. Cir. 2024). *See also PAR Pharm., Inc. v. TWI Pharms., Inc.*, 773 F.3d 1186, 1198 (Fed. Cir. 2014). In order to satisfy the requirements for obviousness, conclusive proof

of efficacy is not required. *OSI Pharm., LLC v. Apotex Inc.*, 939 F.3d 1375, 1385 (Fed. Cir. 2019) ("To be clear, we do not hold today that efficacy data is always required for a reasonable expectation of success. Nor are we requiring ‘absolute predictability of success.’") The objective evidence, also known as “secondary considerations,” includes commercial success, long felt but unmet need, and failure of others. *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966).

While evidence of secondary considerations can tip the balance into finding that an invention is not obvious, the secondary considerations cannot of themselves trump a clear showing that the invention is obvious. The Supreme Court has previously held that “[secondary] considerations are relevant only in a close case where all other proof leaves the question of invention in doubt.” *Dow Chemical Co. v. Halliburton Oil Well Cementing Co.*, 324 U.S. 320, 330 (1945). Further, “[i]n order to accord substantial weight to secondary considerations in an obviousness analysis, the evidence of secondary considerations must have a nexus to the claims. . . . The patentee bears the burden of showing that a nexus exists.” *Fox Factory, Inc. v. SRAM, LLC*, 944 F.3d 1366, 1373 (Fed. Cir. 2019). For example, assertions of industry praise and/or commercial success must be connected to the novel elements of the claims. *S. Alabama Med. Sci. Found. v. Gnosis S.P.A.*, 808 F.3d 823, 827 (Fed. Cir. 2015). Additionally, aspects of secondary considerations may be obviated by early disclosure of claim elements in the prior art. *See, e.g., ABT Sys., LLC v. Emerson Elec. Co.*, 797 F.3d 1350, 11362 (“The disclosures of the prior art references eliminate any serious contention that there was a long-felt need for the invention...”); *see also E.I. du Pont de Nemours & Co. v. Synvina C.V.*, 904 F.3d 996, 1012 (Fed. Cir. 2018) (“Where the prior art is so close, it has not been shown that DuPont copied [the asserted patent] rather than the other references within the prior art.”).

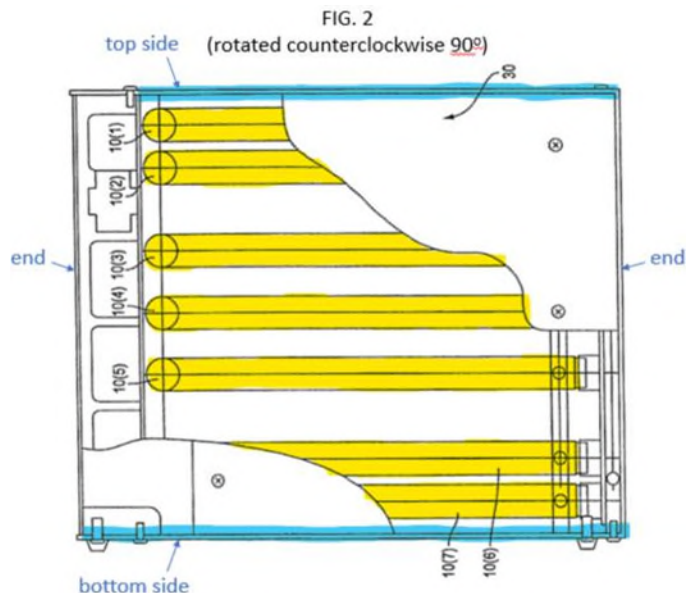
2. Scope and Content of the Prior Art

i. Lundahl (incorporating Kennedy)

U.S. Patent No. 6,223,071 (hereinafter referred to as “Lundahl”) was filed on May 1, 1998. Lundahl qualifies as prior art under §102(a)(1) because it was published before the earliest effective filing date of the '028 and '512 Patents. RX-0006C, Q/A 87-88.

Lundahl teaches an apparatus and method for photodynamic therapy or photodynamic diagnosis using an illuminator comprising a plurality of light sources. Lundahl Abstract. RX-0006C, Q/A 89. “The present invention is directed to photodynamic therapy using an illuminator that provides a uniform distribution of visible light.” RX-0065 (Lundahl), 1:9-11; RX-0006C, Q/A 89.

To achieve this uniformity, Lundahl utilizes the light distribution pattern illustrated in Fig. 2 (which has been highlighted, labeled, and rotated 90° to better illustrate how the light panel lines up with the top and bottom of a patient’s head):



RX-0065, Fig. 2; RX-0006C, Q/A 93.

Lundahl teaches that the spacing of the light sources can be adjusted to address the fall off effect. RX-0006C, Q/A 95. Lundahl explains that “[t]o avoid uniformity problems, one embodiment, of the present invention utilizes a plurality of U-shaped tubes 10(1)-10(7) [An]

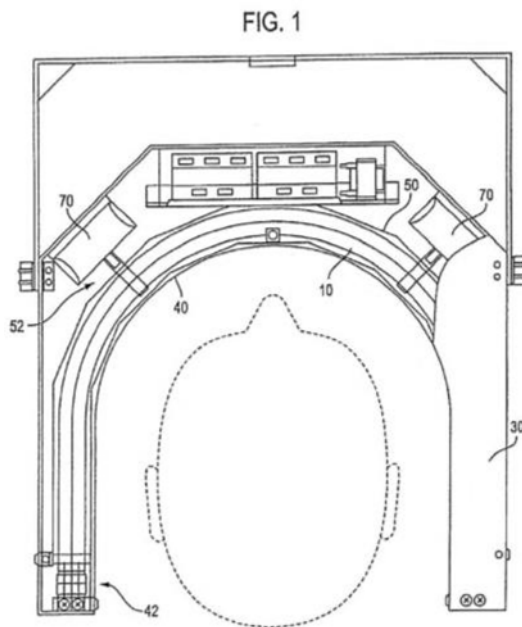


advantage of the arrangement is that uniformity can also be adjusted by varying the lateral spacing of the tubes (relative [vertical] spacing as shown in FIG. 2 [as depicted above, rotated 90 degrees counterclockwise]).” RX-0065, 6:16-25; RX-0006C, Q/A 94. Lundahl teaches to arrange the light bulbs in a higher density near the edges of the panel in order to improve uniformity of light distribution on the treatment surface. RX-0006C, Q/A 95. Lundahl explains that “[t]his is important since it is necessary to compensate for the fact that the output from a flat plane emitting light source drops near the edges. Varying the lateral spacing of the tubes creates the same effect as folding the edges of a larger illuminator in on itself, thus emulating an infinite plane emitter with a compact unit.” RX-0065, 6:25-30; RX-0006C, Q/A 95.

Lundahl states that the desired uniform illumination could be achieved by the spacing of lights within the illuminator, and providing a greater density of lighting near the top and bottom of the panel, stating “[t]he number of tubes used and the spacing between them were chosen to achieve desired uniformity and power output specifications...The present invention provides a highly uniform output irradiance without the use of an additional diffusing element.” Lundahl, 6:43-57; RX-0006C, Q/A 95-97. Importantly, Lundahl states that other design elements, such as “additional diffusing elements,” were not needed to achieve the desired uniform illumination, as the spacing of lights provided the “desired uniformity.” RX-0006C, Q/A 214. Lundahl teaches a higher density light sources near the forehead and chin regions of the head, that is, nearer the top and bottom of the head. RX-0006C, Q/A 97. This is to compensate for the fall off effect at the edges of the illuminator, as well as the lowered absorbance at the treatment surface that results as the head curves away from the illuminator. RX-0006C, Q/A 97.

Lundahl states “the present invention uses a U-shaped emitting surface that more closely follows the contours of the human face and scalp, and minimizes lamp to target distance variations

which in turn minimizes irradiance variations at the target.” RX-0065, 4:34-38; RX-0006C, Q/A 92. Lundahl illustrates this positioning on the PDT device in Fig. 1, showing the positioning of the patient’s head and nose within the device. RX-0006C, Q/A 96.

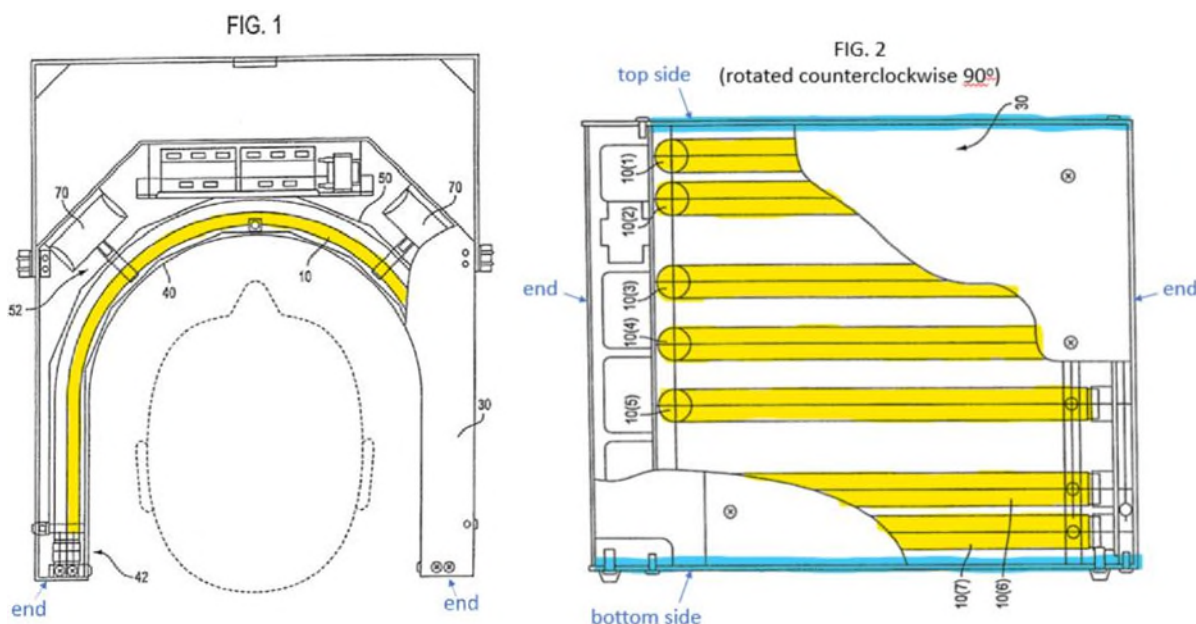


RX-0065, Figure 1.

Lundahl explains that the U-shape of the PDT device helps to maintain the proper distance between the light-emitting panel and the patient head, stating “[t]he U-shape minimizes the variations in distance between the emitter and the target, providing a uniform visible light distribution to the face or scalp of the patient; the tube dimensions were chosen based on the average dimensions of the adult human head.” RX-0065, 6:31-35; RX-0006C, Q/A 98.

Lundahl teaches that its device is designed to achieve uniform illumination of a surface, when the device is positioned at 2 inches and 4 inches from the surface, stating that “according to a preferred embodiment of the present invention, the measured output over the active emitting area is within 70% of the measured maximum when measured with a cosine response detector at distances of 4” and 2”.” RX-0065, 15:22-27; RX-0006C, Q/A 99.

Lundahl teaches that “[t]he number of tubes used and the spacing between them were chosen to achieve desired uniformity and power output specifications.” RX-0065, 6:43-45; RX-0006C, Q/A 178. As shown in the annotated Figures 1 and 2 of Lundahl below (with the light tubes highlighted yellow, the top and bottom sides highlighted blue, and Figure 2 rotated to show the apparatus as oriented during operation), “[o]ptimum output distribution has been found to occur when seven tubes 10(1)10(7) are placed in the chassis in a symmetric pattern with respect to opposite edges of the unit” RX-0065, 6:45-48; RX-0006C, Q/A 213.



Lundahl includes the “following approximate lateral spacing: 7 cm between the center tube 10(4) and each of the two tubes 10(3),10(5) adjacent to the center tube 10(4); 5 cm between the tubes 10(3),10(2) and 10(5),10(6), i.e., the next pairs of tubes out from the center; and 3.5 cm between tubes 10(2),10(1) and 10(6),10(7), i.e., the outermost pairs of tubes at the sides of the unit.” RX-0065, 6:48-54; RX-0006C, Q/A 214. Lundahl also states that “[t]he outermost tubes 10(1),10(7) are approximately 2.5 cm from the edges of the housing” and “[t]he present invention provides a highly uniform output irradiance without the use of an additional diffusing element.” RX-0065, 6:54-57; RX-0006C, Q/A 214. A POSA would have understood that the tubes of

Lundahl are spaced to emit a higher intensity of light proximate the top and bottom sides compared to the intensity of light emitted not proximate the top and bottom sides, and that this spacing “provides a highly uniform output irradiance.” RX-0006C, Q/A 94-95, 97, 321.

Lundahl teaches that “[s]ince total light Dose (J/cm^2) = Irradiance (W/cm^2) $\times$ Time (sec), the only additional parameter that needs to be controlled for delivery of the correct treatment light dose is exposure time”, which is “accomplished in a preferred embodiment of the present invention by the timer which controls electrical power to the ballasts and which can be set by the physician.” RX-0065, 15:55-61.

Additionally, in its discussion of the background on PDT treatment, Lundahl states “[g]eneral background information on PDT using 5-aminolevulinic acid (“ALA”) as the precursor of a photoactivatable agent can be found in U.S. Pat. No. 5,079,262, entitled ‘Method of Detection and Treatment of Malignant and Non-Malignant Lesions Utilizing 5-Aminolevulinic Acid,’ issued to James C. Kennedy et al. on Jan. 7, 1992, and U.S. Pat. No. 5,211,938, entitled ‘Method of Detection of Malignant and Non-Malignant Lesions by Photochemotherapy of Protoporphyrin IX Precursors,’ issued to James C. Kennedy et al. on May 18, 1993. The contents of these patents are incorporated herein by reference.” RX-0065, 1:39-49. Lundahl expressly incorporates all teachings of U.S. Patent No. 5,079,262 to Kennedy et al. (“Kennedy”). RX-0006C Q/A 101. Kennedy, filed on July 28, 1989, qualifies as prior art because it was published before the earliest effective filing date of the ’028 and ’512 Patents. RX-0006C Q/A 117-118.

Kennedy states “[a] method of detecting and treating malignant and non-malignant tissue abnormalities and lesions of the skin” in which “5-aminolevulinic acid is administered to the patient.” RX-0068 (Kennedy), Abstract. Kennedy teaches that red light was preferred for PDT, as it penetrates more deeply into the skin, as compared to blue light, and PpIX (the compound

produced by topical application of ALA) strongly absorbs red light. RX-0006C Q/A 102. Kennedy states that “[i]n preferred aspects of this invention the preferred precursor of protoporphyrin IX is 5-amino-4-oxo-pentanoic acid, otherwise known as 5-aminolevulinic acid, and a preferred wavelength of the photoactivating light is in the range 350-640 nm, more preferably a red light of about 610-630 nm.” RX-0068, 4:3-8. Kennedy also states that “[t]he wavelength of the photoactivating light is of some importance, as it has been shown that between 1 and 10 percent of incident red light (600-700 nm) can pass through a slab of human tissue 1 cm thick, whereas only 0.001 percent or less of blue light (about 400 nm) can pass through the same thickness of human tissue. The photosensitizer will, therefore, be more successful if it strongly absorbs red light. PpIX does strongly absorb red light.” RX-0068, 4:60-68.

Lundahl teaches that visible light in the range of “between 400 and 700 nm” may be used with the illuminator devices described above. *See* Lundahl, 2:14-26. Lundahl also describes applying ALA to a patient for the treatment of actinic keratosis, stating “One example of a treatment method for precancerous lesions, such as actinic keratosis, by PDT utilizing an illuminator described above in conjunction with 5-aminolevulinic acid (ALA) will now be described. Essentially anhydrous ALA is admixed with a liquid diluent just prior to its use. The ALA admixture is topically applied to the lesions using a point applicator to control dispersion of the ALA admixture.” RX-0065, 15:29-37; RX-0006C Q/A, 101-102.

Lundahl further describes the control system of the illuminator device, stating that “[a]ccording to a preferred embodiment of the present invention, an electronic control system 110 consists of six functional blocks. A microcontroller 200 is the central processing unit; it contains firmware which reads the system sensors, determines the system status, controls the ballast voltage (and tube output), and provides user information by way of a system status LED 112 (the firmware

is described in detail below). To achieve output irradiance in the specified range, the microcontroller 200 monitors the tube output via a visible light sensor 120 which is located behind the tube reflector 50.” RX0065, 11:19-29. Additionally, Lundahl teaches a cooling system incorporating fans. RX-0006C, Q/A 265. Lundahl states “a cooling system is provided to ensure proper bulb operation. According to an embodiment of the present invention, the cooling system comprises vents in the polycarbonate shield 40, the reflector 50 and the housing 30, as well as fans 70 to displace cooling air.” RX0065, 9:14-18.

Lundahl is from the same field of endeavor as the '028 and '512 Patents, which also describe illuminators for PDT. '028 Patent, 1:26-2:6; '512 Patent, 1:24-2:4. Lundahl is also directed to the same problem as the '028 and '512 Patents, namely, a PDT device for the treatment of actinic keratosis of the face and scalp, as well as other parts of the body (arms, legs, etc.). RX-0006C, Q/A 90. Therefore, Lundahl is analogous art to the '028 and '512 Patents. RX-0006C, Q/A 91.

ii. Larsen

U.S. Patent Application No. 2005/0075703 (hereinafter referred to as “Larsen”) was published on April 7, 2005, and claims priority to a foreign patent application filed on January 22, 2001. Larsen qualifies as prior art under §102(a)(1) because it was published before the earliest effective filing date of the '028 and '512 Patents. RX-0006C, Q/A 105-106.

Larsen teaches devices and methods for photodynamic therapy applications. RX-0006C, Q/A 107. “The present invention relates in general to electrotherapy devices and more particularly to devices and methods for photodynamic and electromagnetic stimulation of living tissue, directly and also indirectly, by stimulation of photosensitive substances introduced into or onto living tissue.” RX-0099 (Larsen), [0001]. More specifically, Larsen teaches PDT to address skin conditions including “solar keratoses, basal cell carcinoma, melanomas, etc.” using topically applied substances including “5-aminolevulan acid.” RX-0099, [0011]; RX-0006C, Q/A 107.

“Treatments have included the application of substances such as photoflim [sic], aminolevulan acid, hematoporphyrin, verteporfin, chlorins, phthalodyanines, phenothiazine, and benzoporphyrin-derivative monoacid-A (ATMPn) onto or into tissue for healing solar keratoses, basal cell carcinoma, melanomas, etc. such substances are known as ‘biopharmaceuticals’ and treatment with these substances has been called biopharmaceutical therapy. Therapy involving the application of biopharmaceuticals and their subsequent activation by light after they have been absorbed into tissue has been called photodynamic therapy (PDT).” RX-0099, [0011].

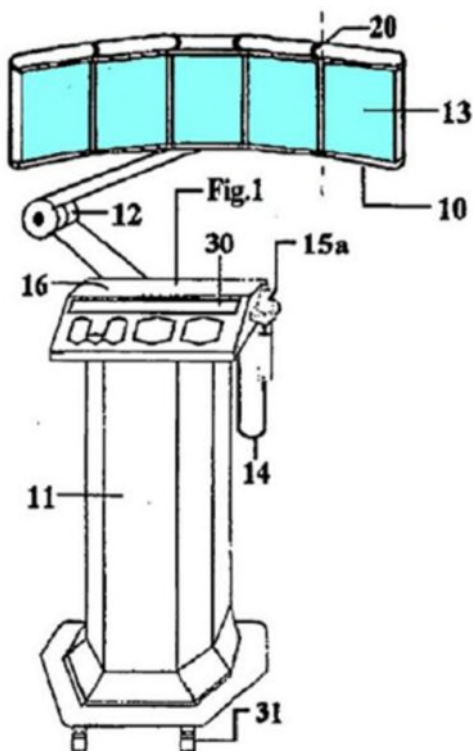
Larsen teaches the desirability and use of phototherapy equipment that can emit light over a large range of wavelengths from 300 nm to 2000 nm. RX-0006C, Q/A 114. “A device able to deliver an intensive light radiation with selective multiple wavelengths within the wavelength area of 300-2000 nm and electromagnetic fields is not at present available. Thus the invention is aimed at creating a device for intensive photodynamic therapy, which is capable of stimulating photodynamic energy of selective multiple light and/or laser radiation within a wavelength range of 300-2000 nanometers, capable of treatment with pulsating electromagnetic fields, and can also be used for stimulating light sensitive biopharmaceuticals.” Larsen, [0025]. A POSA would have understood that this range of wavelengths includes ultraviolet light, visible light, and infrared light. RX-0006C, Q/A 114.

Larsen also teaches use of semiconductor light sources mounted on multiple panels connected with hinges. RX-0006C, Q/A 110. Larsen calls its panels "applicators." RX-0006C, Q/A 110. “The plain surface applicators can consist of several applicators placed side by side and flexibly connected with each other through hinges, whereby the applicators are suitable for the treatment of large-area tissues such as the human back. The applicators contain printed circuit boards mounted with semiconductor diodes and/or laser diodes (in large numbers), and the diodes are mounted with reflectors, which collect the radiation and bundle them in front of the applicator.” RX-0099, [0027]-

[0028]. Semiconductor diodes are another term for light emitting diodes (LEDs). RX-0006C, Q/A 110.

Larsen describes that use of panels connected with hinges allows panels to be placed equidistant from the skin surface and prevent gaps (e.g., regions of low irradiance). RX-0006C Q/A 111. “For the treatment of large-area tissues according to Figure 1, several applicators 13 are flexibly connected to each other through hinges 10, respectively connecting one edge with the other, whereby the applicators are suitable for the treatment of for example, the backs of humans and so become adjustable for an equidistant positioning of the applicators 13 above the skin.” RX-0099, [0072]; RX-0006C, Q/A 113.

The use of multiple panels connected with hinges is illustrated in Figure 1 of Larsen (in which the applicators, i.e., the panels, have been highlighted in light blue). RX-0099, Fig. 1; RX-0006C, Q/A 110.



Larsen discloses controlling uniformity and amount of energy delivered by positioning its rotatable panels so that each panel surface is at roughly the same distance from the skin illuminated from that panel. RX-0006C, Q/A 112.

Larsen is from the same field of endeavor as the '028 and '512 Patents, which also describes illuminators for PDT. '028 Patent, 1:26-2:6; '512 Patent, 1:24-2:4. Larsen is also directed to the same problem as the '028 and '512 Patents, namely, an illuminator that can provide an “even and gap-free radiation of the surface with multiple wavelengths of light.” Larsen, ¶0028. Therefore, Larsen is analogous art to the '028 and '512 Patents. RX-0006C, Q/A 108-109.

iii. Hente

U.S. Patent Publication No. 2010/0118522 (hereinafter referred to as “Hente”) was filed on October 26, 2009, as a §371(c) national stage filing of PCT/IB08/51629 filed on April 28, 2009. Hente qualifies as prior art under §102(a)(1) because it was published before the earliest effective filing date of the '028 and '512 Patents. RX-0006C, Q/A 125-126.

Hente is directed to light emitting devices comprising organic light emitting diodes (i.e., organic LEDs or OLEDs) that allow for adjustable and foldable orientations. Hente, Title, Abstract. Hente explains that a number of illumination devices were known in the art, but that such light emitting devices were generally inefficient (in the case of gas discharged lamps) and did not have the desired flexibility to adjust for different sizes of areas to be illuminated. RX-0576 (Hente), [0002][0004]; RX-0006C, Q/A 128.

Hente teaches light emitting devices that have the flexibility to “illuminate large and point-like limited areas.” RX-0576, [0005]. Specifically, Hente discloses lighting devices with at least one first section and at least one second section. Hente, Abstract. Hente explains that the light emitting device can be expanded to provide a flat illumination surface, stating “In Figure 2 the light emitting device 10 is shown in an expanded position 100...In the expanded position 100 the

first section 20 and the second section 30 are arranged in such a way, that they form a longish stretched sheet like light emitting device 10. The artificial light 45 is primarily emitted through the bottom sides 21, 31 of each section 20, 30. In this position 100 the light emitting device 10 can be used to illuminate large areas....” RX-0576 [0036]; RX-0006C, Q/A 128. Figure 2 is illustrated below.

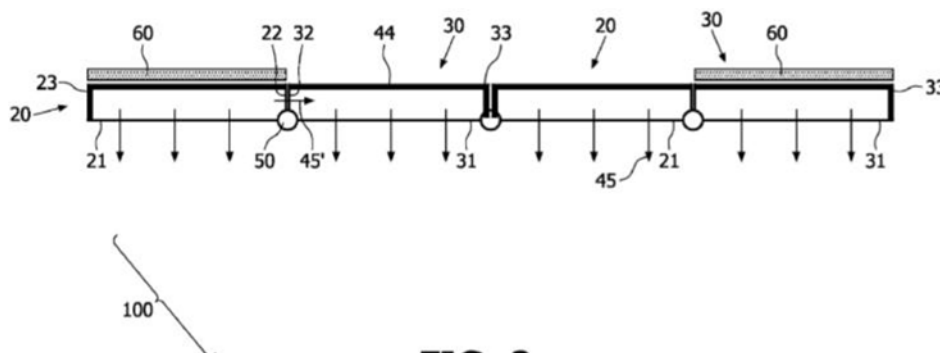
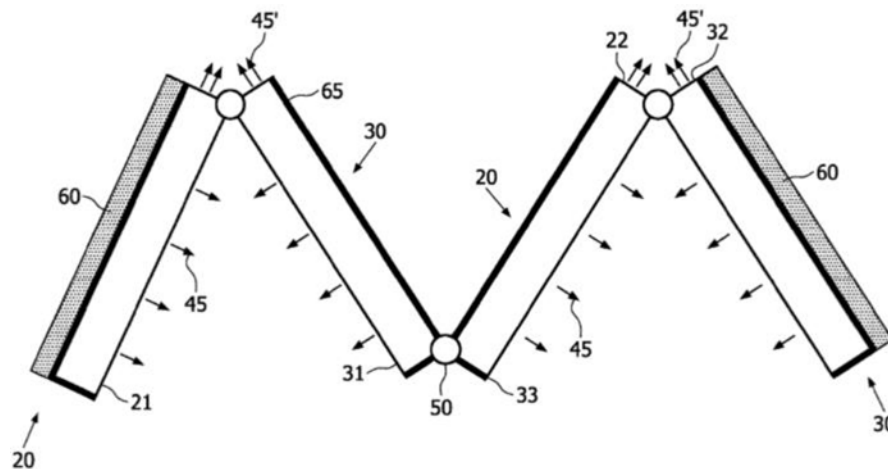


FIG. 2

Hente, Fig. 2.

Hente also teaches that the light emitting device may be adjusted or folded into a smaller, “compact” position, stating “[t]o enable the light emitting device to be converted from the expanded position 100 into the compact position 110 the sections 20, 30 are connected through a connection mean 50. As shown in Figure 3 the connection mean may be a hinges [sic], being located at the outer ends of each section 20, 30.” RX-0576, [0037]; RX-0006C Q/A 128-129. Figure 3 is illustrated below.



RX-0576, Fig. 3.

Furthermore, Hente teaches that at least one panel includes a recess configured to receive a flange of one of the hinges. RX-0006C, Q/A 292. As shown below, at least one panel includes an indentation in a surface to receive a “nested hinge” and the indentation in the surface is positioned at an inner side surface of the panel. RX-0576, Fig. 2; RX-0006C, Q/A 292.

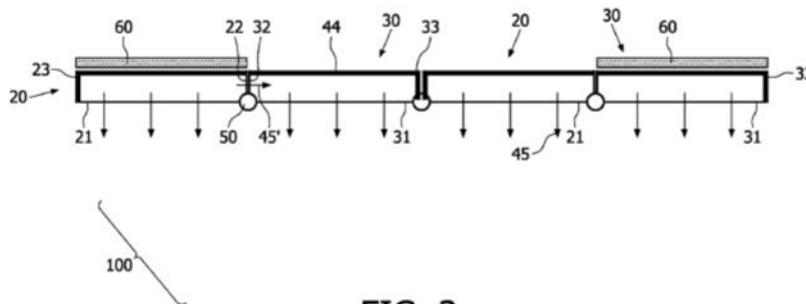


FIG. 2

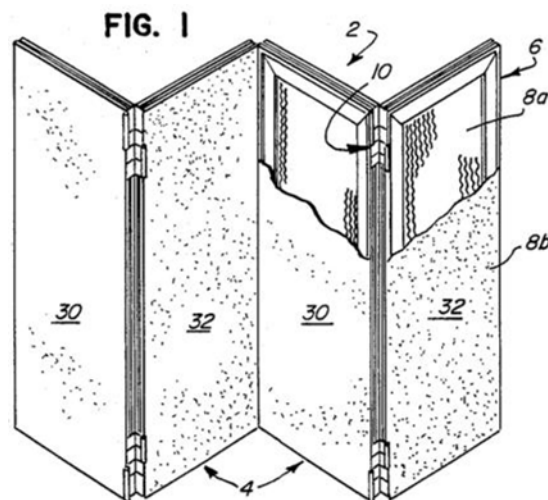
Hente is from the same field of endeavor as the '512 Patent, which also describes illuminators. JX-0001, 1:24-2:4. Both Hente and the Asserted Patents deal with the same problem, namely, providing illuminators that can be adjusted in size and shape depending on the desired area of illumination. In order to do this, both Hente and the Asserted Patents provide flexible illuminators that rotate around hinged connection points and can be positioned closer or farther from one another, depending on the desired shape of the illumination device. RX-0576, Figs. 2-3, [0036]-[0037]; RX-

0006C, Q/A 130. Therefore, Hente is analogous art to the '028 and '512 Patents. RX-0006C, Q/A 130-131.

iv. *Perutz*

U.S. Patent No. 4,823,858 (hereinafter referred to as “Perutz”) was filed on June 02, 1987. Perutz qualifies as prior art because it was filed before the earliest effective filing date of the '512 Patent. RX-0006C, Q/A 134-135.

Perutz teaches a hinged display panel system including “a plurality of display panels arranged in side by side relation and hingedly interconnected whereby one of the panels is capable of being selectively rotated relative to the other panel through a maximum arc of substantially 360°.” RX-0607 (Perutz), Abstract; RX-0006C, Q/A 136.

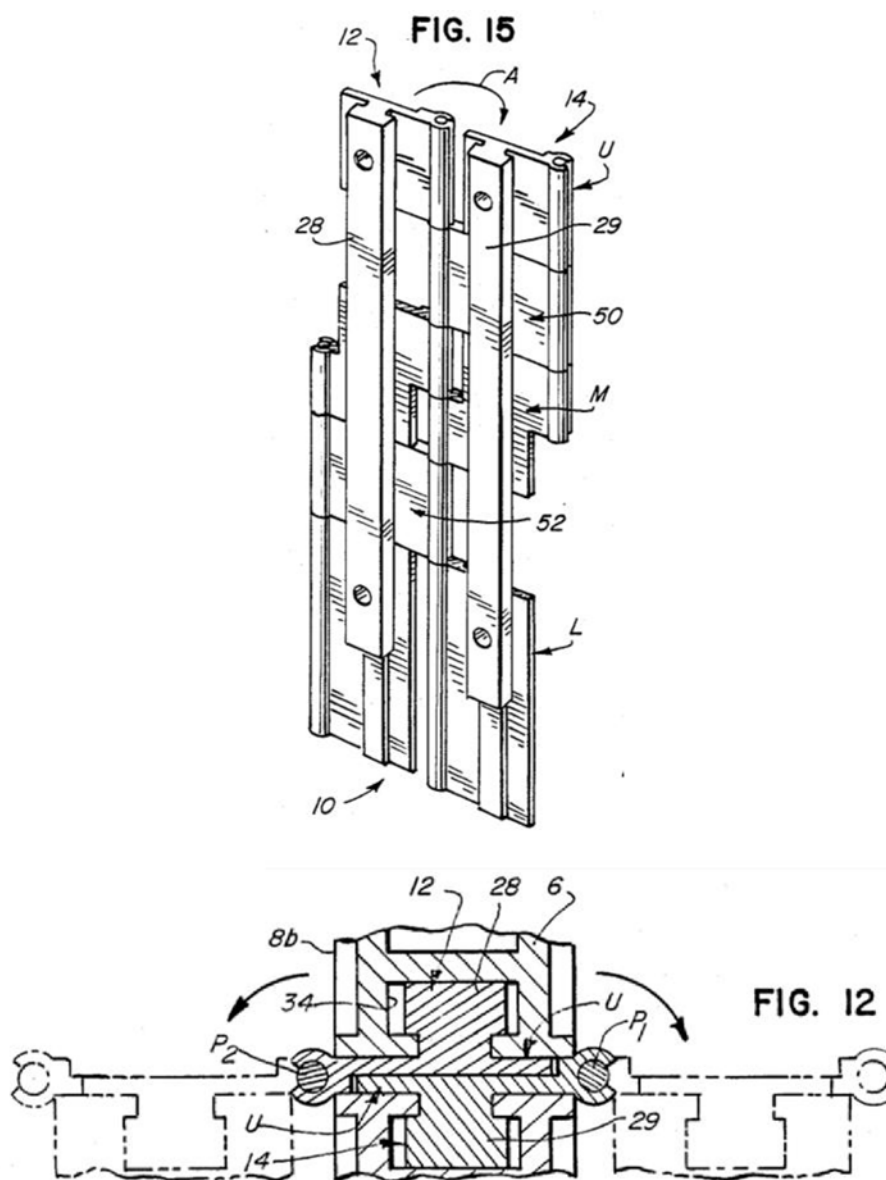


Perutz, Fig. 1.

Perutz is directed to the challenge of connecting panels via hinges. RX-0006C, Q/A 137. As a solution to this challenge, Perutz teaches providing hinges 10 on the inner side surfaces of adjacent panels, which are received in an indentation 34 of the side surfaces to reduce space between adjacent panels. RX-0607, Abstract, Figs. 12 and 15, 3:54-66, 4:16-20 and 33-38; RX-

0006C, Q/A 137. In Figures 15 and 12 of Perutz shown below, ribs 28 and 29 of hinges 10 are received within slots 34 of the panels. RX-0006C, Q/A 137.

Perutz states that the segments of the hinge 10 “are maintained in vertically spaced alignment by an elongated rib or strut 28, 29,” with the ribs 28, 29 being received within slots 34 “formed in the corners of the frame 6 of the adjacent display panels.” RX-0607, 4:16-20 and 33-38.



Perutz, Figs. 12 and 15.

As shown in Figures 12 and 15, reproduced above, the side-mounted hinges of Perutz are received in an indentation in the side surface (*e.g.*, slot 34) to reduce space between adjoining display panels. RX-0006C, Q/A 137.

Thus, Perutz teaches that at least one panel includes an indentation in a side surface configured to receive a flange (such as the upper, middle, and/or lower hinge portions of hinge segments 12, 14) of one of the hinge structures. RX-0006C, Q/A 294.

Perutz is relevant to the problems dealt with by the Asserted Patents, namely how to develop adjacent panels or displays that rotate around a hinge placed between the panels/displays, while minimizing the space between panels. RX-0006C, Q/A 139. A POSA would be well aware of the potential benefits of connecting panels in a manner which allows panels to rotate with respect to one another, while reducing space between adjacent panels. RX-0006C, Q/A 138. Therefore, Perutz is analogous art to the '028 and '512 Patents. RX-0006C, Q/A 138-139.

3. Level of Ordinary Skill in the Art

ALJ Moore has adopted the following definition of a POSA:

A person of ordinary skill in the art would have a M.D. and/or a Ph.D. in an electrical engineering, optoelectronics, physics, optical sciences, optical engineering, or related scientific or engineering field, and at least one to two years of work or research experience in optical engineering, optics, optoelectronics, phototherapy, photodynamic therapy, or a related field.

Order No. 18, 13.

As addressed previously, Dr. Grove and Dr. Ehrenreich both qualify as a POSA under this definition. *Supra* III.C.

4. The Elements of the Asserted Claims Are Taught in the Prior Art

Each element of the Asserted Claims is disclosed or rendered obvious by the prior art, as summarized below.

i. Limitation – System and Method Claims Preamble (“Preamble Limitation”)

Claims 1, 16, 20, and 21 of the '028 Patent and claims 1, 8, and 20 of the '512 Patent each recite what will be referred to as “the preamble limitation.” JX-0002, cls. 1, 16, 20, and 21; JX-0001, cls. 1, 8, and 20. The precise language used in each claim is listed in the table below. RX-0006C, Q/A 141.

<u>Claim Language- System Preamble</u>	<u>Claims</u>
“a system for photodynamically diagnosing or treating a patient”	Claims 1, 16, 20, and 21 of the '028 Patent
“a system for photodynamically diagnosing or treating a patient”	Claims 1, and 20 of the '512 Patent
“a method of photodynamically diagnosing or treating a patient”	Claim 8 of the '512 Patent

As shown above, each of 1, 16, 20, and 21 of the '028 Patent and claims 1, 8, and 20 of the '512 Patent requires a system or a method for/of “photodynamically diagnosing and treating a patient.”¹⁵ Lundahl and Larsen disclose the preamble limitation. RX-0006C, Q/A 142-144; RX-0007C, Q/A 143-149.

By 2015, PDT was a well-known technique for treating various dermatological conditions. RX-0007C, Q/A 146. Lundahl and Larsen disclose how to photodynamically treat a patient by applying ALA and treating at least AK lesions. RX-0007C, Q/A 149.

Specifically with respect to the system claims, Lundahl discloses an “invention . . . directed to photodynamic therapy using an illuminator that provides a uniform distribution of visible light. In particular, the present invention is directed to an apparatus and method for photodynamic

¹⁵ The preamble of the asserted system and method claims, the “preamble limitation,” was found to be limiting in the present proceeding. Order No. 18, at 29; RX-0007C, Q/A 144-145.

treatment (PDT) or diagnosis (PD) of actinic keratosis of the scalp or facial areas of a patient.” RX-0065, 1:9-17; RX-0006C, Q/A 143; RX-0007C, Q/A 134, 148. Lundahl teaches that AK lesions can be treated by topically applying ALA to a contoured surface, like a patient's face or scalp, and irradiating the contoured surface with visible light from a plurality of light sources. RX-0065, 3:3-7, 15:29-32; RX-0007C, Q/A 129.

Larsen similarly teaches a method for using PDT to treat patients, and includes some basic principles related to PDT. RX-0007C, Q/A 141. Larsen discloses an “invention relat[ing] in general to electrotherapy devices and more particularly to devices and methods for photodynamic and electromagnetic stimulation of living tissue, directly and also indirectly, by stimulation of photosensitive substances introduced into or onto living tissue.” RX-0099, [0001]; RX-0006C, Q/A 143. Larsen further states its device “provides multiple wavelength stimulation that is also effective in conjunction with photodynamic therapy (PDT) chemicals.” RX-0099, [0037]; RX-0006C, Q/A 143.

Further, with respect to the method claims, Lundahl discloses a “method for photodynamic treatment (PDT) or diagnosis (PD) of actinic keratosis of the scalp or facial areas of a patient” and “PDT and PD of other indications (e.g., acne) and other areas of the patient (e.g., arms, legs, etc.).” RX-0065, 1:9-17; RX-0006C, Q/A 143. Larsen similarly discloses a method for photodynamically diagnosing or treating a patient: “[t]he present invention relates in general to electrotherapy devices and more particularly to devices and methods for photodynamic and electromagnetic stimulation of living tissue, directly and also indirectly, by stimulation of photosensitive substances introduced into or onto living tissue.” RX-0099, [0001]; RX-0006C, Q/A 143.

Accordingly, Lundahl and Larsen each disclose the “preamble” limitation of the Asserted Claims. RX-0006C, Q/A 144; RX-0007C, Q/A 145.

Limitation	Lundahl	Larsen	Hente	Perutz
Preamble	✓	✓		
Hinges				
Light Sources				
Uniform Illumination				
Center Panel				
Within Approximately Four Inches				
First and Second Edges				
Higher Intensity Proximate Second Edges				
Administering ALA				
Positioning Proximate				
Individually Configurable				

RDX.0017C.022 (excerpt).

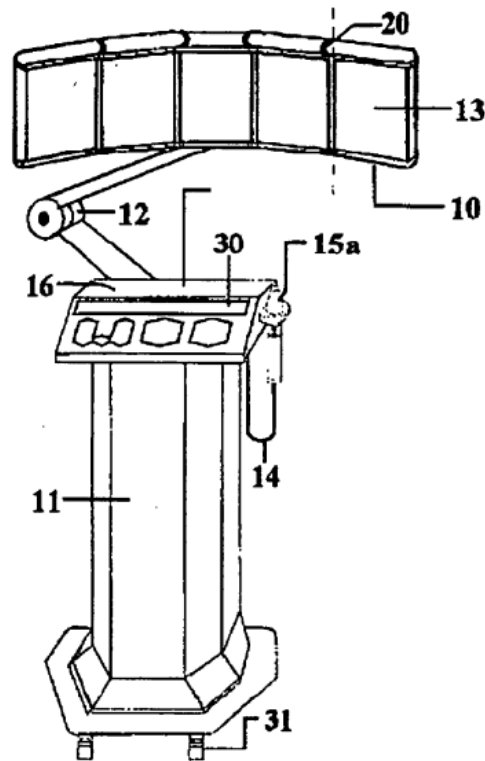
ii. *Limitation – Illuminator with Five Panels Connected by Hinges ("Hinges Limitation")*

Claims 1, 16, 20, and 21 of the '028 Patent and claims 1, 8, and 20 of the '512 Patent each recite what will be referred to as the “hinges limitation.” JX-0002, cls. 1, 16, 20, and 21; JX-0001, cls. 1, 8, and 20. The precise language used in each claim is listed in the table below. RX-0006C, Q/A 145.

Claim Language — Hinges Limitation	Claims
“an illuminator comprising five panels connected by hinged structures on inner side surfaces of adjacent panels”	Claims 1, 20, and 21 of the '028 Patent
“five panels connected by hinged structures”	Claim 16 of the '028 Patent
“an illuminator comprising at least five panels connected by <i>nested hinges</i> on inner side surfaces of adjacent panels”	Claim 1 of the '512 Patent
“an illuminator comprising at least five panels connected by <i>nested hinges</i> on inner side surfaces of adjacent panels, the nested hinges being configured so as to allow continuous illumination across the at least five panels”	Claim 20 of the '512 Patent
“the illuminator comprising at least five panels connected by <i>nested hinges</i> on inner side surfaces of adjacent panels”	Claim 8 of the '512 Patent

As shown above, the “hinges limitation” has slightly differing claim language across claims. In claims 1, 5, 16, 20 and 21 of the '028 Patent the limitation reads “an” or “the” “illuminator comprising five panels connected by hinged structures on inner side surfaces of adjacent panels.” In claim 16 of the '028 Patent, the limitation reads “five panels connected by hinged structures.” In claims 1, 8, and 20 of the '512 Patent, the limitation reads “an” or “the” “illuminator comprising at least five panels connected by *nested hinges* on inner side surfaces of adjacent panels.” As discussed, the term “nested hinges” has been construed to mean “hinges that fit on inner side surfaces of adjacent panels.” Order No. 18, 35. Larsen, or Larsen further in view of Hente, discloses the hinges limitation. RX-0006C, Q/A 149-164.

Specifically, Larsen's illuminator has five panels, as shown in Fig. 1. RX-0099, Fig. 1. Larsen teaches that “[for the treatment of large-area tissues according to Fig. 1, several applicators 13 are flexibly connected to each other through *hinges* 10. . .” RX-0099, [0072]. While this quoted passage of Larsen refers to “hinges 10,” it is clear that this is a typographical error, and that the “10” illustrated in Figure 1 refers to the device as a whole, while the hinge component is correctly illustrated by the dotted line labeled as “20”. RX-0006C, Q/A 151.



RX-0065, Fig. 1.

During the prosecution of the '512 Patent, which is the direct parent of the '028 Patent, the examiner explicitly noted that the hinges had been erroneously labeled as element number 10 in the specification while being correctly shown as element number 20 in the Figures. JX-0004.160 ('512 File History).

Larsen's Reference to "Hinges 10" Was A Typographical Error

RX-0099 at Fig. 1

Applicant). Regarding claim 1, Larsen discloses a method, comprising: administering 5-aminolevulinic acid (ALA) to a patient (see paragraphs [0116], [0119], and [0120] and claims 50 and 51); positioning an illuminator 10 proximate to the patient, the illuminator comprising at least five panels 13, each of the panels comprising at least one light source 17, the five panels connected by a plurality of hinges 20 (indicated as 10 in the specification, but shown as element 20 in the Figures) on inner side surfaces of adjacent panels that connect panels together (see Figures 1-3 and paragraphs [0069] and [0072], lines 1-4); and illuminating a surface of the patient with the illuminator (see paragraphs [0026], [0037], and [0072], and claim 50). However, Larsen

JX-0004.160 ('512 File History)

CONTAINS CONFIDENTIAL BUSINESS INFORMATION, SUBJECT TO PROTECTIVE ORDER

BioFrontiers RDX-0017C.026

RDX-0017C.026. Similarly, after reviewing Larsen during prosecution of the '028 Patent, the examiner determined that it taught “five panels connected by a plurality of **hinges 20** . . . on inner side surfaces of adjacent panels that connect panels together . . .” JX-0003.130 ('028 Patent File History).

The fact that the reference to “hinges 10” was an error is also borne out by the disclosure of Larsen as a whole. For example, Larsen also states that “[a]s shown in FIG. 1, *the invented device 10* for the stimulation of cells with the aid of (PDT) photodynamic light and electromagnetic fields combined with light sensitive substances....” RX-0099, [0069] (emphasis added). In view of this express statement from Larsen, it would be clear to a POSA that the “10” designation of Figure 1 is referencing the device as a whole, rather than hinges. RX-0006C, Q/A 153. Further, Larsen also notes that the several applicators 13 (i.e., the panels) “are flexibly connected to each other through hinges... *connecting one edge with the other.*” RX-0099, [0069] (emphasis added). The

connecting of edges of adjacent applicators (that is, panels) indicates that the hinge structure is located between the inner side surfaces of the adjacent applicators, which is exactly where dotted line 20 is illustrated in Figure 1. RX-0006C, Q/A 153.

In fact, element number 20 is only referenced one time in Larsen's disclosure, where Larsen states that, "[a]ccording to FIGS. 2b and 2c the light sources 17 are placed in regular row arrangements, i.e., 20 equidistant from each other...." RX-0099, [0071]. However, there is no feature "20" illustrated in either of FIGS. 2b or 2c. RX-0099, Figs. 2b-c; RX-0006C, Q/A 154. Further, in Figure 1, where element number 20 is illustrated, it is identified as being between two panels, which does not make sense as a location for "regular row arrangements" of light sources. RX-0006C, Q/A 154.

As "hinges 10" is a typographical error and the hinges are actually indicated by element number 20, Figure 1 of Larsen discloses an illuminator comprising at least five panels connected by hinges on inner side surfaces of adjacent panels. RX-0006C, Q/A 156.¹⁶

In the event that Figure 1 does not explicitly teach hinges 20 on inner side surfaces of panels, it would have been obvious for a POSA to arrive at hinges located on inner side surfaces. RX-0006C, Q/A 157. First, Figure 1 of Larsen shows that the inner edges of each of the panels (13) are nearly flush with each other. RX-0006C, Q/A 157. This disclosure would have motivated a POSA to place the hinges on the inner side surfaces of Larsen's panels in order to facilitate this nearly flush arrangement. RX-0006C, Q/A 157. Such a modification would have involved nothing more than the

¹⁶ Although Sun Pharma has argued that another Larsen patent application (AU 2001/43869) supports its contention that element number 10 in the '028 Patent refers to hinges, AU 2001/43869 is an Australian patent application which is not related to the '028 Patent. RX-0006C, Q/A 155. In fact, AU 2001/43869 appears to be focused on an entirely different device. AU 2001/43896, Abstract. Consequently, the disclosure of AU 2001/43869 does not impact the conclusion regarding the typographical error in Figure 1 of Larsen. RX-0006C, Q/A 155.

use of a known prior art element according to known methods to yield predictable results. RX-0006C, Q/A 157.

Second, there were “a finite number of identified, predictable solutions” for Larsen's panels to be “flexibly connected to each other through hinges.” RX-0006C, Q/A 157; *KSR Intern. Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007). Specifically, from a practical perspective, there are only three options for locations where the hinges can be connected: (1) on the inner side surfaces of the adjacent panels; (2) on the top and bottom of the adjacent panels; and (3) on the rear surface of the panels. RX-0006C, Q/A 157. Based on this limited number of design options, a POSA would have viewed any of these design options as obvious, and would have found it obvious to try placing the hinges on the inner side surfaces of the panels. RX-0006C, Q/A 157; *Teva Pharms. U.S.A., Inc. V. Sandoz, Inc.*, 906 F.3d 1013, 1025 (Fed. Cir. 2018) (Finding claims to a dosing regimen obvious to try where “a POSITA had only a limited number of permutations of dose and frequency to explore...”). And a POSA would have had a reasonable expectation of success, since a POSA would have known that hinges located on the inner side surfaces of the applicator would allow them to be positioned in a nearly flush arrangement as shown in Figure 1. RX-0006C, Q/A 157. Even if the hinges protruded beyond the front of the panels, the distance or “gap” between panels would nonetheless be minimized or eliminated when the panels are angled toward each other (as would be the case, e.g., when the panels are angled to surround the face/scalp of a patient). RX-0006C, Q/A 341.

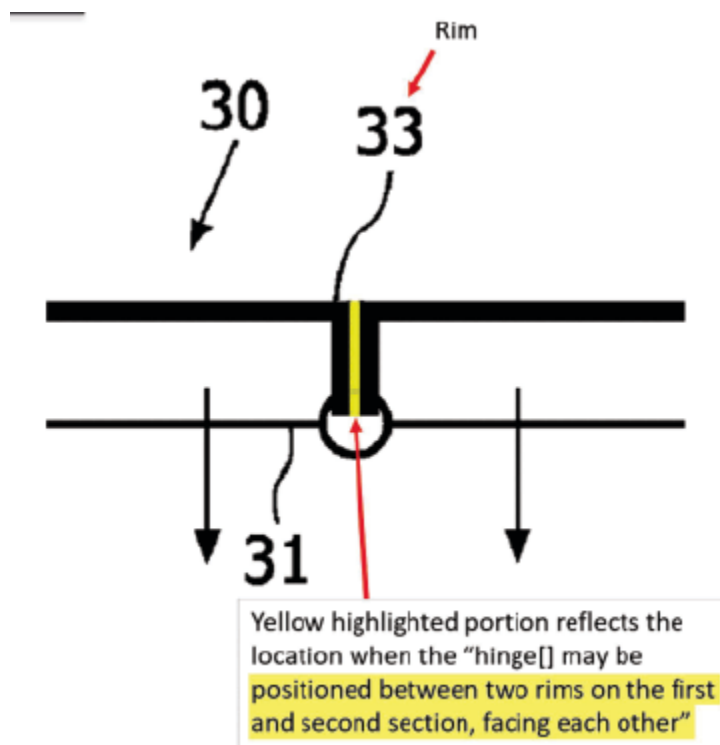
The additional language of claim 20 of the '512 Patent requiring that “the nested hinges being configured so as to allow continuous illumination across the at least five panels” is also disclosed by Larsen. RX-0006C, Q/A 158. As an initial matter, the '512 patent does not state or define what is meant by “continuous illumination” across the at least five panels. RX-0006C, Q/A

158. However, the “continuous illumination across the at least five panels” is simply the result of the configuration of the “nested hinges,” which Sun Pharma alleges to simply be “hinges that fit on inner side surfaces of adjacent panels.” RX-0006C, Q/A 158. In view of this, the “nested hinges” are configured in a way to minimize the gap between adjacent panels to “allow continuous illumination across the at least five panels.” RX-0006C, Q/A 158. As discussed herein, Larsen discloses or renders obvious this limitation. The orientation of adjacent panels illustrated in Figure 1, with “nested” hinges that fit on the inner side surfaces of adjacent panels demonstrates minimal/no gap between the adjacent panels, which is a configuration that would “allow continuous illumination across the at least five panels.” RX-0006C, Q/A 158.

Additionally, Hente also discloses and renders obvious the hinges limitation. RX-0006C, Q/A 159. Hente teaches a light emitting device with multiple sections or panels, which can be used in multiple orientations, including flat and angled (folded) orientations, stating “the disclosed light emitting device possesses two different positions, each resulting in a different type of illumination. In the expanded position the light emitting device forms a longish stretched large area illumination device. In this context the longish stretched arrangement is not limited to a rectangular form but can also include slightly curved or spherically bent arrangements. The sections of the light emitting device may also be arranged in a V- or a W-form, depending on the type of use.” RX-0576, Abstract, [0011]. Hente's device folds or bends along lines between panels or sections. RX-0006C, Q/A 160.

Hente includes a connection means 50 to connect adjacent sections, which may be a hinge, stating “[i]n a preferred embodiment the connection mean may be a hinges [sic], being positioned at the outer rims of the light emitting device respectively sections. Depending on the position of the side surfaces, *the hinges may be positioned between two rims of the first and the second section, facing each other.*” RX-0576, [0015] (emphasis added). The “first and second section” referenced

in the passage above is understood to represent the first section 20 and the second section 30 illustrated in Figure 2. Additionally, Hente explains that the “rim” components are represented by 23 and 33 in the figures. RX-0576, [0048], [0052]. RDX-0017C.028 shows an annotated version of Figure 2 and illustrates the location of the rims and the hinge “positioned between two rims of the first and second section, facing each other.”¹⁷ RX-0006C Q/A 161.



RDX-0017C.028.

¹⁷ Despite assertions by Sun Pharma and Dr. Jokerst that Hente discloses hinges "being positioned at the outer rims of the light emitting device respectively positions," and that "the hinges 50 are located at the corners of the outer rims, and do not fit on the inner side surfaces between adjacent sections," RDX-0017C.0028 illustrates that a POSA would locate the flange for the hinge in the area between adjacent sections (*i.e.*, at the outer rim). RX-0006C, Q/A 162. It is clear from the illustration in RDX-0017C.0028 that part of the hinge is attached to the inner side surface between the rims. RX-0006C, Q/A 162. What is more, Dr. Jokerst's assertions that Hente discloses light flowing through the side surfaces of the sections does not contradict a POSA's understanding that Hente discloses nested hinges on inner side surfaces of adjacent panels based on the middle hinge in Figure 2 of Hente. RX-0006C, Q/A 163.

As shown in this demonstrative, Hente discloses the placement of a hinge between two rims of the first and second section, facing each other, meeting the requirement of a “hinge[] that fits on inner side surfaces of adjacent panels.” RX-0006C, Q/A 161.

Accordingly, Larsen, or Larsen further in view of Hente, disclose the “hinges” limitation of the Asserted Claims. RX-0006C, Q/A 164.

Limitation	Lundahl	Larsen	Hente	Perutz
Preamble	✓	✓		
Hinges		✓	✓	
Light Sources				
Uniform Illumination				
Center Panel				
Within Approximately Four Inches				
First and Second Edges				
Higher Intensity Proximate Second Edges				
Administering ALA				
Positioning Proximate				
Individually Configurable				

RDX-0017C.030 (excerpt).

iii. *Limitation – Light Sources on Five Panels ("Light Sources Limitation")*

Claims 1, 16, 20, and 21 of the '028 Patent and claims 1, 8, and 20 of the '512 Patent each recite what will be referred to as the “light sources limitation.” JX-0002, cls. 1, 16, 20, and 21; JX-0001, cls. 1, 8, and 20. The precise language used in each claim is listed in the table below. RX-0006C, Q/A 165.

Claim Language — Light Sources Limitation	Claims
“light sources disposed on surfaces of the five panels”	Claims 1, 16, 20, and 21 of the '028 Patent
“light sources disposed on surfaces of the at least five panels”	Claims 1 and 20 of the '512 Patent
“light sources disposed on the at least five panels of the illuminator”	Claim 8 of the '512 Patent

As shown above, the “light sources limitation” has slightly differing claim language across claims. However, in all cases it requires light sources disposed on the surface of (at least) five

panels. RX-0006C, Q/A 167. Larsen discloses the light sources limitation. RX-0006C, Q/A 168-171.

Specifically, Larsen discloses that light sources are disposed on the surfaces of five applicators. RDX-0017C.032. Figures 2a-2c of Larsen show “plain surfaced printed circuit boards with light sources mounted in the applicators 13.” RX-0099, [0070].

Additionally, Larsen discloses that these light sources are LEDs. RX-0006C, Q/A 170. Larsen teaches that the applicators are mounted in a shifting order “with semiconductor diodes (LED) and/or laser diodes 17 and 17a (in the following called light sources)”. RX-0099, [0070].

Accordingly, Larsen discloses the “light sources” limitation of the Asserted Claims. RX-0006C, Q/A 171.

Limitation	Lundahl	Larsen	Hente	Perutz
Preamble	✓	✓		
Hinges		✓	✓	
Light Sources		✓		
Uniform Illumination				
Center Panel				
Within Approximately Four Inches				
First and Second Edges				
Higher Intensity Proximate Second Edges				
Administering ALA				
Positioning Proximate				
Individually Configurable				

RDX-0017C.033 (excerpt).

iv. *Limitation – Uniformly Illuminate Treatment Surface (“Uniform Illumination Limitation”)*

Claims 1, 16, 20, and 21 of the ’028 Patent and claims 1, 8, and 20 of the ’512 Patent each recite what will be referred to as the “uniform illumination limitation.” JX-0002, cls. 1, 16, 20, and 21; JX-0001, cls. 1, 8, and 20. The precise language used in each claim is listed in the table below. RX-0006C, Q/A 172.

Claim Language — Uniform Illumination Limitation	Claims
“the illuminator being configured to uniformly illuminate a treatment surface of the patient via the light sources”	Claims 1, 16, 20, and 21 of the '028 Patent
“the illuminator being configured to uniformly illuminate a treatment surface of the patient via the light sources”	Claims 1 and 20 of the '512 Patent
“uniformly illuminating a treatment surface of the patient”	Claim 8 of the '512 Patent

As shown above, the “uniform illumination limitation” has slightly differing claim language across claims. However, in all cases it requires uniform illumination of a treatment surface. RX-0006C, Q/A 174. Applying the agreed upon construction for “uniformly illuminate”/ “uniformly illuminating” adopted in the present proceeding, which is “irradiating light over the active emitting area such that the measured irradiance at a treatment surface of the patient is at least within 60% of the measured maximum,” Lundahl and Larsen each disclose the uniform illumination limitation. RX-0006C, Q/A 176-185.

Uniform Illumination Limitation – Lundahl, Larsen

Lundahl

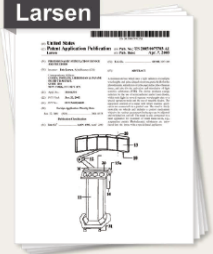


Lundahl

It has been found that, according to a preferred embodiment of the present invention, the measured output over the active emitting area is within 70% of the measured maximum when measured with a cosine response detector at distances of 4" and 2", and within 60% of the measured

RX-0065 at 15:21-24

Larsen



Larsen

netic radiation. The applicators are also equipped with an adjustable scan system, which permits an even and gap-free radiation of the surface with the multiple wavelengths of light.

RX-0057 at [0028]

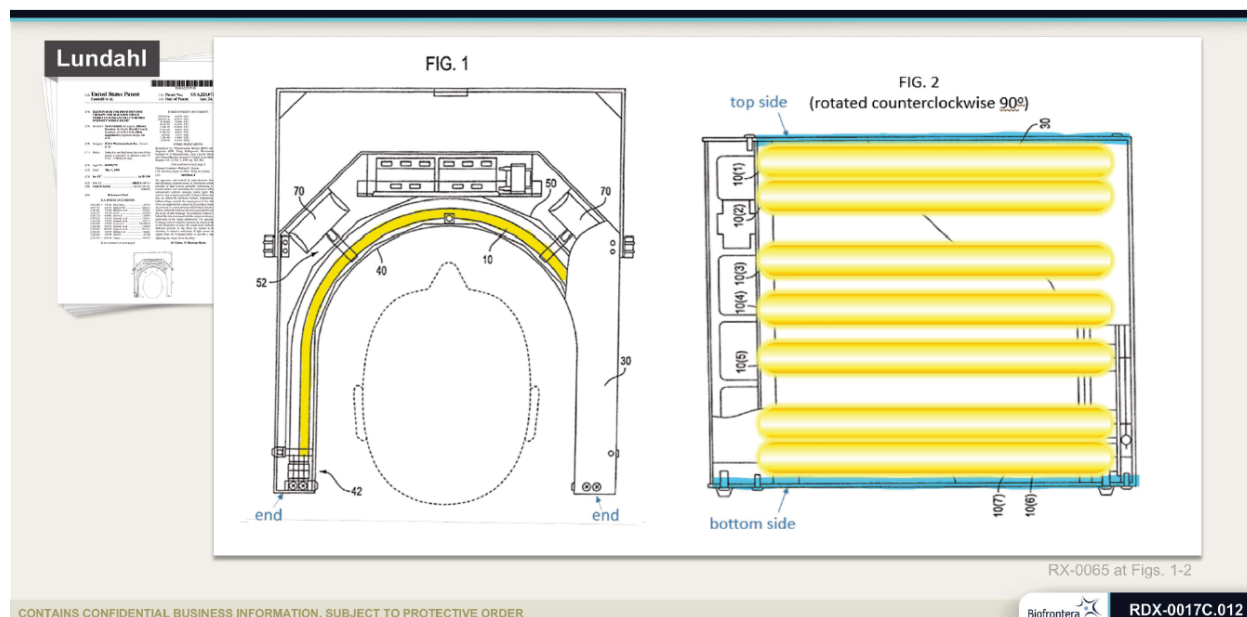
CONTAINS CONFIDENTIAL BUSINESS INFORMATION, SUBJECT TO PROTECTIVE ORDER

Biofrontera RDX-0017C.035

RDX.0017C.035.

Lundahl states “[t]he present invention is directed to photodynamic therapy using an illuminator that provides a uniform distribution of visible light.” RX-0065, 1:9-11; RX-0006C, Q/A 177. To achieve this uniformity, Lundahl utilizes the light distribution pattern illustrated in Fig. 2. RX-0006C, Q/A 177.

Lundahl (U.S. 6,223,071) – Strategy for Uniform Illumination



RDX-0017C.012.

With respect to Fig. 2, Lundahl explains that “[t]o avoid uniformity problems, one embodiment, of the present invention utilizes a plurality of U-shaped tubes 10(1)-10(7).... [An] advantage of the arrangement is that uniformity can also be adjusted by varying the lateral spacing of the tubes (relative vertical spacing as shown in the rotated FIG. 2). This is important since it is necessary to compensate for the fact that the output from a flat plane emitting light source drops near the edges. Varying the lateral spacing of the tubes creates the same effect as folding the edges of a larger illuminator in on itself, thus emulating an infinite plane emitter with a compact unit.” RX-

0065, 6:16-30. Lundahl states that the spacing of lights and greater density of lighting near the top and bottom of the panel provide for uniform illumination, stating “[t]he number of tubes used and the spacing between them were chosen to achieve desired uniformity and power output specifications . . . The present invention provides a highly uniform output irradiance without the use of an additional diffusing element.” RX-0065, 6:43-57.

Accordingly, Lundahl states “[i]t has been found that, according to a preferred embodiment of the present invention, the measured output over the active emitting area is within 70% of the measured maximum when measured with a cosine response detector at distances of 4” and 2”, and within 60% of the measured maximum over all operation distances.” RX-0065, 15:22-26. Consequently, in addition to routinely stating that the devices described therein provide “uniform” illumination, Lundahl discloses that the measured output over the active emitting area is within 70% of the measured maximum at distances of 4” and 2”, and within 60% of the measured maximum over all operation distances, meeting the construed requirement of “irradiating light over the active emitting area such that the measured irradiance at a treatment surface of the patient is at least within 60% of the measured maximum.” RX-0065, 15:22-27; RX-0006C, Q/A 179.

Additionally, Larsen teaches that its panels (applicators) are configured to uniformly illuminate a treatment surface of the patient via the light sources. RX-0006C, Q/A 180. Larsen teaches that “[i]n each applicator the printed circuit board carrying the light sources is connected to a small electrical scan engine 66, which can move the light sources with linear movements, whereby a correctly adjusted scan length and frequency gives the radiated surface a total radiation at the necessary wavelengths without leaving any unradiated gaps.” RX-0099, [0072]. Larsen also teaches that its applicators “*permit an even and gap-free radiation* of the surface with multiple wavelengths of light.” RX-0099, [0028]. An “even and gap-free radiation of the surface” would uniformly

illuminate the treatment surface. RX-0099, [0028]. A POSA would have understood that Larsen's applicator is configured to uniformly illuminate a treatment surface of the patient. RX-0006C, Q/A 180. This is further supported by the file history of the '028 Patent's parent application, the '512 patent, in which the examiner reviewed Larsen's disclosures related to uniformity and confirmed that Larsen taught "the illuminator being configured to uniformly illuminate a treatment surface of the patient via the light sources." JX-0004.555 ('512 Patent File History); RX-0006C, Q/A 181-184.

Accordingly, Lundahl and Larsen disclose or teach the "uniform illumination" limitation of the system and method Asserted Claims. RX-0006C, Q/A 185.

Limitation	Lundahl	Larsen	Hente	Perutz
Preamble	✓	✓		
Hinges		✓	✓	
Light Sources		✓		
Uniform Illumination	✓	✓		
Center Panel				
Within Approximately Four Inches				
First and Second Edges				
Higher Intensity Proximate Second Edges				
Administering ALA				
Positioning Proximate				
Individually Configurable				

RDX-0017C.036.

v. *Limitation – Center Panel with Two or More of the Five Panels Angled Relative to Center Panel ("Center Panel Limitation")*

Claims 1, 17, 20, and 21 of the '028 Patent and claims 1 and 20 of the '512 Patent each recite what will be referred to as the "center panel limitation." JX-0002, cls. 1, 17, 20, and 21; JX-0001, cls. 1 and 20. The precise language used in each claim is listed in the table below. RX-0006C, Q/A 186.

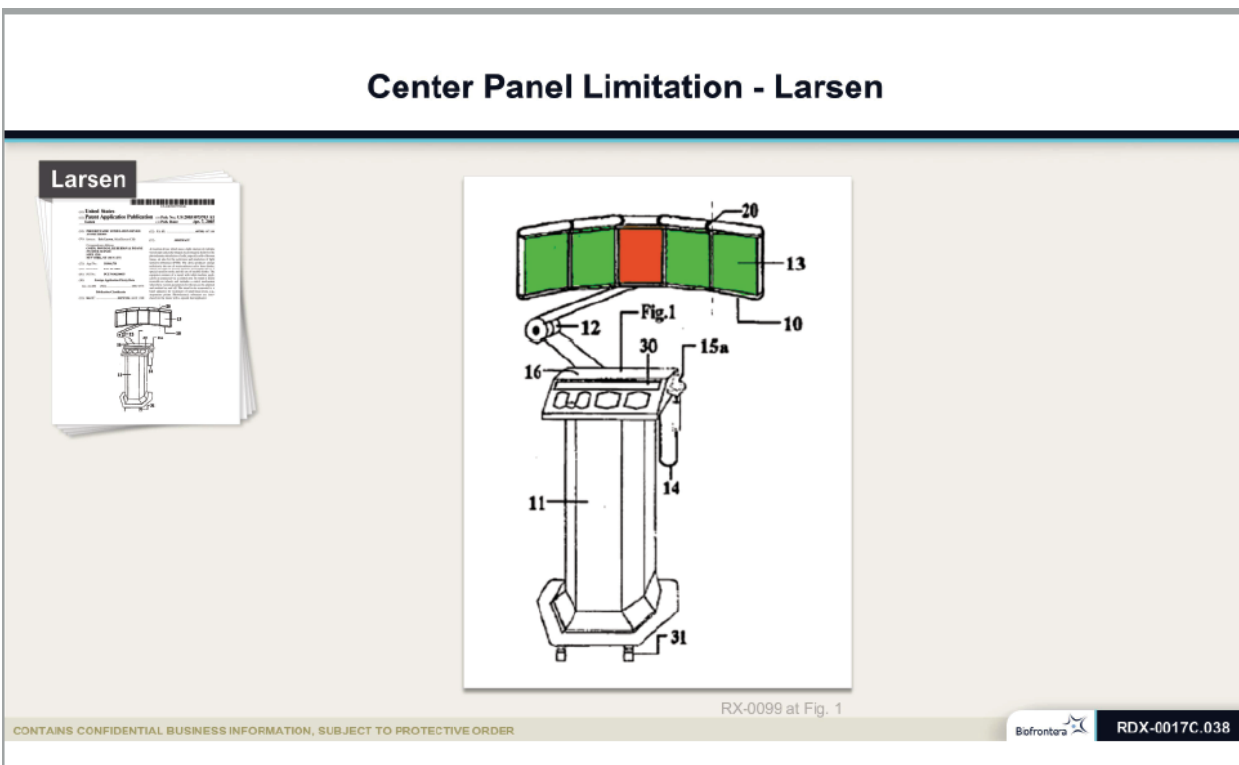
Claim Language — Center Panel Limitation	Claims
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“one of the five panels being positioned as a center panel configured to face the treatment surface, and being configured to be angled relative to the center panel”	Claims 1, 20, and 21 of the '028 Patent
“one of the five panels is positioned as a center panel configured to face the treatment surface, and two or more of the five panels are configured to be angled relative to the center panel”	Claim 17 of the '028 Patent
“one of the at least five panels positioned as a center panel configured to face the treatment surface, and two or more of the at least five panels being configured to be angled relative to the center panel”	Claims 1 and 20 of the '512 Patent

As shown above, the “center panel limitation” has slightly differing claim language across claims. However, it generally requires one of the five panels being positioned as a center panel configured to face the treatment surface, and two or more of the five panels being configured to be angled relative to the center panel. RX-0006C, Q/A 188. Larsen discloses the center panel limitation. RX-0006C, Q/A 189-192.

As shown in RDX-0017C.038, which provides a highlighted version of Figure 1 of Larsen, one of the five panels is positioned as the center panel with two or more of the remaining five panels configured to be angled relative to the center panel.¹⁸ RX-0006C, Q/A 190.

¹⁸ Despite Dr. Jokerst’s assertion that it has not been established that Larsen discloses the center panel limitation because Larsen discloses that the applicators may have “equidistant positioning” above the “backs of humans,” a POSA would expect that equidistant positioning of the five panels of Larsen above the back would nonetheless require angling of the panels on the side because a human’s back is not perfectly flat. RX-0006C, Q/A 191. Additionally, as can be seen from Fig. 1 in RDX-0017C.038, the five panels of Larsen’s device do not have a flat orientation, but instead the panels on the side (shown in green) are angled relative to the center panel (shown in orange), such that the device is shown as having a curvature, and two or more of the panels are angled relative to the center panel. RX-0006C, Q/A 191.



RDX-0017C.038.

Larsen teaches that “the applicators are suitable for the treatment of, for example, the backs of humans and so become adjustable for an equidistant positioning of the applicators 13 above the skin.” RX-0099, [0072]. As shown in the demonstrative, the center panel (annotated in orange) is positioned to illuminate the center of the patient's back, with each adjacent side panel (annotated in green) angled relative to the center panel. RX-0006C, Q/A 190; RX-0099, [0072].

Accordingly, Larsen discloses the “center panel” limitation of the Asserted Claims. RX-0006C, Q/A 192.

Limitation	Lundahl	Larsen	Hente	Perutz
Preamble	✓	✓		
Hinges		✓	✓	
Light Sources		✓		
Uniform Illumination	✓	✓		
Center Panel		✓		
Within Approximately Four Inches				
First and Second Edges				
Higher Intensity Proximate Second Edges				
Administering ALA				
Positioning Proximate				
Individually Configurable				

RDX-0017C.039 (excerpt).

- vi. *Limitation – Five Panels Positioned to Allow Treatment Within Approximately Four Inches ("Within Approximately Four Inches Limitation")*

Claims 1, 20, and 21 of the '028 Patent each recite what will be referred to as the “within approximately four inches limitation.” JX-0002, cls. 1, 20, and 21. The precise language used in each claim is listed in the table below. RX-0006C, Q/A 193.

Claim Language — Within Approximately Four Inches Limitation	Claims
“wherein the five panels are positioned to allow treatment within approximately four inches of the treatment surface”	Claims 1, 20, and 21 of the '028 Patent

As shown above, the “within approximately four inches limitation” requires five panels positioned to allow treatment within approximately four inches of the treatment surface. RX-0006C, Q/A 195. Applying the construction for “within approximately four inches of the treatment surface” adopted in the present proceeding, which is “less than or equal to approximately four inches from the treatment surface,”¹⁹ Lundahl discloses the within approximately four inches of the treatment surface limitation. RX-0006C, Q/A 196-201.

¹⁹ Biofrontera continues to assert that this adopted construction renders the claim indefinite, as there is not reasonable certainty as to what the upper limit distance of "approximately four inches" is, and without that baseline understanding, a POSA cannot determine whether a given

Lundahl explains that the U-shape of its PDT device helps to maintain the proper distance between the light-emitting panel and the patient head, stating “[t]he U-shape minimizes the variations in distance between the emitter and the target, providing a uniform visible light distribution to the face or scalp of the patient; the tube dimensions were chosen based on the average dimensions of the adult human head.” RX-0065, 6:31-35; RX-0006C, Q/A 198. Lundahl further teaches that the light-emitting surface of the PDT device is positioned such that it is at a distance of 2 inches to 4 inches from the treatment surface (i.e., the skin on the patient's head), stating that “according to a preferred embodiment of the present invention, the measured output over the active emitting area is within 70% of the measured maximum when measured with a cosine response detector at distances of 4” and 2”.” RX-0065, 15:22-27; RX-0006C, Q/A 198.

The claims of Lundahl provide additional information regarding treatment distance. RX-0006C, Q/A 199. Claim 16 of Lundahl recites an embodiment further comprising “a shield being supported by said housing and interposed between said plurality of light sources and the contoured surface, wherein irradiance from said plurality of light sources over an active emitting area at distance of 2 inches away from said shield and at a distance of 4 inches away from said shield is at least 70% of maximum irradiance.” RX-0065, 17:42-46. Lundahl explains that the fluorescent tubes in the device are “covered by a polycarbonate shield.” RX-0065, 5:24-28. Fig. 1 of Lundahl illustrates that shield 40 is slightly closer to the patient's face than bulb 10, though the distance between shield 40 and bulb 10 appears to be small. RX-0006C, Q/A 199. Consequently, if the shield

distance is “less than or equal to approximately four inches” (such as, for example, 4.1 inches, 4.25 inches, 4.5 inches, and so on). RX-0006C, Q/A 196. Treatment distances ranging from two to four inches would be considered “less than or equal to approximately four inches,” as “approximately four inches” covers four inches. RX-0006C Q/A 196. Thus, the indefiniteness issue only comes into play when trying to figure out how far above four inches is captured by “approximately four.” RX-0006C, Q/A 196.

is positioned a distance of 2 inches from the treatment surface (face), as taught by claim 16, the distance from the treatment surface to the light source (bulb) would be slightly greater than 2 inches, but nonetheless less than 4 inches. RX-0006C, Q/A 199.

In combining the hinged panel system of Larsen with the PDT device of Lundahl, a POSA would apply the teachings of Lundahl pertaining to positioning relative to the treatment surface (*i.e.*, the patient face and scalp) to the positioning of the hinged panel system, as taught by Larsen. RX-0006C, Q/A 200. Therefore, Lundahl and Larsen render obvious positioning the panels to allow treatment within approximately four inches of the treatment surface. RX-0006C, Q/A 200.

Accordingly, Lundahl discloses the “within approximately four inches” limitation of the system and method Asserted Claims. RX-0006C, Q/A 201.

Limitation	Lundahl	Larsen	Hente	Perutz
Preamble	✓	✓		
Hinges		✓	✓	
Light Sources		✓		
Uniform Illumination	✓	✓		
Center Panel		✓		
Within Approximately Four Inches	✓			
First and Second Edges				
Higher Intensity Proximate Second Edges				
Administering ALA				
Positioning Proximate				
Individually Configurable				

RDX-0017C.042 (excerpt).

- vii. *Limitation – Five Panels Have Two First Edges and Two Second Shorter Edges ("First and Second Edges Limitation")*

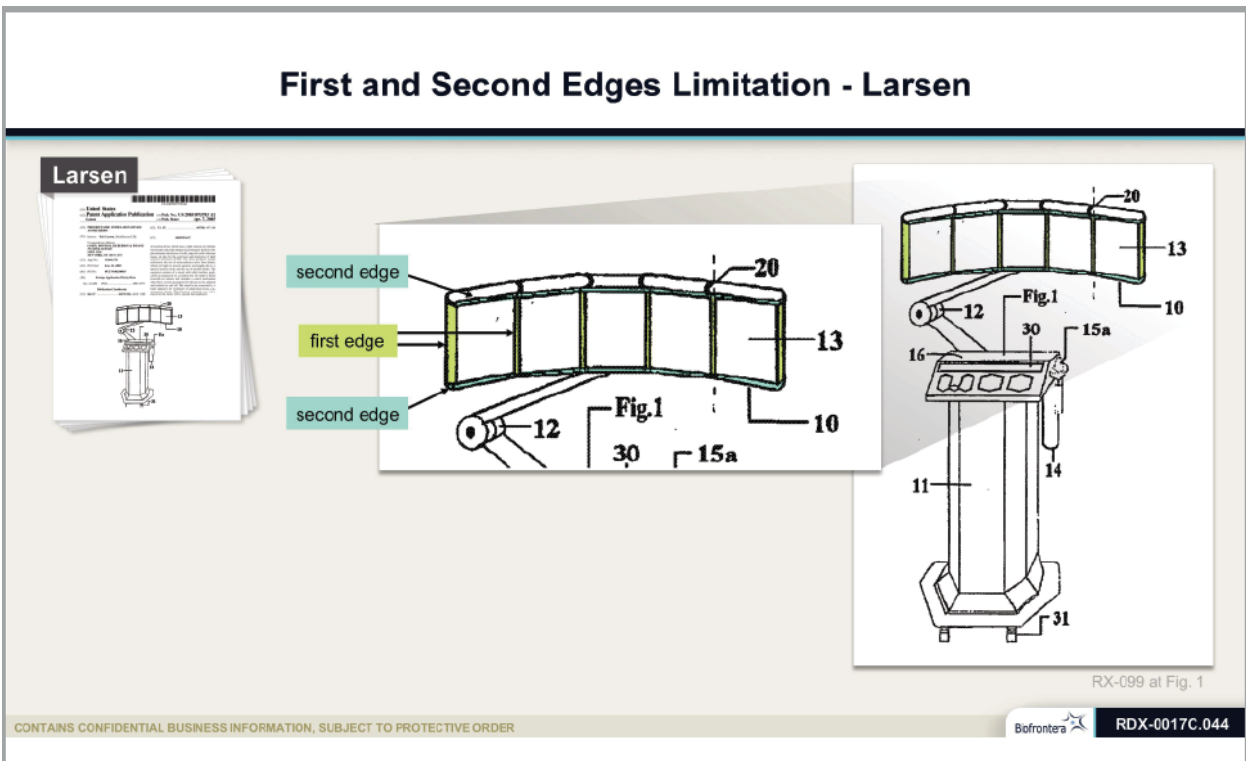
Claims 1, 16, 20, and 21 of the '028 Patent and claims 1, 8, and 20 of the '512 Patent each recite what will be referred to as the “first and second edges limitation.” JX-0002, cls. 1, 16, 20, and 21; JX-0001, cls. 1, 8, and 20. The precise language used in each claim is listed in the table below. RX-0006C, Q/A 202.

Claim Language — First and Second Edges Limitation	Claims
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“each of the five panels has two first edges and two second edges shorter than the two first edges”	Claims 1, 20, and 21 of the '028 Patent
“each of the five panels having two first edges and two second edges shorter than the two first edges”	Claim 16 of the '028 Patent
“each of the at least five panels has two first edges and two second edges shorter than the two first edges”	Claims 1, 8, and 20 of the '512 Patent

As shown above, the “first and second edges limitation” has slightly differing claim language across claims. However, in all cases it requires five panels each having two first edges and two second edges shorter than the two first edges. RX-0006C, Q/A 204. Larsen discloses the first and second edges limitation. RX-0006C, Q/A 205-207.

As shown in RDX-0017C.044, which contains an annotated version of Figure 1 of Larsen, each of the five panels (13) has two first edges (vertical sides) and two second edges (horizontal edges on the top and bottom of the panels that extend along the top and bottom sides of the panel arrangement). RX-0006C, Q/A 206. The two second edges of each panel are shorter than the two first edges. RX-0006C, Q/A 206.



RDX-0017C.044.

Accordingly, Larsen discloses the “first and second edges” limitation of the Asserted Claims. RX-0006C, Q/A 207.

Limitation	Lundahl	Larsen	Hente	Perutz
Preamble	✓	✓		
Hinges		✓	✓	
Light Sources		✓		
Uniform Illumination	✓	✓		
Center Panel		✓		
Within Approximately Four Inches	✓			
First and Second Edges		✓		
Higher Intensity Proximate Second Edges				
Administering ALA				
Positioning Proximate				
Individually Configurable				

RDX-0017C.045 (excerpt).

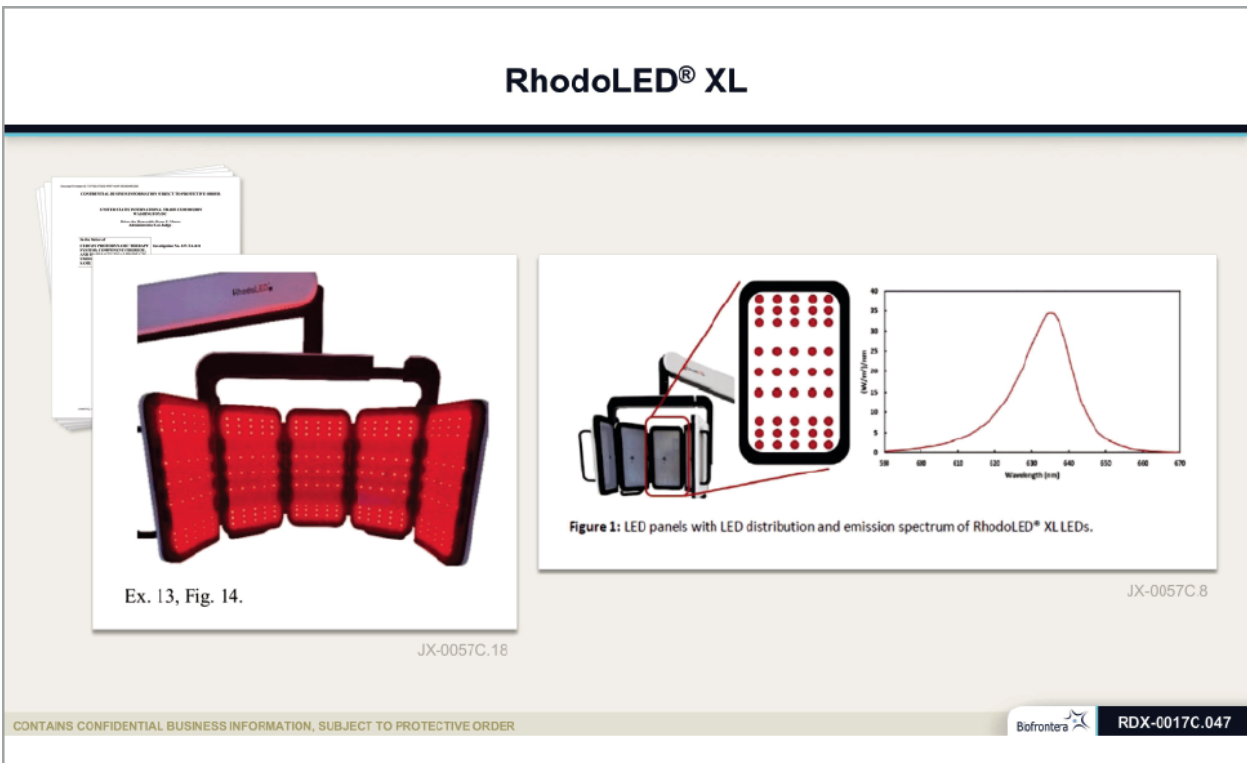
- viii. *Limitation – Higher Intensity of Light Proximate Second Edges Compared to Not Proximate Second Edges (“Higher Intensity Proximate Second Edges Limitation”)*

Claims 1, 16, 20, and 21 of the '028 Patent and claims 1, 8, and 20 of the '512 Patent each recite what will be referred to as the “higher intensity proximate second edges limitation.” JX-0002, cls. 1, 16, 20, and 21; JX-0001, cls. 1, 8, and 20. The precise language used in each claim is listed in the table below. RX-0006C, Q/A 208.

Claim Language — Higher Intensity Proximate Second Edges Limitation	Claims
“the light sources are arranged such that a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges”	Claims 1, 16, 20, and 21 of the '028 Patent, and Claims 1, 8, and 20 of the '512 Patent

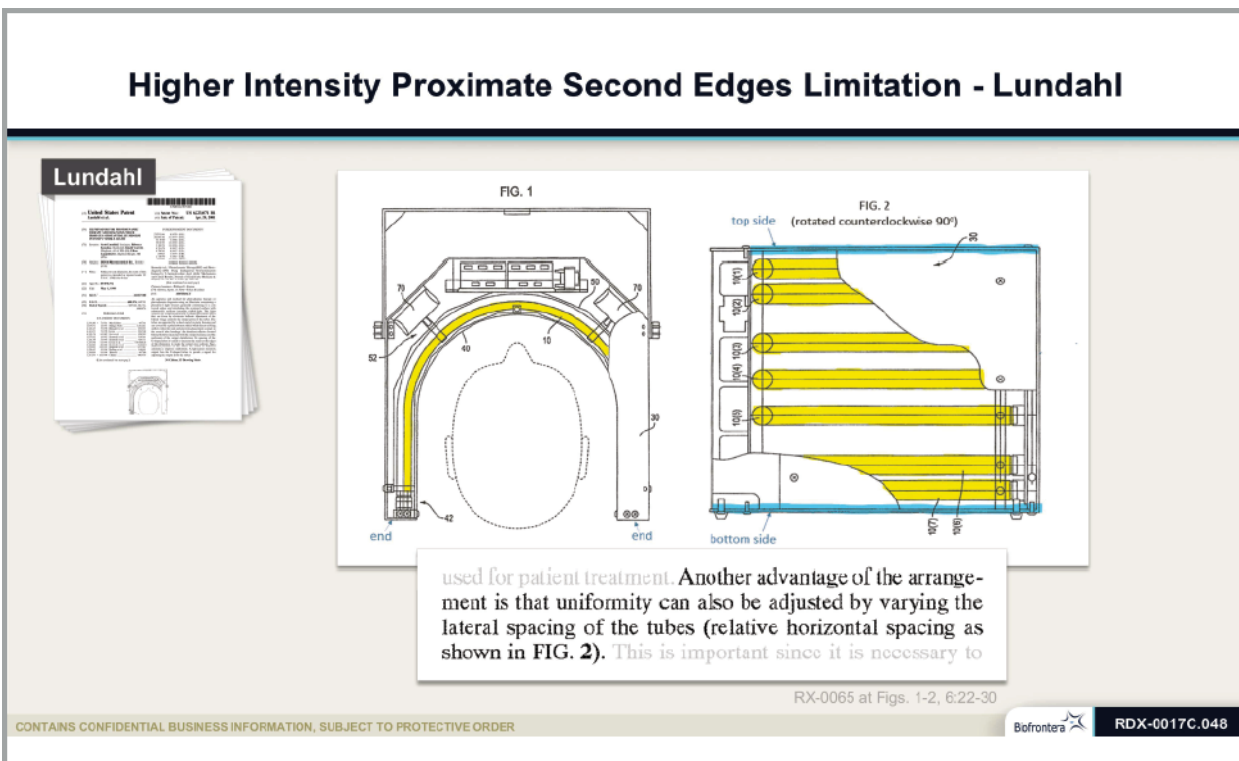
All of the Asserted Claims recite that “the light sources are arranged such that a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges.” RX-0006C, Q/A 209-210. Lundahl discloses the “higher intensity proximate second edges” limitation. RX-0006C, Q/A 211-220.

This assessment of the prior art disclosing the “higher intensity proximate second edges” limitation is based on the claim construction adopted by ALJ Moore of “a higher intensity of light is emitted close to the second shorter edges compared to the intensity of light emitted not close to the second shorter edges” that was argued by Sun Pharma and adopted in the present proceeding. RX-0006C, Q/A 212. As noted, Biofrontera reserves the right to assert that the claim language (as recited in the claims or as construed) is indefinite on appeal and in any related proceedings. However, Sun Pharma has asserted that Biofrontera's RhodoLED[®] XL allegedly meets this claim limitation. RX-0006C, Q/A 212-213. The lighting pattern present in RhodoLED[®] XL is shown in RDX-0017C.047. RX-0006C, Q/A 212-213.



RDX-0017C.047.

Using Sun Pharma's assertions of what light distribution patterns meet this claim language, Lundahl discloses this limitation. RX-0006C, Q/A 212-213. Lundahl teaches that “[t]he number of tubes used and the spacing between them were chosen to achieve desired uniformity and power output specifications.” RX-0065, 6:43-45. As shown in RDX-0017C.0048, containing annotated version of Figures 1 and 2 of Lundahl, “[o]ptimum output distribution has been found to occur when seven tubes 10(1)-10(7) are placed in the chassis in a symmetric pattern with respect to opposite edges of the unit.” RX-0065, 6:45-48; RX-0006C, Q/A 212-213.



RDX-0017C.048.

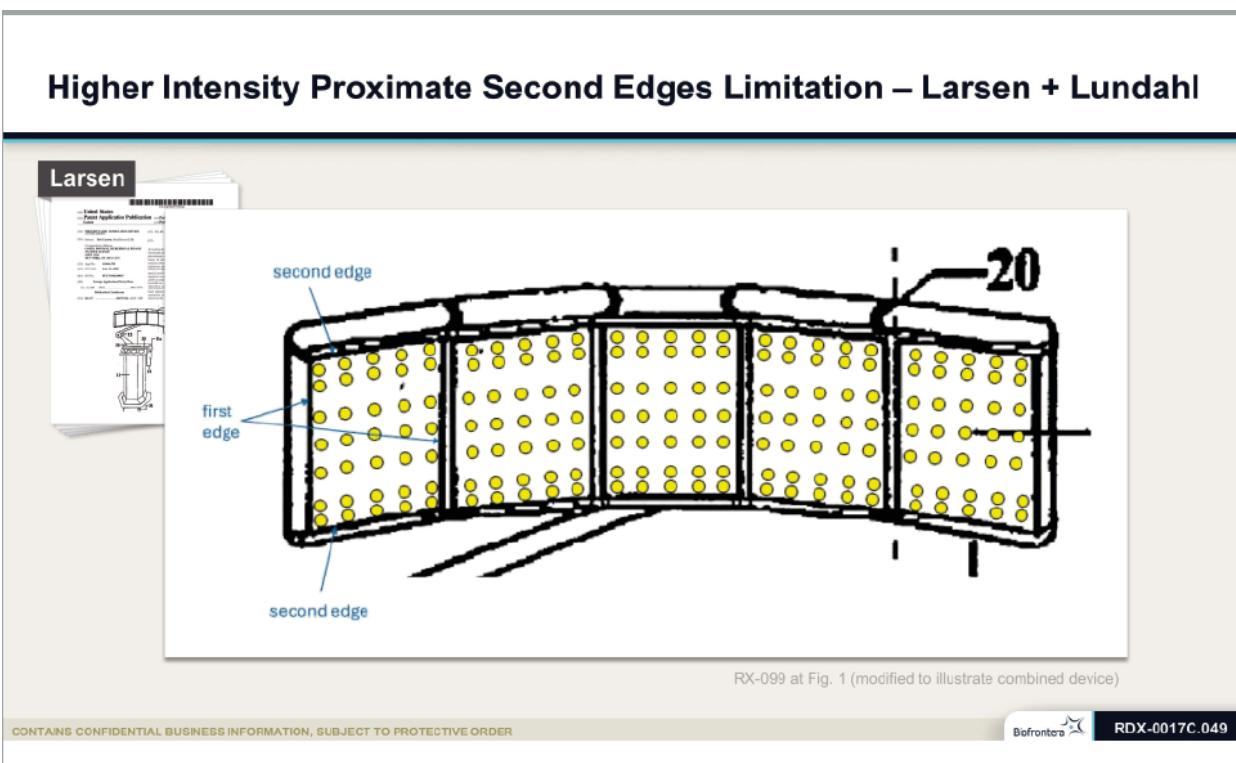
Lundahl includes the “following approximate lateral spacing: 7 cm between the center tube 10(4) and each of the two tubes 10(3),10(5) adjacent to the center tube 10(4); 5 cm between the tubes 10(3),10(2) and 10(5),10(6), i.e., the next pairs of tubes out from the center; and 3.5 cm between tubes 10(2),10(1) and 10(6),10(7), i.e., the outermost pairs of tubes at the sides of the unit.” RX-0065, 6:48-54. Lundahl also states that “[t]he outermost tubes 10(0),10(7) are approximately 2.5 cm from the edges of the housing” and “[t]he present invention provides a highly uniform output irradiance without the use of an additional diffusing element.” RX-0065, 6:54-57. A POSA would have understood that the tubes of Lundahl are spaced to emit a higher intensity of light proximate the top and bottom sides compared to the intensity of light emitted not proximate the top and bottom

sides.²⁰ RX-0006C, Q/A 214. The evidence will show that Dr. Jokerst recognizes this disclosure in Lundahl. RX-0006C, Q/A 214.

By combining the design principles of Larsen related to the hinged panel system containing LED lights with the PDT device and light distribution of Lundahl, a POSA would expect the resulting device to have a design similar to what is provided in RDX-0017C.049, with the yellow circles representing LEDs.²¹ RX-0006C, Q/A 215.

²⁰ Although Sun Pharma has asserted that this claim limitation is not rendered obvious because the “top and bottom sides” of Lundahl’s device are “the longer edges, not the shorter edges,” this assertion entirely overlooks the fact that incorporating the five panel design of Larsen into the Lundahl device (effectively taking the single, long U-shaped panel of Lundahl and dividing it into five sections, as illustrated in Larsen) results in a device with a design as illustrated in RDX-0017C.0049. RX-0006C, Q/A 217. As illustrated in this demonstrative, the device has a shorter second edge at the top and bottom, and a longer first edge on the side, and the device also has a higher intensity of light emitted close to the second shorter edges compared to the intensity of light emitted not close to the second shorter edges, based on what Sun Pharma has asserted to meet the claimed requirement in RhodoLED[®] XL. RX-0006C, Q/A 217.

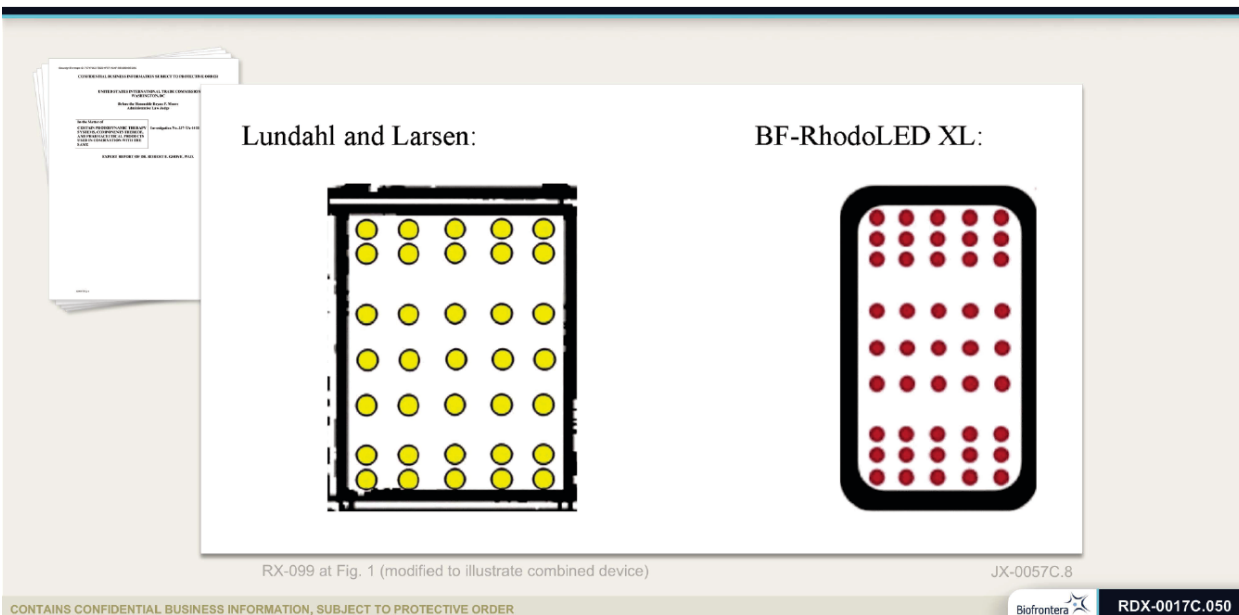
²¹ The annotated figure provided in this demonstrative demonstrates a rendering whereby the hinged panels and LEDs taught by Larsen are incorporated into the device of Lundahl, while maintaining the same light distribution pattern Lundahl utilized for the fluorescent bulbs, as was shown in Figure 2 of Lundahl, and as described in the text of Lundahl. RX-0006C, Q/A 215.



RDY-0017C.049.

As shown in RDY-0017C.050, the light distribution illustrated in this rendering combining the teachings of Lundahl and Larsen is very similar to the light distribution in Biofrontera's RhodoLED® XL, which Sun Pharma has asserted to meet the claimed requirement of “higher intensity of light is emitted close to the second shorter edges compared to the intensity of light emitted not close to the second shorter edges.” RX-0006C, Q/A 216.

Higher Intensity Proximate Second Edges Limitation – Lundahl + Larsen



RDX-0017C.050.

Accordingly, Lundahl and Larsen disclose and render obvious the “higher intensity proximate second edges” limitation of the Asserted Claims. RX-0006C, Q/A 220.

Limitation	Lundahl	Larsen	Hente	Perutz
Preamble	✓	✓		
Hinges		✓	✓	
Light Sources		✓		
Uniform Illumination	✓	✓		
Center Panel		✓		
Within Approximately Four Inches	✓			
First and Second Edges		✓		
Higher Intensity Proximate Second Edges	✓	✓		
Administering ALA				
Positioning Proximate				
Individually Configurable				

RDX-0017C.053 (excerpt).

- ix. *Limitation – Administering 5-Aminolevulinic Acid to Patient ("Administering ALA Limitation")*

Claim 8 of the '512 Patent recites what will be referred to as the “administering ALA limitation.” JX-0001, cl. 8.²² The precise language used in the claim is listed in the table below. RX-0006C, Q/A 221.

Claim Language — Administering ALA Limitation	Claims
“administering 5-aminolevulinic acid (ALA) to the patient”	Claim 8 of the '512 Patent

The limitation requires “administering 5-aminolevulinic acid (ALA) to the patient.” RX-0006C, Q/A 222-223. Lundahl discloses the administering ALA limitation. RX-0007C, Q/A 150; RX-0006C, Q/A 225-227.

ALA has been used as a photoactivating agent in PDT for decades. RX-0007C, Q/A 150. As of the priority date of the Asserted Patents, it was well-within a dermatologist's knowledge that ALA should be applied to a patient's treatment areas. RX-0007C, Q/A 150. Lundahl and Larsen expressly teach applying ALA to a patient as part of PDT treatment. RX-0007C, Q/A 150.

Lundahl teaches that “[a]ccording to one preferred embodiment of the present invention, blue light having wavelengths exceeding 400 nm (nanometers) is particularly advantageous for certain diagnostic purposes and treatments, especially when ALA is the photoactivatable agent used for PD and PDT of actinic keratosis” and that “visible light in other ranges of the spectrum, particularly in the green and red ranges between 400 and 700 nm, may also be used.” RX-0065, 2:14-26; RX-0006C, Q/A 226. Lundahl describes applying ALA to a patient for the treatment of actinic keratosis, stating “One example of a treatment method for precancerous lesions, such as actinic keratosis, by PDT utilizing an illuminator described above in conjunction with 5-

²² The Asserted Claims do not put any limitations on how to administer the ALA, what concentration or dose of ALA to administer, or how long to let the ALA incubate on the patient before applying light from the illuminator. RX-0007C, Q/A 231.

aminolevulinic acid (ALA) will now be described. Essentially anhydrous ALA is admixed with a liquid diluent just prior to its use. The ALA admixture is topically applied to the lesions using a point applicator to control dispersion of the ALA admixture.” RX-0065, 15:29-37.²³

Accordingly, Lundahl discloses the “administering ALA” limitation of the Asserted Claims. RX-0006C, Q/A 227; RX-0007C, Q/A 150.

Limitation	Lundahl	Larsen	Hente	Perutz
Preamble	✓	✓		
Hinges		✓	✓	
Light Sources		✓		
Uniform Illumination	✓	✓		
Center Panel		✓		
Within Approximately Four Inches	✓			
First and Second Edges		✓		
Higher Intensity Proximate Second Edges	✓	✓		
Administering ALA	✓			
Positioning Proximate				
Individually Configurable				

RDX-0017C.056 (excerpt).

x. *Limitation – Positioning Proximate to the Patient ("Positioning Proximate Limitation")*

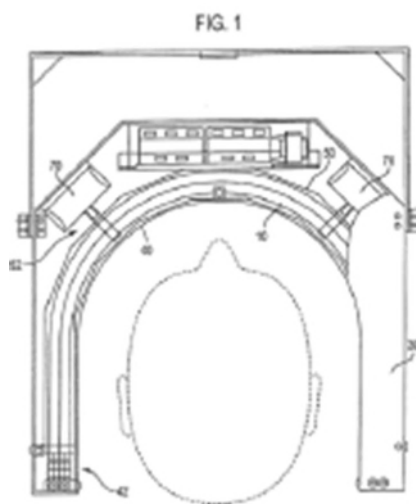
Claim 8 of the '512 Patent recites what will be referred to as “the positioning proximate limitation.” JX-0001, 8. Specifically, as shown in the table below, claim 8 of the '512 Patent recites, *inter alia*, “positioning an illuminator proximate to the patient.” The precise language used in the claim is listed in the table below. RX-0006C, Q/A 141.

<u>Claim Language – Positioning Proximate</u>	<u>Claims</u>
“positioning an illuminator proximate to the patient”	Claim 8 of the '512 Patent

Lundahl teaches positioning the PDT device proximate to the patient’s head for treatment. RX-0006C, Q/A 230-234. For example, Lundahl teaches positioning an illuminator between two

²³ Larsen also discloses administration of ALA at paragraphs [0015], [0116], and [0120].

and four inches from the treatment surface. RX-0007C, Q/A 154. Lundahl also states “the present invention uses a U-shaped emitting surface that more closely follows the contours of the human face and scalp, and minimizes lamp to target distance variations which in turn minimizes irradiance variations at the target.” RX-0065, 4:33-38; RX-0006C, Q/A 233. Additionally, Lundahl illustrates the positioning of the PDT device proximate to the patient’s head in Fig. 1. RX-0006C, Q/A 233. Further, as Dr. Ehrenreich explains, “[t]his is [an] aspect of the claims that was well-understood by dermatologists in the context of PDT by 2015.” RX-0007C Q/A 153.



Accordingly, Lundahl discloses the positioning proximate limitation. RX-0006C, Q/A 230-234. This limitation would also have been obvious to a POSA as of 2015. RX-0007C, Q/A 152-154.

Limitation	Lundahl	Larsen	Hente	Perutz
Preamble	✓	✓		
Hinges		✓	✓	
Light Sources		✓		
Uniform Illumination	✓	✓		
Center Panel		✓		
Within Approximately Four Inches	✓			
First and Second Edges		✓		
Higher Intensity Proximate Second Edges	✓	✓		
Administering ALA	✓			
Positioning Proximate	✓			
Individually Configurable				

RDX-0017C.059 (excerpt).

xi. Limitation – Individually Configurable Limitation

Claims 16 and 21 of the '028 Patent each recite what will be referred to as “the individually configurable limitation.” JX-0002, cls. 16 and 21. The precise language used in each claim is listed in the table below. RX-0006C, Q/A 235-236.

<u>Claim Language – Individually Configurable</u>	<u>Claims</u>
“five panels connected by hinged structures to allow continuous illumination across the five panels, wherein the five panels are individually configurable to control illumination from each of the five panels”	Claims 16 of the '028 Patent
“the five panels are individually configurable to control illumination from each of the five panels”	Claim 21 of the '028 Patent

As shown above, claim 21 recites “the five panels are individually configurable to control illumination from each of the five panels,” and claim 16 recites the broader clause of “five panels connected by hinged structures to allow continuous illumination across the five panels, wherein the five panels are individually configurable to control illumination from each of the five panels.” JX-0002, cls. 16 and 21; RX-0006C, Q/A 237. The “five panels are individually configurable to control illumination from each of the five panels” was construed to mean “the power output and/or light intensity of each panel can be individually controlled.” Order No. 18, 40.

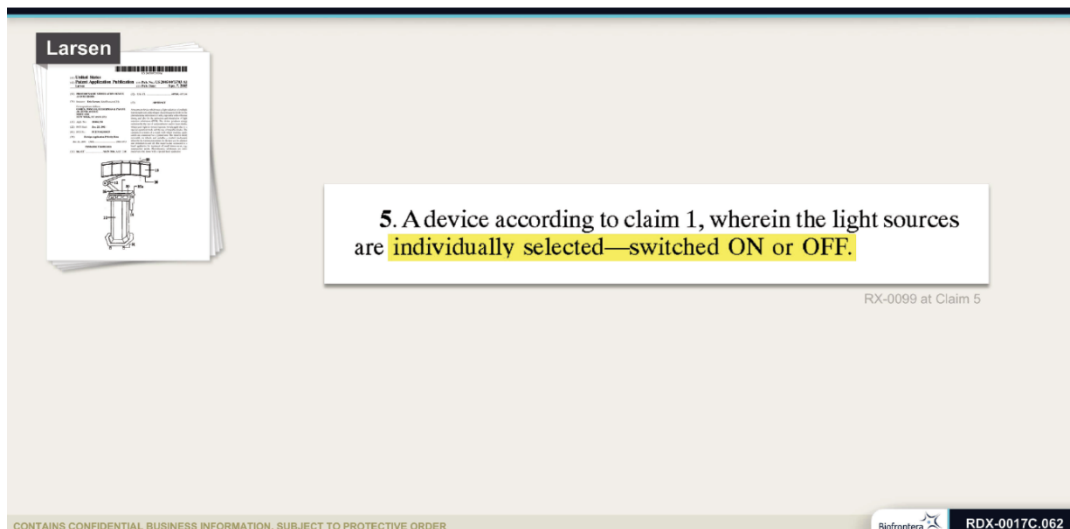
Larsen discloses several applicators (i.e., panels) “flexibly connected to each other through hinges...” which each applicator (i.e., panel) containing multiple light sources. RX-0099, [0070]-[0072]; RX-0006C, Q/A 240, 243. Thus, Larsen teaches illuminating or darkening individual light

sources within an applicator (i.e., panel), which necessarily alters or configures the power output and/or light intensity of the associated applicator(s) or panels. RX-0006C, Q/A 243.

Additionally, Larsen discloses that each of the applicators (i.e., panels) is connected to a control mechanism 16. RX-0099, Figs. 1 and 4; RX-0006C, Q/A 241. Using the control mechanism, “the invented device is adjustable within a relatively large range with reference to duration, amplitude and frequency of surge of current, so that the semiconductor diodes 17, 17a and 18, as well as laser 17 diodes with the same realisation as semiconductor diode 17, can be used as light sources.” RX-0099, [0074]; RX-0006C, Q/A 241. The control mechanism includes “a switch select system for operating different types of semiconductor diodes 17 and/or with laser diodes. Both semiconductor diodes and/or laser diodes with tuneable wavelengths can be operated, which is a great advantage, and therefore the printed circuit boards can be equipped with a more intensive radiation effect.” RX-0099, [0074]; RX-0006C, Q/A 241.

Additionally, as shown below, claim 5 of Larsen recites “wherein the light sources are ***individually selected***—switched ON or OFF.” RX-0099, cl. 5 (emphasis added); RX-0006C, Q/A 243.

Individually Configurable – Larsen



RDX-0017C.062.

Based on the disclosure of claim 5, Larsen teaches illuminating or darkening individual light sources, which a POSA would know to necessarily alter or configure the power output and/or light intensity of the associated applicator(s). RX-0006C, Q/A 243. It was within the know-how of a POSA at the time Larsen was published to use a control panel to individually select light sources amongst one or more multiple applicators (i.e. the printed circuit boards) to vary the illumination provided therefrom. *Id.*

Accordingly, Larsen discloses the “individually configurable limitation” of the Asserted Claims. RX-0006C, Q/A 246.

Limitation	Lundahl	Larsen	Hente	Perutz
Preamble	✓	✓		
Hinges		✓	✓	
Light Sources		✓		
Uniform Illumination	✓	✓		
Center Panel		✓		
Within Approximately Four Inches	✓			
First and Second Edges		✓		
Higher Intensity Proximate Second Edges	✓	✓		
Administering ALA	✓			
Positioning Proximate	✓			
Individually Configurable		✓		

RDX-0017C.063 (excerpt).

xii. Limitation – Illuminator Limitations of Claim 16

Claim 16 of the '028 Patent recites a number of limitations related to mechanical components of an illuminator, which do not appear in other Asserted Claims.” JX-0002, cl. 16. These limitations are shown in the table below, along with associated abbreviations. RX-0006C, Q/A 247.

<u>Claim Language – Illuminator Limitations of Claim 16</u>	<u>Claim 16</u>
“a mobile base supported by at least four wheels;	(“16- mobile base”)
“a pillar perpendicular to the base”	(“16- pillar”)
“a controller disposed to be supported by the pillar”	(“16- controller”)
“an arm mounted to a top portion of the pillar”	(“16- arm”)
“an illuminator connected at an end of the arm, the arm being hinged to allow adjustment of a position of the illuminator relative to the base	(“16- illuminator connected”)
“the light sources being configured to output light uniformly during at least part of a time when the treatment surface is illuminated”	(“16- light sources output light uniformly”)
“one or more fans mounted to at least one of the five panels.”	(“16- fans”)

Initially, Larsen teaches the 16-mobile base limitation. RX-0006C, Q/A 254. Specifically, Fig. 1 of Larsen discloses a mobile base supported by wheels. RX-0099, Fig. 1; RX-0006C, Q/A 248. Larsen teaches that the device is “freely moveable on wheels.” RX-0099, [0027], [0069]; RX-0006C, Q/A 248. Further, during prosecution of the '028 Patent, the Examiner found that, based on Fig. 1 of U.S. Pat. No. 7,033,381 – which is the exact same image as Fig. 1 of Larsen - “it is

inherent that there are at least two more wheels, for a total of 4, in order for the device to be stable.” JX-003.130-31; RX-0006C, Q/A 249-252.

To the extent that Larsen does not expressly or inherently disclose “at least four wheels,” it would have been obvious to a POSA to use at least four wheels to support the stand/pillar of Larsen depicted in Fig. 1. It was well known that a four-wheeled stand is more stable than a stand with only three wheels. RX-0006C, Q/A 248, 253. Further, using at least four wheels to support the stand was one of a finite number of known solutions to support a mobile stand. RX-0006C, Q/A 253. A POSA would have been motivated with a reasonable expectation of success to use four wheels, since the stability provided by four wheels was a well-known outcome. RX-0006C, Q/A 253. Accordingly, Larsen teaches and/or renders obvious the 16-mobile base limitation. RX-0006C, Q/A 254.

Second, Larsen discloses the 16-pillar limitation. RX-0006C, Q/A 255-256. Specifically, Larsen’s Fig. 1 shows “stand 11,” which is perpendicular to the base, and meets the limitation. RX-0099, Fig. 1; RX-0006C, Q/A 255.

Third, each of Lundahl and Larsen discloses the 16-controller limitation. RX-0006C, Q/A 257-58. Specifically, Lundahl teaches that “[a]ccording to a preferred embodiment of the present invention, an electronic control system 110 consists of six functional blocks. A microcontroller 200 is the central processing unit; it contains firmware which reads the system sensors, determines the system status, controls the ballast voltage (and tube output), and provides user information by way of a system status LED 112 (the firmware is described in detail below). To achieve output irradiance in the specified range, the microcontroller 200 monitors the tube output via a visible light sensor 120 which is located behind the tube reflector 50.” RX-0065, 11:19-29; RX-0006C, Q/A 257. In addition to these teachings in Lundahl, Larsen discloses controller 16 in its Fig. 1.

RX-0099, Fig. 1; RX-0006C, Q/A 257. Accordingly, each of Lundahl and Larsen discloses the 16-controller limitation. RX-0006C, Q/A 257-58.

Fourth, Larsen discloses the 16-arm limitation. RX-0006C, Q/A 260. Specifically, Larsen's Fig. 3 shows a joint arm 12 mounted to a top portion of the stand in Figure 3. RX-0099, Fig. 3; RX-0006C, Q/A 259. Larsen discloses that the joint arm 12 is mounted to the top of the stand/pillar 11: "The joint carrier 21 is connected with the stand 11 through a joint 27 and one or more joints can also be produced as friction-adjustable ball-joints, which gives almost unlimited adjustment possibilities and user comfort." RX-0099, [0073], Fig. 1; RX-0006C, Q/A 259. Thus, Larsen discloses the 16-arm limitation. RX-0006C, Q/A 260.

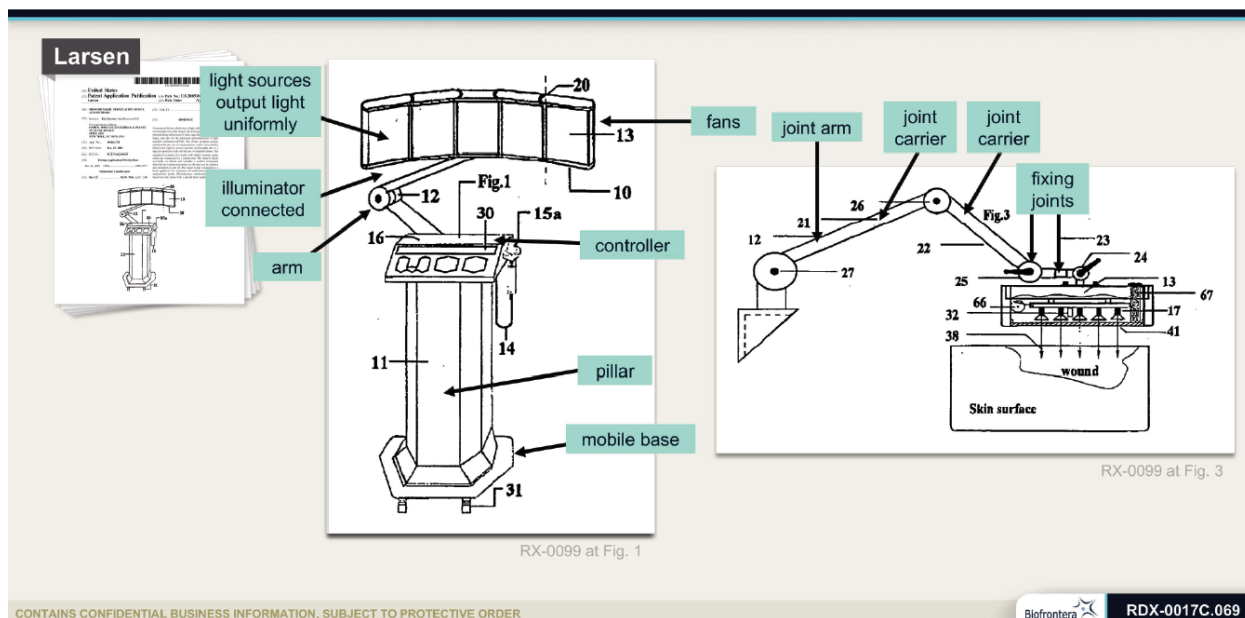
Fifth, Larsen discloses the 16-illuminator connected limitation. RX-0006C, Q/A 262. Specifically, as shown in Fig. 3, Larsen's applicator 13 is connected to the end of the joint arm 12, with hinges that allow adjustment of its position. RX-0099, Fig. 3; RX-0006C, Q/A 261. Furthermore, "[t]he jointed arm 12 has three joint carriers 21, 22, 23, where the joint carrier 21, together with the stand 11 and the joint carrier 23 are moveable at a free end through a fixing joint 24 connected with one or more applicators 13." RX-0099, [0073]; RX-0006C, Q/A 261. Another fixing joint 25 "connects the joint carrier 23 with 21, while the joint carrier 22 is connected with the joint carrier 21 with a hinge 26." RX-0099, [0073]; RX-0006C, Q/A 261. Larsen discloses that "[t]he joint carrier 21 is connected with the stand 11 through a joint 27 and one or more joints can also be produced as friction-adjustable ball-joints, which gives almost unlimited adjustment possibilities and user comfort." RX-0099, [0073]; RX-0006C, Q/A 261. Accordingly, "[t]he jointed arm 12 thereby allows the positioning of the applicators 13 in front of, or above, a tissue area while maintaining a correct positioning distance." RX-0099, [0073]; RX-0006C, Q/A 261. Therefore, Larsen discloses the 16-illuminator connected limitation. RX-0006C, Q/A 262.

Sixth, Larsen discloses the 16-light sources output light uniformly limitation. RX-0006C, Q/A 264. Specifically, Larsen discloses light sources that are configured to output light uniformly during at least part of a time when the treatment surface is illuminated. RX-0006C, Q/A 263. For example, Larsen teaches that “[t]he semiconductor diodes and/or laser diodes useable in this invention emit a light radiation with either SPE (single photon emission), TPE (Two photon emission) and/or MTE (multiple photon emission) within the wavelength area of 300-2000 nanometers in order to correspond with available light sensitive substances (PDT).” RX-0099, [0071], [0076]; RX-0006C, Q/A 263. Furthermore, “[i]n each applicator the printed circuit board carrying the light sources is connected to a small electrical scan engine 66, which can move the light sources with linear movements, whereby a correctly adjusted scan length and frequency gives the radiated surface a total radiation at the necessary wavelengths without leaving any unradiated gaps.” RX-0099, [0072]; [RX-0006C, Q/A 263](#). As such, Larsen discloses the 16-light sources output light uniformly limitation. RX-0006C, Q/A 264.

Seventh, Larsen, in combination with Lundahl, teaches and/or renders obvious the 16-fans limitation. RX-0006C, Q/A 266. Initially, Lundahl teaches that “a cooling system is provided to ensure proper bulb operation. According to an embodiment of the present invention, the cooling system comprises vents in the polycarbonate shield 40, the reflector 50 and the housing 30, as well as fans 70 to displace cooling air.” RX-0065, 9:14-18; RX-0006C, Q/A 265. While Larsen does not explicitly disclose one or more fans mounted to at least one of the five panels, Larsen recognizes that “[a] disadvantage of the known device is that the semiconductor diodes tend to overheat during use, which causes a decrease in the effectiveness of the device.” RX-0099, [0006]; RX-0006C, Q/A 265. Thus, a POSA would have found it obvious to add one or more fans mounted

to at least one of the five panels to cool the device in Larsen. RX-0006C, Q/A 265. Consequently, Lundahl and Larsen, disclose and render obvious the 16-fans limitation. RX-0006C, Q/A 266.

Illuminator Limitations of Claim 16 – Larsen



RDX-0017C.069.

Accordingly, each of the mechanical limitations specific to claim 16 is disclosed and/or rendered obvious by one or more of Lundahl and Larsen. RX-0006C, Q/A 267.

Limitation	Lundahl	Larsen	Hente	Perutz
Mobile Base		✓		
Pillar		✓		
Controller	✓	✓		
Arm		✓		
Illuminator Connected		✓		
Light Sources Output Light Uniformly		✓		
Fans		✓		

RDX-0017C.073 (excerpt).

- xiii. *Limitation – Illuminator Configured to Output Light at Variable Irradiance Density ("Variable Irradiance Limitation")*

Claim 20 of the '028 Patent recites what will be referred to as “variable irradiance limitation.” JX-0002, cl. 20. The precise language used in the claim is listed in the table below. RX-0006C, Q/A 268-269.

<u>Claim Language – Variable Irradiance</u>	<u>Claims</u>
“the illuminator is configured to output light at a variable irradiance density during treatment”	Claim 20 of the '028 Patent

With respect to this limitation, Larsen teaches that the applicators can produce “an intensive light radiation with selective multiple wavelengths” in order to provide intensive photodynamic therapy to a patient. RX-0099, [0025]-[0026]; RX-0006C, Q/A 272. Larsen further teaches that the energy output from its applicators is adjustable “within a relatively large range with reference to duration, amplitude and frequency of surge of current, so that semiconductor diodes 17, 17a and 18 . . . can be used as light sources.” RX-0099, [0074]; RX-0006C, Q/A 272. Larsen’s applicators are connected to sensors measuring the amount of energy radiated away from the skin surface and the temperature of the skin surface. RX-0099, [0079]-[0080], Figs. 2a-2c; RX-0006C, Q/A 272. In response to readings from the sensors, “[a]n increase of the registered amount of energy can be achieved by the invented device by increasing the operating potential (and thereby the pulse amplitude) or the pulse frequency and/or prolonging the duration of the treatment time through an adjustment of the control mechanism 16.” RX-0099, [0079], [0308]; RX-0006C, Q/A 272.

Accordingly, Larsen discloses the variable irradiance limitation. RX-0006C, Q/A 273.

Limitation	Lundahl	Larsen	Hente	Perutz
Preamble	✓	✓		
Hinges		✓	✓	
Light Sources		✓		
Uniform Illumination	✓	✓		
Center Panel		✓		
Within Approximately Four Inches	✓			
First and Second Edges		✓		
Higher Intensity Proximate Second Edges	✓	✓		
Administering ALA	✓			
Positioning Proximate	✓			
Variable Irradiance		✓		
Red Light				
Dose Range				
Wavelength				
Recess				
Recess Location				

RDX-0017C.076 (excerpt).

- xiv. *Limitation – Red Light and Dose Range ("Red Light and Dose Range Limitations")*

Claims 2 and 19 of the '028 Patent and claim 3 of the '512 Patent recite what will be referred to as the “red light” and “dose range” limitations. JX-0002, cls. 2 and 19; JX-0001, cl. 3.

The precise language used in each claim is listed in the table below. RX-0006C, Q/A 274-275.

<u>Claim Language – Dose Limitation</u>	<u>Claims</u>
“the illuminator is configured to output red light at a dose of 30 J/cm ² to 150 J/cm ² ”	Claim 2 of the '028 Patent
“the illuminator is configured to output red light at a dose of about 30 J/cm ² to about 150 J/cm ² ”	Claim 3 of the '512 Patent
“the light sources are configured to output red light during at least part of the time when the treatment surface is illuminated”	Claim 19 of the '028 Patent

More specifically, claim 2 of the '028 Patent and claim 3 of the '512 Patent contain the limitations directed to “red light at a dose of 30 J/cm² to 150 J/cm²” and “red light at a dose of about 30 J/cm² to about 150 J/cm²,” respectively. JX-0002, cl. 2; JX-0001, cl. 3. Claim 19 of the

'028 Patent contains the limitation that the illuminator/light sources output “red light during at least part of the time when the treatment surface is illuminated.” JX-0002, cl. 19.

Lundahl expressly incorporates all teachings of U.S. Patent No. 5,079,262 to Kennedy et al. (“Kennedy”). RX-0065, 1:39-59. With respect to the “red light” limitation, Kennedy teaches that “[i]n preferred aspects of this invention the preferred precursor of protoporphyrin IX is 5-amino-4-oxo-pentanoic acid, otherwise known as 5-aminolevulinic acid, and a preferred wavelength of the photoactivating light is in the range 350-640 nm, **more preferably a red light** of about 610-630 nm.” RX-0068, 4:3-8 (emphasis added); RX-0006C, Q/A 277. Kennedy also states that “[t]he wavelength of the photoactivating light is of some importance, as it has been shown that between 1 and 10 percent of incident **red light** (600-700 nm) can pass through a slab of human tissue 1 cm thick, whereas only 0.001 percent or less of blue light (about 400 nm) can pass through the same thickness of human tissue. The photosensitizer will, therefore, be more successful if it strongly absorbs red light. **PpIX does strongly absorb red light.**” RX-0068, 4:60-69 (emphasis added); RX-0006C, Q/A 277.

With respect to the “light dose” limitation, Kennedy teaches a red light dose of 30 J/cm² to 150 J/cm². RX-0006C, Q/A 278. Specifically, Examples 1-4 of Kennedy provide PDT treatment of patients with various skin conditions and disease states, including specific light doses of 52.5 mWhr/cm² (Example 1); 26 mWhr/cm² (Example 2); 17, 26 and 50 mWhr/cm² (Example 3); and 37 mWhr/cm² (Example 4). RX-0068, 5:47-6:47; RX-0006C, Q/A 278. In all cases, treatment was found to effectively resolve the treated lesions. RX-0068, 5:47-6:47; RX-0006C, Q/A 278. As 1 mWhr/cm² = 3.6 J/cm², Examples 1-4 of Kennedy provide PDT treatment with red light doses ranging from approximately 61 J/cm² to 189 J/cm². RX-0006C, Q/A 278. Therefore, Kennedy’s teaching of a red light dose range of 61 J/cm² to 189 J/cm² (including specific values of 61.2 J/cm²

(Example 3), 93.6 J/cm² (Example 2), and 133.2 J/cm² (Example 4)), which overlaps the claimed range of 30 J/cm² to 150 J/cm², discloses the claimed range. RX-0006C, Q/A 278. *Ineos USA LLC v. Berry Plastics Corp.*, 783 F.3d 865, 869 (Fed. Cir. 2015) (“When a patent claims a range, as in this case, that range is anticipated by a prior art reference if the reference discloses a point within the range.”); *Genentech, Inc. v. Hospira, Inc.*, 946 F.3d 1333, 1338 (Fed. Cir. 2020) (Finding that a prior art reference that discloses a range overlapping the claimed range can anticipate that claimed range.).

Additionally, it would be obvious to optimize light dose to arrive at the claimed range. RX-0006C, Q/A 279. “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” *In re Aller*, 220 F.2d 454, 456 (CCPA 1955). Total light Dose (J/cm²) = Irradiance (W/cm²) × Time (sec), meaning the dose is simply a function of the amount of time the patient is exposed to the light at the specific irradiance. RX-0006C, Q/A 279. Consequently, a POSA knew and understood that any of the specific doses disclosed could be changed to a different light dose of any value in the range from 30 J/cm² to 150 J/cm² simply by increasing or decreasing the light exposure time. RX-0006C, Q/A 279. Because of this ability to routinely optimize the light dose, the claimed range of 30 J/cm² to 150 J/cm² is also rendered obvious by Kennedy. *Id.*

Accordingly, Lundahl, via its incorporation of Kennedy, discloses the “red light” and “dose range” limitations. RX-0006C, Q/A 280.

Limitation	Lundahl	Larsen	Hente	Perutz
Preamble	✓	✓		
Hinges		✓	✓	
Light Sources		✓		
Uniform Illumination	✓	✓		
Center Panel		✓		
Within Approximately Four Inches	✓			
First and Second Edges		✓		
Higher Intensity Proximate Second Edges	✓	✓		
Administering ALA	✓			
Positioning Proximate	✓			
Variable Irradiance		✓		
Red Light	✓	✓		
Dose Range	✓			
Wavelength				
Recess				
Recess Location				

RDX-0017C.079 (excerpt).

- xv. *Limitation – Light Having Wavelength of 400-700 nm ("Wavelength Limitation")*

Claim 4 of the '028 Patent and claim 5 of the '512 Patent recite what will be referred to as the “wavelength limitation.” JX-0002, cl. 4; JX-0001, cl. 5. The precise language used in each claim is listed in the table below. RX-0006C, Q/A 281-282.

<u>Claim Language – Wavelength Limitation</u>	<u>Claims</u>
“a plurality of the light sources are configured to emit light having a wavelength in a range of 400 nm to 700 nm”	Claim 4 of the '028 Patent
“a plurality of the light sources are configured to emit light having a wavelength in a range of 400 nm to 700 nm”	Claim 5 of the '512 Patent

With respect to this limitation, Lundahl teaches that “[a]ccording to one preferred embodiment of the present invention, blue light having wavelengths exceeding 400 nm (nanometers) is particularly advantageous for certain diagnostic purposes and treatments, especially when ALA is the photoactivatable agent used for PD and PDT of actinic keratosis” and

that “visible light in other ranges of the spectrum, particularly in the green and red ranges between 400 and 700 nm, may also be used.” RX-0065, 2:18-26; RX-0006C, Q/A 285.

Accordingly, Lundahl discloses the wavelength limitation. RX-0006C, Q/A 285-286.

Limitation	Lundahl	Larsen	Hente	Perutz
Preamble	✓	✓		
Hinges		✓	✓	
Light Sources		✓		
Uniform Illumination	✓	✓		
Center Panel		✓		
Within Approximately Four Inches	✓			
First and Second Edges		✓		
Higher Intensity Proximate Second Edges	✓	✓		
Administering ALA	✓			
Positioning Proximate	✓			
Variable Irradiance		✓		
Red Light	✓	✓		
Dose Range	✓			
Wavelength	✓			
Recess				
Recess Location				

RDX-0017C.082 (excerpt).

xvi. Limitation – Recess to Receive Hinge Flange ("Recess Limitation")

Claim 17 of the '512 Patent recites what will be referred to as the “recess limitation.” JX-0001, cl. 17. The precise language used in this limitation is listed in the table below. RX-0006C, Q/A 287-288.

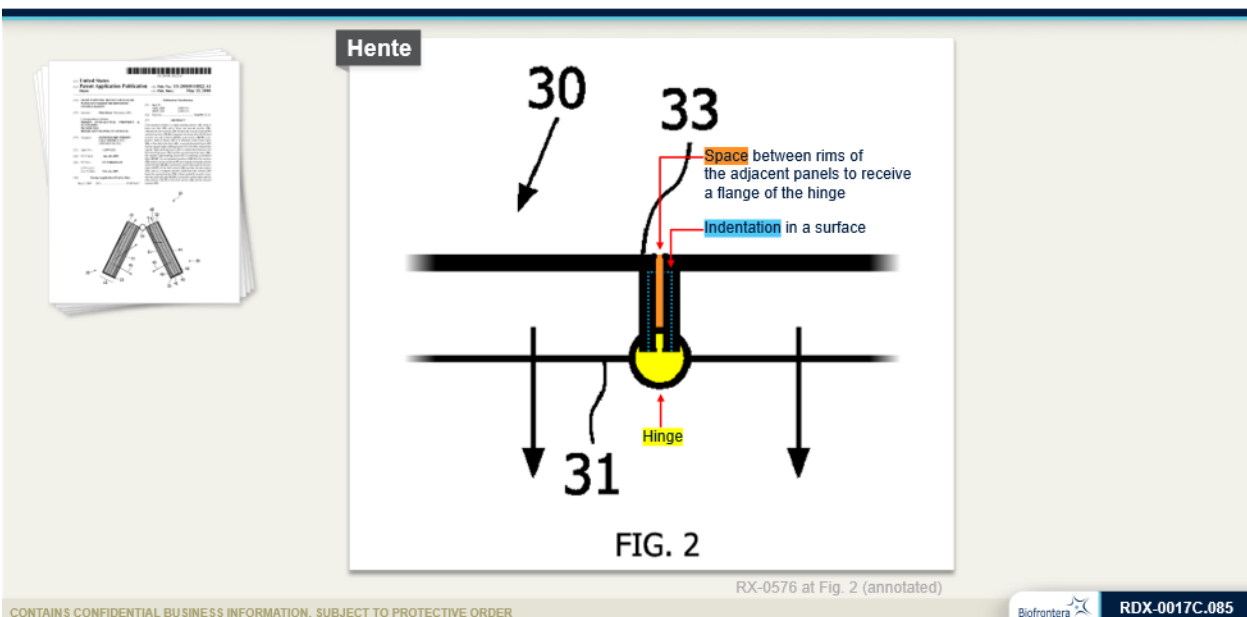
<u>Claim Language – Recess Limitation</u>	<u>Claims</u>
“at least one panel includes a recess configured to receive a flange of one of the nested hinges”	Claim 17 of the '512 Patent

The term “recess” has been construed to mean “indentation, small hollow, or cleft” and “nested hinges on inner side surfaces of adjacent panels” has been construed to mean “hinges that fit on inner side surfaces of adjacent panels.” Order No. 18, 35, 47. Accordingly, as construed,

claim 17 requires an “indentation, small hollow, or cleft configured to receive a flange of one of the hinges that fit on inner side surfaces of adjacent panels.”

As shown in the annotated figure in RDX-0017C.084, Hente discloses the placement of a hinge in a location that fits on the inner side surfaces between adjacent sections. RX-0006C, Q/A 292. As illustrated in Figure 2 of Hente, the inner edges of adjacent sections 20 and 30 are nearly flush with each other. RX-0006C, Q/A 292. As Dr. Grove has illustrated below, this disclosure would have motivated a POSA to place the flange of the hinges in an indentation at the inner side surfaces of Larsen’s panels in order to facilitate this nearly flush arrangement, and to minimize the space between the adjacent sections, which was a well-established design motivation from the teachings of Hente and Larsen. RX-0006C, Q/A 292.

Recess Limitation – Hente



RDX-0017C.085.

A POSA would recognize this as nothing more than applying known design elements and strategies to a known device (*i.e.*, the panels of Larsen) to predictably decrease the space between

Additionally, Perutz teaches connecting adjoining display panels 30, 32 with hinges 10. RX-0607, 3:54-4:14. As shown in RDX-0017C.086, provided by Dr. Grove, the hinges 10 connect adjoining display panels 30, 32 at an inner side surface of the display panels 30, 32. RX-0607, Figure 1 (annotated).

[illegible]

Perutz states that the segments of the hinge 10 “are maintained in vertically spaced alignment by an elongated rib or strut 28, 29,” with the ribs 28, 29 being received within slots 34

“formed in the corners of the frame 6 of the adjacent display panels.” RX-0607, 4:16-20 and 33-38.

As shown in Figures 12 and 15 of Perutz, the side surface of adjoining display panels includes an indentation in a surface (*e.g.*, slot 34 in frame 6) to receive the side-mounted hinges, specifically a flange (*e.g.*, ribs 28, 29) of the hinges 10, to reduce space between adjoining display panels. RX-0607, Figures 12 and 15. Thus, Perutz teaches that at least one panel includes a recess configured to receive a flange of one of the hinge structures.

Accordingly, a POSA would have found it obvious and would have been motivated with a reasonable expectation of success to include an indentation at the inner side surfaces between adjacent sections to receive a flange of a hinge. RX-0006C, Q/A 292. Locating a hinge between panels in a recess would have been a mere application of known design elements and strategies to a known device (*i.e.*, the panels of Larsen) to predictably decrease the space between the adjacent panels. RX-0006C, Q/A 292. *KSR*, 550 U.S. at 417.

Accordingly, Hente and Pertuz each disclose and/or render obvious the recess limitation. RX-0006C, Q/A 295.

Limitation	Lundahl	Larsen	Hente	Perutz
Preamble	✓	✓		
Hinges		✓	✓	
Light Sources		✓		
Uniform Illumination	✓	✓		
Center Panel		✓		
Within Approximately Four Inches	✓			
First and Second Edges		✓		
Higher Intensity Proximate Second Edges	✓	✓		
Administering ALA	✓			
Positioning Proximate	✓			
Variable Irradiance		✓		
Red Light	✓	✓		
Dose Range	✓			
Wavelength	✓			
Recess			✓	✓
Recess Location				

RDX-0017C.87 (excerpt).

xvii. *Limitation – Recess Located at Inner Side Surface ("Recess Location Limitation")*

Claim 18 of the '512 Patent recites what will be referred to as the “recess location limitation.” JX-0001, cl. 18. The precise language used in this limitation is listed in the table below.

RX-0006C, Q/A 296-297.

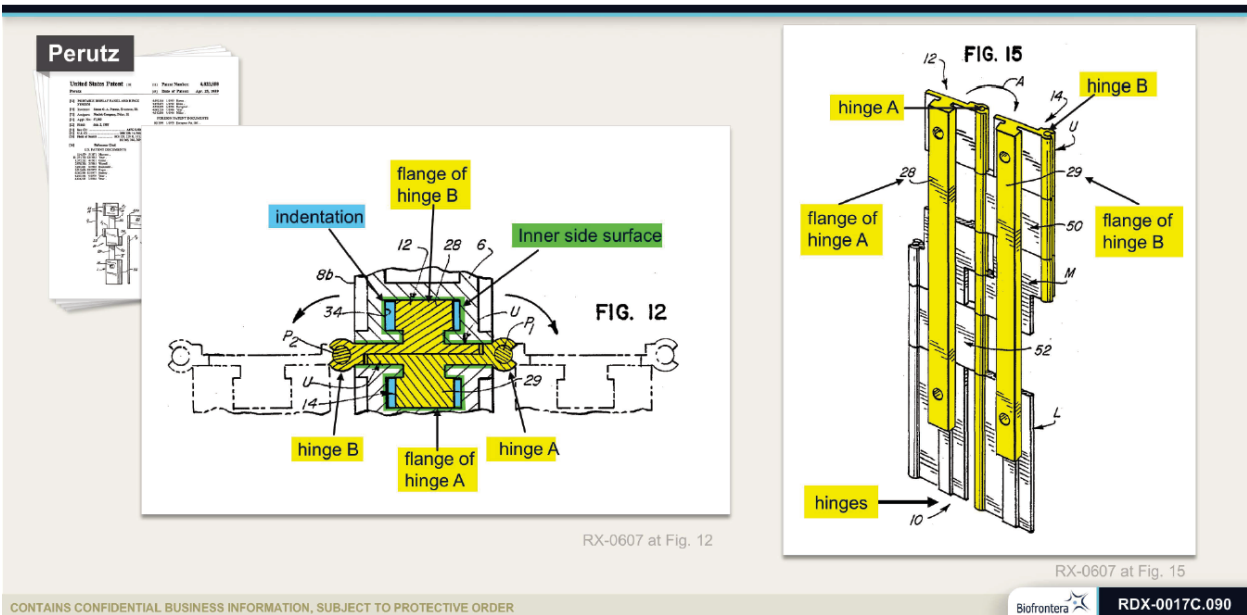
<u>Claim Language – Recess Location Limitation</u>	<u>Claims</u>
“the recess is positioned at an inner side surface of the at least one panel”	Claim 18 of the '512 Patent

In light of the claim construction of “recess,” the claim term of claim 18 recites “the indentation, small hollow, or cleft is positioned at an inner side surface of the at least one panel.” Order No. 18, 47.

For the same reasons discussed with respect to the recess limitation Hente renders obvious the placement of the indentations at the inner side surfaces of the adjacent section, meeting the claimed requirement that “the recess is positioned at an inner side surface of the at least one panel.”

Additionally, Perutz teaches connecting adjoining display panels 30, 32 (having a frame 6) with hinges 10. RX-0607, Fig. 10, 3:54-4:14. Perutz states that the segments of the hinge 10 “are maintained in vertically spaced alignment by an elongated rib or strut 28, 29,” with the ribs 28, 29 being received within slots 34 “formed in the corners of the frame 6 of the adjacent display panels.” RX-0607, 4:16-20 and 33-38. As shown in RDX-0017C.090, Figures 12 and 15 of Perutz show the side surface of adjoining display panels includes an indentation in a surface (*e.g.*, slot 34 in frame 6) to receive the side-mounted hinges, specifically a flange (*e.g.*, ribs 28, 29) of the hinges 10, to reduce space between adjoining display panels. RX-0006C, Q/A 302.

Recess Location Limitation – Perutz



RDX-0017C.090.

A POSA would be well aware of the potential benefits related to maintaining close proximity between panels, whether the panels are light panels of an illuminator or adjacent panels of a display panel assembly, to minimize the distance between, and improve the alignment of, the panels. RX-0006C, Q/A 302.

Accordingly, Hente and Perutz each disclose and/or render obvious the recess limitation.

RX-0006C, Q/A 303.

Limitation	Lundahl	Larsen	Hente	Perutz
Preamble	✓	✓		
Hinges		✓	✓	
Light Sources		✓		
Uniform Illumination	✓	✓		
Center Panel		✓		
Within Approximately Four Inches	✓			
First and Second Edges		✓		
Higher Intensity Proximate Second Edges	✓	✓		
Administering ALA	✓			
Positioning Proximate	✓			
Variable Irradiance		✓		
Red Light	✓	✓		
Dose Range	✓			
Wavelength	✓			
Recess			✓	✓
Recess Location			✓	✓

RDX-0017C.091 (excerpt).

Accordingly, the prior art teaches each and every limitation of the Asserted Claims of the '028 and '512 Patents. Specifically, as illustrated below, all of the limitations of claims 1, 2, 4, 16-17, and 19-21 of the '028 Patent are taught by the prior art. RX-0006C, Q/A 304.

Limitations	Asserted Claims of the '028 Patent							
	1	2	4	16	17	19	20	21
Preamble	✓	✓	✓	✓	✓	✓	✓	✓
Hinges Limitation	✓	✓	✓	✓	✓	✓	✓	✓
Light Sources on Five Panels	✓	✓	✓	✓	✓	✓	✓	✓
Uniform Illumination	✓	✓	✓	✓	✓	✓	✓	✓
Center Panel	✓	✓	✓	n/a	✓	n/a	✓	✓
Within Approximately Four Inches	✓	✓	✓	n/a	n/a	n/a	✓	✓
First and Second Edges	✓	✓	✓	✓	✓	✓	✓	✓
Higher Intensity Proximate Second Edges	✓	✓	✓	✓	✓	✓	✓	✓
Administering ALA	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
Positioning Proximate to Patient	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
Variable Irradiance	n/a	n/a	n/a	n/a	n/a	n/a	✓	n/a

RDX-0017C.092 (excerpt).

Limitations	Asserted Claims of the '028 Patent							
	1	2	4	16	17	19	20	21
Individually Configurable	n/a	n/a	n/a	✓	✓	✓	n/a	✓
Mobile Base	n/a	n/a	n/a	✓	✓	✓	n/a	n/a
Pillar	n/a	n/a	n/a	✓	✓	✓	n/a	n/a
Controller	n/a	n/a	n/a	✓	✓	✓	n/a	n/a
Arm	n/a	n/a	n/a	✓	✓	✓	n/a	n/a
Illuminator Connected	n/a	n/a	n/a	✓	✓	✓	n/a	n/a
Light Sources Output Light Uniformly	n/a	n/a	n/a	✓	✓	✓	n/a	n/a
Fans	n/a	n/a	n/a	✓	✓	✓	n/a	n/a
Red Light	n/a	n/a	n/a	n/a	n/a	✓	n/a	n/a
Dose Range	n/a	✓	n/a	n/a	n/a	n/a	n/a	n/a
Wavelength	n/a	n/a	✓	n/a	n/a	n/a	n/a	n/a

RDX-0017C.093 (excerpt).

Additionally, as illustrated below, all of the limitations of claims 1, 3, 5, 8, 17, 18, and 20 of the '512 Patent are also taught by the prior art. RX-0006C, Q/A 304.

Limitations	Asserted Claims of the '512 Patent						
	1	3	5	8	17	18	20
Preamble	✓	✓	✓	✓	✓	✓	✓
Hinges Limitation	✓	✓	✓	✓	✓	✓	✓
Light Sources on Five Panels	✓	✓	✓	✓	✓	✓	✓
Uniform Illumination	✓	✓	✓	✓	✓	✓	✓
Center Panel	✓	✓	✓	n/a	n/a	n/a	✓
First and Second Edges	✓	✓	✓	✓	✓	✓	✓
Higher Intensity Proximate Second Edges	✓	✓	✓	✓	✓	✓	✓

RDX-0017C.094 (excerpt).

Limitations	Asserted Claims of the '512 Patent						
	1	3	5	8	17	18	20
Administering ALA	n/a	n/a	n/a	✓	✓	✓	n/a
Positioning Proximate to Patient	n/a	n/a	n/a	✓	✓	✓	n/a
Dose Range	n/a	✓	n/a	n/a	n/a	n/a	n/a
Wavelength	n/a	n/a	✓	n/a	n/a	n/a	n/a
Recess	n/a	n/a	n/a	n/a	✓	✓	n/a
Recess Location	n/a	n/a	n/a	n/a	n/a	✓	n/a

RDX-0017C.095 (excerpt).

5. Motivation to Combine and Reasonable Expectation of Success

There are many sources of motivation to combine or modify prior art references or devices. Sometimes, these motivations can be found within the prior art itself, explicitly or implicitly. However, such motivation may also be found in market forces, in design incentives, in

“interrelated teachings of multiple patents,” and/or in the background knowledge, creativity, and common sense of the person of ordinary skill. *Adapt Pharma Operations Ltd. v. Teva Pharms. USA, Inc.*, 25 F.4th 1354, 1365 (Fed. Cir. 2022). In some cases, the market provides a strong incentive to update prior art devices to fall in line with new standards brought on by technological developments. *KSR Int’l Co. v. Teleflex, Inc.*, 550 U. S. at 419. Further, in making these updates, “[t]he test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference, but rather whether a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention.” *Allied Erecting & Dismantling Co. v. Genesis Attachments, LLC*, 825 F.3d 1373, 1381 (Fed. Cir. 2016). Additionally, “a finding of obviousness does not require a guarantee of success,” but merely a reasonable expectation. *Pfizer Inc. v. Sanofi Pasteur Inc.*, 94 F.4th 1341, 1352 (Fed. Cir. 2024).

i. A Motivation Existed to Combine the Teachings of Lundahl and Larsen, and a Reasonable Expectation of Success Existed

Lundahl teaches a PDT device shaped to curve around a patient’s head, that uses fluorescent tubes that are spaced more closely near the edges of the device that correlate with the positioning of the patient’s forehead and chin (*i.e.*, the top and bottom of the treatment surface) in order to emit higher intensities in those areas, and provide uniform illumination across the entire treatment surface. RX-0006C, Q/A 307. While this is a useful concept, and while Lundahl provided an effective light device for certain aspects of PDT treatment, known problems and shortcomings associated with the Lundahl device would have motivated a POSA to combine the teachings of Lundahl with Larsen, which would have led a POSA to modify Lundahl’s device to incorporate the hinged LED panels of

Larsen. RX-0006C, Q/A 307. Under ALJ Moore's adopted definition of a POSA²⁴, the combined opinions and experiences of Biofrontera's experts, Dr. Ehrenreich (who is a medical doctor) and Dr. Grove (who has a Ph.D. in Instrumentation in the field of laser applications), is an appropriate POSA combination from which the motivation to combine and modify the prior art can be judged.

Dr. Ehrenreich sees patients diagnosed with AK nearly every day, and routinely treats these patients with PDT, including treatment using the combination of Levulan[®] and Sun Pharmaceuticals' BLU-U[®] lamp device. RX-0007C, Q/A 106; RX-0006C, Q/A 308. The BLU-U[®] 4170D lamp device used by Dr. Ehrenreich often in his practice, including the years preceding 2015, resembles the lamp device described in Lundahl. RX-0007C, Q/A 106, 115-118, 127-128; RX-0006C, Q/A 308. Comparing the known pictures and disclosure of the BLU-U[®] 4170D with the disclosure provided in Lundahl, the Lundahl patent appears to disclose the BLU-U[®] 4170D, particularly given the fact that Lundahl is assigned on its face to DUSA Pharmaceuticals, Inc., the manufacturer of BLU-U[®] 4170D. RX-0006C, Q/A 308. Consequently, Dr. Ehrenreich's comments regarding his experience with BLU-U[®] 4170D are equally applicable to the device described in Lundahl, as the two appear to be the same. RX-0006C, Q/A 308. This was confirmed by Mr. Lundahl in his deposition that "the '071 patent was a design that eventually became the BLU-U[®] fluorescent product that was on the market." See JX-0017C (Lundahl Dep. Designation), 37:6-9; RX-0006C, Q/A 309.

There were known issues and flaws with the BLU-U[®] 4170D/Lundahl design. RX-0007C, Q/A 181; RX-0006C, Q/A 310. Lundahl discloses a fixed U-shape, which was developed based on "the average dimensions of the human head," and, because of this, the Lundahl design may not be

²⁴ A POSA would have a M.D. and/or a Ph.D. in an electrical engineering, optoelectronics, physics, optical sciences, optical engineering, or related scientific or engineering field, and at least one to two years of work or research experience in optical engineering, optics, optoelectronics, phototherapy, photodynamic therapy, or a related field. Order No. 18, at 13.

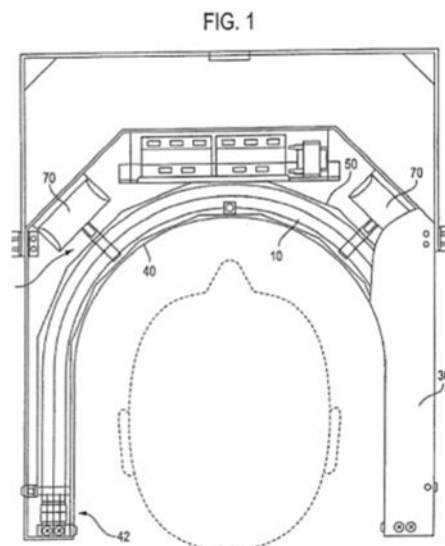
ideal given the variety of sizes and shapes of patients' heads. RX-0007C, Q/A 159-161; RX-0006C, Q/A 310, 314. In addition, the fixed U-shape design of Lundahl does not provide the flexibility needed to treat other parts of the patients' bodies that would typically have AK lesions, including the arms, back, chest, and hands, particularly in view of the need to maintain a distance of 2-4" from the treatment surface (skin) to the lighting surface. RX-0007C, Q/A 159-161; RX-0006C, Q/A 314.

There were also known problems with the fluorescent tubes utilized in the Lundahl design, including that the uniformity of light from fluorescent tubes varies across the length of the tube, and the uniformity of lighting can also be affected by heat and the ability to cool the Lundahl device. RX-0007C, Q/A 164-166; RX-0006C, Q/A 310.

Consequently, Dr. Ehrenreich experienced the identified problems associated with the Lundahl device design first-hand in his use of the BLU-U[®] 4170D device, including: (1) the inflexibility of the fixed U-shape of Lundahl not only created issues ensuring the proper 2-4" treatment distance for the wide variety of patient head sizes and shapes, but also would not allow for proper treatment of other parts of the anatomy requiring AK treatment, including the arms, back, chest, and hands; and, (2) the fluorescent tubes utilized in Lundahl had inherent shortcomings due to the lack of uniform light output across the length of the tube and sensitivity to temperature. RX-0007C, Q/A 159-166; RX-0006C, Q/A 310. These issues (and others) represent known problems for which a POSA would have been motivated to find solutions. RX-0006C, Q/A 310-315.

- a. A Motivation Existed to Incorporate the Hinged Panel System of Larsen into the Illuminator of Lundahl to Increase the Flexibility of the Lundahl Device for Use with All Head Sizes and Shapes, As Well as Varying Anatomies and A POSA Would Have Had A Reasonable Expectation of Success in Doing So

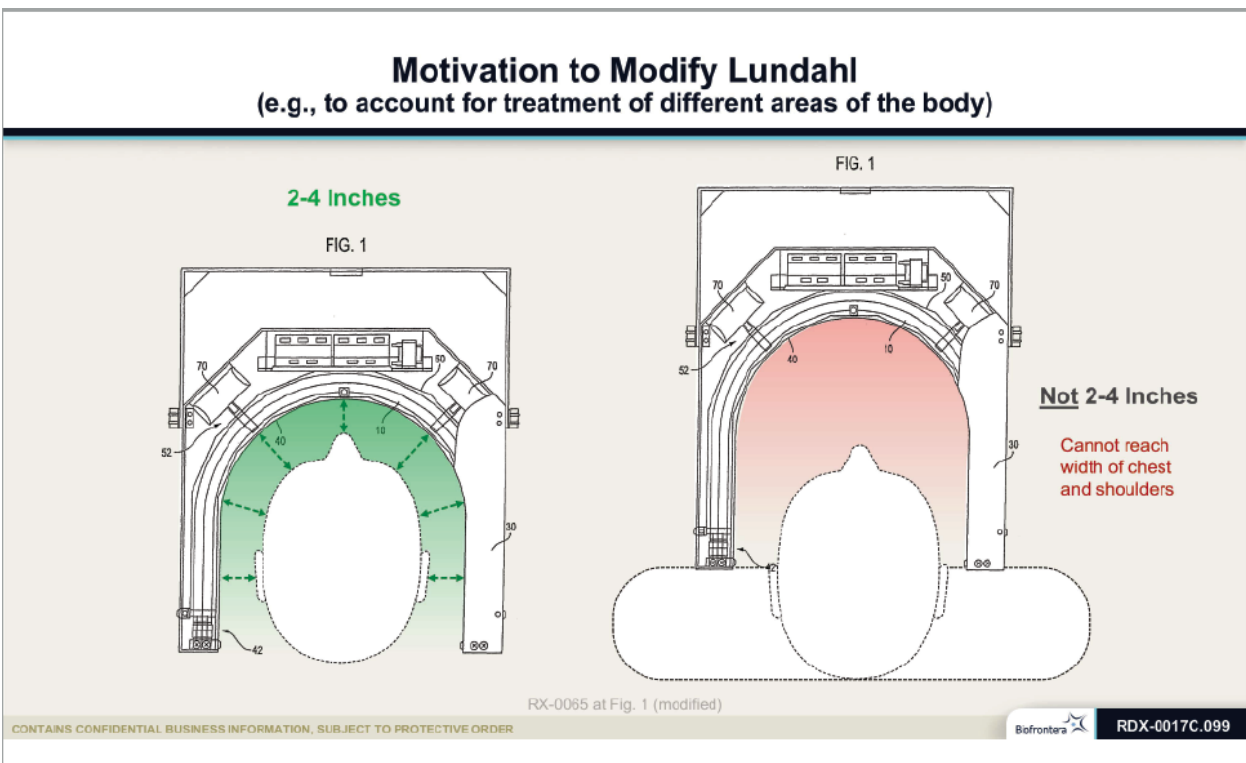
The PDT device and design of Lundahl appears to be the same design utilized for BLU-U[®] 4170D, a device publicly known and used in the treatment of AK lesions from 1999-2015. RX-0006C, Q/A 308. Mr. Lundahl confirmed in his deposition that “the ’071 patent was a design that eventually became the BLU-U[®] fluorescent product that was on the market.” JX-0017C, 37:6-9; RX-0006C, Q/A 309. Lundahl teaches that “[t]he U-shape minimizes the variations in distance between the emitter and the target, providing a uniform visible light distribution to the face or scalp of the patient; **the tube dimensions were chosen based on the average dimensions of the adult human head.**” RX-0065, 6:31-35 (emphasis added); RX-0006C, Q/A 311. Further, Lundahl teaches that “[t]he U-shape minimizes the variations in distance between the emitter and the target, providing a uniform visible light distribution to the face or scalp of the patient; the tube dimensions were chosen based on the average dimensions of the adult human head.” RX-0065, 6:31-35; RX-0006C, Q/A 311. “Moreover, 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.” RX-0065, 6:31-42; RX-0006C, Q/A 311. Lundahl illustrates the “U” shape design in Figure 1:



RX-0065, Fig. 1; RX-0006C Q/A 312.

However, distance between the light sources and the treatment surface — i.e., the skin — is important. RX-0006C, Q/A 313. As can be seen from Figure 1, the various points of the treatment surface (i.e., the various points on the patient's skin) will have varying distances from the light surface (e.g., the nose will be closer to the light surface than the point where the nose meets the cheek). Lundahl specifies that the light device should be placed within 2-4" from all points on the treatment surface (RX-0065, 15:22-27, which is consistent with the FDA approved indication for the treatment of AK using Levulan[®] and BLU-U[®], which requires that the light surface be 2-4" from all points on the treatment surface (i.e., all points on the patient's nose, cheeks, chin, ears, etc.). RX-0006C, Q/A 313, 316. While it is possible that a patient having head dimensions similar to "the average dimensions of the adult human head" would allow for positioning within the Lundahl device similar to Figure 1, a POSA would also envision many scenarios where the shape and dimensions of the patient would not allow for the required 2-4" distance required by the FDA approved indication. RX-0006C, Q/A 313.

A POSA considering Lundahl would have been motivated to increase the flexibility of the device to ensure the light surface could be maintained at a distance of 2-4" from the entire treatment surface of the patient (i.e., face, nose, forehead, ears, sides of head, etc.), particularly given the wide variety of head shapes and sizes. RX-0006C, Q/A 313. Additionally, a POSA would have understood that there are other bodily anatomies that may require treatment for AK lesions, including the arms, back, and other body parts. RX-0006C, Q/A 314. The surface and/or diameter of these body parts may be either too big or too small to fit within Lundahl's fixed U-shape, and it would have been difficult, if not impossible, to maintain a treatment distance of 2-4 inches for these other parts of the body, as illustrated in RDX-0017C.099. RX-0006C, Q/A 314.



RDX-0017C.099.

In fact, Lundahl expressly contemplates the treatment of other parts of the body, stating that “[t]he present invention is directed to photodynamic therapy using an illuminator that provides a uniform distribution of visible light. In particular, the present invention is directed to an apparatus and method for photodynamic treatment (PDT) or diagnosis (PD) of actinic keratosis of the scalp or facial areas of a patient. The present invention is also directed to an apparatus and method for PDT and PD of other indications (*e.g.*, acne) and other areas of the patient (*e.g.*, arms, legs, etc.).” RX-0065, 1:9-17; RX-0006C, Q/A 314. But nowhere in Lundahl is it explained how a fixed U-shape design can be used to accommodate treatment of different anatomies, across different patients, particularly where different patients will have varying anatomical sizes and shapes, all while maintaining the desired 2-4” treatment distance across the variety of anatomies to be treated.

Consequently, a POSA would have been motivated to improve the design of the system of Lundahl to allow for adjustment of the device and light surface to ensure a 2-4” distance from the

face and from other varying anatomies. RX-0006C, Q/A 314. Based on the teachings and disclosure of Larsen, a POSA would have understood that the easiest way to modify the fixed, curved U-shape of Lundahl would be to incorporate hinged panels that could be individually adjusted to account for variations in head shape/size or other anatomies selected for treatment. RX-0006C, Q/A 315.

Larsen teaches that “[f]or the treatment of large-area tissues according to Figure 1, **several applicators 13 are flexibly connected to each other through hinges 10, respectively connecting one edge with the other**, whereby the applicators are **suitable for the treatment of for example, the backs of humans and so become adjustable for an equidistant positioning of the applicators 13 above the skin.**” RX-0099, [0072] (emphasis added); RX-0006C, Q/A 315. These teachings would have motivated a POSA to incorporate Larsen’s solution of connecting panels containing light applicators by hinges, to allow for adjustability of Lundahl’s device to provide the desired irradiance and irradiance uniformity to all target areas during PDT. RX-0006C, Q/A 315.

In addition, a POSA would have had a reasonable expectation of success in combining Lundahl with Larsen, because both references describe similar illuminators for the treatment of conditions on a patient’s skin. RX-0006C, Q/A 320. Specifically, Lundahl expressly states that the invention is directed to “an illuminator for PDT or PD of a contoured surface. The illuminator comprises a plurality of light sources generally conforming to the contoured surface and irradiating the contoured surface with substantially uniform intensity visible light, and a housing supporting the plurality of light sources with respect to the contoured surface.” RX-0065, 2:61-67; RX-0006C, Q/A 320. Similarly, Larsen is directed to devices for PDT therapy that incorporate five flexibly connected hinged panels that may be angled relative to one another so that panels can be positioned equidistant above the skin (treatment surface). *See* RX-0099, [0037], [0072], claim 11; RX-0006C, Q/A 320. Consequently, the subject

matter of Lundahl and Larsen is very similar, as both are directed to illumination devices that can provide PDT to different parts of the patient's anatomy. RX-0006C, Q/A 320; *Teva Pharms. USA, Inc. v. Sandoz Inc.*, 906 F.3d 1013, 1025-26 (Fed. Cir. 2018) ("Because a thrice-weekly 40mg injection would result in a total weekly dose very close to that in the already-approved daily 20mg injection. . .the district court [correctly] found a POSITA would have had a reasonable expectation of success. . .This is not a situation where the prior art gave no direction in how to reach a successful result.") Moreover, the incorporation of Larsen's hinged panels into the Lundahl device would be considered a straightforward design change by the time the Asserted Patents were filed, meaning a POSA would reasonably expect that these design changes could be successfully incorporated into the Lundahl device. RX-0006C, Q/A 317-318, 320, 322.

(i) *Sun Pharma's Assertion of No Motivation Because Lundahl Discloses Uniform Illumination of the Face and Scalp Ignores Treatment of Other Parts of the Body is Unfounded*

Dr. Jokerst asserts a lack of motivation based on the fixed U-shape design of Lundahl, because "Lundahl at 1:14-17 already expressly teaches that the invention is 'directed to...other areas of the patient (*e.g.*, arms, legs, etc.).'" CX-0014C, Q/A 466; RX-0006C, Q/A 316. However, the FDA approved indication for the treatment of AK using Levulan[®] and BLU-U[®] requires that the light surface be 2-4" from *all* points on the treatment surface (*i.e.*, all points on the patient's nose, cheeks, chin, ears, etc.). RX-0006C, Q/A 316. While this might be possible for treatment of the face and scalp using Lundahl's fixed U-shape (though this is likely not always the case given the variability in shape and dimensions of patients' heads), it is simply not possible to ensure the 2-4" treatment distance for other parts of the body, including the arms, legs, chest, back, etc., without modifying the Lundahl U-shaped design to allow for adjustability of the illuminator. RX-0006C, Q/A 316.

(ii) *Sun Pharma's Assertion of No Motivation Because of Unwanted Gaps Between Panels Overlooks the Design Characteristics of Larsen*

Sun Pharma also asserts that a POSA would have been discouraged from modifying Lundahl's U-shape, because doing so would introduce unwanted gaps. CX-0014C, Q/A 469; RX-0006C, Q/A 317. However, Sun's position overlooks the fundamental design aspects of Larsen. RX-0006C, Q/A 317. Larsen is directed to a hinged-panel illuminator, meaning that the illuminator may be positioned in a "flat" orientation, or may also be positioned in an orientation where the adjacent panels are angled toward one another, creating a curved orientation (approximating a U-shape depending on the desired shape of the treatment surface). RX-0006C, Q/A 317. Larsen expressly states the illuminator "comprises several single applicators hinged together so as to be adjustable *at angles with respect to one another.*" RX-0099, cl. 11 (emphasis added); RX-0006C, Q/A 317. By positioning the panels of the Larsen illuminator at angles with respect to one another (e.g., in a bent/curved orientation), any gaps between panels will also be minimized or eliminated. RX-0006C, Q/A 317. Consequently, Larsen is not just a "flat emitting surface," and Sun's assertions that a POSA would not have combined Lundahl and Larsen based on Lundahl's alleged criticism of flat emitting surfaces is not accurate and does not impact the motivation that exists to combine the references. RX-0006C, Q/A 317.

(iii) *The Necessity for Additional Cables Would Not Change the Motivation to Combine*

Sun Pharma has further argued that a POSA would have been discouraged from modifying Lundahl's U-shape configuration to incorporate Larsen's five panels because of the possibility that the cables leading from panel to panel could result in burdensome assembly of the device. RX-0016C (Jokerst Reb. R.), ¶. But this is a very minor design consideration, as a POSA would look for ways to minimize difficulties associated with assembly. RX-0006C, Q/A 322. It would be well within the

capability of a POSA to design appropriate cable connections and management solutions that minimize difficulties associated with assembly. RX-0006C, Q/A 322. Additionally, even if any cables between panels result in more difficult assembly, that would be an acceptable design choice in developing an illuminator that provides the desired uniform illumination and functionality. RX-0006C, Q/A 323. Consequently, this does not change that a motivation existed to combine Lundahl and Larsen, and a POSA would have a reasonable expectation of success in implementing this combination. RX-0006C, Q/A 323.

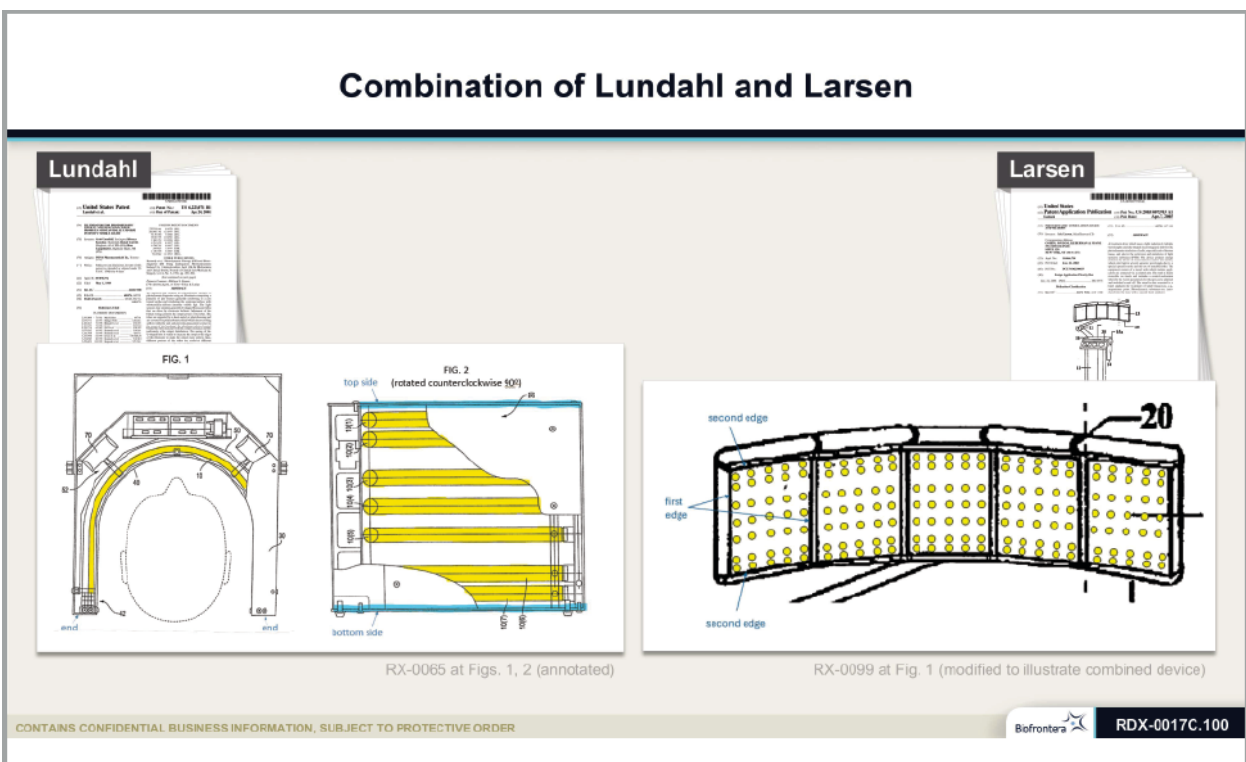
(iv) *A POSA Would Reasonably Expect the Resulting Device to Provide the Required Uniform Illumination*

Dr. Jokerst asserts that Biofrontera “never address[es] the uniformity of the light from th[e] combined modified device” but “only addresses the references individually.” CX-0014C, Q/A 286.

However, as noted previously (*see supra* V.A.4.d), the resulting combination of Lundahl and Larsen (incorporating the same light spacing orientation taught by Lundahl) would be expected to provide uniform illumination of the face/scalp in the same manner that Lundahl’s device provided uniform illumination of the face and scalp. RX-0065, Q/A 321.

According to the agreed upon claim construction for “uniformly illuminate a treatment surface”/ “uniformly illuminating a treatment surface” adopted by ALJ Moore, the standard for “uniform illumination” is “irradiating light over the active emitting area such that the measured irradiance at a treatment surface of the patient is at least within 60% of the measured maximum.” Order No. 18, 13. Consequently, to meet the requirement for a reasonable expectation of success, a POSA must have reasonably expected that modifying Lundahl’s device with Larsen’s five panels and LEDs would provide the required irradiance of at least 60% of the measured maximum over the entire treatment surface. RX-0006C, Q/A 321. Combining the design principles of Larsen related to hinged panels and LED lights with the PDT device and light distribution of Lundahl, a

POSA would expect the resulting device to have a design similar to what was provided in RDX-0017C.100. RX-0006C, Q/A 321. *OSI Pharm., LLC v. Apotex Inc.*, 939 F.3d 1375, 1385 (Fed. Cir. 2019) ("To be clear, we do not hold today that efficacy data is always required for a reasonable expectation of success. Nor are we requiring 'absolute predictability of success.'"). As shown in RDX-0017C.100, this light distribution is the same as what is illustrated in Figs. 1 and 2 of Lundahl. RX-0006C, Q/A 321.



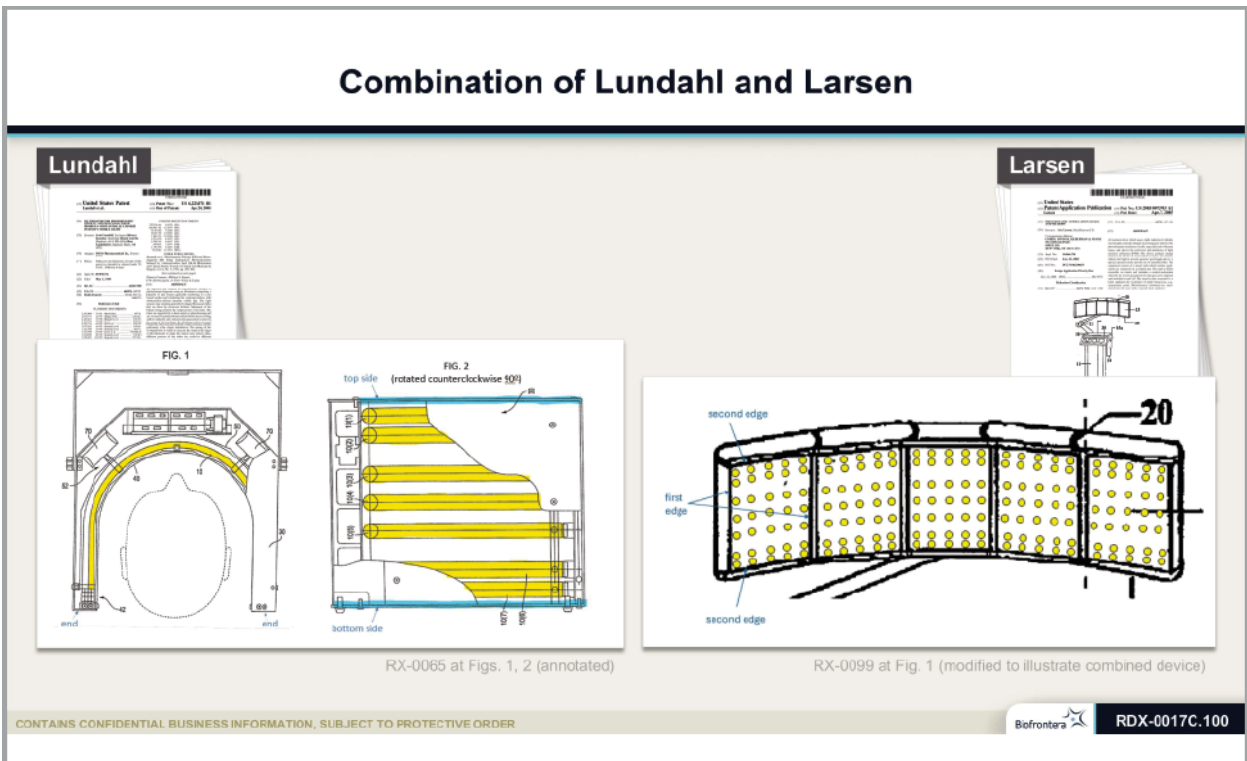
RDX-0017C.100.

Lundahl explains that "[t]o avoid uniformity problems, one embodiment, of the present invention utilizes a plurality of U-shaped tubes 10(1)-10(7)...[An] advantage of the arrangement is that uniformity can also be adjusted by varying the lateral spacing of the tubes (relative vertical spacing as shown in the rotated FIG. 2). This is important since it is necessary to compensate for the fact that the output from a flat plane emitting light source drops near the edges. Varying the lateral spacing of the tubes creates the same effect as folding the edges of a larger illuminator in on itself, thus emulating

an infinite plane emitter with a compact unit." RX-0065, 6:16-30; RX-0006C, Q/A 321. Lundahl states that the spacing of lights and greater density of lighting near the top and bottom of the panel provide for uniform illumination, stating "[t]he number of tubes used and the spacing between them were chosen to achieve desired uniformity and power output specifications... The present invention provides a highly uniform output irradiance without the use of an additional diffusing element." RX-0065, 6:43-57 (emphasis added); RX-0006C, Q/A 328. Thus, a POSA understood from Lundahl that the light arrangement of Fig. 2 was chosen to achieve the "desired uniformity and power output specifications." RX-0006C, Q/A 321.

Additionally, Lundahl explains that "[i]t has been found that, according to a preferred embodiment of the present invention, the measured output over the active emitting area is within 70% of the measured maximum when measured with a cosine response detector at distances of 4" and 2", and within 60% of the measured maximum over all operation distances." RX-0065, 15:22-26; RX-0006C, Q/A 321. Therefore, the lighting arrangement and pattern illustrated in Fig. 2 of Lundahl would be considered the preferred embodiment (as, by Lundahl's own acknowledgement, it gave the "desired uniformity and power output specifications"), indicating that the light pattern and arrangement of Fig. 2 would provide a measured output over the active emitting area of within 70% of the measured maximum when measured with a cosine response detector at distances of 4" and 2", and within 60% of the measured maximum over all operation distances. RX-0006C, Q/A 321.

In view of this understanding established by Lundahl, the device resulting from combining the teachings of Lundahl and Larsen, which is illustrated in RDX-0017C.100 and shown above, has effectively the same light arrangement and pattern as Fig. 2 of Lundahl. RX-0006C, Q/A 321.



RDX-0017C.100.

Because of this, a POSA would at least reasonably expect that this resulting device would provide an irradiance of at least 60% of the measured maximum over the entire treatment surface, as required by the Asserted Claims. RX-0006C, Q/A 321. In fact, the motivation to combine Lundahl and Larsen is at least partly based on the desire to even further **increase** light output consistency by changing the light source from fluorescent tubes to LEDs. RX-0006C, Q/A 218. This was one of the very problems with the design of Lundahl that a POSA would have sought to fix, and incorporating the LEDs of Larsen would have corrected this issue. Fluorescent tubes are known to have inconsistent light output within the tube itself, as acknowledged in Lundahl (the tubes have “non-emitting area at their ends” (RX-0065, 6:31-42) and that “tube output may vary over its length” (RX-0065, 6:31-42, 4:41-42)). RX-0006C, Q/A 218. LEDs did not suffer from this inconsistent lighting (e.g., “non-emitting areas at their ends”), meaning that incorporating the five

panel LED design of Larsen into the Lundahl device (as illustrated in the previous demonstrative) would have eliminated this concern.²⁵ RX-0006C, Q/A 218.

Further, the subject matter of Lundahl and Larsen is very similar, as both are directed to illumination devices for providing PDT to different parts of a patient's body. RX-0006C, Q/A 318. As noted, the incorporation of Larsen's hinged panels into the Lundahl device, and the replacement of Lundahl's fluorescent tubes with Larsen's LEDs would both be considered straightforward design changes by the time the Asserted Patents were filed. RX-0006C, Q/A 318. Consequently, Lundahl and Larsen do not have "very different designs and modes of operation," and these assertions by Sun do not impact the motivation that existed to combine the teachings of Lundahl and Larsen, as well as the reasonable expectation that the design elements of Lundahl and Larsen could be successfully combined. RX-0006C, Q/A 318.

(v) *The Use of Nine Reflectors in Lundahl Would Not Alter the Motivation to Combine Lundahl and Larsen*

Finally, Sun Pharma asserts that a POSA would have been discouraged from incorporating the five-panel design of Larsen into the device of Lundahl, because Lundahl describes the use of a reflector with nine segments (not five), with the nine segments conforming to the U-shaped configuration of the tubes. CX-0014C, Q/A 307 RX-0006C, Q/A 319. Larsen teaches the inclusion

²⁵ Sun Pharma argues that the combination of Lundahl and Larsen fails to render obvious the proximate light limitation because the Lundahl fluorescent tubes would be expected to have areas of reduced emission near the cathodes of the U-shaped tubes. RX-0006C, Q/A 218. However, this is based on illustrations provided by Dr. Jokerst that mischaracterize the teachings of Lundahl, as a POSA would not expect that the area of reduced emission would be as large as what is illustrated in Dr. Jokerst's rebuttal report. RX-0006C, Q/A 218-219. At most, the area of reduced emission would be a small area next to the cathode. RX-0006C Q/A 218. The illustration provided by Dr. Jokerst shows an area of reduced emission that is next to and even in front of the ears. CX-0014C, Q/A 256; RX-0006C, Q/A 219. However, this is not what Lundahl discloses, as Lundahl states that the reduced emission is behind the ears. RX-0006C, Q/A 219. Consequently, Dr. Jokerst's positions on the areas of reduced emission mischaracterize the teachings of Lundahl. RX-0006C, Q/A 219.

of LEDs, which, by the time of filing of the Asserted Patents (*i.e.*, October 2015), were widely replacing the use of fluorescent tubes in illumination devices. RX-0006C, Q/A 319.

Consequently, because it was obvious (based on the teachings of Larsen) to replace the fluorescent tubes of Lundahl (which was filed in May 1998 when the use of fluorescent tubes was still a prominent design choice) with LEDs, a POSA would not seek to replicate the design of the reflector of Lundahl with nine sections conforming to the shape of the U-shaped fluorescent tubes. RX-0006C, Q/A 319. In other words, once the fluorescent tubes of Lundahl are replaced with LED panels (as taught by Larsen), to the extent that a POSA sought to include reflectors in the resulting device, at most, he or she would simply include five reflectors, matching the number of panels disclosed by Larsen (if reflectors were even deemed to be necessary). RX-0006C, Q/A 319. In fact, Larsen even states that “[t]he applicators contain printed circuit boards mounted with semiconductor diodes and/or laser diodes (in large numbers), and the diodes are mounted with reflectors, which collect the radiation and bundle them in front of the applicator.” RX-0099, [0028]; RX-0006C, Q/A 319. Thus, these assertions by Sun do not impact the motivation that existed to combine the teachings of Lundahl and Larsen. RX-0006C, Q/A 319.

- b. A Motivation Existed to Replace Lundahl’s Fluorescent Tubes with Larsen’s LEDs to Improve Light Output Consistency and Address the Shortcomings of Fluorescent Tubes and A POSA Would Have Had A Reasonable Expectation of Success in Doing So

Lundahl discloses horizontally oriented fluorescent tube lights. RX-0006C, Q/A 92 POSA would have been motivated to use solid-state light-emitting diodes (LEDs) as the illumination source for at least four reasons. RX-0006C, Q/A 325. First, LEDs have a lower cost and a longer lifetime than fluorescent tubes. RX-0006C, Q/A 325. Second, fluorescent tubes are known to have inconsistent light output within the tube itself, as acknowledged in Lundahl (the tubes have “non-emitting area at their ends” (6:31-42) and that “tube output may vary over its length” (4:41-42)).

RX-0006C, Q/A 324-325. This was acknowledged by Dr. Jokerst, who recognized this problem and stated during her deposition that "[the fluorescent tubes] have a dark [] area." RX-1379C (Jokerst Tr.), 141:5-10; RX-0006C, Q/A 324. Third, by moving to adjustable panels connected by hinges to increase flexibility, the use of LEDs would be more practical to reduce spacing between light sources and the edges of the panels, as opposed to the bulky metal couplings at the end of fluorescent tubes, thereby reducing optical dead space across the light surface. RX-0006C, Q/A 325. Fourth, the relatively narrow output spectrum of LEDs allows for an illuminator with an output wavelength ideally matched to an absorption band of the photosensitizer. RX-0006C, Q/A 325.

Mark Carota, one of the named inventors of the Asserted Patents, testified that regulatory pressures contributed to a trend in the industry away from fluorescent tubes and that this was a driving factor for Sun Pharma's decision to modify their device to a new version using LEDs. RX-0006C, Q/A 326. Specifically, Carota testified that "the Efficiency Act that was put in place by the federal government around ballasts that drive fluorescent tubes rendered the ballasts that we used in the BLU-U[®] to be essentially illegal. So, it obsoleted them, and that's what drove" Sun Pharma's decision to design a new device. JX-0015C (Carota Dep. Tr.), 36:11-16; RX-0006C, Q/A 326. Similarly, both remaining named inventors, Brian Mazejka and Thomas Boyajian, in addition to Sun Pharma's Vice President of IP, Scott Lundahl, similarly testified that the governmental ban on fluorescent technology was a driving factor in switching from fluorescent and incandescent technology to LEDs. JX-0006C (Mazejka Dep. Tr.), 53:13-16; JX-0014C (Boyajian Dep. Tr.), 33:16-34:10; JX-0017C (Lundahl Dep. Tr.), 46:19-47:9; RX-0006C, Q/A 326.

Larsen teaches that light sources are disposed on the surfaces of five applicators, the light sources being "semiconductor diodes (LED) and/or laser diodes." RX-0099, [0070]; RX-0006C,

Q/A 327. The state of illumination technology as described in the previous paragraph along with this teaching of Larsen would have motivated a POSA to incorporate Larsen's solution of disposing light sources, specifically LEDs, on the surface of the light applicators to Lundahl's device. RX-0006C Q/A 327.

A POSA would have had a reasonable expectation of success in combining Lundahl with Larsen, because, again, both references describe similar illuminators and the conversion from fluorescent tubes to LEDs was a routine practice prior to 2015. RX-0006C, Q/A 329. Specifically, while the electrical needs and design of Lundahl's system for operating fluorescent tubes would need to be changed to accommodate the electrical needs and design of Larsen's LED panels, this would have been considered a straight-forward and routine design process for a POSA by the time of filing of the Asserted Patents. RX-0006C, Q/A 329.

(vi) *Maintaining the Spacing of Lundahl Would Not Alter the Motivation to Combine Lundal and Larsen*

Sun Pharma has asserted that there was not a motivation to modify Lundahl's device to incorporate LEDs as taught by Larsen, because "Biofrontera cherry-picks Larsen's LEDs (together with the five panels) and purports to arrange them according to 'the uneven spacing' of Lundahl's fluorescent tubes." CX-0014C, Q/A 496he number of tubes used and the spacing between them were chosen to achieve desired uniformity and power output specifications...The present invention provides a highly uniform output irradiance without the use of an additional diffusing element." (RX-0065, 6:43-57) Based on Lundahl's disclosure that the spacing of lights achieved the desired uniformity and highly uniform output irradiance, the decision to arrange the LEDs taught by Larsen in a similar uneven spacing disclosed by Lundahl would have been based on the desire to maintain the desired uniformity and highly uniform output. RX-0006C, Q/A 328. Based on Lundahl's disclosure that uniformity was achieved for the face and scalp (see RX-0065, 6:39-42, "Moreover,

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”), a motivation existed to modify Lundahl’s device to incorporate LEDs as taught by Larsen (as LEDs were a superior technology by 2015 as noted previously), while maintaining the spacing taught by Lundahl. RX-0006C, Q/A 328.

- c. A Motivation Existed to Utilize Red Light Emission as a Preferred Wavelength and to Increase Light Absorption at Deeper Skin Depths and A POSA Would Have Had a Reasonable Expectation of Success in Doing So

Moreover, a POSA was motivated to utilize red light wavelengths in the PDT device rendered obvious by Lundahl and Larsen. RX-0006C, Q/A 307. Based on the expectation of enhanced light penetration and absorption by the photosensitizer, both Lundahl and Larsen would have provided that motivation to a POSA. RX-0006C, Q/A 330. In its discussion of the background on PDT treatment, Lundahl states “[g]eneral background information on PDT using 5-aminolevulinic acid (“ALA”) as the precursor of a photoactivatable agent can be found in U.S. Pat. No. 5,079,262, entitled “Method of Detection and Treatment of Malignant and Non-Malignant Lesions Utilizing 5-Aminolevulinic Acid,” issued to James C. Kennedy et al. on Jan. 7, 1992, and U.S. Pat. No. 5,211,938, entitled “Method of Detection of Malignant and Non-Malignant Lesions by Photochemotherapy of Protoporphyrin IX Precursors,” issued to James C. Kennedy et al. on May 18, 1993. The contents of these patents are incorporated herein by reference.” RX-0065, 39-49. Thus, Lundahl expressly incorporates all teachings of U.S. Patent No. 5,079,262 to Kennedy et al. (“Kennedy”). RX-0006C, Q/A 330.

Kennedy teaches that red light was preferred for PDT, as it penetrates deeper into the skin, as compared to blue light, and PpIX (the compound produced by topical application of ALA) strongly absorbs red light. RX-0006C, Q/A 330. Kennedy states “[a] method of detecting and

treating malignant and non-malignant tissue abnormalities and lesions of the skin” in which “5-aminolevulinic acid is administered to the patient.” RX-0068, Abstract. Kennedy states that “[i]n preferred aspects of this invention the preferred precursor of protoporphyrin IX is 5-amino-4-oxo-pentanoic acid, otherwise known as 5-aminolevulinic acid, and a preferred wavelength of the photoactivating light is in the range 350-640 nm, more preferably a red light of about 610-630 nm.” RX-0068, 4:3-8. Kennedy also states that “[t]he wavelength of the photoactivating light is of some importance, as it has been shown that between 1 and 10 percent of incident red light (600-700 nm) can pass through a slab of human tissue 1 cm thick, whereas only 0.001 percent or less of blue light (about 400 nm) can pass through the same thickness of human tissue. The photosensitizer will, therefore, be more successful if it strongly absorbs red light. PpIX does strongly absorb red light.” RX-0068, 4:60-69. Based on the teachings of Kennedy, a POSA would have expected red light (preferably at wavelengths of about 610-630) to more effectively penetrate skin tissue, and for PpIX to more effectively absorb the red light, resulting in greater activation of the photosensitizer. RX-0006C, Q/A 330. These enhancements in the penetration of light and absorption by the photosensitizer would have led a POSA to reasonably expect enhanced efficacy of the PDT device. RX-0006C, Q/A 330.

Additionally, Larsen teaches that its applicators are configured to output red light: “devices are available for the photodynamic stimulation of human cell energy in the form of red and infrared radiation . . .” RX-0099, [0024]; RX-0006C, Q/A 331. Larsen also teaches using light radiation within the wavelength of 300 – 2000 nm, which includes red light. RX-0099, [0025], [0071]-[0076], and [0083]; RX-0006C, Q/A 330.

Based on the expectation of enhanced light penetration and absorption by the photosensitizer, a POSA would have been motivated to combine the teachings of Lundahl, incorporating Kennedy, and Larsen to use red light for PDT. RX-0006C, Q/A 331.

Additionally, Kennedy reports in Examples 1-4 that patients were administered PDT with a light source that was “filtered to remove both infrared (heat filter) and wavelengths below 600 nm,” meaning red light, likely with wavelengths of 600-700 nm was utilized. RX-0068, 5:47 to 6:47. Kennedy reports that PDT with this red light demonstrated clearance of treated lesions. RX-0068, 5:47 to 6:47. In view of this, a POSA had at least a reasonable expectation that red light could be utilized in the device rendered obvious by Lundahl (incorporating Kennedy) and Larsen. RX-0006C, Q/A 330-331.

d. A Motivation Existed to Combine the Teachings of Lundahl, Larsen, and Hente, and a Reasonable Expectation of Success Existed

As discussed herein, Larsen teaches an illuminator comprising five panels connected by hinges on inner side surfaces of adjacent panels. *Supra* V.A.4.b. For all the reasons noted above, Lundahl and Larsen disclose and render obvious the inclusion of hinged panels (as taught by Larsen) in the illumination device taught by Lundahl via attachment to the inner side surface of adjacent panels, as doing so would allow for flexibility in the arrangement of panels to allow for adjustment based on the variations in size/dimensions of patient heads, and also would allow for treatment of other parts of the body (*e.g.*, chest, arms, etc.). RX-0006C, Q/A 334. However, based on the teachings of Lundahl and Larsen, uniformity of illumination is still a key design motivation, as a POSA would want to minimize gaps between the adjacent panels (appreciable gaps between panels might impact the ability to produce uniform illumination). RX-0006C, Q/A 334. Hente teaches hinges that allow for movement and adjustment of adjacent panels/sections, while also minimizing the gap between the adjacent panels/sections. RX-0006C, Q/A 334.

Hente is directed to light emitting devices comprising organic light emitting diodes (i.e., organic LEDs or OLEDs) that allow for adjustable and foldable orientations. RX-0576, Title, Abstract; RX-0006C, Q/A 336. Hente teaches light emitting devices that have the flexibility to “illuminate large and point-like limited areas.” RX-0576, [0005]; RX-0006C, Q/A 336. Specifically, Hente discloses lighting devices with at least one first section and at least one second section. RX-0576, Abstract; RX-0006C, Q/A 336. Hente explains that the light emitting device can be expanded to provide a flat illumination surface, stating “In FIG. 2 the light emitting device 10 is shown in an expanded position 100...In the expanded position 100 the first section 20 and the second section 30 are arranged in such a way, that they form a longish stretched sheet like light emitting device 10. The artificial light 45 is primarily emitted through the bottom sides 21, 31 of each section 20, 30. In this position 100 the light emitting device 10 can be used to illuminate large areas” RX-0576, [0036]; RX-0006C, Q/A 336. Figure 2 is illustrated below.

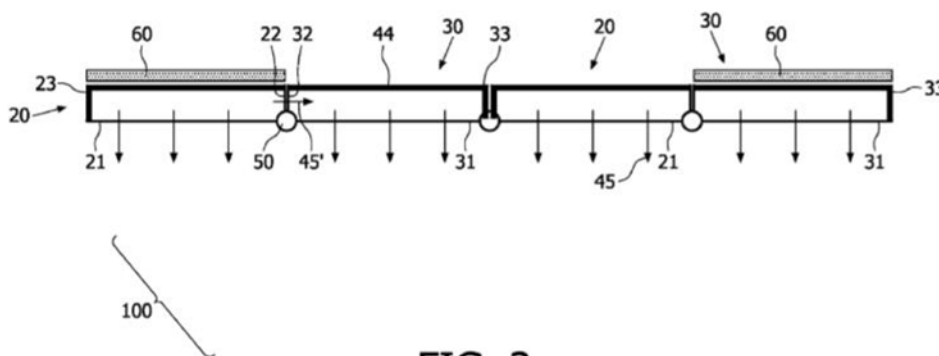
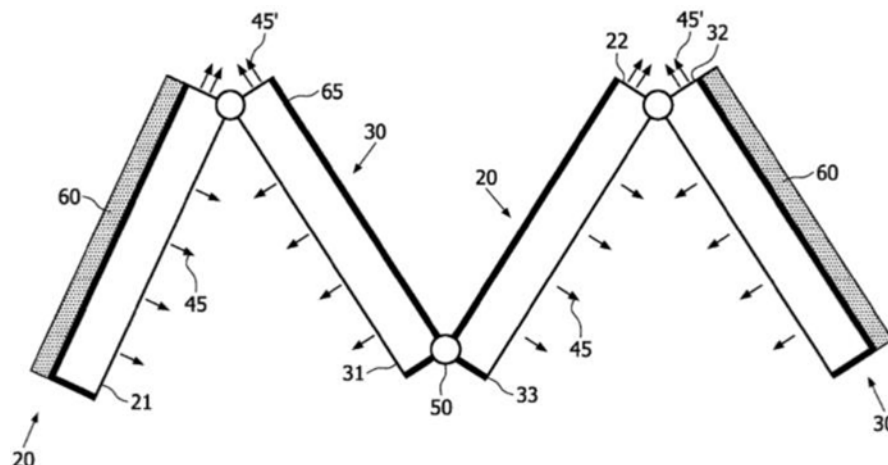


FIG. 2

RX-0576, Fig. 2; RX-0006C, Q/A 336.

Hente also teaches that the light emitting device may be adjusted or folded into a smaller, “compact” position, stating “[t]o enable the light emitting device to be converted from the expanded position 100 into the compact position 110 the sections 20, 30 are connected through a connection mean 50. As shown in Figure 3, the connection mean may be a hinges [sic], being

located at the outer ends of each section 20, 30." RX-0576, [0037]; RX-0006C, Q/A 335. Figure 3 is illustrated below.



RX-0576, Fig. 3. As depicted in Figure 3 of Hente, the "outer ends" correspond to inner side surfaces of the sections 20, 30. RX-0006C, Q/A 335. Accordingly, Hente's hinges connect panels on inner side surfaces. RX-0006C, Q/A 335.

Hente is from the same field of endeavor as the Asserted Patents, which also describes illuminators having multiple adjacent sections/panels incorporating light emitting diodes, that can be rotated relative to each other. JX-0001, 1:24-2:4. Like Larsen (in combination with Lundahl) Hente is also directed to light emitting devices that allow for adjustable and foldable orientations. RX-0576, Title, Abstract; RX-0006C, Q/A 337. Like Larsen, Hente teaches that its foldable light emitting device has multiple sections (i.e. panels) that may bend or fold along the lines between panels. RX-0576, Figs. 2-3, Abstract, [0036]-[0037]; RX-0006C, Q/A 337. Like Larsen, Hente teaches hinges connecting these multiple panels, positioned on inner side surfaces. RX-0576, Fig. 3, [0037]. RX-0006C, Q/A 337.

Given this knowledge, a POSA would be motivated to combine the hinge system of Hente with the panels of Larsen and would have a reasonable expectation that the hinges of Hente could be successfully utilized in the device rendered obvious by Lundahl and Larsen. RX-0006C, Q/A

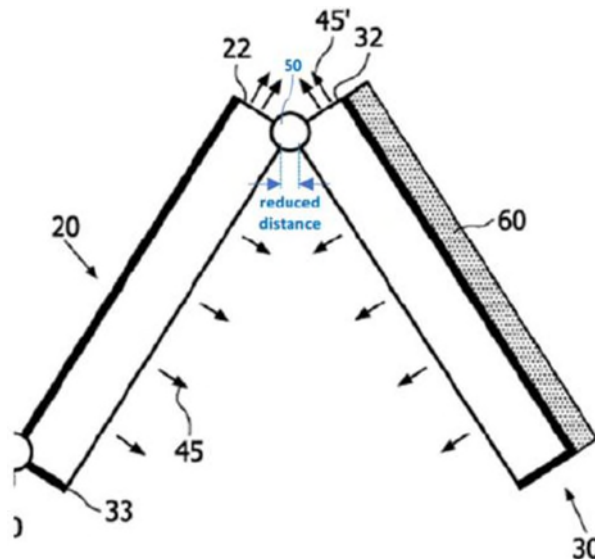
339. Specifically, a POSA would have had a reasonable expectation of success in combining Hente with Lundahl and Larsen because Hente and Larsen both describe methods of "hingedly" connecting panels. RX-0006C, Q/A 339. Further, it would have been well within the ambit of a POSA to select, adjust, substitute, and implement types and configurations of hinges. RX-0006C, Q/A 339.

Hente provides a design strategy via hinges that allow for movement and adjustment of adjacent panels/sections, while also minimizing the gap between the adjacent panels/sections. RX-0006C, Q/A 338. Consequently, even though Larsen teaches hinges on inner side surfaces of adjacent panels, a POSA would also be motivated to further look to the teachings of Hente related to the use of hinges that might minimize gaps/space between adjacent panels/section. RX-0006C, Q/A 338.

Additionally, the modification of hinges between panels would be a routine design process for a POSA, such that any POSA would reasonably expect that the hinges of Hente could be successfully incorporated into the illuminator rendered obvious by Lundahl and Larsen. RX-0006C, Q/A 339. Hente provides guidance for multiple orientations of the adjacent sections of the illumination device. As discussed above, the disclosure provided in the text of Hente and the illustration of Fig. 2 (representing a "nearly flush" orientation) would nonetheless motivate a POSA to locate the hinges on inner side surfaces of adjacent sections. Hente's disclosure of other orientations (*i.e.*, the "partially expanded" and "compact" orientations) would not change this motivation. RX-0006C, Q/A 340.

Sun Pharma asserts that Hente's disclosure does not allow for continuous illumination because the hinges of Hente "protrude beyond the front of the light emitting sections..." CX-0014C, Q/A 363. However, the possibility of the hinges protruding beyond the front of the light-emitting panels is not a design characteristic that would prevent a POSA from utilizing the hinge design of

Hente. RX-0006C, Q/A 341. Specifically, even with the hinge potentially protruding beyond the front of the panels, the distance or “gap” between panels will nonetheless be minimized or eliminated when the panels are angled toward each other (as would be the case, e.g., when the panels are angled to surround the face/scalp of a patient), as illustrated below in the annotated version of Fig. 3 from Hente:



Hente, Fig. 3; RX-0006C, Q/A 341.

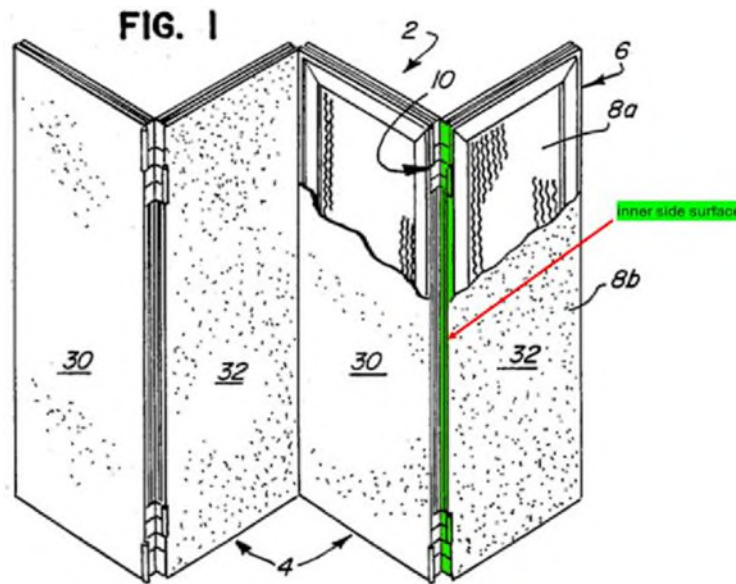
Consequently, the possibility that the hinges of Hente may protrude beyond the front surface of the adjacent sections/panels does not change that a motivation existed to combine the teachings of Hente’s hinges with the illuminator rendered obvious by Lundahl and Larsen. RX-0006C, Q/A 341.

- e. A Motivation Existed to Combine the Teachings of Lundahl, Larsen, Hente, and Perutz, and a Reasonable Expectation of Success Existed

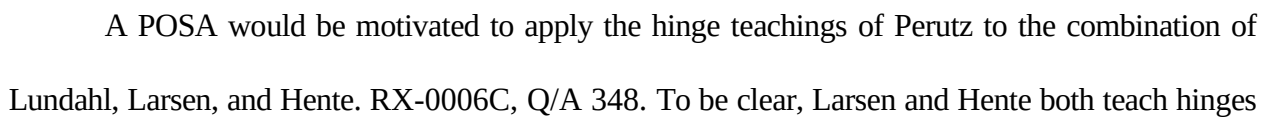
As discussed herein, a motivation existed to combine the teachings of Lundahl, Larsen, and Hente. RX-0006C, Q/A 314. For all the reasons discussed previously, Lundahl, Larsen, and Hente disclose and render obvious the inclusion of hinged panels (as taught by Larsen) in the illumination device taught by Lundahl via attachment to the inner side surface of adjacent panels. Further, as discussed previously, Hente discloses and renders obvious the inclusion of the claimed

"recess configured to receive a flange of one or the hinges." However, to the extent that Lundahl, Larsen, and Hente do not expressly or implicitly disclose or render obvious at least one panel including a recess configured to receive a flange of one of the hinges, the recess being positioned at an inner side surface of the at least one panel, this design option is disclosed by Perutz. RX-0006C, Q/A 344. Based on the teachings of Lundahl, Larsen, and Hente, uniformity of illumination was a key design motivation, as a POSA would want to minimize gaps between the adjacent panels (appreciable gaps between panels might impact the ability to produce uniform illumination). RX-0006C, Q/A 344. Like Larsen (in combination with Lundahl) and Hente, Perutz is also directed to foldable panels connected by hinges. RX-0607, Abstract, 3:54-66. RX-0006C, Q/A 347. Perutz teaches accommodating hinges in recesses on inner side surfaces of panels. RX-0607, 4:16-20 and 33-38; RX-0006C, Q/A 347. Perutz teaches a hinge configuration which minimizes the gap between the adjacent panels/sections. RX-0006C, Q/A 344. Therefore, a POSA would have been motivated to apply Perutz's hinge teachings to the aforementioned combination. RX-0006C, Q/A 344.

Perutz teaches a display panel and hinge system having "a plurality of display panels arranged in side by side relation and hingedly interconnected whereby one of the panels is capable of being selectively rotated relative to the other panel through a maximum arc of substantially 360°." RX-0607, Abstract; RX-0006C, Q/A 345. Perutz teaches connecting adjoining display panels 30, 32 with hinges 10, the display panels 30, 32 having a frame 6. RX-0607, 3:54-66; RX-0006C, Q/A 345. As shown in annotated Figure 1 below, the hinges 10 connect adjoining display panels 30, 32 at an inner side surface of the display panels 30, 32. RX-0006C, Q/A 345.



Perutz states that the segments of the hinge 10 “are maintained in vertically spaced alignment by an elongated rib or strut 28, 29,” with the ribs 28, 29 being received within slots 34 “formed in the corners of the frame 6 of the adjacent display panels.” RX-0607, 4:16-20 and 33-38; RX-0006C, Q/A 346. As shown in annotated Figures 12 and 15 below, the side surface of adjoining display panels includes an indentation in a surface (e.g., slot 34 in frame 6) to receive the side-mounted hinges, specifically a flange (e.g., ribs 28, 29) of the hinges 10, to reduce space between adjoining display panels. RX-0006C, Q/A 346.



on inner side surfaces of panels and Hente teaches and renders obvious accommodating hinge flanges within recesses on inner side surfaces of panels. RX-0006C, Q/A 348. However, a POSA additionally reading Pertuz would understand that Perutz adds to the teachings of Hente, further disclosing that the flange of a hinge may be placed within an indentation in the side surface (*i.e.*, a "recess"), which would further minimize the space between adjacent panels (the width of the flange being housed within the indentation on the side surface reduces the amount of space necessary between the adjacent panels). RX-0006C, Q/A 348. Consequently, the subject matter of Hente and Perutz is similar (both directed to hinge designs that eliminate space between adjacent sections) and a POSA would be motivated to combine the disclosure of Perutz with the teachings of Lundahl, Larsen, and Hente. RX-0006C Q/A 348.

A POSA would have had a reasonable expectation of success in combining Perutz with Lundahl, Larsen, and Hente, because Perutz, Hente, and Larsen all describe methods of connecting adjacent panels via hinges. Further, it would have been well within the ambit of a POSA to select, adjust, substitute, and implement types and configurations of hinges. RX-0006C, Q/A 349.

6. Secondary Considerations

The alleged secondary considerations do not render the Asserted Claims non-obvious. RX-0006C, Q/A 350. The evidence does not support Sun Pharma's assertion that the secondary considerations of long-felt need, industry praise, commercial success, and copying support non-obviousness of the Asserted Claims of the '512 and '028 patents. RX-0006C, Q/A 351-353.

ii. Long-Felt Need

There was no long-felt need addressed by the Asserted Claims of the '512 and '028 Patents because the subject matter addressed by the Asserted Claims was widely known before the priority date of the '512 and '028 Patents and clearly disclosed in the prior art. RX-0006C, Q/A 354. *ABT*

Sys., LLC v. Emerson Elec. Co., 797 F.3d 1350 (Fed. Cir. 2015), 11362 (“The disclosures of the prior art references eliminate any serious contention that there was a long-felt need for the invention...”)

In fact, Sun Pharma represents a long-felt need was addressed many years earlier, by the filing of their own patents no less. RX-0006C, Q/A 355. Specifically, Lundahl was assigned to DUSA Pharmaceuticals, Inc., and DUSA later became a part of Sun Pharma. As discussed previously, Lundahl discloses an illuminator that provided the uniform illumination that Sun Pharma alleges to be a long-felt need. RX-0006C, Q/A 355. Lundahl states that “[t]he U-shape minimizes the variations in distance between the emitter and the target, providing a uniform visible light distribution to the face or scalp of the patient...” RX-0065, 6:31-33. Lundahl further explains that “in order to achieve uniform facial or scalp irradiation, variations in output irradiance with distance must be minimized. A flat emitting surface would not deliver a uniform light dose to all contours of the face simultaneously because the non-planar facial and scalp surfaces could not be placed at a constant distance from the emitting surface. To ameliorate this problem, the present invention uses a U-shaped emitting surface that more closely follows the contours of the human face and scalp, and minimizes lamp to target distance variations which in turn minimizes irradiance variations at the target.” RX-0065, 4:27-38. Lundahl illustrates this uniform illumination in Figure 1. RX-0006C, Q/A 355.

Lundahl discloses that the device described therein provided "uniform illumination" (as claimed in the '512 and '028 Patents) stating “[i]t has been found that, according to a preferred embodiment of the present invention, the measured output over the active emitting area is within 70% of the measured maximum when measured with a cosine response detector at distances of 4” and 2”, and within 60% of the measured maximum over all operation distances.” RX-0065, 15:2226. Consequently, in addition to routinely stating that the devices described therein provide “uniform”

illumination, Lundahl discloses that the measured output over the active emitting area is within 70% of the measured maximum at distances of 4” and 2”, and within 60% of the measured maximum over all operation distances, meeting the construed requirement of “irradiating light over the active emitting area such that the measured irradiance at a treatment surface of the patient is at least within 60% of the measured maximum.” RX-0006C, Q/A 355. Consequently, there was no “long-felt need” for “uniform illumination,” because an illuminator designed to provide “uniform illumination” of a patient's head and face (for the purposes of PDT treatment) was addressed at least 17 years prior to the filing of the ’512 and ’028 Patents, when Sun Pharma filed the Lundahl patent. RX-0006C, Q/A 355.

Additionally, there was no long-felt need addressed by the Asserted Claims of the ’512 and ’028 Patents for an illuminator that can treat lesions further apart on the patient's face (for example on opposite sides of the face) in a single session. RX-0006C, Q/A 356. This very “need” for an illumination device that provides a larger treatment area, capable of treating lesions on opposite sides of the face, was already met with the filing of Lundahl, as demonstrated in Figure 1. RX-0006C, Q/A 356. As can clearly be seen from Figure 1, the illuminator of Lundahl provided a large treatment area that could illuminate lesions further apart on a patient's face (*e.g.*, on opposite sides of the face) in a single illumination session. with the filing of the Lundahl patent family, and the original Blu-U[®] device. RX-0006C, Q/A 356. Thus, there was no “long-felt need” for a larger illumination area capable of illuminating lesions further apart in a single session, as an illuminator with this design was disclosed at least 17 years prior to the filing of the ’512 and ’028 Patents, when Sun Pharma filed the Lundahl patent. RX-0006C, Q/A 356.

iii. Industry Praise

The evidence does not support Sun Pharma’s allegation that the alleged invention, as recited in the Asserted Claims of the ’512 and ’028 Patents, was the subject of industry praise due

to the features recited in the Asserted Claims. RX-0006C, Q/A 357. For assessing non-obviousness, industry praise must be related to allegedly novel features of the Asserted Claims, not merely to features present in the prior art. RX-0006C, Q/A 357; *S. Alabama Med. Sci. Found. v. Gnosis S.P.A.*, 808 F.3d 823, 827 (Fed. Cir. 2015) (affirming a finding of no nexus where the patent owner "failed to connect the evidence of industry praise to the novel elements of the claims.").

The BLU-U[®] 4170E is not yet on the market and available for sale. RX-0006C Q/A 358. In view of this, Sun Pharma has only provided press releases and statements related to RhodoLED[®] XL, demonstrating praise for the "features and versatility" of RhodoLED[®] XL. RX-0006C, Q/A 358. Sun Pharma argues that the praise for RhodoLED[®] XL is based on Sun Pharma's discoveries as reflected in the claims of the '512 and '028 Patents, namely the development of a larger illumination field, to treat multiple lesions on various parts of the face in a single session. RX-0006C, Q/A 358. However, as noted in the above discussion of the "long-felt need" secondary consideration, the development of an illuminator with a larger illumination field has long been known in the art, as evidenced by the filing of Lundahl more than 17 years prior to the earliest priority date of the '512 and '028 Patents.

iv. Commercial Success

Sun Pharma will not establish the commercial success of any product allegedly practicing the Asserted Patents, as it has not yet sold the BLU-U[®] 4170E, and the evidence will show that the RhodoLED[®] XL does not practice the Asserted Patents. Even if Sun Pharma were able to show that the RhodoLED[®] XL practices the alleged inventions of the Asserted Patents, and that the product has enjoyed commercial success, a patentee bears the burden of demonstrating that the relevant commercial success is attributable to the claimed invention "as opposed to other economic and commercial factors unrelated to the technical quality of the patented subject matter." *Cable Elec.*

Prods, Inc. v. Genmark, Inc., 770 F. 2d 1015, 1027 (Fed. Cir. 1987). The evidence will show that Sun Pharma has not and cannot establish that the RhodoLED[®] XL's alleged success is due to the inventions of the Asserted Patents.

Sun Pharma alleges that commercial success of the RhodoLED[®] XL is due to concepts discussed in the Asserted Patents, however, those concepts are also present in the prior art, as described above in Section V.A.4, and thus this does not show any commercial success that is relevant to the question of obviousness. *Tokai Corp. v. Easton Enterprises, Inc.*, 632 F.3d 1358, 1369-70 (Fed. Cir. 2011) ("If commercial success is due to an element in the prior art, no nexus exists."); *In re Huai-Hung Kao*, 639 F.3d 1057, 1068 (Fed. Cir. 2011) ("Where the offered secondary consideration actually results from something other than what is both claimed and novel in the claim, there is no nexus to the merits of the claimed invention."); *Ormco Corp. v. Align Tech., Inc.*, 463 F.3d 1299, 1312 (Fed. Cir. 2006) ("[I]f the feature that creates the commercial success was known in the prior art, the success is not pertinent.").

Sun Pharma cannot point to sales of its own product to establish commercial success because the BLU-U[®] 4170E Domestic Industry product is not on the market and does not yet have a projected release date. Thus, Sun Pharma instead relies on the less than a years' worth of mediocre sales of the RhodoLED[®] XL to attempt to establish commercial success. Sun Pharma's expert, Dr. Vander Veen, argues that "Sun Pharma's BLU-U[®] 4170E is *likely* to be commercially successful, and that success will also be a direct result of the claimed features of the Asserted Patents." See CX-0016C (Vander Veen Rebuttal WS), Q/A 16 (emphasis added). The evidence will show that Biofrontera's sales have not reached a level sufficient to conclude that the RhodoLED[®] XL has been commercially successful, and further, that the RhodoLED[®] XL has not even sold anywhere near what was projected, much less captured a significant share of the dermatology practices in the

United States. See RX-0008C (Rowe Initial WS), Q/A 23; JX-0010C (Baldyga Dep. Tr.), 213:6-20; JX-0007C (Leffler Dep. Tr.), 39:2-10. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED].

Finally, the evidence will also show that there are other factors that have contributed to the sales of the RhodoLED[®] XL that cannot be attributed to the Asserted Patents, including: 1) the majority of the devices were purchased by existing users of Ameluz[®]; 2) features of the XL that were improvements on Biofrontera's older RhodoLED[®] lamp; and 3) trade-in discounts for owners of the RhodoLED[®]. See RX-0008C, Q/A 42-51.

v. Copying

The evidence does not support any aspect of the Asserted Claims of the '512 and '028 Patents being copied and incorporated into Biofrontera's RhodoLED[®] XL. RX-0006C, Q/A 359. Consequently, the "copying" factor does not render the Asserted Claims of the '512 and '028 Patent non-obvious and does not change the conclusion that the Asserted Claims of the '512 and '028 Patents are obvious over the prior art. RX-0006C, Q/A 359.

To the extent that Sun Pharma alleges that one or more aspects of the design of the RhodoLED[®] XL was copied from the Asserted Claims of the '028 Patent or '512 Patent, these design features were previously disclosed and/or rendered obvious by the prior art, for all the reasons discussed in the preceding obviousness analysis. *E.I. du Pont de Nemours & Co. v. Synvina C.V.*, 904 F.3d 996, 1012 (Fed. Cir. 2018) ("Where the prior art is so close, it has not been shown that DuPont copied [the asserted patent] rather than the other references within the prior art."). Consequently, to the extent Biofrontera utilized a 5-panel design with hinges mounted/attached to inner side surfaces of adjacent panels, these design features were well known in the art at least 10

years prior to the effective date of Sun Pharma's Asserted Patents — *see, e.g.*, Larsen, which was published April 7, 2005, prior to the October 15, 2015, effective date of the Asserted Patents. RX-0006C, Q/A 360.

B. All Asserted Claims Are Invalid for Lack of Enablement Under 35 U.S.C. § 112(a)

All Asserted Claims contain a preamble reciting “[a] [system for / method of] photodynamically diagnosing or treating a patient.” The claim construction order correctly determined that the preamble was limiting. Order No. 18, 29. Yet the specification of the Asserted Patents is devoid of guidance or examples for photodynamically diagnosing a patient using the claimed illuminator that would enable a POSA to practice the full scope of the claims without undue experimentation. Sun Pharma relies heavily on related patent specifications and prior art publications to demonstrate that photodynamic diagnosis as a technique was known to be useful in some limited circumstances. But the issue is not whether some photodynamic diagnosis was enabled under some circumstances *in the prior art*. Rather, the question is whether the Asserted Patents’ specifications enable the *full scope of the Asserted Claims*. It does not.

1. Legal Standards

Section 112(a) requires that “[t]he specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to *enable* any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention.” 35 U.S.C. § 112(a) (emphasis added). In particular, the specification must “enable any person skilled in the art ... to make and use” the claimed invention without undue experimentation, which is known as the enablement requirement. 35 U.S.C. § 112(a); *ALZA Corp. v. Andrx Pharms., LLC*, 603 F.3d 935, 940 (Fed. Cir. 2010). Enablement is a question of law based on underlying factual evidence. *Alza*, 603 F.3d at 940.

“The purpose of the enablement requirement is to ensure that the public is told how to carry out the invention, *i.e.*, to make and use it.” *Amgen Inc. v. Sanofi, Aventisub LLC*, 987 F.3d 1080, 1084 (Fed. Cir. 2021) *aff’d sub nom. Amgen Inc. v. Sanofi*, 598 U.S. 594, (2023). The “disclosure must be at least commensurate with the scope of the claims.” *Id.* (cleaned up). As the Supreme Court explained, “the specification must enable the full scope of the invention as defined by its claims. The more one claims, the more one must enable.” *Amgen Inc. v. Sanofi*, 598 U.S. 594, 610 (2023).

“Although a specification does not need to describe how to make and use every possible variant of the claimed invention, when a range is claimed, there must be reasonable enablement of the scope of the range.” *Amgen*, 987 F.3d at 1085 (cleaned up). Further, “the enablement inquiry for claims that include functional requirements can be particularly focused on the breadth of those requirements, especially where predictability and guidance fall short.” *Id.* at 1086. “In particular, it is important to consider the quantity of experimentation that would be required to make and use, not only the limited number of embodiments that the patent discloses, but also the full scope of the claims.” *Id.* Functional claim limitations “pose high hurdles in fulfilling the enablement requirement.” *Id.* at 1087.

The analysis of whether undue experimentation would have been required is considered from the perspective of a POSA as of the filing date of the Asserted Patents. *Wyeth & Cordis Corp. v. Abbott Lab’ys*, 720 F.3d 1380, 1384 (Fed. Cir. 2013). To determine whether experimentation would have been “undue,” courts typically consider the *Wands* factors: “(1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the

breadth of the claims.” *In re Wands*, 858 F.2d 731, 737, 8 U.S.P.Q.2d 1400 (Fed. Cir. 1988). While the analysis and conclusion of a lack of enablement are based on the factors discussed above and the underlying factual evidence, it is not necessary to discuss or show a lack of enablement on each *Wands* factor. *Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1213 (Fed. Cir. 1991) (noting that *Wands* factors are “illustrative, not mandatory”).

2. The Scope of the Asserted Claims and the Specification

As discussed above, the enablement inquiry involves assessing whether the specification enables a POSA to practice the *full scope of the claims* without the need to engage in undue experimentation. 598 U.S. at 610. As explained below, the Asserted Claims in this Investigation are broad.

i. *The Asserted Claims Have Broad Preambles and Few Limitations on Diagnosis Variables*

The Asserted Claims are broad in two senses: (1) the preambles place no limitations on the types of diseases or disorders that can be “photodynamically diagnos[ed] or treat[ed]” and (2) the bodies of the Asserted Claims do not meaningfully limit several important factors relevant to photodynamic diagnosis.

First, the preambles in all Asserted Claims were construed as limiting on the claims. Order No. 18, 29. With respect to the asserted method claims, claims 8, 17, and 18 of the ’512 patent, ALJ Moore explained that “[t]he preamble is ‘not merely a context in which the invention may be used, but [is] the essence of the invention without which performance of the recited steps is nothing but an academic exercise.’” *Id.* at 26 (quoting *Teva Pharm. Int’l GMBH v. Eli Lilly*, 8 F.4th 1331, 1341 (Fed. Cir. 2021)). And ALJ Moore held that “the specification further demonstrates that photodynamically diagnosing and treating patients is central to the invention.” Order No. 18, 26.

Further, with respect to the asserted system claims, claims 1, 3, 5, and 20 of the '512 patent and claims 1, 2, 4, 16, 17, and 19-21 of the '028 patent, ALJ Moore held that they were limiting because “there is not a way to sever the preamble such that one part could be consider[ed] limiting (‘a patient’), while the other part would not (‘photodynamically diagnosing or treating’).” *Id.* at 28-29. And ALJ Moore explained that the asserted system claims “refer to a ‘treatment surface’” in the body of the claims. *Id.* at 29. “By using these words, the claims specify that the system is used for treating (or diagnosing) a patient.” *Id.* ALJ Moore concluded by explaining that “this is not a case in which the intention is only expressed in the preamble itself, but it is instead woven throughout the claims.” *Id.*

Consistent with ALJ Moore’s construction of the preambles, the Asserted Claims encompass systems and methods *for* photodynamically diagnosing or treating a patient. While the preambles use the disjunctive “or” between “diagnosing” and “treating,” the Asserted Claims encompass *both* photodynamically diagnosing *and* treating a patient. RX-0007C.0043, Q/A 210-211. In other words, the Asserted Claims must enable a POSA to use the claimed “illuminator” to photodynamically diagnose and photodynamically treat a patient without undue experimentation. *Id.*

A POSA would have been able to use the claimed illuminator to photodynamically *treat* a patient using the claimed illuminator, which was obvious and routine in the art as of the priority date, as explained above. *Supra* V.A.4.a. However, PDT illuminators were not commonly used for photodynamic diagnosis as of the priority date, and thus a POSA would have needed guidance from the specification of the Asserted Patents to be able to photodynamically diagnose a patient using the claimed illuminator. RX-0007C.0043-44, Q/A 209, 212.

In addition, the preambles broadly recite “photodynamically diagnosing ... a patient.” *Supra* Section III.B. The preambles do not specify *what* diseases and conditions can or should be diagnosed, and instead broadly encompass any disease or condition in the context of photodynamic therapy. RX-0007C.0044-45, Q/A 216-217.

The specification of the Asserted Patents does little to narrow what diseases and conditions are encompassed by the claims, and refers to the treatment and diagnosis of both internal and external conditions:

Photodynamic therapy (PDT), ***photodynamic diagnosis (PD)***, or photochemotherapy is generally used to treat and/or ***diagnose several types of ailments in or near the skin or other tissues, such as those in a body cavity. For example***, PDT or PD may be used for treatment or diagnosis of actinic keratosis of the scalp or facial areas of a patient. In addition, PDT and PD ***may be used*** for treatment and diagnosis of other indications (e.g., acne, warts, psoriasis, photo-damaged skin, cancer) and other areas of the patient (e.g., arms, legs).

JX-0001, 1:24-33 (emphasis added); *see also* RX-0007C.0044-45, Q/A 217. Thus, the specification broadly refers to diagnosing “several types of ailments in or near the skin or other tissues, such as those in a body cavity” and lists some examples (e.g., actinic keratosis, acne, warts, psoriasis, photo-damaged skin, and cancer). JX-0001, 1:24-33.

In view of the specification, Dr. Ehrenreich testified that “it’s difficult for me to say exactly what types of diseases and conditions the preambles encompass, but it would be essentially all dermatological conditions, at a minimum.” RX-0007C.0044-45, Q/A 217. And Dr. Ehrenreich explained that “there are hundreds, maybe thousands, of distinct types of dermatological diseases and conditions.” *Id.* at Q/A 218.

Dr. Shmuylovich agreed in his rebuttal expert report that the preambles broadly relate to the “diagnosis and treatment of ***dermatological*** conditions.” RX-0017C.0001 (Shmuylovich Reb. Rep.), ¶ 49; *see also id.* at ¶ 50 (“The fact that the claims are directed to ***dermatological conditions***

is further emphasized in the Asserted Patents’ discussion regarding uniformity.”) (emphasis added), ¶ 53 (“Given the patent’s disclosures and the state of the art at the time relating to photodynamic diagnosis and treatment in combination with ALA, a POSITA would understand that ***the claimed device and methods were directed to the diagnosis and treatment of skin conditions.***”) (emphasis added). But in his rebuttal witness statement, Dr. Shmuylovich attempted to narrow these opinions, testifying that “there are ***certain*** dermatological conditions listed in the Asserted Patents as examples that may be suitable for photodynamic diagnosis.” CX-0013C.22 (Shmuylovich Reb. Witness Statement), Q/A 77 (emphasis added).

This fails as a legal matter because limiting the Asserted Claims to only ***certain*** dermatological conditions discussed as ***examples*** in the specification, as Dr. Shmuylovich has argued, would require reading limitations from the specification into the claims. The Federal Circuit “has repeatedly stated that while claims are to be construed in light of the specification, they are not necessarily limited by the specification.” *Enercon GmbH v. Int’l Trade Comm’n*, 151 F.3d 1376, 1384 (Fed. Cir. 1998); *see also Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir. 2004) (“Even when the specification describes only a single embodiment, the claims of the patent will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using ‘words or expressions of manifest exclusion or restriction.’”). Here, the Asserted Claims broadly encompass photodynamically diagnosing a patient, and the specification does not use express language to limit the types of dermatological diseases or conditions that the claimed illuminator can be used to diagnose. Thus, as Dr. Ehrenreich testified, the Asserted Claims broadly encompass photodynamically diagnosing any dermatological condition.

But the preambles are not the only broad limitations in the Asserted Claims that are relevant to the enablement inquiry. In fact, the bodies of the Asserted Claims place few limitations on how to use the claimed “illuminator” for the purpose of “photodynamically diagnosing ... a patient,” thus increasing the amount of experimentation necessary to practice the claims.

As Dr. Ehrenreich testified, a POSA would understand that photodynamic diagnosis relies on three general components:

- (1) Applying a photoactivating agent to the patient’s skin and allowing PpIX molecules to form;
- (2) Illuminating the patient’s skin with proper light so that the PpIX molecules fluoresce; and
- (3) Ensuring that the right fluence, or dose, and irradiance of light are applied.

See, e.g., RX-0007C.0045-48, Q/A 220-232. The Asserted Claims place almost no limitations on any of these photodynamic diagnosis variables.

For example, most of the Asserted Claims do not include any limitations about what photoactivating agent to use, what dose or concentration to use, or how it should be administered to the patient. RX-0007C.0047, Q/A 228-230. While certain asserted method claims (8, 17, and 18 of the ’512 patent) require administering a specific photoactivating agent—ALA—even those claims are silent about what dose or concentration to use, or how it should be administered to the patient. *Id.*

In addition, the Asserted Claims are silent about what wavelengths of light to use to photodynamically diagnose a patient. *Id.* at Q/A 221-227. However, at least some dependent claims of the Asserted Patents recite the use of “light having a wavelength in a range of 400 nm to 700 nm.” *See, e.g.*, JX-0002, claim 4. Because dependent claims must be narrower than the independent claims from which they depend, the other claims of the Asserted Patents must

encompass at least a range of wavelengths from 400 nm to 700 nm. RX-0007C.0046, Q/A 222-224.

Finally, most Asserted Claims are silent on what light fluence or irradiance density to use. Certain dependent claims recite light fluences ranging from 30 J/cm² to 150 J/cm², or irradiance densities ranging from 10 mW/cm² to 30 mW/cm². *See, e.g.*, JX-0001, claims 3, 4; JX-0002, claims 2, 3. As above, all other Asserted Claims must encompass at least these broad ranges of light fluences and irradiance densities. RX-0007C.0048, Q/A 232.

Accordingly, the Asserted Claims have a broad scope that encompasses: (1) photodynamically diagnosing a patient for any dermatological condition by (2) using the claimed illuminator according to the full scope of the claims, including across the variables and ranges discussed above. RX-0007C.0048-49, Q/A 234.

ii. *The Specification Provides Little Guidance to a POSA About How to Use the Claimed Illuminator to Photodynamically Diagnose a Patient*

The specification does not enable a POSA to practice the full scope of the Asserted Claims because it does not enable a POSA to use the claimed illuminator to (1) photodynamically diagnose a patient for any dermatological condition by (2) using the claimed illuminator across the full scope of the photodynamic diagnosis variables discussed above. *Supra* V.B.2.a. However, the specification contains little guidance, and no examples, about how to photodynamically diagnose a patient using the claimed illuminator.

In both Asserted Patents, the Abstract refers generally to the use of the “illuminator for photodynamically diagnosing or treating a surface.” JX-0001, Abstract; JX-0002, Abstract; *see also* RX-0007C.0060, Q/A 283. But it does not include any other details about how to use the illuminator to photodynamically diagnose a patient. *Id.*

Next, the background section of the Asserted Patents generally discusses photodynamic treatment and diagnosis, and acknowledges that the techniques were known in the prior art. *See, e.g.,* JX-0001, 1:24-33. As explained above, the background section of the specification broadly refers to photodynamically diagnosing “several types of ailments in or near the skin or other tissues, such as those in a body cavity” and lists some examples (e.g., actinic keratosis, acne, warts, psoriasis, photo-damaged skin, and cancer). *Id.* It also explains that a photoactivating agent, like ALA, should be administered to a patient as part of a photodynamic treatment or diagnosis. *Id.* at 1:34-47. Finally, the background section incorporates a number of other patents by reference “for the techniques, methods, compositions, and devices related to PDT and PD.” *Id.* at 1:50-52.

The Summary section of the specification likewise includes a general and high-level discussion about PDT and phototherapy devices. *Id.* at 1:62-3:19. For example, the specification explains that it is important to ensure that a patient receives both the correct fluence of light and that the light uniformly illuminates the patient. *Id.* at 2:5-20.

The summary section also compares “conventional illuminators” (i.e., those known in the prior art) with the illuminators disclosed and claimed in the Asserted Patents, but primarily discuss treatment, rather than diagnosis. *Id.* at 2:21-3:19. According to the specification:

[C]onventional illuminators are used for phototherapy of acne, which typically does not require the administration of a photoactivatable agent for effective treatment. Thus, exposure to the light alone is generally sufficient treatment. Moreover, because multiple treatment sessions can be utilized to effectively treat the condition, uniformity of light across the target area during a given treatment is less of a concern in some situations. However, 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.

Id. at 2:21-31. In contrast, the illuminators disclosed in the Asserted Patents were designed to produce a more uniform light and to be adjustable for the **treatment** of various areas of a patient’s body. *Id.* at 2:50-3:19; *see also* RX-0007C.0061, Q/A 289.

While the summary section includes a description of photodynamic diagnosis generally, JX-0001, 2:50-54, and an overview of prior art illuminators and the illuminators claimed in the Asserted Patents, *id.* at 2:21-3:19, it does not include any meaningful discussion about how to photodynamically diagnose a patient for any particular dermatological conditions or what parameters to use.

Likewise, the detailed description and figures of the specification include few references to, and no examples of, photodynamic diagnosis. For example, Figures 1-6 in the Asserted Patents are related to the structure and function of the illuminators. JX-0001, 3:21-40, Figs. 1-6. In the context of Figure 2A, the specification provides for a wide range of potential wavelengths that may be used, colors of light, and combinations or sequential applications of different wavelengths and colors of light. *Id.* at 3:66-4:22.

Further, most of the detailed description section from the specification generally reiterates what was already known in the prior art about photodynamic treatment. RX-0007C.0061-62, Q/A 290-292. And like the Asserted Claims, it broadly discusses the use of a photoactivating agent, the dose of light (i.e., fluence), various wavelengths of light, and combinations of different wavelengths and colors of light. *Id.* But it does not discuss how to specifically apply these variables to photodynamically *diagnose* a patient for any particular disease or condition. *Id.*

The specification also explains that Figure 8 illustrates the light uniformity produced by the claimed illuminator. JX-0001, 8:39-63. Figure 8 and the accompanying description of Figure 8 in the specification teaches that total light doses of about 10 J/cm² occur across all regions of the face when the claimed illuminator was used. *Id.* It also says that “total light dose drops off minimally ... at the extreme outer boundaries of the patient’s face.” *Id.* And the specification explains that the “measured output over the emitting area” is within at least 60% of the measured

maximum. *Id.* As Dr. Ehrenreich explained, that means that the illuminator can deliver uniform light across a patient's face, but it offers no guidance on how to use the illuminator to photodynamically diagnose a patient. RX-0007C.0063, Q/A 300-301.

Further, the specification does not include *any* examples of using the claimed illuminator to photodynamically diagnose a patient. RX-0007C.0062-63, Q/A 293-297. The only example disclosed in the specification describes *treating* a patient with precancerous lesions in conjunction with the application of ALA as the photoactivating agent. JX-0001, 8:64-9:43; RX-0007C.0062, Q/A 294-295.

In addition, as explained above, certain patents are incorporated by reference in the background section of the specification. JX-0001, 1:50-52. For example, Kennedy and Lundahl are incorporated by reference in the specification of the Asserted Patents. *Id.* Like the specification of the Asserted Patents, Kennedy disclosed some basic points and principles related to photodynamic diagnosis. *See, e.g.*, RX-0068, 1:50-58; *see also* RX-0007C.0065, Q/A 307-309. But as Dr. Ehrenreich testified, Kennedy and Lundahl did not explain how to photodynamically *diagnose* the broad scope of dermatological conditions encompassed by the claims, and did not explain how to use a photodynamic illuminator according to the full scope of the Asserted Claims (e.g., using the full scope of wavelengths of light from 400-700 nm, using different types and amounts of photoactivating agents, using various fluences and irradiances of light). RX-0007C.0065, Q/A 307-309. Rather, they disclosed examples of how to photodynamically treat and diagnose a patient using a specific set of treatment and diagnosis parameters—but those limited examples fall short of enabling the *full scope* of the Asserted Claims. *Id.*

The specification also incorporates by reference U.S. Patent Nos. 5,211,938 (“the ’938 patent”) and 8,758,418 (“the ’418 patent”). JX-0001, 1:52-54. But as Dr. Ehrenreich explained,

the '938 patent had essentially the same disclosure as Kennedy. RX-0007C.0065-66, Q/A 310-312. Likewise, as Dr. Shmuylovich testified, the '418 patent disclosed the same basic principles and methods, which both experts agree have been known for decades. CX-0013C.38, Q/A 138-141. Thus, for the same reasons, the '938 patent did not explain how to photodynamically diagnose the broad scope of dermatological conditions encompassed by the claims, and did not explain how to use a photodynamic illuminator to photodynamically diagnose patients according to the *full scope* of the Asserted Claims. RX-0007C.0065-66, Q/A 310-312.

Overall, the specification includes references to using the claimed illuminator to photodynamically diagnose patients and explains the basic concepts and principles related to photodynamic diagnosis. But it does so in different parts of the specification, and provides only vague references to photodynamic diagnosis, without ever tying the different variables together to explain how to use the claimed illuminator to photodynamically diagnose a patient. Consistent with the expert testimony already submitted in this case, and as the evidence will show, the specification would not have enabled a POSA to photodynamically diagnose a patient using the claimed illuminator across the *full scope* of the Asserted Claims.

3. The *Wands* Factors Weigh in Favor of a Finding that a POSA Would Have Been Required to Engage in Undue Experimentation to Practice the Full Scope of the Asserted Claims

To determine whether experimentation would have been “undue,” courts typically consider the *Wands* factors: “(1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.” *In re Wands*, 858 F.2d at 737. While the analysis and conclusion of a lack of enablement are based on the factors discussed above and the underlying factual evidence, it is not necessary to discuss or show a lack of enablement on

each *Wands* factor. *Amgen*, 927 F.2d 1213 (noting that *Wands* factors are “illustrative, not mandatory”).

i. The Breadth of the Claims

As explained above, the Asserted Claims are broad. *Supra* Section V.B.2.a. Specifically, the Asserted Claims have a broad scope that encompasses: (1) photodynamically diagnosing a patient for at least any dermatological condition by (2) using the claimed illuminator according to the full scope of the claims, including across the variables and ranges discussed above. *Id.*; see also, e.g., RX-0007C.0048-49, Q/A 234. In view of the breadth of the Asserted Claims, the specification must contain a commensurate disclosure to enable the full scope of the Asserted Claims. *Amgen*, 598 U.S. at 610 (“the specification must enable the full scope of the invention as defined by its claims. The more one claims, the more one must enable.”); see also *Amgen*, 987 F.3d at 1085 (“Although a specification does not need to describe how to make and use every possible variant of the claimed invention, when a range is claimed, there must be reasonable enablement of the scope of the range.”).

ii. The Nature of the Invention and the Level of One of Ordinary Skill

As discussed above, the “invention” described in the Asserted Patents relates to methods and systems for photodynamically diagnosing or treating a patient. *Supra* Section I.B. For example, the specification explains that the “Field” of the “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.**” JX-0001, 1:15-20; see also RX-0007C.0049, Q/A 236-237. As Biofrontera’s obviousness arguments demonstrate, certain embodiments within the broad scope of the Asserted Claims were well understood by the priority date of the Asserted Patents. However, the evidence will show that it would have been

difficult for a POSA to practice the full scope of the Asserted Claims as to diagnosing. RX-0007C.0049, Q/A 238.

Further, under the POSA definition adopted by ALJ Moore in this Investigation, a POSA must have either an M.D. or a Ph.D. in a relevant field. Order No. 18, 13. And to practice the photodynamic diagnosis aspects of the Asserted Claims, a POSA would have an M.D. and experience photodynamically diagnosing patients. RX-0007C.0049-50, Q/A 239. While a POSA would have understood how to diagnose or delineate a small number of dermatological conditions (*e.g.*, cancerous and pre-cancerous lesions) using known photosensitizing agents, wavelengths of light, and light irradiances, they would have had less experience and understanding with respect to photodynamically diagnosing other types of dermatological conditions. *Id.* Because the Asserted Claims broadly encompass dermatological conditions and the use of various photodynamic diagnosis variables, the level of skill relative to the broad scope of the Asserted Claims would have been low as it relates to photodynamic diagnosis. *Id.*

iii. The State of the Prior Art and the Level of Predictability in the Art

As explained above, certain embodiments of photodynamic diagnosis within the broad scope of the Asserted Claims were well-understood and predictable as of the priority date of the Asserted Patents. *Supra* Section V.B.2.a; *see also* RX-0007C.0051, Q/A 244. However, photodynamic diagnosis in general was limited to a relatively narrow number of dermatological conditions, and relied on specific diagnostic parameters (*e.g.*, using specific amounts of ALA and blue light). *Supra* Section V.B.2.a; *see also* RX-0007C.0051, Q/A 244. But beyond those relatively narrow points, photodynamic diagnosis was an unpredictable field, as evidenced by the prior art. RX-0007C.0051, Q/A 244-245.

For example, photodynamic diagnosis was primarily used to detect pre-cancerous lesions, certain types of skin cancer, and other non-dermatological conditions. RX-0007C.0051, Q/A 246.

But even in the context of diagnosing pre-cancerous and cancerous lesions on a patient's skin, photodynamic diagnosis had limitations. *Id.*

For example, CX-0108 (Fritsch) was an article published in 1998 that disclosed the basic technique for photodynamic diagnosis. CX-0108.2; see also RX-0007C.0052, Q/A 248. Fritsch also reported that basal cell carcinoma, squamous cell carcinoma, Bowen's disease, SK and extramammary Paget's disease showed an intensive, uniform red fluorescence. CX-0108.2; see also RX-0007C.0052, Q/A 249. But Fritsch also explained that all other melanotic or amelanotic, benign or malignant tumors, such as malignant melanoma, lentigo senilis, verruca seborrhioica, nevus cell nevus, demonstrated no or only minimal fluorescence, and thus could not be effectively diagnosed using the traditional method disclosed in Fritsch. CX-0108.2; *see also* RX-0007C.0052, Q/A 249.

As Dr. Ehrenreich testified, Fritsch demonstrates that not every type of skin cancer, let alone all dermatological conditions encompassed by the Asserted Claims, could be diagnosed using traditional photodynamic diagnosis methods. RX-0007C.0052, Q/A 249. And Fritsch shows that the only way to determine if a particular dermatological condition can be photodynamically diagnosed is through the type of trial-and-error experiments disclosed in Fritsch. *Id.* Finally, Fritsch also highlighted that several factors influence whether photodynamic diagnosis as a technique will work, including the amount and type of photosensitizing agent, and the wavelengths and type of light being used. CX-0108.6-7; see also RX-0007C.0052, Q/A 250-251.

As another example, CX-1170 (Tyrrell) discussed the photobleaching issue that comes up in the context of photodynamic treatment and diagnosis. CX-1170.3-4; *see also* RX-0007C.0054, Q/A 254-255. Specifically, Tyrrell disclosed that high doses or irradiances of light (e.g., 37 J/cm²) can quickly "photobleach" any PpIX molecules on the patient's skin such that they stop fluorescing

extremely fast and cannot be detected. CX-1170.3-4; *see also* RX-0007C.0054, Q/A 254-255. Under photobleaching conditions, photodynamic diagnosis with high fluences or irradiances will be ineffective for diagnosis—but as noted above, the Asserted Claims encompass ranges of fluences and irradiances far above those in Tyrrell that resulted in photobleaching. And, on the other end of the spectrum, as Dr. Ehrenreich explained, low light fluences or irradiances may not be sufficient to activate the PpIX molecules, meaning that they may not be detected if the correct fluence and intensity of light is not used. CX-1170.3-4; *see also* RX-0007C.0054, Q/A 254-255.

As explained above, the Asserted Claims broadly encompass a range of both light fluences and irradiance densities. *Supra* Section V.B.2.a. But the specification contains virtually no guidance about the issues raised in Tyrrell—the specification does not explain what light fluences or irradiance densities from the claimed illuminator would be suitable to photodynamically diagnose a patient, which ones would be too weak, and which ones could result in photobleaching. Thus, Tyrrell demonstrates that a POSA would need this information in order to be able to use the claimed illuminator to photodynamically diagnose a patient according to the full scope of the ranges of light fluences and irradiance densities encompassed by the Asserted Claims. RX-0007C.0052, Q/A 254-256.

Sun Pharma relies on CX-1076 (Redondo) as another prior art article that disclosed the photodynamic diagnosis of basal cell carcinoma, which is one type of skin cancer. CX-1076.1; *see also* RX-0007C.0055, Q/A 258-259. Redondo's results highlight that there was unpredictability associated with photodynamic diagnosis—three false positives and three missed diagnoses were reported. CX-1076.2-3; *see also* RX-0007C.0055, Q/A 258-259.

Likewise, Sun Pharma relies on CX-0343 (Kalka), which primarily focused on photodynamic treatment, not diagnosis. CX-0343.1-2. Kalka explained that there were potential

uses for photodynamic diagnosis as a skin cancer detection modality, but concluded that photodynamic diagnosis held “*promise* with regard to tumor detection,” not that it was a widely used or refined technique. CX-0343.17 (emphasis added); *see also* RX-0007C.0055-56, Q/A 260-261.

Further, as Dr. Ehrenreich testified, and as the evidence will show, the prior art primarily relied on small, hand-held devices like the Wood’s lamp. RX-0007C.0056, Q/A 262-263. But those devices are not the same as the large illuminators used for photodynamic treatment and claimed in the Asserted Patents. *Id.*; *see also* RX-1355 (Lopez) at RX-1355.0002-0004. For example, the Wood’s lamp primarily uses ultraviolet light for photodynamic diagnosis. RX-0007C.0056, Q/A 262-263; *see also* RX-1358 (Cheung) at RX-1358.0001; RX-1356 (Ulubay) at RX-1356.0002. And other prior art references disclosed the use of blue light have a wavelength around 410-420 nm for photodynamic diagnosis. *See, e.g.*, CX-1079.3; RX-0007C.0058, Q/A 277. UV and blue light were typically used because PpIX fluoresces red—while those wavelengths of light were known to be useful for photodynamic diagnosis, the Asserted Claims encompass at least wavelengths in the range of 400-700 nm, which is in the visible light spectrum, not the UV light spectrum. RX-0007C.0056-57, Q/A 262-272; *see also* CX-1079 (Wan) at CX-1079.3.

Thus, absent guidance from the specification about how to use other wavelengths of light across the broad range of wavelengths encompassed by the Asserted Claims, a POSA would need to engage in experimentation to understand how to photodynamically diagnose a patient with the claimed illuminator. Likewise, a POSA would need guidance about how to use different types of photoactivating agents, and what amounts to administer. And a POSA would need further information about how all of those variables can be used to diagnose the broad scope of dermatological conditions encompassed by the Asserted Claims. But as explained above, and as

the evidence will show, the specification contains none of that necessary guidance and information.

Supra Section V.B.2.b.

iv. *The Amount of Direction Provided by the Patents and the Existence of Working Examples*

As explained above, the specification of the Asserted Patents contains little guidance, and ***no working examples***, about how to use the claimed illuminator to photodynamically diagnose a patient. *Supra* Section V.B.2.b. Specifically, the specification only reiterates the general principles and concepts that were known in the prior art about photodynamic diagnosis. *Id.* And the specification otherwise discusses how to use the claimed illuminator for treatment, and what specific parameters (*i.e.*, type and amount of photoactivating agent, wavelength of light, fluence and irradiance) to use for treatment in separate parts of the specification without tying them together. Accordingly, the narrow disclosures for diagnosis in the specification would not have enabled a POSA to use the claimed illuminator to photodynamically diagnose a patient across the full scope of the Asserted Claims. *Amgen*, 598 U.S. at 610 (“the specification must enable the full scope of the invention as defined by its claims. The more one claims, the more one must enable.”); *see also Amgen*, 987 F.3d at 1085 (“Although a specification does not need to describe how to make and use every possible variant of the claimed invention, when a range is claimed, there must be reasonable enablement of the scope of the range.”).

v. *The Quantity of Experimentation Needed to Make or Use the Invention Based on the Content of the Disclosure*

For many of the reasons already addressed above, the evidence will show that a POSA would need to engage in undue experimentation to use the claimed illuminator to photodynamically diagnose a patient across the full scope of the Asserted Claims. For example, Dr. Ehrenreich testified, and the evidence will show, that the only way for a POSA to know whether the claimed illuminator could be used to diagnose the full scope of dermatological

conditions encompassed by the Asserted Claims would be to conduct trial-and-error experimentation. RX-0007C.0066, Q/A 313-314.

Indeed, the prior art discussed above demonstrates that the application of different types and amounts of photoactivating agents, wavelengths of light, and light fluences and irradiances directly affects whether different dermatological conditions can be photodynamically diagnosed. *Supra* Section V.B.3.c. But because the specification offers virtually no guidance on any of those factors, a POSA would be left to engage in a significant amount of experimentation. RX-0007C.0066-67, Q/A 313-314, 317-318. In fact, Dr. Ehrenreich testified that there may be thousands of different permutations of (1) dermatological conditions, (2) wavelengths of light, (3) types and amounts of photoactivating agent, and (4) light fluences and irradiances encompassed by the Asserted Claims. *Id.*, Q/A 319-320.

Accordingly, in view of the scope of the Asserted Claims, the limited guidance in the specification of the Asserted Patents, and the *Wands* factors, the evidence will show that the Asserted Claims are invalid for lack of enablement.

C. All Asserted Claims Are Invalid for Lack of Adequate Written Description Under 35 U.S.C. § 112(a)

1. Legal Standards

35 U.S.C. § 112(a) requires that “[t]he specification shall contain a written description of the invention.” 35 U.S.C. § 112(a). The test for whether a patent satisfies the written description requirement of § 112(a) is whether the specification objectively demonstrates to a POSA that the inventors actually invented, or “possessed,” the claimed subject matter when the patent application was filed. *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (*en banc*). The written description must “sufficiently demonstrate[] that the inventors possessed the full scope of the claimed invention.” *Juno Therapeutics, Inc. v. Kite Pharma, Inc.*, 10 F.4th 1330, 1336 (Fed.

Cir. 2021). Even “proof of a reduction to practice” is not “by itself” sufficient to “provide a written description in the patent specification.” *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 969 (Fed. Cir. 2002).

In addition, “[a] ‘mere wish or plan’ for obtaining the claimed invention is not adequate written description. *Centocor Ortho Biotech, Inc. v. Abbott Lab’s*, 636 F.3d 1341, 1348 (Fed. Cir. 2011) (quoting *Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 1566 (Fed.Cir.1997)). “For generic claims,” the Federal Circuit has “set forth a number of factors for evaluating the adequacy of the disclosure, including ‘the existing knowledge in the particular field, the extent and content of the prior art, the maturity of the science or technology, [and] the predictability of the aspect at issue.’” *Juno*, 10 F.4th at 1335 (quoting *Ariad*, 598 F.3d at 1351). And “[f]or genus claims using functional language ... the written description ‘must demonstrate that the applicant has made a generic invention that achieves the claimed result and do so by showing that the applicant has invented species sufficient to support a claim to the functionally-defined genus.’” *Id.* at 1335 (quoting *Ariad*, 598 F.3d at 1351). “Generally, a genus can be sufficiently disclosed by ‘either a representative number of species falling within the scope of the genus or structural features common to the members of the genus so that one of skill in the art can “visualize or recognize” the members of the genus.’” *Id.* at 1335 (quoting *Ariad*, 598 F.3d at 1351).

Further, “a description that merely renders the invention obvious does not satisfy the [written description] requirement.” *Ariad*, 598 F.3d at 1352. Put another way, the specification must “describ[e] the *invention*, with all its claimed limitations, not that which makes [the invention] obvious.” *Lockwood v. Am. Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997) (emphasis in original). And the Federal Circuit has made it clear that “the specification must present each claim as an ‘integrated whole,’” and that “pointing to an ‘amalgam of disclosures’

from which an artisan could have created the claimed invention does not satisfy this requirement.” *Flash-Control, LLC v. Intel Corp.*, 2021 WL 2944592, at *3 (Fed. Cir. July 14, 2021) (quoting *Novozymes A/S v. DuPont Nutrition Biosciences APS*, 723 F.3d 1336, 1349 (Fed. Cir. 2013)).

2. The Specification Does Not Convey to a POSA that the Inventors Possessed the Claimed Invention as of the Priority Date

As explained above, all Asserted Claims broadly encompass photodynamically diagnosing a patient with the claimed illuminator using a broad range of wavelengths of light, types and amounts of photoactivating agents, and light fluences and doses. *Supra* V.B.2.a. Accordingly, the Asserted Claims encompass a broad genus of dermatological conditions, wavelengths of light, types and amounts of photoactivating agents, and light fluences and doses. *Id.* The specification, however, does not demonstrate that the inventors *possessed* this broad genus, as discussed above. *Id.*

One way to show possession of a broad genus, like the Asserted Claims, is by pointing to “a representative number of species falling within the scope of the genus.” *Ariad*, 598 F.3d at 1350. But as explained above, the specification does not include a *single* example of using the claimed illuminator to photodynamically diagnose a patient. *Supra* V.B.2.b. At most, the specification discloses a narrow set of photodynamic diagnostic parameters that were already known in the prior art, and were useful only for a small number of dermatological conditions. *Id.* That can hardly be considered a representative number of species relative to the broad genus that Sun Pharma elected to claim in the Asserted Patents. And as the Federal Circuit has explained, “a description that merely renders the invention obvious does not satisfy the [written description] requirement.” *Ariad*, 598 F.3d at 1352.

Another way to show possession of a genus claim is to disclose “structural features common to the members of the genus so that one of skill in the art can ‘visualize or recognize’ the

members of the genus.” *Juno*, 10 F.4th at 1335 (quoting *Ariad*, 598 F.3d at 1351). Again, the specification falls short of this requirement. For example, it vaguely refers to using the claimed illuminator to “diagnose several types of ailments in or near the skin or other tissues, such as those in a body cavity.” ’512 patent at 1:24-27. And it reiterates that various wavelengths of light across the range of 400-700 nm, different types and amounts of photoactivating agents, and ranges of light fluences and irradiances can be used. *See, e.g.*, ’512 patent, 3:66-4:22, 8:39-63, 9:53-10:10.. But the specification does not point to any specific parameters or variables to apply when using the claimed illuminator to photodynamically diagnose a patient. That amounts to a failure of “the specification [to] present each claim as an ‘integrated whole.’” *Flash-Control*, 2021 WL 2944592, at *3 (quoting *Novozymes*, 723 F.3d at 1349). Rather, the specification “point[s] to an ‘amalgam of disclosures’ from which an artisan could have created the claimed invention,” which “does not satisfy [the written description] requirement.” *Id.*

Indeed, Dr. Ehrenreich testified, and the evidence will show, that the specification of the Asserted Patents does not convey to a POSA that the inventors possessed what the patents claim. RX-0007C, Q/A 346-356. For example, Dr. Ehrenreich explained that there are likely thousands of species within the genera of the Asserted Claims, but the specification at most includes cursory references to prior art methods for photodynamically diagnosing a patient. RX-0007C, Q/A 349-350. And Dr. Ehrenreich testified that where the specification does discuss factors and issues relevant to photodynamic diagnosis, it fails to explain how each of those variables should be applied to any particular dermatological condition or disease, except for those that were known in the prior art. RX-0007C, Q/A 351-353. Finally, as Dr. Ehrenreich explained, the patents that are incorporated by reference in the specification of the Asserted Patents render the treatment and diagnosis aspects of the Asserted Claims obvious—but that does not mean that they satisfy the

written description requirement. RX-0007C, Q/A 354. One only need compare the heavy reliance Sun Pharma has placed on third-party disclosures to prop up their weak enablement position in *Wands* factor related to third-part, CX-0013C.29-40, Q/A105-148, to the sparse disclosure in the specification to see that the inventors were not in possession of the full scope of the claims.

Accordingly, the Asserted Claims are invalid because the specification does not demonstrate to a POSA that the inventors possessed the subject matter recited in the Asserted Claims.

VI. DOMESTIC INDUSTRY – TECHNICAL PRONG

Sun Pharma has asserted that the BLU-U® 4170E practices, or has been used according to, claims 1, 2, 4, 5, 8, 19, and 20 of the '512 patent and claims 1, 3, 4, 5, 7, 9, 16–18, 21 of the '028 patent. As discussed below, Sun Pharma has failed to produce evidence in this Investigation that demonstrates that the BLU-U® 4170E practices, or has been used according to, these claims of the Asserted Patents.

A. Legal Standards

Section 337 requires that the complainant establish that a domestic industry relating to the articles protected by the Asserted Patents exists or is in the process of being established. 19 U.S.C. § 1337(a)(2). There are two prongs to the domestic industry requirement—the technical prong and the economic prong. 19 U.S.C. § 1337(a)(2)–(3); *see also InterDigital Communications, LLC v. Int’l Trade Comm’n*, 707 F.3d 1295, 1298 (Fed. Cir. 2013).

“For the technical prong, the question ‘is essentially same as that for infringement, *i.e.*, a comparison of domestic products to the asserted claims.’” *Lashify, Inc. v. Int’l Trade Comm’n*, 130 F.4th 948, 954 (Fed. Cir. 2025) (quoting *Alloc, Inc. v. Int’l Trade Comm’n*, 342 F.3d 1361, 1375 (Fed. Cir. 2003)). “In other words, the technical prong requires proof that the patent claims cover the articles of manufacture that establish the domestic industry. Put simply, the complainant

must practice its own patent.” *Crocs, Inc. v. Int’l Trade Comm’n*, 598 F.3d 1294, 1307 (Fed. Cir. 2010).

“The relevant date at which to determine whether the domestic industry exists or is in the process of being established is the filing date of the complaint.” *Certain Televisions, Remote Controls, & Components Thereof Comm’n Opinion*, Inv. No. 337-TA-1263, Comm’n Op. at 20 (Nov. 30, 2022) (citing *Motiva, LLC v. Int’l Trade Comm’n*, 716 F.3d 596, 601 n.6 (Fed. Cir. 2013)). Further, “a schematic or source code” is not necessarily “sufficient to show a domestic industry in the process of being established for technical prong purposes.” *Certain Televisions, Remote Controls, & Components Thereof*, Comm’n Op. at 15. “What is required will depend on a number of factors, including the type of article and the patent claims at issue.” *Id.*

1. The Domestic Industry Claims

As noted above, Sun Pharma has asserted that the BLU-U[®] 4170E practices, or has been used according to, claims 1, 2, 4, 5, 8, 19, and 20 of the ’512 Patent and claims 1, 3, 4, 5, 7, 9, 16–18, 21 of the ’028 Patent (“the Asserted DI Claims”). Like the claims that Sun Pharma has asserted against Biofrontera, the Asserted DI Claims include both “method” and “system” claims.

For example, claims 8 and 19 of the ’512 patent and claims 5, 7, and 9 of the ’028 Patent recite “[a] method for photodynamically diagnosing or treating a patient.” ’512 Patent, claims 8, 19; ’028 Patent, claims 5, 7, and 9. As Sun Pharma and its experts have acknowledged, these “method” claims can only be practiced when a healthcare provider uses the claimed “illuminator” to photodynamically diagnose or treat a patient according to the method steps recited in the bodies of the claims. *See, e.g.*, CX-0010C.37, Q/A 175-176; CX-0009C.4, Q/A 3.

Further, claims 1, 2, 4, 5, and 20 of the ’512 patent and claims 1, 3, 4, 16-18, and 21 of the ’028 patent recite “[a] system for photodynamically diagnosing or ***treating a patient.***” ’512 patent, claims 1, 2, 4, 5, and 20; ’028 patent, claims 1,3, 4, 16-18, and 21. While these claims do not recite

a “method” on their face, the claim construction opinion in this Investigation explained that the “system” claims “refer to a ‘treatment surface’” in the body of the claims. Order No. 18, 29. “By using these words, the claims specify that the system is used for treating (or diagnosing) a patient.” *Id.* ALJ Moore concluded by explaining that “this is not a case in which the intention is only expressed in the preamble itself, but it is instead woven throughout the claims.” *Id.* Thus, as Dr. Ehrenreich testified, the system claims of the Asserted Patents also require the presence of a patient’s treatment surface and performance of certain actions relative to that treatment surface in the real world, like the method claims. *See, e.g.*, RX-0011C.0018-19, Q/A 66-68.

Accordingly, to satisfy the technical prong requirement, Sun Pharma must establish that the BLU-U[®] 4170E has been used for “photodynamically diagnosing or treating a patient.” Merely establishing that the BLU-U[®] 4170E meets the structural limitations of the Asserted DI Claims is not “sufficient to show a domestic industry in the process of being established for technical prong purposes.” *Certain Televisions, Remote Controls, & Components Thereof*, Inv. No. 337-TA-1263, Comm’n Op. at 13-15 (holding that complainant failed to satisfy the domestic industry, technical prong requirement because complainant’s “mere assertion” that its product “will practice the patent” in the future was not supported by sufficient evidence).

2. Sun Pharma Has Not Established that the BLU-U[®] 4170E Has Been Used to Photodynamically Diagnose or Treat a Patient

As of June 2024, when the Complaint was filed in this Investigation, Sun Pharma had received FDA approval to market the BLU-U[®] 4170E device on its own, not in combination with Levulan[®], for treatment of acne vulgaris. CX-0205.2. On May 1, 2025, the FDA approved the use of the BLU-U[®] 4170E in combination with Levulan[®]. CX-1343.1. However, as of the time this prehearing brief was filed, and as the evidence will show, Sun Pharma has not produced any

evidence that shows that the BLU-U[®] 4170E has been used to photodynamically diagnose or treat a patient according to the steps and other requirements recited by the Asserted DI Claims.

For example, Drs. Shmuylovich and Jokerst testified that they “understand” from Scott Lundahl, Sun Pharma’s Vice President of Regulatory Affairs and Intellectual Property, that the BLU-U[®] 4170E was used to treat a patient in combination with Levulan[®]. CX-0009C.15; CX-0010C.22-23. Scott Lundahl’s testimony on this issue was that “patients with actinic keratosis have already been treated using the BLU-U[®] 4170E device, in accordance with its operating manual, and in combination with Levulan[®] Kerastick[®] in the United States. Patients will continue to be treated by using the BLU-U[®] 4170E device, in accordance with its operating manual, and in combination with Levulan[®] Kerastick[®] in the future.” CX-0011C (Lundahl WS) Q/A 170. But no underlying evidence was offered to support this testimony: no documents, no video, and not even details in Mr. Lundahl’s testimony about where and when the alleged treatment occurred, how many patients were treated, or who the treating physicians were. More fundamentally, even if the Commission were to accept Mr. Lundahl’s unsupported testimony at face value, none of Sun Pharma’s fact or expert witnesses have testified that the BLU-U[®] 4170E was used according to all of the limitations recited in the Asserted DI Claims. *See, e.g.*, RX-0011C.0052, Q/A 195-196.

Accordingly, Sun Pharma has failed to establish with evidence that the BLU-U[®] 4170E device has been used to photodynamically diagnose or treat a patient according to the requirements of the Asserted DI Claims.

VII. DOMESTIC INDUSTRY – ECONOMIC PRONG²⁶

²⁶ Sun Pharma has only claimed expenses under subsections (B) and (C). CX-0016C (Vander Veen WS) Q/A 66. It has not claimed the existence of a domestic industry or a domestic industry in the process based on investments in plant and equipment under subsection (A).

Sun Pharma's attempt to satisfy the economic prong requirement is based on minimal, stale, hypothetical, and insignificant expenses related to a single DI Product that was not on sale at the time of the filing of the Complaint and is still not on sale. The record evidence exposes several fatal flaws in Sun Pharma's domestic industry claims. *First*, Sun Pharma's claimed investments are exaggerated; Sun Pharma includes a future payment to a third party manufacturer for products it has yet to receive, and decade-old payments to a third party R&D contractor. These non-cognizable expenditures account for over 50% of Sun Pharma's claimed investments. Sun Pharma's remaining claimed investments are mainly composed of payments to third parties, which have also decreased over the past few years. Such investments cannot be relied on to show the presence of a domestic industry at the time of the Complaint, or even one in the process of being established. Sun Pharma will also fail to show that its claimed investments satisfy the nexus requirement of subsection (C). Neither Sun Pharma, nor its expert Dr. Vander Veen, explained the nature of the claimed R&D and regulatory labor investments or their nexus to the Asserted Patents.

Sun Pharma's BLU-U[®] 4170E investments, when properly accounted for, are neither significant nor substantial. Its claimed investments are small by Sun Pharma's own admission and even smaller when compared to Sun Pharma's investments in its other products. Sun Pharma attempts to mask this fact by comparing its investments to less meaningful benchmarks, such as the revenue of Sun Pharma's existing PDT lamp and a preliminary budget for Biofrontera investments. Accordingly, the ALJ should find that Sun Pharma has not satisfied the economic prong of the domestic industry requirement.

A. Legal Standard

To establish a violation of Section 337, complainant must prove that a domestic industry relating to each asserted patent exists. 19 U.S.C. § 1337(a)(2). The statute provides that

“an industry in the United States shall be considered to exist if there is in the United States, with respect to the articles protected by the patent . . . concerned-

- (A) Significant investment in plant and equipment;
- (B) Significant employment of labor or capital; or
- (C) Substantial investment in its exploitation, including engineering, research and development, or licensing.”

19 U.S.C. § 1337(a)(3).

Complainant bears the burden of showing it has satisfied the economic prong of the domestic industry. The relevant date for determining the existence and sufficiency of the economic prong of domestic industry is the date of the filing of the Complaint. *See, e.g., Hyosung TNS Inc. v. ITC*, 926 F.3d 1353, 1361 (Fed. Cir. 2019) (citing *Motiva v. ITC*, 716 F.3d 596, 601 n.6 (Fed. Cir. 2013)); *Certain Display Controllers with Upscaling Functionality & Prods. Containing Same*, Inv. No. 337-TA-481, Order No. 27, at 5 (Apr. 28, 2003) (citing *Bally/Midway Mfg. Co. v. USITC*, 714 F.2d 1117, 1122 (Fed. Cir. 1983)). Investments made years prior to the complaint do not count towards proving the existence of a domestic industry without proof of ongoing investments. *See Certain Video Games Systems & Controllers*, Inv. No. 337-TA-743, Initial Determination at 164 (Dec. 8, 2011) *reviewed and affirmed*, Comm’n Op. (Jan. 20, 2012) (declining to count investments in domestic industry product R&D which had occurred 3.5 years before the filing of the complaint); *Certain Television Sets, Television Receivers, Television Tuners, & Components Thereof*, Inv. No. 337-TA-910, Comm’n Op. at 74 (Oct. 30, 2015) (noting that past investments cannot suffice to show that a domestic industry currently exists if the only ongoing investments are non-cognizable).

Qualitative and quantitative factors must both be considered in evaluating whether the economic prong is satisfied under 19 U.S.C. § 1337(a)(3)(A), 19 U.S.C. § 1337(a)(3)(B), and/or 19 U.S.C. § 1337(a)(3)(C). *See generally Lelo Inc. v. ITC*, 786 F.3d 879 (Fed. Cir. 2015). The alleged investments must be “significant” under 19 U.S.C. § 1337(a)(3)(A) or (B), or “substantial”

under 19 U.S.C. § 1337(a)(3)(C) when viewed in context. *See Certain Printing & Imaging Devices & Components Thereof*, Inv. No. 337-TA-690, Comm’n Op. at 26- 28 (Feb. 17, 2011) (commenting that complainant’s investment in plant and equipment must be shown to be “significant in relation to the article protected by the intellectual property right concerned,” including considering domestic value added, comparative domestic contribution relative to product-related foreign activities) *see also Certain Carburetors & Prods. Containing Such Carburetors*, Inv. No. 337-TA-1123, Comm’n Op. at 17 (Oct. 28, 2019) (“[Complainant’s] reliance on the numerical amounts, which the ID refers to as ‘absolute values,’ of its domestic investments fails to evaluate significance based on any context of [Complainant’s] operations, the marketplace, or the industry in question”). However, the Federal Circuit has expressly held that “qualitative factors alone are insufficient to show ‘significant investment in plant and equipment’ and ‘significant employment of labor or capital’ under prongs (A) and (B)...” *Lelo Inc.*, 786 F.3d at 884-85. Investments are not significant or substantial when they make up only a small percentage of the complainant’s operations. *Certain Electronic Candle Prods. & Components Thereof*, Inv. No. 337-TA-1195, Remand Initial Determination at 16, 18 (Dec. 29, 2021) (noting that no “complainant has satisfied the domestic industry requirement based on research and development expenditures that are only 6% of net sales”). Nor are investments likely significant when they do not relate to patented features of the product. *Id.* at 18 (“The activities performed by L&L and Sotera Design in the United States are related to the aesthetics of the DI Product—not the patented features.”).

To satisfy the economic prong under 19 U.S.C. § 1337(a)(3)(C), Complainant must additionally show that there is a nexus between the alleged R&D or licensing investments and the asserted patent. *Certain Non-Volatile Memory Devices & Prods. Containing the Same* (“Non-

[REDACTED]

Volatile Memory Devices”), Inv. No. 337-TA-1046, Comm’n Op. at 41 n.11 (Oct. 26, 2018) (citing 19 U.S.C. § 1337(a)(3)(C)); *Certain Integrated Circuit Chips & Prods. Containing the Same*, Inv. No. 337-TA-859, Comm’n Op. at 32 (Aug. 22, 2014)). In order to fulfill this nexus requirement “[t]he Commission routinely requires a connection or relationship between investment and the patents asserted in that particular investigation, rather than surrogates of the patents.” *Certain Digital Video-Capable Devices & Components Thereof*, Inv. No. 337-TA-1224, Initial Determination at 159 (Oct. 21, 2021) (rejecting allocation to “patent families” as a surrogate for allocation to asserted patents) *unreviewed*, Comm’n Op. (Apr. 26, 2022).

B. Sun Pharma Relies on Expenditures Which Have Not Materialized, Stale Investments, And Dwindling Third-Party Expenditures

The evidence will show that Sun Pharma’s claimed investments in its unreleased BLU-U® 4170E product are overinclusive, as they contain expenses which Sun Pharma has not paid, expenditures nearly a decade old, and decreasing payments to third parties

1. Sun Pharma Inappropriately Attempts to Claim Expenditures which have not Materialized

The evidence will show that Sun Pharma attempts to claim [REDACTED] from a purchase order with a third-party contract manufacturer for the BLU-U® 4170E, [REDACTED]. And the evidence will further show that this [REDACTED] order to [REDACTED] encompasses a substantial part of Sun Pharma’s total claimed investments, specifically, approximately one-third of Dr. Vander Veen’s overall estimates for claimed investments in the BLU-U® 4170E. RX-0010C (Rowe Rebuttal WS) Q/A 21; see RX-0014C (Vander Veen Expert Rpt.), Tab 3b.

However, the evidence will show that, at the time of filing the Complaint, and even today, [REDACTED]. This purchase order pertains to the manufacture of [REDACTED] BLU-U® 4170E devices, supposedly to be delivered during [REDACTED] through [REDACTED]. JX-0103C (Sun Pharma Purchase Order). Sun Pharma claimed an April 2025

[REDACTED]

launch date for the BLU-U[®] 4170E, however, the product is not yet on sale. The evidence will show that Sun Pharma has paid [REDACTED] in the purchase order to [REDACTED] and has received none of the units in the order. CX-0011C, Q/A 185-186; JX-0017C (Lundahl Dep. Tr.) 93:6-8; RX-0010C, Q/A 21; *see* Sun Pharma's Mot. for Summary Determination at 33 (Mot. No. 1411-013).

Over the course of this Investigation Sun Pharma has provided no cites to any precedent for its argument that it can claim amounts that it has not invested (*i.e.*, paid) for products which have not been delivered. And the evidence will show that Sun Pharma is unlikely to need additional large purchase orders from Cogmedix. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]).

i. Sun Pharma's Alleged Investments Include Stale Investments Which Should not be Considered to show the Existence of a Domestic Industry or One in the Process of Being Established

Sun Pharma cannot claim stale investments which dwindled years ago to establish a domestic industry or a domestic industry in the process of being established. The evidence will show that in 2016, nine years ago, Sun Pharma began paying a third-party [REDACTED] to assist with the development of an LED version of Sun Pharma's BLU-U[®] 4170 lamp. Sun Pharma's Mot. for Summary Determination (Mot. No. 1411-013) at 22; CX-0016C, Q/A 102-103; RX-0014C, Tab 3b.

Investments made years prior to the Complaint do not count towards proving the existence of a domestic industry, especially where there is also no proof of ongoing investments. *See Certain Video Games Systems & Controllers*, Inv. No. 337-TA-743, Initial Determination at 164 (declining

[REDACTED]

to count investments in domestic industry product R&D which had occurred 3.5 years before the filing of the complaint). Sun Pharma's claimed payments to [REDACTED] occurred up to eight years prior to the filing of the Complaint, which is significantly longer than the 3.5-year difference between expenditure and complaint in *Certain Video Games Systems*. And the investments have not continued (and they have in fact significantly declined over time). While Sun Pharma paid [REDACTED] six years ago in 2018, Sun Pharma only paid [REDACTED] in 2023. CX-0016C, Q/A 104; RX-0014C, Tab 3b.

Sun Pharma has made no attempt to explain how these investments, which form a significant part of Sun Pharma's claimed investments, are indicative of a domestic industry at the time of the Complaint. As Ms. Rowe will testify, these investments, made years ago, do not bear on the existence of a domestic industry at the time of the filing of the Complaint. RX-0010C, Q/A 34-36. Ms. Rowe will further testify that Sun Pharma's payments to [REDACTED] constitute [REDACTED] of Sun Pharma's total claimed domestic industry investments. See RX-0014C, Tab 3b ([C] / [Total]); RX-0010C, Q/A 33. And removing Sun Pharma's purchase order to [REDACTED], which Sun Pharma has paid no part of, raises this percentage to [REDACTED] of Sun Pharma's claimed domestic industry investments over the last nine years. See RX-0014C, Tab 3b. Therefore, the [REDACTED] payments represent a large portion of Sun Pharma's total claimed investments. These old investments are not cognizable and Sun Pharma cannot satisfy the domestic industry requirement on the basis of these investments.

ii. *Sun Pharma's Decreasing Investments in Third-Party Contractors are not Cognizable*

Sun Pharma relies on decreasing investments in third parties and fails to adequately explain how the work of these third parties relates to the Domestic Industry Product, the BLU-U[®] 4170E device. The evidence will show that Vander Veen includes various payments to third

parties in his expert report, including [REDACTED]

[REDACTED] for regulatory, labor, equipment, and testing services, and is expected to testify to the same at the hearing. CX-0016C, Q/A 55, 176; RX-0010C, Q/A 16-17. But Biofrontera will show that Sun Pharma has not produced adequate evidence to indicate the nature of each entity's work and its alleged connection to the BLU-U[®] 4170E device. *Id.* Furthermore, the evidence shows that these investments are generally declining, as seen in Sun Pharma's investments in "other United States contractors" falling from [REDACTED] in 2022 to [REDACTED] in 2024. RX-0014C, Tab 4e. The ALJ should afford these investments less weight as their declining nature suggests that these payments will not continue.

iii. *Sun Pharma Has Failed to Establish a Nexus Between its Claimed Investments and the Asserted Patents*

Sun Pharma will not be able to show a nexus between its claimed investments in the BLU-U[®] 4170E and the Asserted Patents, which is required under subsection (C). The language of Section 337 related to the economic prong differentiates between subsection (A) and (B) investments, which may simply be investments in "plant and equipment" or "labor or capital" and subsection (C) investments, which must be investments in "its exploitation, including engineering, research and development, or licensing." 19 U.S.C. § 1337(a)(3) (emphasis added). In this context, the word "its" refers to "the asserted patent or other intellectual-property right being asserted" and not "the articles protected by the patent." *See Certain Computer & Computer Peripheral Devices & Components Thereof & Prods. Containing the Same*, Inv. No. 337-TA-841, Comm'n Op. at 36 (Jun. 23, 2015) (emphasis in original); *see also Certain Microcomputer Memory Controllers, Components Thereof & Prods. Containing Same*, Inv. No. 337-TA-331, Order No. 6, 1992 WL 811299, at *2 (Jan. 8, 1992), *not reviewed*, 57 Fed. Reg. 5710 (Feb. 12, 1992); *see also InterDigital*

Commc'ns, 707 F.3d at 1297 (“The parties agree that the word ‘its’ in the last clause of paragraph 337(a)(3) refers to the intellectual property at issue.”).

Based on these differences in the statutory language, it is black letter Commission law that “an investment in the article is not automatically an investment in the asserted patent.” *Certain Integrated Circuit Chips & Prods. Containing the Same*, Inv. 337-TA-859, Comm’n Op. at 49 (Aug. 22, 2014). Indeed, permitting subsection (C) investments that are investments in products and not in the asserted patent “would impermissibly read out of subparagraph (a)(3)(C) the ‘its.’” *See id.* It is this statutory language that underpins the nexus requirement: in order to proceed under subsection (C), a complainant must show that its proffered investments have a nexus to the asserted patent, not simply a nexus to the protected articles generally. *See Certain Dynamic Sequential Gradient Compression Devices & Component Parts Thereof*, Inv. No. 337-TA-335, Comm’n Op., Pub. No. 2575 (EDIS Doc. ID 217027), at 64-65 (Nov. 1992) (“While it is not necessary that a particular research and development project result in a completed product to be considered part of the relevant domestic industry, it must be clear that the project is devoted to the exploitation of the patent.”); *see also Certain Wearable Electronic Devices with ECG Functionality & Components Thereof*, Inv. No. 337-TA-1266, Comm’n Op. at 12-13 (Jan. 20, 2023).

Yet Sun Pharma has not made any arguments that its claimed investments have a nexus to the Asserted Patents. The burden is on Sun Pharma to satisfy the nexus requirement, yet, Dr. Vander Veen will testify that the Domestic Industry product “cover the main features of the BLU-U® 4170E device,” so there is a nexus. CX-0016C, at Q/A 226; RX-0010C, Q/A 42. Simply stating that the claimed investments are related to a product practicing the Asserted Patents is insufficient to satisfy the nexus requirement. *Certain Integrated Circuit Chips & Prods. Containing the Same*, Inv. 337-TA-859, Comm’n Op. at 49. Therefore, the ALJ should

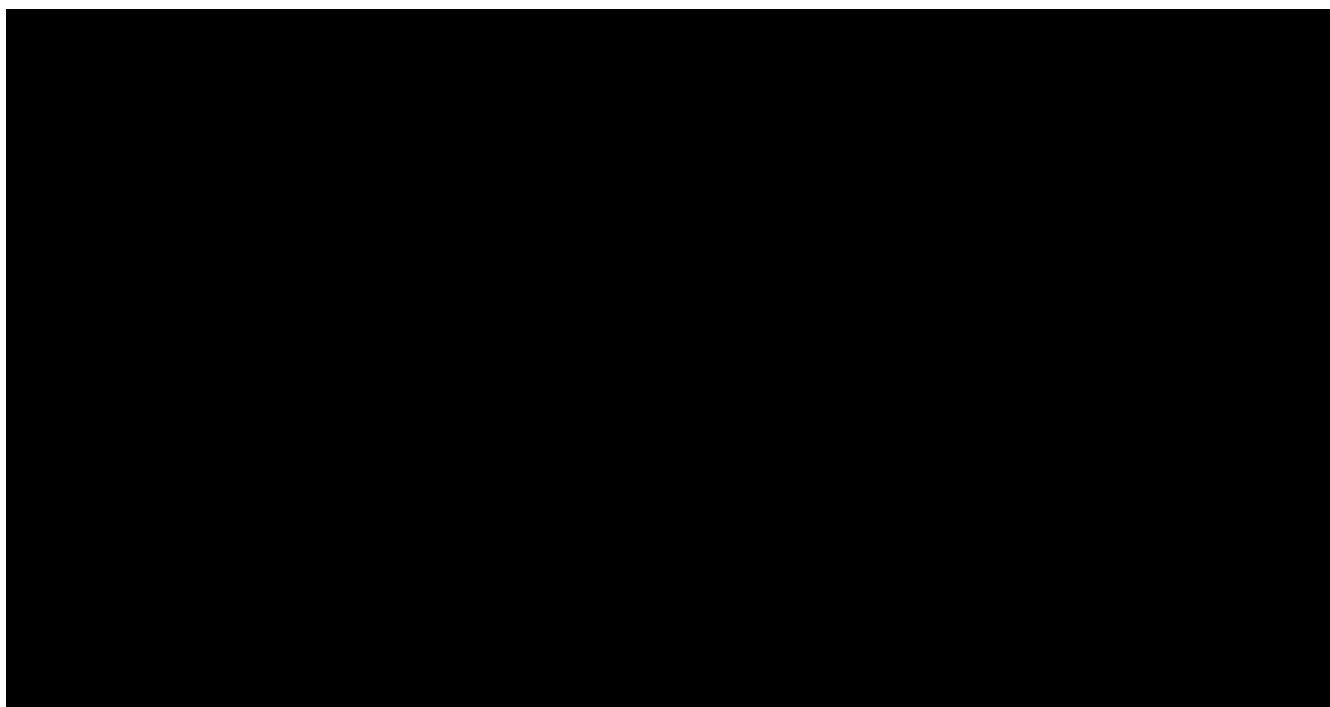
not find that Sun Pharma has satisfied subsection (C) of the domestic industry requirement because it failed to show a nexus between the claimed investments and Asserted Patents.

C. Sun Pharma's Claimed Investments Are Not Significant or Substantial

Even if Sun Pharma's claimed investments were not in dispute, they are neither significant nor substantial. The evidence will show that Sun Pharma's investments in the unreleased BLU-U® 4170E are meager compared to its investments in other products, including its average investment in R&D of its products. Sun Pharma's proposed contextual analysis ignores this and attempts to replace it with meaningless benchmarks.

1. Sun Pharma's Investments are not Qualitatively Significant or Substantial in Relation to the Rest of Sun Pharma's Expenditures

The evidence will reveal that Sun Pharma's claimed investments are small and insignificant when compared to expenditures in other Sun Pharma products, namely the current BLU-U® 4170 device and Levulan®. The following chart summarizes the amounts Sun Pharma claimed related to each product:

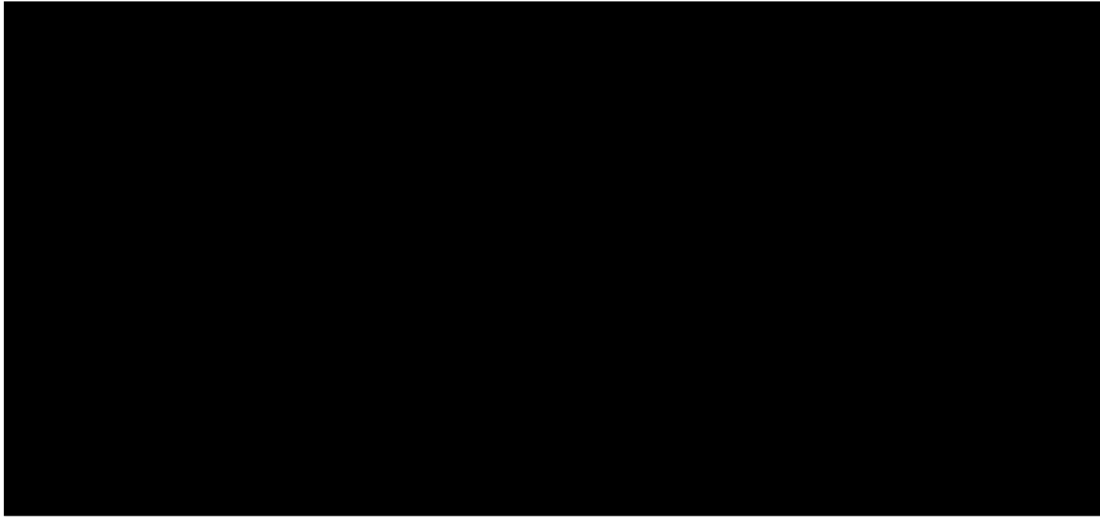


[REDACTED]

RX-0010C, Q/A 49-52; RX-1393C (Rowe Rebuttal Rpt. Ex. 1); JX-0239C (Sun Employee Salaries). The evidence will show that, overall, Sun Pharma records document [REDACTED] in internal labor costs allocated to the BLU-U[®] 4170 and [REDACTED] in internal labor costs allocated to Levulan[®]. RX-0010C, Q/A 50; RX-1393C. The evidence will further show that the [REDACTED] Dr. Vander Veen claims for the domestic industry product, the BLU-U[®] 4170E, comprised approximately [REDACTED] of the total investments in these other PDT products. RX-0010C, Q/A 50; RX-1393C. Said differently, Sun Pharma invested approximately [REDACTED] times more in labor for PDT products that were *not* the domestic industry product than it did in labor for the BLU-U[®] 4170E.

The evidence will indicate that Sun Pharma indeed fails to compare R&D on the BLU-U[®] 4170E device to the R&D for Levulan[®]. Even though Levulan[®] was approved by the FDA in 1999 and has been on the market for more than 20 years, the evidence will indicate that [REDACTED] [REDACTED] for the BLU-U[®] 4170E device in each year analyzed by Dr. Vander Veen. RX-0010C, Q/A 50; RX-1393C; RX-0014C, Tab 4e, Tab 7.

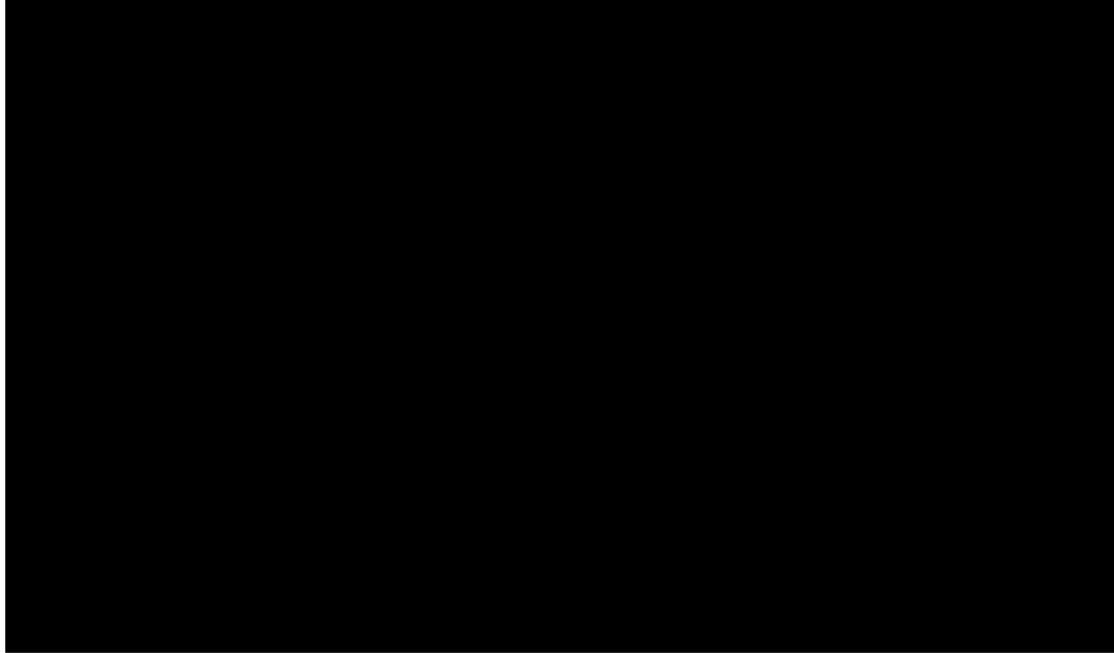
These comparisons grow increasingly unfavorable to Sun Pharma. Julia Rowe is expected to testify that the R&D for the BLU-U[®] 4170E averaged just [REDACTED] of Sun Pharma's company-wide R&D costs. RX-0010C, Q/A 56; RX-1394C (Rowe Rebuttal Rpt. Ex. 2). Sun Pharma has not compared the amounts quantified for the R&D of the BLU-U[®] 4170E device to Sun Pharma's total revenues. This comparison is provided below:



RX-0010C, Q/A 58-59; RX-1394C. As shown in the foregoing table, R&D for the BLU-U® 4170E averaged less than [REDACTED] of Sun Pharma's company-wide revenues. RX-0010C, Q/A 58; RX-1394C. Evidence will show that Sun Pharma's parent company invests "up to 6-8% of our global revenues into Research and Development (R&D) every year." JX-0043 ("About Us" Sun Pharma Website). Proportionally, Sun Pharma's alleged investments in R&D for BLU-U® 4170E are much lower than Sun Pharma's company-wide benchmark.

The evidence will show that Sun Pharma's claimed investments in labor for the BLU-U® 4170E are also insubstantial when compared to all PDT labor costs: Sun Pharma's labor costs from April 2021 to June 2024, including corporate functions, customer service, marketing, R&D and regulatory are shown below:

**Summary of Sun Pharma Internal Labor Costs
Allocated to PDT By Sun Pharma
April 1, 2021 through June 25, 2024¹⁸⁶**



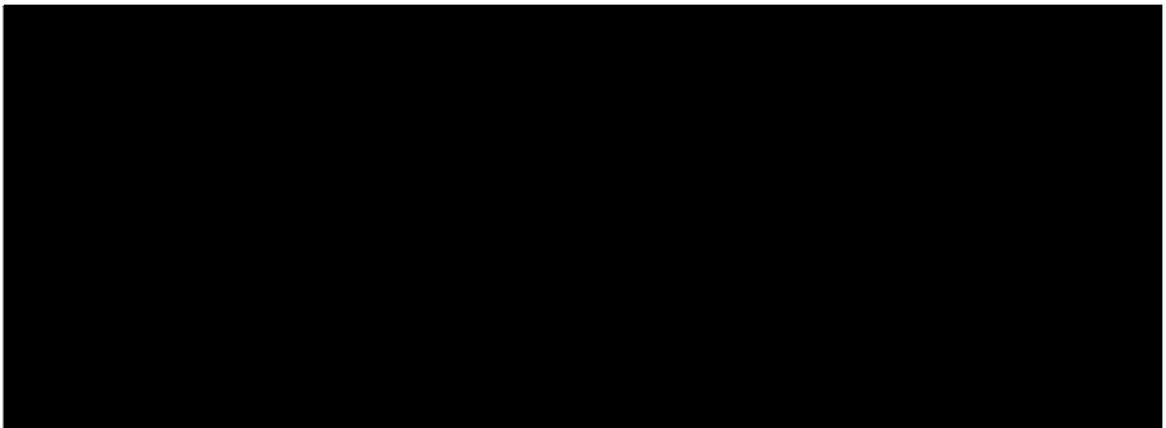
RX-0010C, Q/A 62-63; RX-1393C; JX-0239C. The amounts above reflect the labor costs Sun Pharma allocated to PDT. RX-0010C, Q/A 63; RX-1393C. Ms. Rowe will testify that the amount Sun Pharma claims to have invested in internal labor for the BLU-U® 4170E device comprised less than [REDACTED] of Sun Pharma's total internal costs for employees allocated to PDT. RX-0010C, Q/A 63; RX-1393C. This amount would be even lower if it included all Sun Pharma internal costs.

2. Sun Pharma's Attempts to Show Significance Fail

Sun Pharma attempts to mask this fact by comparing its investments to less meaningful benchmarks, such as revenue of Sun Pharma's existing PDT lamp and a preliminary budget for Biofrontera investments.

First, Sun Pharma's comparison of its claimed BLU-U[®] 4170E investments to its BLU-U[®] 4170 revenue is inapposite. The evidence will show that the BLU-U[®] 4170E is not yet sold, so there are no revenues to serve as a benchmark. And the testimony of several witnesses will show that the PDT market, the sale of lamps is not *intended* to produce much revenue, rather, they serve to "enhance the sales of the related pharmaceutical drugs, Levulan and Ameluz," as Dr. Vander Veen will testify at the hearing. CX-0016C, Q/A 235; RX-0014C, ¶ 92; JX-0017C, 146:14-19 (explaining that profits on lamps are not high: "when it comes to photodynamic therapy devices in the U.S., the basic rule is that you need to sell at cost or above. [REDACTED] [REDACTED]"); JX-0008C, 141:16-20 ("The lamp isn't a business, as you know. The pharmaceutical is the business."). Therefore, the investment to revenue ratio for the BLU-U[®] 4170E lamp, and indeed, any PDT lamp, would be unnaturally inflated due to the business model for this treatment. The evidence will show that when the revenue of Levulan[®], the product intended to generate revenue, is compared to Sun Pharma's alleged investments, the ratio is much less favorable. The alleged BLU-U[®] 4170E investments comprised approximately [REDACTED] of sales of Levulan[®] and BLU-U[®] 4170. This is shown below:

**Sun Pharma's Alleged Investments As A
Percent Of Levulan[®] and BLU-U[®] 4170 Revenues²⁰³**



[REDACTED]

RX-0010C, Q/A 58-59; RX-1394C. Given the business model of the PDT market is to sell the lamps near cost and generate revenue through sales of the related pharmaceutical product, the above analysis is a more accurate reflection of Sun Pharma's actual investment to revenue ratio. And this analysis suggests that Sun Pharma's investments are not significant.

Second, Biofrontera will show that Sun Pharma's comparison to Biofrontera is baseless. Biofrontera does not argue that it has established a domestic industry in the United States; that is Sun Pharma's burden. To the extent that Sun Pharma argues that this is a relevant comparison because Sun Pharma and Biofrontera are the only providers of PDT treatment, that would also be incomplete as there are other treatments for AK. For example, Dr. Luebbert will testify that the biggest competitor to PDT in the AK market is cryotherapy, with PDT occupying only 2% of the market. RX-0010C, Q/A 71; JX-0080C (Biofrontera Commercial Plan); RX-0004C Q/A 133-135; JX-0008C, 48:9-22. Sun Pharma has provided no analysis as to whether its investments are significant compared to the broader AK market. Finally, even if relevant, the figure that Sun Pharma cites for Biofrontera's development costs for the RhodoLED® XL is misleading and understated. JX-0011C, 79:5-80:10 ([REDACTED])

[REDACTED]; CX-0145C (R&D and Technical Operations Budget). Therefore, Sun Pharma's comparison of its investments to Biofrontera is not a basis to find its investments significant or substantial.

D. Sun Pharma has Failed to Show that there is a Domestic Industry in the Process of Being Established

Sun Pharma relies on the same investments to show a domestic industry at the time of filing of the Complaint that it relies on to argue that there is a domestic industry in the process of being established. Therefore, Sun Pharma fails to show a domestic industry in the process for the

[REDACTED]

same reasons it failed to show a domestic industry at the time of the Complaint, as detailed above.

It is undisputed that the BLU-U[®] 4170E has not yet launched. Mr. Lundahl will testify that Sun Pharma planned to launch the BLU-U[®] 4170E device in April 2025. CX-0011C, Q/A 185-186. And he will further testify that by April 2025, the BLU-U[®] 4170E had not received FDA approval. Though it has now received FDA approval, the BLU-U[®] 4170E has yet to launch. And the evidence will indicate that Sun Pharma has received [REDACTED], either. JX-0017C, 93:6-8; CX-0016C, Q/A 36; Sun Pharma's Mot. for Summary Determination at 33 (Mot. No. 1411-013) (admitting that [REDACTED]).

The amount of Sun Pharma's investments upon launch of the BLU-U[®] 4170E are also unknown. The evidence will show that Sun Pharma provided no evidence of planned domestic R&D, manufacturing, customer service, or other costs. What little information there is, in the form of a purchase order, is also uncertain. Sun Pharma's future domestic industry depends on customers replacing the BLU-U[®] 4170 device with the BLU-U[®] 4170E. But there are no certain plans for how, or when, this will occur. And the evidence will show that customer demand for the newer generation of lamps is lower than anticipated. JX-0010C, 68:5-22, 76:9-12. Therefore, Sun Pharma will not show that there is a domestic industry in the process of being established.

VIII. REMEDY AND BONDING

Sun Pharma cannot show that it is entitled to any remedy in this Investigation. Neither a limited exclusion order nor cease and desist order is appropriate as there is no violation of Section 337 because Respondents have not and do not directly or indirectly infringe any valid claim of the Asserted Patents, either literally or under the doctrine of equivalents, or otherwise commit any acts in violation of 35 U.S.C. § 271 or 19 U.S.C. § 1337. Additionally, Sun Pharma will not establish

the existence of a domestic industry for the Asserted Patents as required by Section 337(a)(2) and defined by Section 337(a)(3).

In the event that the Commission finds a violation of Section 337, any remedy, including any limited exclusion order or cease and desist order, issued should identify and be restricted to (1) the specific parties who import into the U.S., sell for importation into the U.S., or sell within the U.S. the specific Accused Products found to infringe the Asserted Claims of the Asserted Patents; and (2) those specific Accused Products found to infringe the Asserted Claims of the Asserted Patents, as the remedy provided must have a “reasonable relation to the unlawful practices found to exist.” *Hyundai Elecs. Indus. Co., Ltd. v. U.S. Int’l Trade Comm’n*, 899 F.2d 1204, 1209 (Fed. Cir. 1990); *see also* 19 U.S.C. § 1337(d). Also, any exclusion order should include a certification provision that “will ease the burden both on legitimate trade and on U.S. Customs’ enforcement of the exclusion order.” *Certain Optoelectronic Devices, Components Thereof, & Prods.* (“*Optoelectronic Devices*”), Inv. No. 337-TA-669, Comm’n Op. at 7 (July 26, 2010); *Certain Road Construction Machines & Components Thereof* (“*Road Construction Machines*”), 337-TA-1088 (Modification) Comm’n Op. at 14 (Sep. 14, 2020) (calling certification provisions “standard” and stating that they have a “longstanding” form). Further, in keeping with Commission precedent, a cease and desist order is not appropriate for any products imported and provided to customers before the issuance of a limited exclusion order. *See Certain Sleep-Disordered Breathing Treatment Systems & Components Thereof* (“*Sleep-Disordered Breathing Treatment Systems*”), Inv. No. 337-TA-890, Comm’n. Op. at 47 (Jan. 16, 2015). Finally, as remedial orders should not affect respondents’ ability to service existing customers’ products, exemptions for warranty and repair are common. *See id*; *see also Certain Digital Video Receivers & Related Hardware & Software Components* (“*Digital Video Receivers*”), Inv. No. 337-TA-1103,

Comm’n Op. at 24 (May 13, 2020) (including an exemption to the remedial order for replacement parts used to repair previously-imported products under warranty).

A. LEO

1. Certification Provision

If an LEO is issued, it should include “the standard certification provision as typically requested by U.S. Customs and Border Protection (“CBP”)” whereby Respondent can certify as to which imported products and/or components are not included within the scope of the order. *Certain Movable Barrier Operator Sys. & Components Thereof* (“*Movable Barriers*”), Inv. No. 337-TA-1209, Comm’n Op. at 68 (Mar. 11, 2022); *Certain Beverage Dispensing Sys. & Components Thereof* (“*Beverage Systems*”), Inv. No. 337-TA-1130, Comm’n Op. at 24-25 (Mar. 26, 2020). Such a certification provision “will ease the burden both on legitimate trade and on U.S. Customs’ enforcement of the exclusion order.” *Optoelectronic Devices*, Inv. No. 337-TA-669, Comm’n Op. at 7; *Road Construction Machines*, Inv. No. 337-TA-1088 (Modification) Comm’n Op. at 14 (calling certification provisions “standard” and stating that they have a “longstanding” form). The evidence will show that, if the Commission issues a remedy, any LEO should contain a certification provision permitting the importation of Ameluz[®] for use with non-Accused Products, including the RhodoLED[®] device, and Accused Products purchased prior to the issuance of any remedy. Ameluz[®] which will not be used with the RhodoLED[®] XL lamp is not within the scope of the Investigation and such a certification provision would be consistent with Sun Pharma’s Complaint. See JX-0198, ¶ 6 (“Sun Pharma does not seek to exclude Biofrontera’s pharmaceutical products that Biofrontera certifies are not being sold for use with Biofrontera’s accused photodynamic therapy treatments.”). The evidence will also show that because the RhodoLED[®] XL is not indicated for use without Ameluz[®], and thus any certification provision should also apply for sales of Ameluz[®] to any customers purchasing a RhodoLED[®] XL before the remedial orders

take effect. Any finding to the contrary would unfairly harm customers who would then have an unusable product. JX-0011C, 29:17-30:9; RX-1176 (Biofrontera AG Receives FDA-Approval of the BF-RhodoLED[®] XL Lamp); JX-0074.1 (Ameluz[®] Label). Remedial relief at the Commission is not intended to punish U.S. consumers that purchased the Accused Products prior to any finding of violation. *Certain Digital Video Receivers & Related Hardware & Software Components*, Inv. No. 337-TA-1103, Initial Determination at 314-15 (Jun. 4, 2019); *see also Sleep Disordered Breathing Treatment Systems*, Inv. No. 337-TA-890, Comm'n Op. at 51 (Dec. 23, 2014).

2. Service & Repair

Any remedial order should narrowly tailor relief to include a service, warranty, and repair exemption provision to prevent disruption for existing customers. *See Movable Barriers*, Inv. No. 337-TA-1209, Comm'n Op. at 67-68. Warranty and repair exemptions, to both LEOs and CDOs, are appropriate where a respondent is obligated to repair or replace defective products. *See id.* at 69-72. They are routinely granted by the Commission under appropriate circumstances. *See, e.g., id.* at 68-69, fn.30; *Certain Motorized Vehicles & Components Thereof*, Inv. No. 337-TA-1132, Comm'n Op. at 34 (Jun 18, 2020); *Digital Video Receivers*, Inv. No. 337-TA-1103, Comm'n Op. at 24 (including an exemption to the remedial order for replacement parts used to repair previously-imported products under warranty). The evidence will show that warranty and repair exemption is appropriate in the present case as Biofrontera provides customers with a three-year warranty which includes replacement, service, and repair. RX-0045C (Blank Purchase Terms and Conditions Agreement); RX-0003C, Q/A 53-55; JX-0007C, 30:4-18. The evidence will show that Biofrontera's warranty covers any issue during the warranty period and that Biofrontera sends its own quality team members or service partners to repair or replace the lamps. RX-0003C, Q/A 53; JX-0022C (Blank Purchase Terms and Conditions Agreement). A unit that is under warranty may either be repaired by Biofrontera or replaced with a new lamp, depending on the issue. RX-0003C,

Q/A 55. Additionally, Biofrontera may ship lamps to Germany to fix damage to the head lamp and would potentially need to use such repaired lamps for warranty purposes. RX-0002C, Q/A 117.

B. CDO

A cease and desist order is “generally issued when there is a ‘commercially significant’ amount of infringing, imported product in the United States that could be sold by an infringing respondent resulting in evasion of the remedy provided by an exclusion order.” *Certain Mobile Devices, Associated Software, & Components Thereof*, Inv. No. 337-TA-744, Comm’n Op. at 24 (June 5, 2012); *Certain High-Density Fiber Optic Equipment & Components Thereof*, Inv. No. 337-TA-1194 Comm’n Op. at 82 (Aug. 23, 2021). “Complainants bear the burden of proving that respondents have commercially significant inventories of infringing products in the United States.” *Sleep-Disordered Breathing Treatment Systems*, Inv. No. 337-TA-890, Comm’n. Op. at 49. The evidence will demonstrate that Biofrontera currently has [REDACTED] RhodoLED® XL lamps in inventory. RX-0003C, Q/A 38. The evidence will also show that Sun Pharma has failed to establish that this is a commercially significant inventory of Accused Product and that a CDO is required.

If the Commission issues a CDO, then it should clarify that the scope of any CDO issued would not include Ameluz®, which is not an Accused Product. As explained above in Section VIII.A.1, Biofrontera should therefore be permitted to sell Ameluz® for non-infringing uses, including with existing customers’ RhodoLED® and RhodoLED® XL lamps.

Furthermore, any CDO should also include an exemption for RhodoLED® XLs and their components used for repair or replacement under Biofrontera's warranty obligations to existing customers. See Section VIII.A.2.

C. BOND

In the event the Commission finds a violation of Section 337, it should impose no bond during the Presidential Review Period. The purpose of a bond is to protect the complainant from

any injury. 19 U.S.C. § 1337(j)(3). The complainant bears the burden of establishing that (i) a bond is necessary to prevent injury and (ii) the proposed bond amount is necessary to offset injury. Long standing precedent makes clear that when a complainant fails to demonstrate that a bond is warranted, the Commission should not impose a bond. *See Certain Magnetic Tape Cartridges & Components Thereof*, Inv. No. 337-TA-1058, Comm’n Op. at 73-74 (Apr. 10, 2019) (imposing zero bond during the Presidential review period where Complainant failed to show a bond is warranted); *Certain Coenzyme Q-10 Prods. & Methods of Making Same*, Inv. No. 337-TA-790, Initial and Recommended Determination (Sept. 27, 2012) (recommending no bond because the complainant “failed in its burden to demonstrate the appropriate bond amount”). Complainant must demonstrate both the need for a bond and a reasonable bond amount “sufficient to protect the complainant from any injury”; and there is no injury, given that Sun Pharma’s BLU-U® 4170E is not even on the market. *Certain Routers, Access Points, Controllers, Network Management Devices, Other Networking Prods. & Hardware & Software Components Thereof (“Routers”)*, Inv. No. 337-TA-1227, Initial Determination at 317-8 (Dec. 7, 2021); *Certain Rubber Antidegradants*, Inv. No. 337-TA-533, Comm’n Op. at 39-40 (July 21, 2006). “When reliable price information is available, the Commission has often set bond by eliminating the differential between the domestic product and the imported, infringing product,” or alternatively, through a “reasonable royalty” to license an asserted patent. *Routers*, Inv. No. 337-TA-1227, Initial Determination at 317 (citing *Certain Magnetic Tape Cartridges*, Inv. No. 337-TA-1058, Comm’n Op. at 73-74). Where the record evidence demonstrates that the average selling price of the Accused Products is greater than the average selling price of the DI Product, the appropriate bond is 0%. *See Certain Access Control Systems & Components Thereof*, Inv. No. 337-TA-1016, Comm’n. Op. at 39-44 (Aug. 21, 2018);

Certain Table Saws Incorporating Active Injury Mitigation Technology & Components Thereof, Inv. No. 337-TA-965, Comm’n Op. at 15 (Jan. 27, 2017).

Sun Pharma has failed to establish that a bond is necessary, especially given that the DI Product is not on sale, and therefore a bond of zero is appropriate. In all of its supplemental discovery responses regarding bond, Sun Pharma has presented minimal argument regarding why bond is necessary, other than the fact that the products are generally used for many years and that the parties are competitors in the PDT market. *See* RX-1406C (Complainants’ 4th Supplemental Responses), ROG No. 13. Dr. Vander Veen admits that “there is no established royalty rate for the Asserted Patents, so a reasonable royalty rate can not be used to establish bond in this case.” CX-0016C, Q/A 333. And he additionally concludes that a “price comparison is not practical to determine a bond here.” CX-0016C, Q/A 330. But Dr. Vander Veen wrongly concludes that bond should be set at 100% to “eliminate any price difference” between the products. CX-0016C, Q/A 332. This reasoning falls apart if Biofrontera’s RhodoLED[®] XL lamp is sold at a higher price than the Sun Pharma BLU-U[®] 4170E.

The evidence will show that Biofrontera’s RhodoLED[®] XL will be priced *higher* than Sun Pharma’s DI Product, making any bond based on price comparison between the products inappropriate. The evidence will show that, although the price for the BLU-U[®] 4170E has changed over time, Mr. Lundahl will testify that it will be priced at approximately \$14,000. CX-0015C (Lundahl Rebuttal WS) Q/A 72; CX-0011C, Q/A 183; JX-0016C, 31:12-20; JX-0017C, 99:17-100:11. The evidence will also show that this price is appreciably lower than the price for Biofrontera’s Accused Product, which is priced at \$18,500 and generally sells for \$15,250-\$16,500, but in any case, would not sell for less than 5% over the full-loaded cost of the unit. RX-0837C (Sales and Inventory Report for Q3-2024); RX-0003C, Q/A 43, 50-51 (testifying that the

MSRP is \$18,500 and minimum sales price is [REDACTED]); RX-0008C (Rowe WS) Q/A 27 (calculating an average sales price of [REDACTED] using Biofrontera's sales data); JX-0007C, 29:9-17, 54:18-56:1; 62:12-63:13; 63:20-4; 63:8-13. The fact that the Accused Product is priced higher than the DI Product establishes that a bond of zero is appropriate. *See Certain Access Control Systems & Components Thereof*, Inv. No. 337-TA-1016, Comm'n. Op. at 39-44. While Dr. Vander Veen may testify that that Biofrontera may lower its price for the Accused Product and, potentially, sell its product at a loss, he admitted that he is unaware that Biofrontera must sell the RhodoLED® XL at a profit. RX-0014C, ¶ 110; RX-1381C (Vander Veen Dep. Tr.) 159:12-160:20; RX-0003C, Q/A 50; JX-0007C, 62:12-63:13; 63:20-4; 63:8-13.

CERTIFICATE OF COMPLIANCE WITH WORD LIMIT

The foregoing filing complies with the word limits set forth in Ground Rule 11.2 and contains 59,125 words. The brief has been prepared using Microsoft Word in 12-point Times New Roman font. As permitted by G.R. 1.6, the undersigned has relied upon the word count feature of this word processing system in preparing this certificate.

/s/ Lauren E. Peterson
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Dated May 23, 2025

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CERTIFICATE OF SERVICE

I, Antoine R. Bland, hereby certify that on June 11, 2025, copies of the foregoing were served upon the following as indicated:

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