

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

**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

**COMPLAINANT SUN PHARMACEUTICAL INDUSTRIES, INC.'S
POST-HEARING BRIEF**

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TABLE OF ABBREVIATIONS

<i>Abbreviation</i>	<i>Meaning</i>
'028 Patent	U.S. Patent No. 11,697,028
'512 Patent	U.S. Patent No. 11,446,512
'902 Provisional	U.S. Provisional Patent Application No. 62/241,902
Accused Products	RhodoLED® XL, alone or in combination with Ameluz®
AK	Actinic keratosis
ALA	5-aminolevulinic acid
Asserted Claims	'028 Patent, Claims 1–2, 4, 16–17, and 19–21 and '512 Patent, Claims 1, 3, 5, 8, 17–18, and 20
Asserted Patents	U.S. Patent No. 11,446,512 and U.S. Patent No. 11,697,028
Biofrontera	Respondents Biofrontera AG, Biofrontera Bioscience, GmbH, Biofrontera Pharma GmbH, and Biofrontera, Inc. (individually or collectively)
CDO	Cease and Desist Order
DI	Domestic industry
DI Claims	'028 Patent, Claims 1, 3, 4, 5, 7, 9, 16–18, and 21 and '512 Patent Claims 1, 2, 4, 5, 8, 19, and 20
FDA	United States Food and Drug Administration
Hente	U.S. Patent Application Publication No. 2010/0118522
IPR	<i>Inter partes</i> review
Larsen	U.S. Patent Application Publication No. US2005/0075703
LED	Light emitting diode
LEO	Limited exclusion order
Levulan®	Levulan® Kerastick®
Lundahl	U.S. Patent No. 6,223,071
OLED	Organic light emitting diode
PD/PDD	Photodynamic diagnosis
PDT	Photodynamic therapy
Perutz	U.S. Patent No. 4,823,858
POSITA	Person of ordinary skill in the art.
PpIX	Protoporphyrin IX
PTO	United States Patent and Trademark Office
RPre-HB	Respondents' Pre-Hearing Brief (filed May 23, 2025)
Sun Pharma	Complainant Sun Pharmaceutical Industries, Inc.
Tr.	Evidentiary Hearing Transcript

I. INTRODUCTION

Biofrontera presents a kitchen sink of conclusory attorney arguments to avoid the plain fact that Biofrontera infringes Sun Pharma's valid Asserted Claims. The evidentiary hearing laid bare those unsupported arguments, confirming that Biofrontera violates Section 337. Even setting aside Sun Pharma's litany of affirmative evidence, Biofrontera's admissions *alone* show how its attorney arguments fail.

Infringement: Biofrontera's primary non-infringement argument asserts that RhodoLED® XL lacks hinges "on inner side surfaces of adjacent panels" because it claims the hinges are not "on" the inner side surfaces, but rather, extend "through" and are "not connected to" the inner side surfaces.

But testimony from Dr. Grove, Biofrontera's expert, undermines the non-infringement argument. He admitted that his non-infringement analysis depends on requiring the hinge to be "mounted to" the inner side surface. Tr. (Grove), 446:19–24, 453:25–454:11. That "mounting" requirement conflicts with the ALJ's construction, which only requires the hinges to "fit on inner side surfaces of the panels."

He agreed that the "hinge...on a surface" is not so limited:

Q. Okay. So you agree that a hinge can be on a surface but the flanges can be attached to something else. You can agree to that, right? A. Depending on the design, yes, it's possible.

Tr. (Grove), 446:15–18. That contradicts Biofrontera's tortured reading of "on" to require physical connection, and aligns with the ALJ's construction and Sun Pharma's argument that the claim language does not require physical connection of the hinges to the inner side surfaces.

And, even if physical contact is required, he admitted that RhodoLED® XL hinge flanges physically contact the side surfaces, including both the exterior portion of the tab and the shell of the panel:

Q. Okay. Now, why don't we go back to -- yes, thank you -- slide 16, RDX-0020C.16. All right.

Now, Dr. Grove, as we can see in the image on the right, the hinge is in physical contact with the portion of the tab which extends from the panel into the space between adjacent panels. Right?

A. The hinge flanges are, yes.

Tr. (Grove), 444:2–8.

Q. Okay. And you're not saying that Dr. Jokerst was wrong when she saw contact between the friction hinge and the shell of the panel; is that correct?

A. If she was referring to the flanges of the friction hinge, what she said was correct.

I'm not disputing her statement.

Id., 444:13–18.

Because RhodoLED® XL's hinges "fit on inner side surfaces of adjacent panels" in accordance with the ALJ's construction, Biofrontera infringes the Asserted Patents.

§103 Validity: Biofrontera relies on an obviousness combination of Lundahl (one of Sun Pharma's patents protecting its prior-generation single-panel BLU-U® 4170 device), and Larsen (a generic five-panel system lacking the claimed light source arrangements and uniformity). Both were already considered by the examiner during prosecution. JX-0001.3; JX-0002.3; JX-0003.48, .100; JX-0004.160. Yet Biofrontera selects parts of Lundahl and Larsen with blatant hindsight reconstruction. Once again, Dr. Grove's admissions expose fatal flaws in Biofrontera's arguments.

For example, all claims require “wherein each of the at least five panels has two first edges and two second edges...and the light sources are arranged such that a higher intensity of light is emitted proximate the second edges...”

Dr. Grove admits Lundahl does not have five panels, and thus does not disclose this entire element. Tr. (Grove), 566:1–11. He also admits that Lundahl emits higher intensity light from the **longer edges** “near the forehead and chin of a patient.” Tr. (Grove), 565:4–8. To address these shortcomings, Dr. Grove purports to “us[e] Lundahl’s spacing and light distribution of the light sources, and then divid[e] Lundahl’s one-panel device into five panels” pulled from Larsen. Tr. (Grove), 570:15–19. But that analysis divorces the language “higher intensity of light emitted proximate the [shorter] edges” from the whole claim element—that requires the arrangement for **“each of the at least five panels...”** Instead, Dr. Grove breaks this element, and others, into bits and pieces to be assembled piecemeal from various references. Dr. Grove’s obviousness conclusion is “based on the hindsight combination of components selectively culled from the prior art to fit the parameters of the patented invention.” *See Univ. of Strathclyde v. Clear-Vu Lighting LLC*, 17 F.4th 155, 162 (Fed. Cir. 2021). Even then, Dr. Grove does not limit his proposed combinations to features actually disclosed by the prior art. For example, he opines that it would have been obvious to place hinges “on inner side surfaces” even as Dr. Grove confirmed at the hearing that no reference he relied on, including Lundahl, Larsen, and Hente, disclosed hinges **in any detail**. Tr. (Grove), 562:15–17, 563:1–9, 585:5–12.

The hearing testimony confirmed that Dr. Grove’s analysis is filled with legally inappropriate hindsight. It is undisputed that no reference describes how to place hinges on inner side surfaces, no reference discloses higher intensity of light emitted proximate the shorter edges, and no reference discloses achieving the claimed degree of uniformity using LEDs—yet Dr. Grove

claims, without support in the record, those are all obvious teachings. Moreover, Dr. Grove admitted his hindsight bias when he testified that his invalidity analysis of the “higher intensity” element “compare[s his] combined device of Lundahl and Larsen to the accused RhodoLED XL.” Tr. (Grove), 571:6–572:13; *see Zenith Elecs. Corp. v. PDI Commc’n Sys., Inc.*, 522 F.3d 1348, 1363 (Fed. Cir. 2008) (“[M]ere proof that the prior art is identical, in all material respects, to an allegedly infringing product cannot constitute clear and convincing evidence of invalidity.”). Dr. Grove’s hindsight reconstruction of the patents must be rejected. *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007) (“[A] factfinder should be aware ... of the distortion caused by hindsight bias and must be cautious of arguments reliant upon ex post reasoning.”); *W.L. Gore & Assocs. v. Garlock, Inc.*, 721 F.2d 1540, 1553 (Fed. Cir. 1983) (“To imbue one of ordinary skill in the art with knowledge of the invention in suit, when no prior art reference or references of record convey or suggest that knowledge, is to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher.”)

Finally, on commercial success, Biofrontera’s attorneys argued “Biofrontera’s sales have not reached a level sufficient to conclude that RhodoLED® XL has been commercially successful, and further, [] RhodoLED® XL has not even sold anywhere near what was projected.” RPre-HB, 177. But Biofrontera’s CEO, Dr. Luebbert, disagreed with both propositions:

Q. Okay. So do you agree with Biofrontera's position in this case that RhodoLED XL has not even sold anywhere near what was projected? A. No.

Tr. (Luebbert), 316:10–13, 316:23–317:6 (asked whether RhodoLED has been commercially successful, replying that “launching the XL has been a success for the company”). Once again,

Biofrontera's own witness admissions align with Sun Pharma's affirmative evidence and arguments, confirming that RhodoLED® XL is indeed commercially successful.

Enablement/Written Description: Biofrontera claims the Asserted Patents do not enable or adequately describe how to perform PD pursuant to the preambles, which require “[a] [system/method] for photodynamically diagnosing or treating a patient.” Once again, Biofrontera's own expert's admissions undermine this defense.

First, Dr. Ehrenreich admitted PD¹ and PDT were both known as of the Asserted Patents' priority date. Tr. (Ehrenreich), 615:25–616:2, 617:3–6.

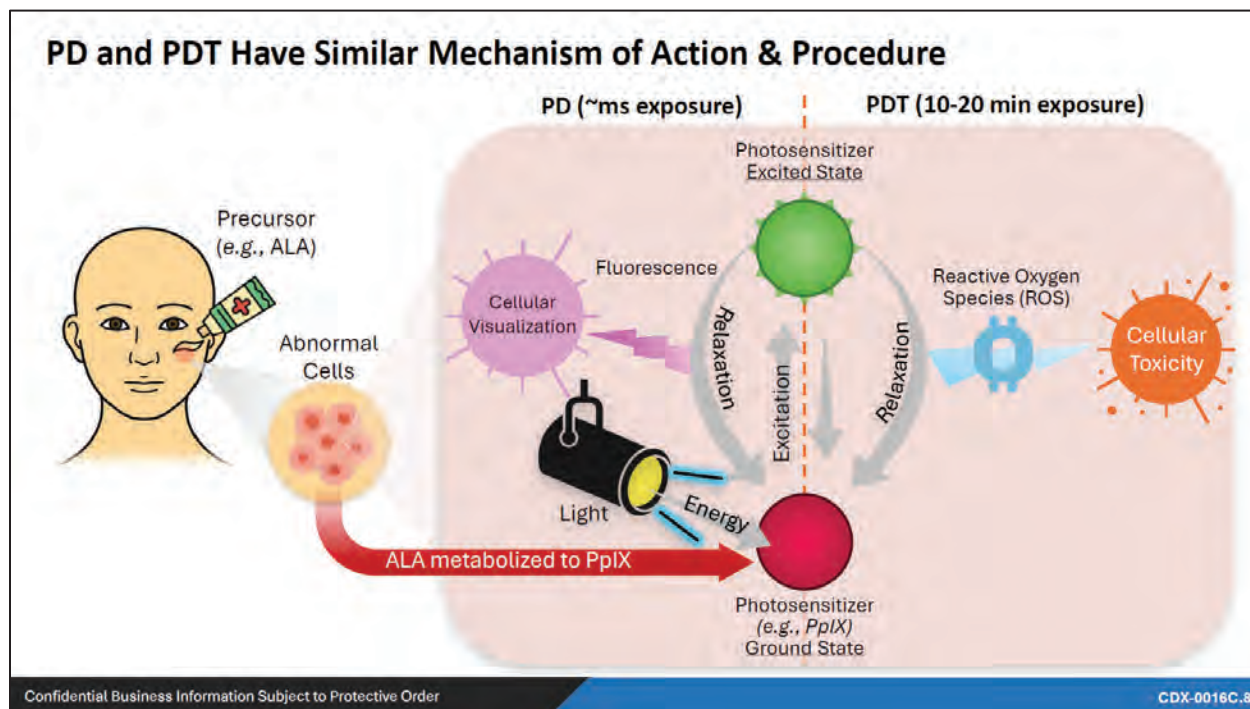
Second, Dr. Ehrenreich admitted the process of PD and PDT is the same until the final step, as follows:

- Step A: Apply a photosensitizer precursor (*e.g.*, ALA), to the skin. Tr. (Ehrenreich), 617:7–10 and CDX-1100.4 (PD); Tr. (Ehrenreich), 607:17–22 and CDX-1100.3 (PDT).
- Step B: The precursor accumulates in abnormal cells (*i.e.*, lesions). Tr. (Ehrenreich), 617:11–14 and CDX-1100.4 (PD); Tr. (Ehrenreich), 607:23–608:4 and CDX-1100.3 (PDT).
- Step C: The abnormal cells metabolize the precursor into a photosensitizer/fluorophore (*e.g.*, PpIX). Tr. (Ehrenreich), 617:11–14 and CDX-1100.4 (PD); Tr. (Ehrenreich), 610:18–22 and CDX-1100.3 (PDT).
- Step D: Expose the abnormal cells to light within the photosensitizer/fluorophore's absorption spectrum. Tr. (Ehrenreich), 617:15–18 and CDX-1100.4 (PD); Tr. (Ehrenreich), 610:23–611:23 and CDX-1100.3 (PDT).
- Step E:
 - o **PD**: the photosensitizer/fluorophore fluoresces with a bright red color. Tr. (Ehrenreich), 617:15–18 and CDX-1100.4 (PD).

¹ As Dr. Shmuylovich, Sun Pharma's medical expert, explained, the terms “PD” and “PDD” are used interchangeably. Tr. (Shmuylovich), 704:20–705:1. Sun Pharma will use “PD” in this brief, except where a quote uses “PDD.”

- o **PDT:** the photosensitizer/fluorophore interacts with oxygen to create reactive oxygen species that kill the abnormal cells. Tr. (Ehrenreich), 615:9–24 and CDX-1100.3 (PDT).

Notably, Dr. Ehrenreich's recitation of the steps follows the description provided by Sun Pharma's expert, Dr. Shmuylovich:



Compare CDX-1100.4 (Ehrenreich) with CDX-0016C.8 (Shmuylovich) (excerpted above); see also, Tr. (Shmuylovich), 697:19–701:8 (explaining PD/PDT), 702:14–708:22 (same), 712:9–714:5 (same). As Dr. Shmuylovich explained, the key mechanistic difference between PD & PDT is the length of illumination time for fluorescence (nearly instantaneous) vs. tissue destruction (minutes). CX-0013C.27 (Shmuylovich), Q93; Tr., (Shmuylovich), 697:19–699:5, 701:2–8

Third, in the coup de grace, Dr. Ehrenreich admitted that undue experimentation is **not required** to practice “the photodynamic treatment aspects” of the Asserted Claims. Tr. (Ehrenreich), 616:3–19; RX-0007C.0043 (Ehrenreich), Q209. If PD and PDT were known by the priority date, and PD and PDT use the same general process, one struggles to understand how

Biofrontera and Dr. Ehrenreich can argue it **would** have required undue experimentation to perform PD at the priority date, when Dr. Ehrenreich admits it **would not** have required undue experimentation to perform PDT at that same date. **Neither** require undue experimentation.

Technical Prong of DI: Biofrontera’s attorney argument that “notably absent is any hard proof demonstrating that the [4170E] device has actually been used in a manner...that satisfies and meet[s] every patent claim,” Tr. (Opening Statement), 54:14–55:3, is contradicted by the unrebutted hearing record. [REDACTED]

[REDACTED]. As reviewed herein, Drs. Jokerst and Shmuylovich testified in detail how treatment following that label practices the DI Claims, and notably, no Biofrontera expert rebuts their analysis.

In light of these admissions, combined with Sun Pharma’s affirmative evidence discussed below, it is clear Biofrontera infringes the following valid claims when it imports, sells for importation, and sells after importation, RhodoLED® XL device (alone and with Ameluz®):

Patent	Claims
'512 Patent	1, 3, 5, 8, 17–18, and 20
'028 Patent	1–2, 4, 16–17, and 19–21.

It is also clear that Sun Pharma practices the following valid claims for DI:

Patent	Claims
'512 Patent	1, 2, 4, 5, 8, 19, and 20
'028 Patent	1, 3, 4, 5, 7, 9, 16–18, and 21.

Therefore, Biofrontera violates Section 337, and an LEO, CDO, and 100% bond during Presidential Review are appropriate.

II. OVERVIEW OF THE TECHNOLOGY

The patented technology relates to illumination systems used in combination with a pharmaceutical for PD or PDT of dermatological conditions like AK. AK is a common skin lesion that presents as scaly papules or plaques on sun-exposed body parts, most commonly the nose, ears, forehead, and scalp. *See* CX-0009C.9 (Shmuylovich), Q30; JX-0207.2.

PDT is designed to minimize the number of treatments; therefore, it is essential that each area with lesions gets a sufficient light dose at the proper wavelength. CX-0009C.11 (Shmuylovich), Q41. If the light dose—*a.k.a.* “fluence”—is too low, treatment effectiveness is reduced, which may require repeated treatment. CX-0009C.11 (Shmuylovich), Q42; JX-0063C.13. Similarly, if the PDT light source is not uniform, it becomes a major challenge to achieve sufficient fluence across the entire treatment area. CX-0009C.11 (Shmuylovich), Q41. Thus, uniform illumination is critical in PDT. *Id.* (Shmuylovich).

III. IMPORTATION

Respondents stipulated they import, sell for importation, or sell after importation, RhodoLED® XL. *See* CX-0608C.3, ¶ 3 (referencing Ex. A); CX-1196C. Biofrontera AG and Biofrontera Inc. also import, sell for importation, or sell after importation, Ameluz®, which is made in Switzerland, and sold by Biofrontera AG (a German company) to Biofrontera Inc. (a U.S. company) for sale in the U.S. *See* CX-0058.2 (Ameluz® packaging stating “Product of Switzerland” and “Distributed by Biofrontera Inc.” in Woburn, MA). *Tr.* (Foguet), 369:5–8; RX-0002C.0011 (Foguet), Q29–30.

IV. CLAIM CONSTRUCTION

The ALJ’s constructions are below. *See* Order No. 18.

Term & Claims	ALJ's Construction
“uniformly illuminate a treatment surface” / “uniformly illuminating a treatment surface” '512 and '028 Patents: All Asserted Claims	“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”
“a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges” '512 and '028 Patents: All Asserted Claims	Not 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”
“photodynamically diagnosing or treating a patient” '512 and '028 Patents: All Asserted Claims	Preamble is limiting
“nested hinges on inner side surfaces” '512 Patent: All Asserted Claims	Not indefinite. “hinges that fit on inner side surfaces of adjacent panels”
“a recess” '512 Patent: Claims 17–18	“indentation, small hollow, or cleft”
“within approximately four inches of the treatment surface” '028 Patent: Claims 1, 2, 4–6, and 20–21	“less than or equal to approximately four inches from the treatment surface”
“the five panels are individually configurable to control illumination from each of the five panels” '028 Patent: Claims 16–17, 19, and 21	Not indefinite. Plain and ordinary meaning, which is “the power output and/or light intensity of each panel can be individually controlled”

V. INFRINGEMENT

Biofrontera, via RhodoLED® XL, alone or in combination with Ameluz®, directly and/or indirectly infringes each Asserted Claim.

Biofrontera contests only the following limitations:

- “five panels connected by [nested hinges/hinged structures] on inner side surfaces of adjacent panels” (’512 Patent Claims 1, 8, 20; ’028 Patent Claims 1, 20, 21);
- “recess” (’512 Patent Claims 17–18);
- “within approximately four inches” (’028 Patent Claims 1, 20, 21); and
- “individually configurable” (’028 Patent Claims 16, 21).

Biofrontera’s GR 14.1 Identification of Undisputed Claim Limitations (July 9, 2025) (“Biofrontera’s GR 14.1”), 8–12. **Appendix A** lists the Asserted Claims, with a letter for each limitation, and notes whether the limitations in dispute.

A. ’512 Patent Asserted Claims

Biofrontera, via RhodoLED® XL, alone or in combination with Ameluz®, directly and/or indirectly infringes ’512 Patent Claims 1, 3, 5, 8, 17–18, and 20.

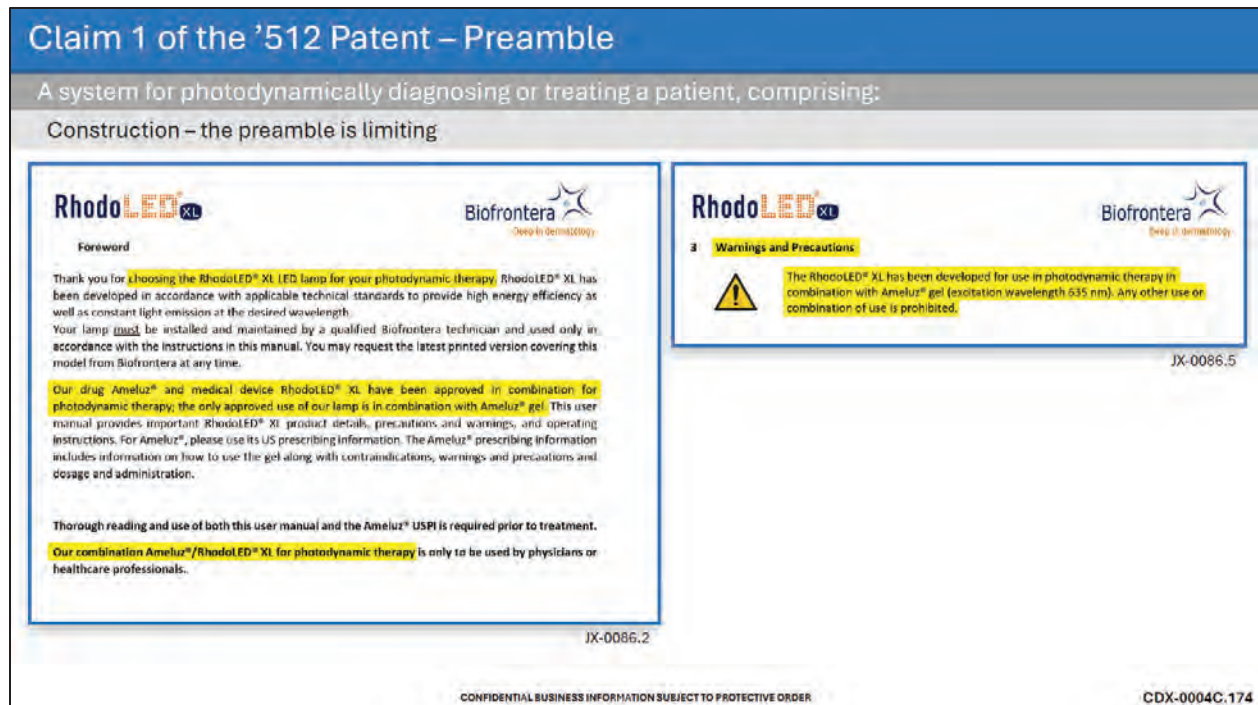
1. Direct Infringement

a. Claim 1

i. Element 1[p] - Undisputed²

RhodoLED® XL meets the preamble. CX-0010C.79–80 (Jokerst), Q425–36.

² See Appendix A.



CDX-0004C.174; JX-0086.2, .5.

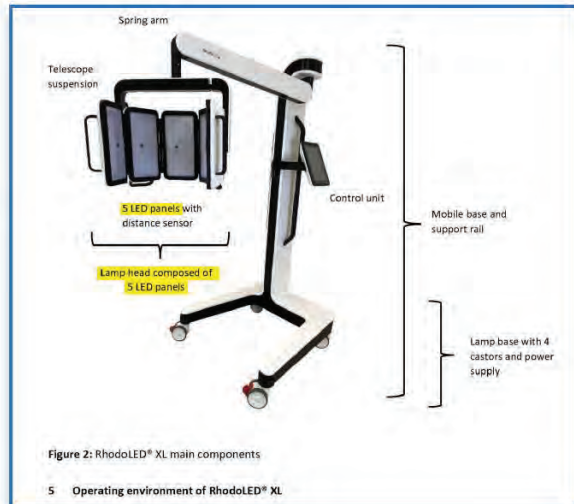
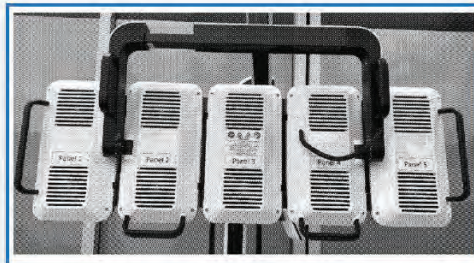
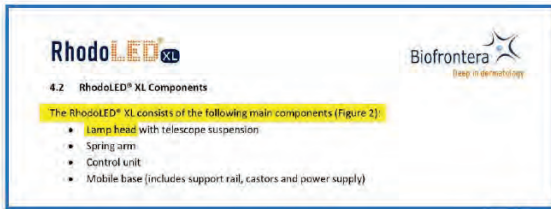
ii. Element 1[a] - Disputed

RhodoLED® XL is an illuminator comprising at least five panels connected by nested hinges on inner side surfaces of adjacent panels. CX-0010C.81–87 (Jokerst), Q437–475.

First, as Biofrontera admits and Dr. Jokerst confirmed, RhodoLED® XL includes an illuminator comprising five LED panels.

Claim 1 of the '512 Patent – First Element

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



CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER

CDX-0004C.177

CDX-0004C.177; CX-0010C.81–82 (Jokerst), Q437–444; JX-0086.8; JX-0065C.45 (Service Manual); CX-0027C.5 (RFA Response No. 10).

Second, the five RhodoLED[®] XL panels are connected by hinges. CX-0010C.82 (Jokerst), Q447. Biofrontera admitted that “five LED panels of the RhodoLED[®] XL include hinges that connects adjacent panels,” CX-0028C.2 (RFA Response No. 27), and “each of the five LED panels of the RhodoLED[®] XL lamp head is connected by two hinges to at least one other panel,” CX-0024C.3 (First Suppl. RFA Response No. 11); see Tr. (Luebbert), 338:4–7; Tr. (Grove), 434:10–15. The hinges are called “Friction Hinges”:

Claim 1 of the '512 Patent – First Element

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

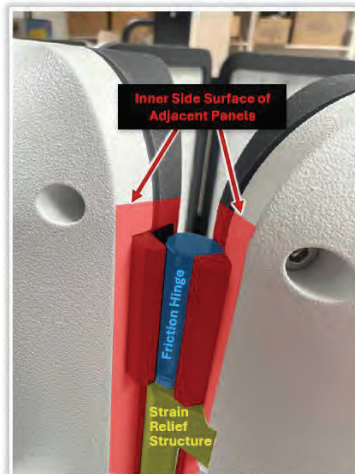
Construction: “nested hinges on inner side surfaces of adjacent panels” is “hinges that fit on inner side surfaces of adjacent panels”

Allgemein/General Information		Werkstoff/Material		Oberflächen-/Surface treatment	
Tolerierung/ISO 8015		Herstellungsverfahren/Technology		Masse/Mass	
Charakteristika/ Surface ISO 1302	ISO 13115	Panel 2		1,398 kg	
Datum/Date	Name	Bezeichnung/Name		Prüfverfahren/ Testing method	
22.07.2021	F. Erbe	9453		Projektionsmethode/ Projection	
Gepr./Ctd		Projektklassifizierung/Project classification		Maßstab/Scale	
Freig./Rls		9453 0602		1:2	
Änderung/ Change		Dokumentnummer/Document number		Blattformel/Size	
		9453 0602		A1	
Biofrontera		Doc.-Art/ Doc. type		Bl.- nos	
		XB		1	
		Teil-Des./ Doc. part		1	
		Version		05	
		Doc.-Art/ Doc. type		XB	
		Teil-Des./ Doc. part		001	
		Version		05	
		Doc.-Art/ Doc. type		XB	
		Teil-Des./ Doc. part		001	
		Version		05	
		Doc.-Art/ Doc. type		XB	
		Teil-Des./ Doc. part		001	
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		Version		05	
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		Version		05	
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		Teil-Des./ Doc. part		001	
		Version		05	
		Doc.-Art/ Doc. type		XB	
		Teil-Des./ Doc. part		001	
		Version		05	
		Doc.-Art/ Doc. type		XB	
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Claim 1 of the '512 Patent – First Element

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

Construction: “nested hinges on inner side surfaces of adjacent panels” is “hinges that fit on inner side surfaces of adjacent panels”



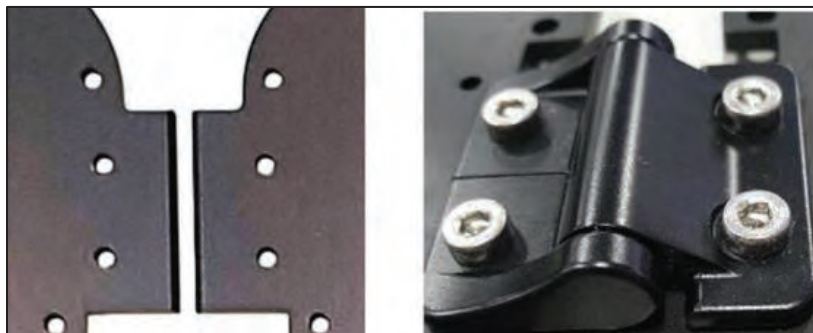
CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER

JX-0111 (annotated)

CDX-0004C.182

CDX-0004C.182; JX-0111; CX-0010C.84 (Jokerst), Q460. When assembled, the inner side surfaces of adjacent panels (highlighted red) comprise multiple components: (1) a portion of the front black panel casing; (2) a portion of the back white panel casing; and (3) the rectangular structures, or tabs, extending laterally from the panel on either side of the friction hinge (blue). CX-0010C.84–85 (Jokerst), Q461–62, Q465–67.

The tabs are part of the panel’s support plate, to which various panel components, like the front and rear shells, are attached. CX-0010C.85 (Jokerst), Q463.

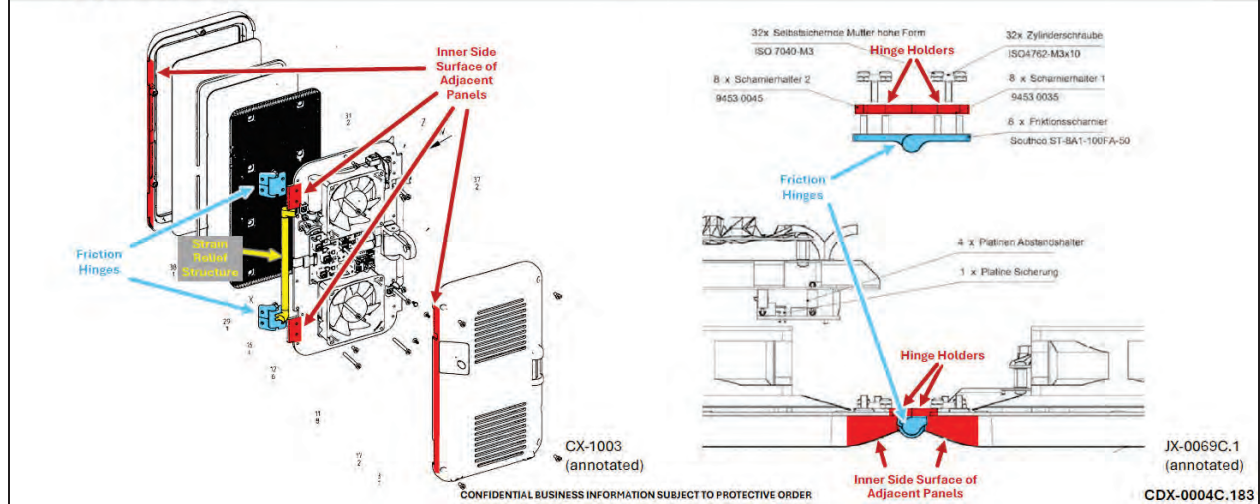


CX-0031C.68. Biofrontera calls the tabs “Scharnierhalter,” or “hinge holder.” JX-0069C.1.

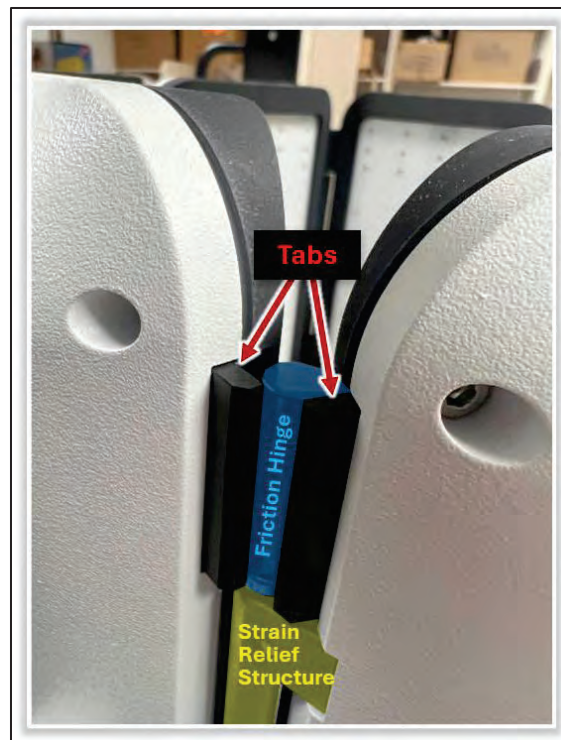
Claim 1 of the '512 Patent – First Element

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

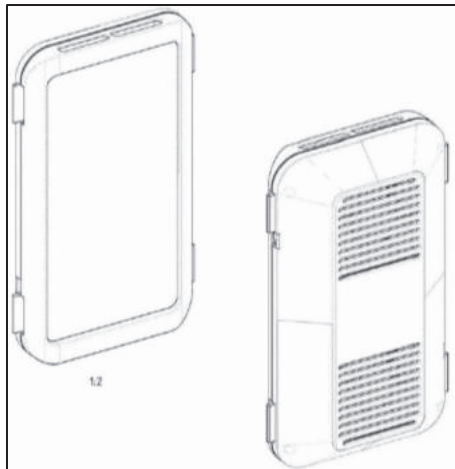
Construction: “nested hinges on inner side surfaces of adjacent panels” is “hinges that fit on inner side surfaces of adjacent panels”



CDX-0004C.183; CX-0010C.85 (Jokerst), Q463–465; CX-1003; JX-0069C.1. The tabs (“hinge holders”) visibly extrude when the panels are assembled:



JX-0111.



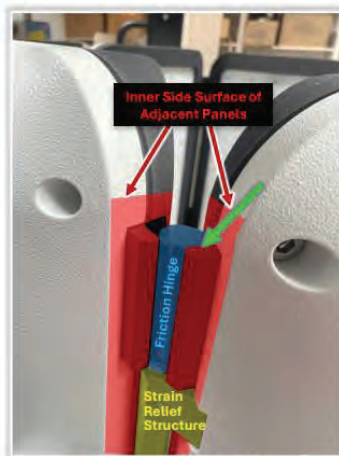
JX-0161C.

The friction hinges are in physical contact with the hinge holder as well as the panel shell.

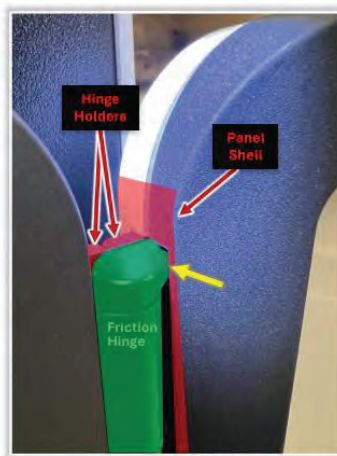
Claim 1 of the '512 Patent – First Element

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

Construction: “nested hinges on inner side surfaces of adjacent panels” is “hinges that fit on inner side surfaces of adjacent panels”



JX-0111 (annotated)

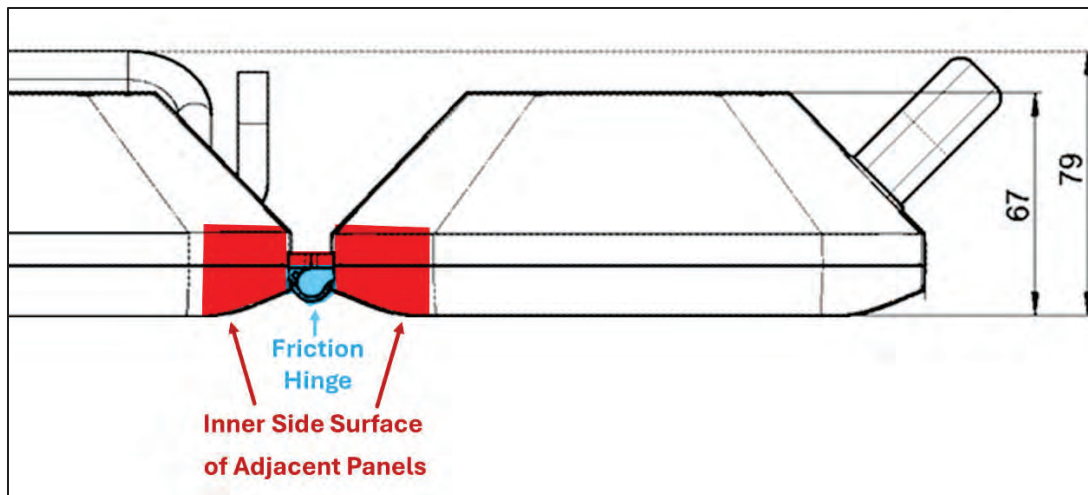


CX-1157C (annotated)

CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER

CDX-0004C.184

CDX-0004C.184; CX-0010C.85–86 (Jokerst), Q469–71; JX-0111; CX-1157C. Additionally, Biofrontera’s design drawing (JX-0069C.1) marks an elevation of “67” corresponding to the distance between front and back of the panels, with the friction hinge resting entirely within that distance, and not extending past the front or back of the panels.



JX-0069C.1; CX-0010C.121 (Jokerst), Q650. Thus, the friction hinges fit on the inner side surfaces because they are located between adjacent panels, do not intrude on the front, back, top, or bottom of the panels, and are in contact with the inner side surfaces. CX-0010C.86 (Jokerst), Q472.

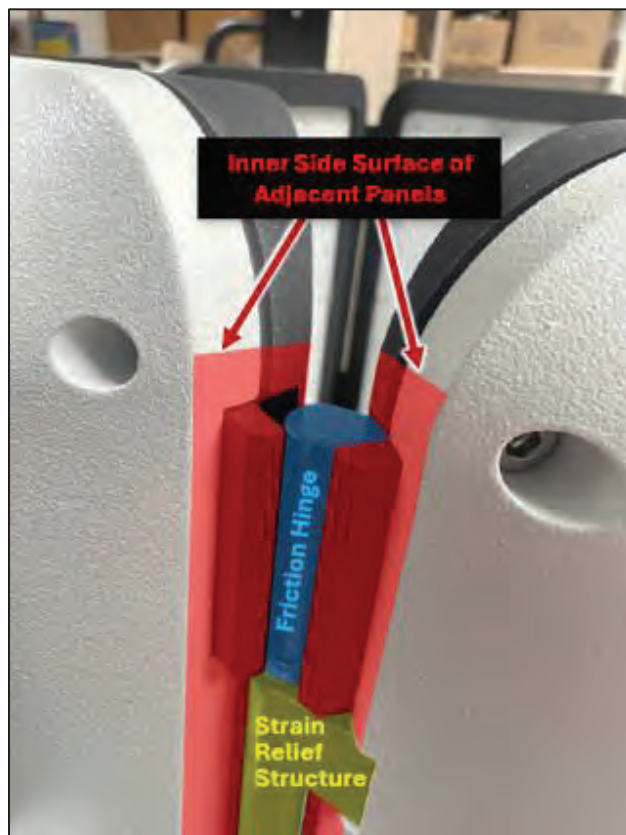
At the hearing, both parties' experts gave testimony supporting that RhodoLED® XL has hinges on inner side surfaces.

First, Drs. Jokerst and Grove both testified that the inner side surface of a panel can be “made up of multiple components.” Tr. (Jokerst), 246:5–7; *see* Tr. (Grove), 438:15–19 (admitting that “[w]hen the panel is assembled, the inner side surface of the panel is made up of more than one piece.”).

Second, both Drs. Jokerst and Grove testified that the hinge holders are an external part of the panel and are located on the side between the front and back of the panels. For example, Dr. Jokerst testified that “[t]he hinge holder is an external piece of the panel that extends into the space located between adjacent panels...and is found between the front and back of the panel....” CX-0010C.85 (Jokerst), Q467.

Likewise, Dr. Grove admitted that “the tabs are part of the panel,” the tab is “located in the space between adjacent panels,” and “the portion of the tab that is exterior to the casing is located between the front and back of the panel.” Tr. (Grove), 441:19–21, 442:15–19, 443:14–444:1.

Third, both Drs. Jokerst and Grove testified that the inner side surfaces need not be planar and that portions of a surface **not** facing the adjacent panel could still be considered an inner side surface. For example, Dr. Jokerst testified that portions of the panel’s inner side surface can stick in or stick out and will face in different directions in a curved configuration. Tr. (Jokerst), 248:3–12; CX-0010C.87 (Jokerst), Q475 (“The Asserted Patents clearly contemplate that the side surfaces need not be perfectly planar.”). This is shown in her annotations:



JX-0111 (annotated). Dr. Grove was impeached with his prior testimony that the side surfaces need not be planar:

"Question: I am asking do the claims require the inner side surfaces of the adjacent panels to be planar?"

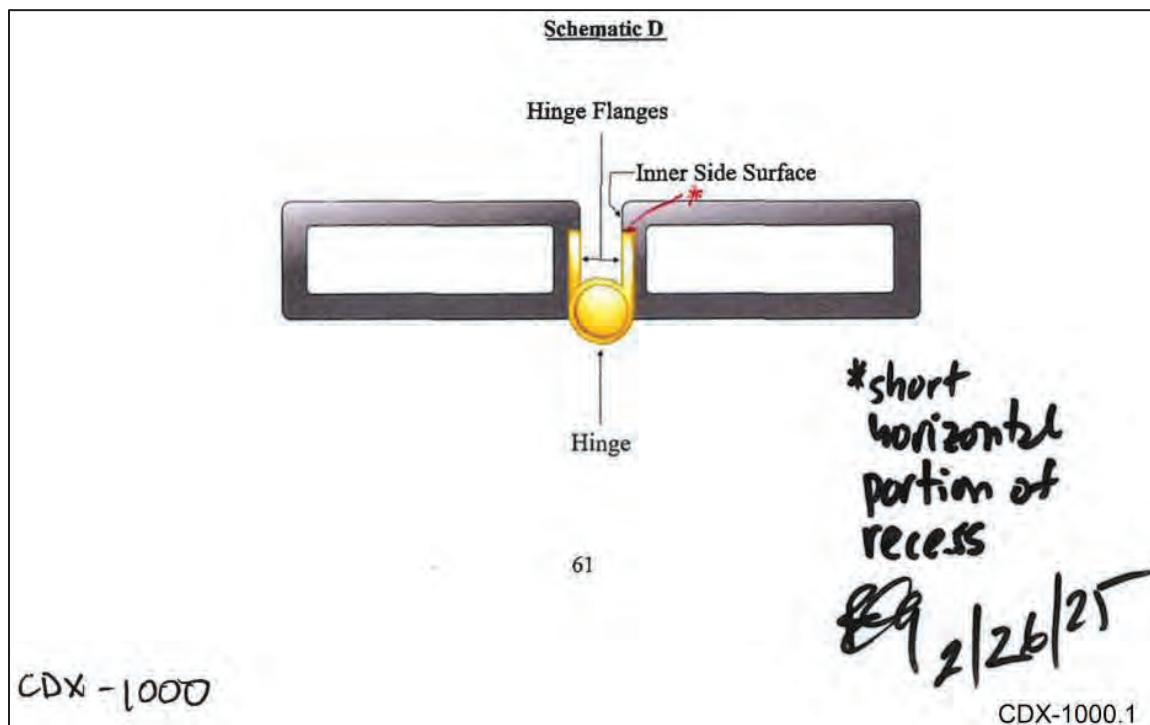
And you answered:

"Answer: I don't believe that's a requirement that can be interpreted from the claim language." And then you go on from there.

Were you asked that question and did you give that answer?

A. Yes, I did.

Tr. (Grove), 439:17–25; *see id.*, 438:20–23 (confirming that the flanges of a hinge do not need to be flat). Additionally, Dr. Grove testified that the short horizontal section of the recess shown in CDX-1000.1, below, can be considered a part of the inner side surface—even though it does not face the adjacent panel.



CDX-1000.1.

Q.... Dr. Grove, it would not be unreasonable to declare that the inner side surface to be both what's shown in [CDX-1000] as the short horizontal section and the longer vertical section in the recess. You agree with that statement?

A. I do.

Q. Okay. And as we can see in [CDX-1000], the short horizontal section marked with an asterisk is not facing the adjacent panel, correct?

A. It is not.

Tr. (Grove), 451:20–452:4.

Fourth, both Dr. Jokerst and Dr. Grove testified that the hinges are in physical contact with the surface of the hinge holders and the panels' shells. Tr. (Jokerst), 248:13–18; CX-0010C.86 (Jokerst), Q470; Tr. (Grove), 444:2–8 (testifying that “hinge flanges” are “in physical contact with the portion of the tab which extends from the panel.”); Tr. (Grove), 445:6–19 (impeachment of Dr. Grove where he agrees with Dr. Jokerst that the friction hinge of the RhodoLED® XL is in contact with the shell of the panel).

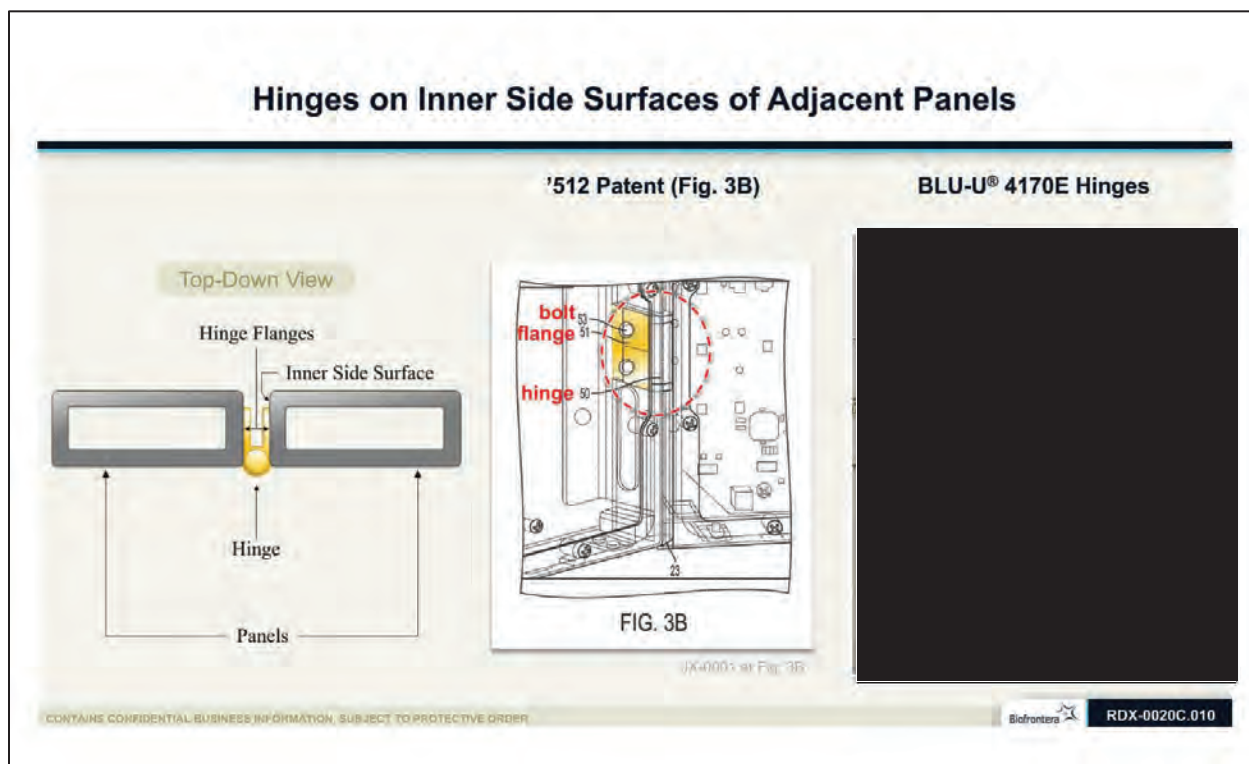
Fifth, Dr. Jokerst testified that a hinge could still be a nested hinge on an inner side surface even if the hinge flange is not bolted or screwed to the inner side surface. Tr. (Jokerst), 249:16–20. Dr. Grove echoed Dr. Jokerst's testimony by agreeing that “a hinge can be on a surface but the flanges can be attached to something else.” Tr. (Grove), 446:15–18.

Based on the foregoing, the hinge holders as well as portions of the panel shells form the inner side surface, and the friction hinges fit on the inner side surfaces of adjacent panels.

Dr. Grove argues that RhodoLED® XL does not meet this element because the hinges are not **mounted** to the inner side surfaces of the panels: he testified that, “in the claims, either the nested hinges or the hinge structures need to be mounted on the inner side surfaces.” Tr. (Grove),

446:19–24; see RX-0009C.12–13 (Grove), Q66; Tr. (Grove), 453:24–454:11 (under “[his] interpretation of the claims ... the hinges need to be mounted on the inner side surfaces),

That contradicts the claims as construed—the hinges must only “fit on inner side surfaces of adjacent panels.” There is nothing requiring the hinges to be “connected” or “mounted” to a particular surface. The recitation of “connected” in the claims modifies “five panels”—but Biofrontera’s expert improperly reads in a requirement that the hinges themselves connect to the inner side surfaces. Dr. Grove wrongly narrows the claims by relying on the patents’ Figure 3B embodiment³ and BLU-U® 4170E’s hinge design, where the hinges lay flat and are directly bolted to the panels. RX-0009C.0008–10 (Grove), Q37–48.



RDX-0020C.010, JX-0001, RX-1084C; Tr. (Grove), 447:1–448:5.

³ Fig. 3B does not depict the hinge flanges in a recess, Tr. (Jokerst), 251:6–8, which is another embodiment described in the specification and claims, JX-0001, 5:1–8, claims 7, 17, and 18.

Such comparisons are legally erroneous. *Kara Tech. Inc. v. Stamps.com Inc.*, 582 F.3d 1341, 1348 (Fed. Cir. 2009) (“[W]e will not limit [the patentee] to his preferred embodiment or import a limitation from the specification into the claims.”); *Myco Indus., Inc. v. BlephEx, LLC*, 955 F.3d 1, 15 (Fed. Cir. 2020) (“The law is clear, however, that infringement is determined on the basis of the claims, not on the basis of a comparison with the patentee’s commercial embodiment of the claimed invention.”).

Moreover, Biofrontera’s interpretation would read out embodiments in the specification and would conflict with the dependent claims that recite “a recess” which can receive a flange of the nested hinges. “Recess” as recited in ’512 Patent Claims 17–18 was construed as an “indentation, small hollow, or cleft.” Claim 17 recites that the recess is configured to receive the flange of the hinges that “fit on inner side surfaces,” but that recess can be located anywhere. *Compare* ’512 patent, claim 17, *with* ’claim 18 (further requiring that the recess is positioned at an inner side surface).

Thus, notwithstanding Biofrontera’s arguments, this element is met by RhodoLED® XL.

iii. Element 1[b] - Undisputed

RhodoLED® XL meets this limitation. CX-0010C.87–96 (Jokerst), Q476–517.

Claim 1 of the '512 Patent – Second Element

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

4 RhodoLED® XL Technical Description

4.1 Light emitting diodes (LED)

RhodoLED® XL is a red-light emitting LED lamp, comprised of three main components, the lamp head, an easily adjustable spring arm, and the mobile base with castors for smooth transport. In addition, the lamp has a convenient touchscreen monitor and aids for positioning the lamp head. RhodoLED® XL has 45 LEDs per panel with a total of 5 panels (225 LEDs), which emit a uniform, visible red light. The typical peak wavelength is approximately 635 nm with a half-band width of 16 nm.

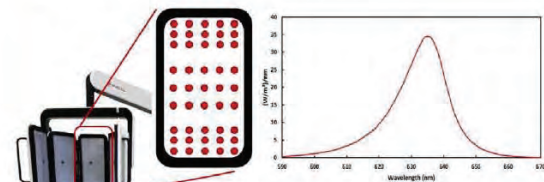


Figure 1: LED panels with LED distribution and emission spectrum of RhodoLED® XL LEDs.

The LEDs are distributed on each panel in a specific way (see Figure 1), such that they are more densely packed towards the upper and lower edges than in the center region of each panel. This distribution optimizes the homogeneity of illumination over the treated skin.



CX-1067

JX-0086.7

CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER

CDX-0004C.186

CDX-0004C.186; JX-0086.7; CX-1067.

Claim 1 of the '512 Patent – Second Element

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

Construction: “uniformly illuminate” 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”

RhodoLED® XL

Biofrontera
Deep in dermatology

13.2 Specification

Type	RhodoLED® XL Medical device class III; Device of protection class 1
Certification	UL certified E513735
Software Version No.	g2.12.00.3739
Service interval	Biofrontera recommends performing service every 2 years
Number of LEDs	225
Typical peak wavelength	635 nm $\pm$ 5 nm
Light dose	Approx. 37 J/cm ² at 4.9 inch (12.5 cm) distance, 13.5 min
Typical irradiance	approx. 46 mW/cm ² $\pm$ 20 % at 4.9 inch (12.5 cm) distance
Max irradiance	approx. 55 mW/cm ² at 4.9 inch (12.5 cm) distance
Illuminated area	An area of 9.06 x 11.42 inch (23 cm x 29 cm) is illuminated using all panels in curved shape.
Max. deviation of the intensity over the treatment area	Approx. 20 %
Treatment distance	4.9 $\pm$ 0.6 inch (12.5 cm $\pm$ 1.5 cm) Measuring accuracy $\pm$ 0.3 cm (0.1 inch)

JX-0086.27

CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER

CDX-0004C.187

CDX-0004C.187; JX-0086.27.

iv. Element 1[c] - Undisputed

RhodoLED® XL meets this limitation. See CX-0010C.96–99 (Jokerst), Q518–28.

Claim 1 of the '512 Patent – Third Element

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

! The RhodoLED® XL LED panels should only be used in curved shape and not in fully unfolded form. This is necessary to ensure the application of 37 J/cm² during the illumination.

JX-0086.6

8.4.6 Treatment Area

The illumination area of RhodoLED® XL is 9.06 x 11.42 inch (23 cm x 29 cm) when all panels are arranged in the standard curved shape. This usually allows a full-face illumination. However, face and head sizes are subject to strong variations between patients. As a rough guidance, the midlines of the outer two panels marks the outer boundaries of the illumination area (see Figure 13 as guidance).

Note: The RhodoLED® XL LED panels should only be used in curved shape and not in fully unfolded form. This is necessary to ensure the application of 37 J/cm² during the illumination.

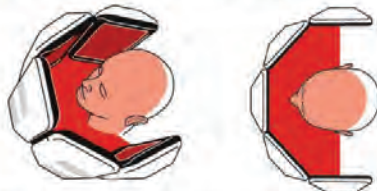


Figure 13: Treatment area of RhodoLED® XL, from the side and in top view.

JX-0086.17

The orientation of the panels can be changed from a curved shape to an unfolded form by pulling the holding bracket apart (Figure 5).

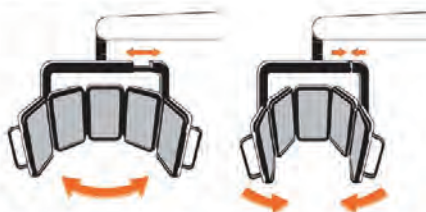


Figure 5: Movement range of the lamp head.

Note: The RhodoLED® XL LED panels should only be used in curved shape and not in a fully unfolded form. This is necessary to ensure the application of 37 J/cm² during the illumination.

JX-0086.12

CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER

CDX-0004C.202

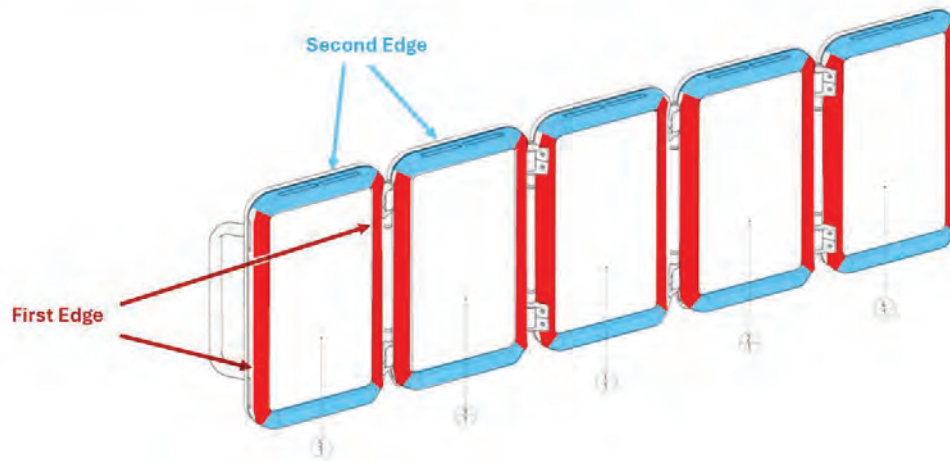
CDX-0004C.202; JX-0086.12, .17.

v. Element 1[d] - Undisputed

RhodoLED® XL meets this limitation. See CX-0010C.99–108 (Jokerst), Q529–75.

Claim 1 of the '512 Patent – Fourth Element

wherein each of the at least five panels has two first edges and two second edges shorter than the two first edges ...



JX-0160C (annotated)

CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER

CDX-0004C.207

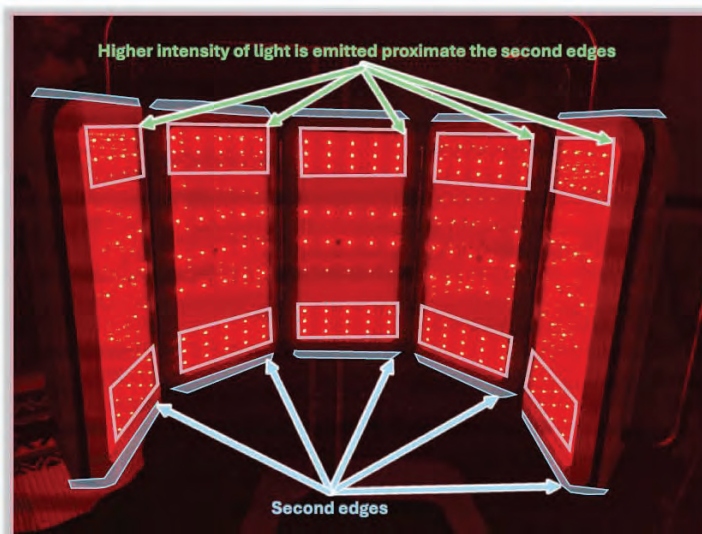
CDX-0004C.207; JX-0160C.

Claim 1 of the '512 Patent – Fourth Element

... a higher intensity ...



JX-0110 (annotated)



CX-1067 (annotated)

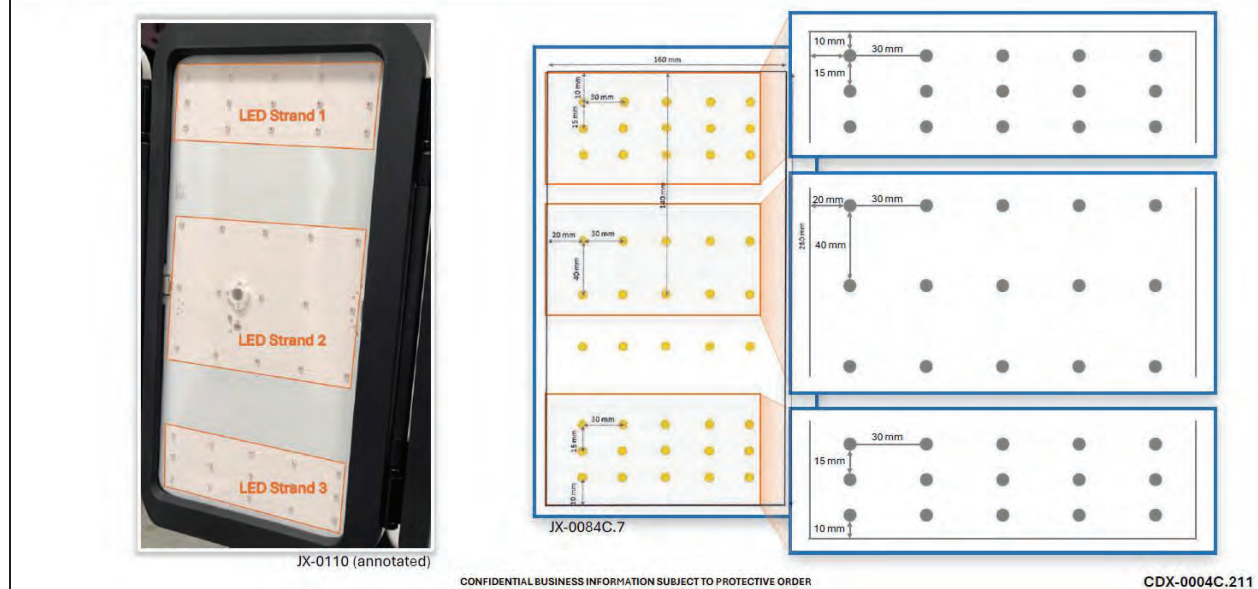
CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER

CDX-0004C.209

CDX-0004C.209; JX-0110; CX-1067.

Claim 1 of the '512 Patent – Fourth Element

... a higher intensity ...



CDX-0004C.211; JX-0110; JX-0084C.7.



CDX-0004C.212; CX-1165C; JX-0199C.76.

b. Claim 3**i. Element 3[p] – Disputed, in part**

RhodoLED® XL infringes Claim 1. See §V.A.1.a.

ii. Element 3[a] - Undisputed

RhodoLED® XL meets this element. See CX-0010C.108–09 (Jokerst), Q576–83.

Claim 3 of the '512 Patent

wherein the illuminator is configured to output red light at a dose of about 30 J/cm² to about 150 J/cm²

4 RhodoLED® XL Technical Description

4.1 Light emitting diodes (LED)

RhodoLED® XL is a red-light emitting LED lamp, comprised of three main components, the lamp head, an easily adjustable spring arm, and the mobile base with castors for smooth transport. In addition, the lamp has a convenient touchscreen monitor and aids for positioning the lamp head. RhodoLED® XL has 45 LEDs per panel with a total of 5 panels (225 LEDs), which emit a uniform, visible red light. The typical peak wavelength is approximately 635 nm with a half-band width of 16 nm.

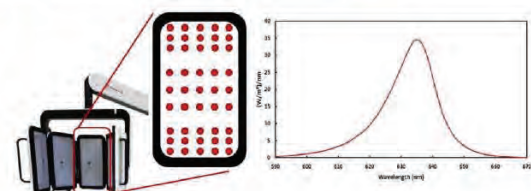


Figure 1: LED panels with LED distribution and emission spectrum of RhodoLED® XL LEDs.

The RhodoLED® XL LEDs are calibrated such that the skin being treated receives a light dose of approximately 37 J/cm² under the following conditions:

- Illumination time of 13.5 minutes
- Treatment distance of 4.9 ± 0.6 inch (12.5 cm ± 1.5 cm)

Note: The RhodoLED® XL LED panels should only be used in curved shape and not in fully unfolded form. This is necessary to ensure the application of 37 J/cm² during the illumination.

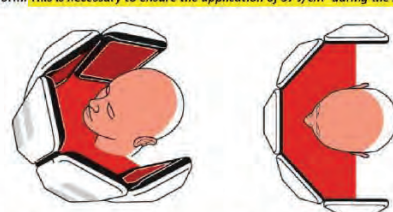


Figure 13: Treatment area of RhodoLED® XL from the side and in top view.

JX-0086.17

JX-0086.7

CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER

CDX-0004C.216

CDX-0004C.216; JX-0086.7, .17.

c. Claim 5**i. Element 5[p] – Disputed, in part**

RhodoLED® XL infringes Claim 1. See §V.A.1.a.

ii. Element 5[a] – Undisputed

RhodoLED® XL meets this element. See CX-0010C.109–10 (Jokerst), Q584–90.

Claim 5 of the '512 Patent

wherein a plurality of the light sources are configured to emit light having a wavelength in a range of 400 nm to 700 nm.

4 RhodoLED® XL Technical Description

4.1 Light emitting diodes (LED)

RhodoLED® XL is a red-light emitting LED lamp, comprised of three main components, the lamp head, an easily adjustable spring arm, and the mobile base with castors for smooth transport. In addition, the lamp has a convenient touchscreen monitor and aids for positioning the lamp head. RhodoLED® XL has 45 LEDs per panel with a total of 5 panels (225 LEDs), which emit a uniform, visible red light. The typical peak wavelength is approximately 635 nm with a half-band width of 16 nm.

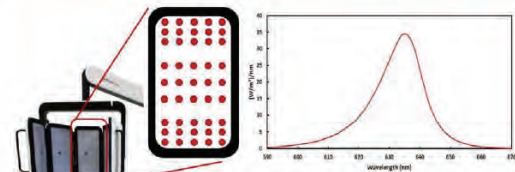


Figure 1: LED panels with LED distribution and emission spectrum of RhodoLED® XL LEDs.

The RhodoLED® XL LEDs are calibrated such that the skin being treated receives a light dose of approximately 37 J/cm² under the following conditions:

- Illumination time of 13.5 minutes
- Treatment distance of 4.9 ± 0.6 inch (12.5 cm ± 1.5 cm)

JX-0086.21

CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER

RhodoLED® XL



13.2 Specification

Type	RhodoLED® XL
Certification	Medical device class III; Device of protection class 1
Software Version No.	UL certified E513735
Service interval	Biofrontera recommends performing service every 2 years
Number of LEDs	225
Typical peak wavelength	635 nm ± 5 nm
Light dose	Approx. 37 J/cm ² at 4.9 inch (12.5 cm) distance, 13.5 min

JX-0086.27

The two most important factors for successful PDT, namely wavelength and light dose are not affected by this change. The total light dose of 37 J/cm² utilizing the appropriate peak wavelength of 635 nm is not modified and is sufficient for a successful PDT treatment with Ameluz.

CX-0324C.5

CDX-0004C.220

CDX-0004C.220; JX-0086.7, .21, .27; CX-0324C.5.

d. Claim 20

i. Element 20[p] - Undisputed

RhodoLED® XL meets this element for the same reasons as Element 1[p]. See §V.A.1.a.i.

ii. Element 20[a] – Disputed

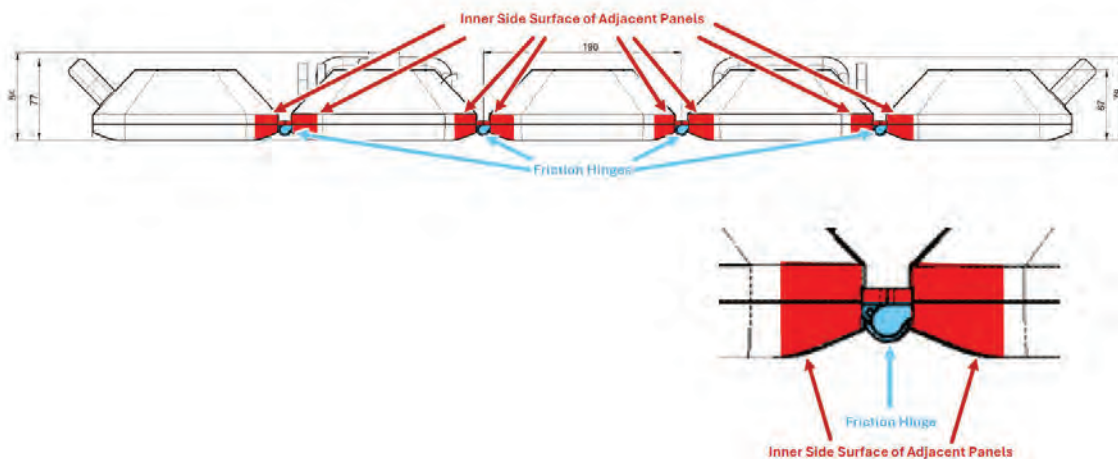
RhodoLED® XL meets this element.

First, it comprises at least five panels connected by nested hinges on inner side surfaces of adjacent panels for the same reasons as Element 1[a]. See §V.A.1.a.ii..

Second, it comprises nested hinges configured to allow continuous illumination across the at least five panels. CX-0010C.120–21 (Jokerst), Q649–52. The hinges fit between adjacent panels and do not interfere with the continuous illumination across the five panels. *Id.* The hinges do not extend past the plane of the front of the panels and do not block any light from reaching the patient:

Claim 20 of the '512 Patent – First Element

... the nested hinges being configured so as to allow continuous illumination across the at least five panels



JX-0069C (annotated)

CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER

CDX-0004C.243

CDX-0004C.243; CX-0010C.121 (Jokerst), Q650; JX-0069C. Indeed, Biofrontera's documents describe how Biofrontera designed the friction hinges on RhodoLED® XL to reduce the distance between the panels, which would allow for continuous illumination across the five panels. JX-0068C.26; CX-0321C.14; CX-0323C.3 [REDACTED]; CX-1005C.35 [REDACTED]; [REDACTED]; JX-0008C (Luebbert), 82:7–11 (noting that the distance between panels can effect homogeneity).



CDX-0004C.244; CX-0010C.121 (Jokerst), Q651–52; JX-0068.26; CX-0321C.14; CX-0323C.3; CX-1005.35. Biofrontera’s experts do not dispute this portion of the element.

iii. Element 20[b] - Undisputed

RhodoLED® XL meets this element for the same reasons as Element 1[b]. *See* §V.A.1.a.iii.

iv. Element 20[c] - Undisputed

RhodoLED® XL meets this element for the same reasons as Element 1[c]. *See* §V.A.1.a.iv.

v. Element 20[d] - Undisputed

RhodoLED® XL meets this element for the same reasons as Element 1[d]. *See* §V.A.1.a.v.

2. Indirect Infringement

Biofrontera indirectly infringes method Claims 8, 17, and 18. CX-0010C.75 (Jokerst), Q404. Biofrontera actively induces infringement of the Asserted Claims by making, selling, and/or offering for sale the RhodoLED® XL, individually or in combination with Ameluz®, along

with promotional, training, and instructional materials instructing the infringing use of the Accused Products. CX-0010C.75 (Jokerst), Q404; CX-0009C.34–35 (Shmuylovich), Q182 (explaining that dermatologists rely on those materials). Biofrontera indirectly infringes the asserted system claims of the '512 Patent by inducing its customers to use the RhodoLED® XL, which infringes those claims as discussed in preceding sections. 35 U.S.C. §271; *ACCO Brands, Inc. v. ABA Locks Mfrs. Co.*, 501 F.3d 1307, 1313–14 (Fed. Cir. 2007).

Knowledge of infringement. Biofrontera knew or should have known of the Asserted Patents and Sun Pharma's infringement assertions since at least the Complaint on June 25, 2024. 35 U.S.C. §271(b); JX-0198; JX-0019–20; CX-0010C.75 (Jokerst), Q405; Tr. (Luebbert) 325:8–326:10 (“Q.... when [the Asserted Patents] were brought to your attention, Biofrontera had not yet launched the RhodoLED XL product, right? A. Right.”); CX-0014C.147 (Jokerst), Q629; JX-0011C (Foguet), 41:24–42:2. Biofrontera admits that “RhodoLED® XL has been developed for use in photodynamic therapy in combination with Ameluz® gel.” JX-0086.5; *see* CX-0027C.3 (RFA Response No. 3) (admitting that “RhodoLED® XL can be used for photodynamic therapy (‘PDT.’)”); JX-0181.2 (Ameluz® indication for PDT using RhodoLED XL to treat AKs); JX-0104.4–5; RX-0002C.0018 (Foguet), Q40.

Acts of direct infringement. Biofrontera admitted its customers used RhodoLED® XL with Ameluz® to treat patients. CX-0024C.2 (RFA Response No. 9); CX-0024C.5–6 (No. 26); CX-0010C.78 (Jokerst), Q419–23; JX-0009C (Lyons), 76:16–77:15 (testifying as to Biofrontera's customers' use), 95:20–96:13; JX-0010C (Baldyga), 37:13–42:1, 212:3–22. Customers can use RhodoLED® XL in an infringing manner when sold by Biofrontera—the customer need not alter the default settings in to infringe. CX-0010C.75 (Jokerst), Q406. Biofrontera's marketing team even produced a video of a Biofrontera customer using the RhodoLED® XL with Ameluz to treat

a patient. JX-0073C (Dr. Lain video); JX-0009C (Lyons), 93:17–94:7; JX-0010C (Baldyga), 184:16–185:3.

Acts of inducement. Biofrontera conducts training to use RhodoLED® XL in accordance with the instructions in the User Manual. CX-0010C.75–77 (Jokerst), Q407–17; CX-0009C.35–36 (Shmuylovich), Q184–90; CX-1008C.21 (“[t]he user must be trained prior to using the device.... training is conducted by personnel authorized by Biofrontera.”); JX-0180C.4 (RhodoLED® XL will be “used exclusively by adequately trained health care professionals”); JX-0086.5 (“The user manual must be read carefully prior to using the RhodoLED® XL.”); JX-0010C (Baldyga), 152:19–155:9 (training occurs at customer site), 212:3–14; JX-0009C (Lyons), 95:20–96:13 (discussing customer training), 96:24–97:8, 100:2–101:8, 101:14–20 (discussing training of RhodoLED® XL sales force), 113:1–115:12; CX-0331C.3 (internal training presentation); RX-0002C.0036–38 (Foguet), Q104–07, Q114; RX-0004C.0022–23 (Luebbert), Q87–88. Biofrontera’s training includes an illustration of “the basic operation of the RhodoLED XL” and an overview of device components and instruct using the panels in the curved “C-shape” configuration. CX-0331C.8.

Encouraging infringing uses. Biofrontera encourages, recommends, and promotes infringing uses of RhodoLED® XL. For example, Biofrontera’s presentations and videos are intended to encourage sales and treatments using RhodoLED® XL. JX-0010C (Baldyga), 37:13–42:1, 40:6–11, 44:1–8, 184:16–185:3; JX-0009C (Lyons), 93:17–94:7. In those presentations, Biofrontera emphasizes infringing features including the uniform light output for PDT with ALA, from a five-panel illuminator in a curved configuration with the claimed LED arrangement:

Biofrontera Promotes That The RhodoLED® XL Has The Claimed Features

Shorter edge

Higher intensity of light emitted proximate the shorter edges

5 Panels with 225 LEDs in total (45 LEDs/panel) emit a uniform light

RhodoLED® XL is a red light-emitting LED lamp used in combination with AMELUZ® for

All five panels illuminated

Allows for full-face of full-scalp illumination treatment

RhodoLED® XL

Biofrontera

- RhodoLED® XL is a red light-emitting LED lamp used in combination with AMELUZ® for lesion- and field-directed Photodynamic Therapy treatment of mild-to-moderate AKs on the face and scalp
- Telescoping suspension and spring arm capabilities adds flexibility for patient and lamp head positioning
- Wheels provide easy mobility with safe locking mechanism

RhodoLED® XL

Biofrontera

Peak wavelength of ~635 nm

5 Panels with 225 LEDs in total (45 LEDs/panel) emit a uniform light

Allows for full-face of full-scalp illumination treatment

Treating with RhodoLED® XL:

- 15.5 minutes illumination time
- 37 J/cm² of energy delivery
- Total illumination area of 9.06 x 11.42 in (23 cm x 29 cm) when all 5 panels are used in curved configuration
- Treatment distance of 4.9 ± 0.59 in (12.5 cm ± 1.5 cm)

JX-0078C.6

CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER

JX-0078C.7

CDX-0018C.182

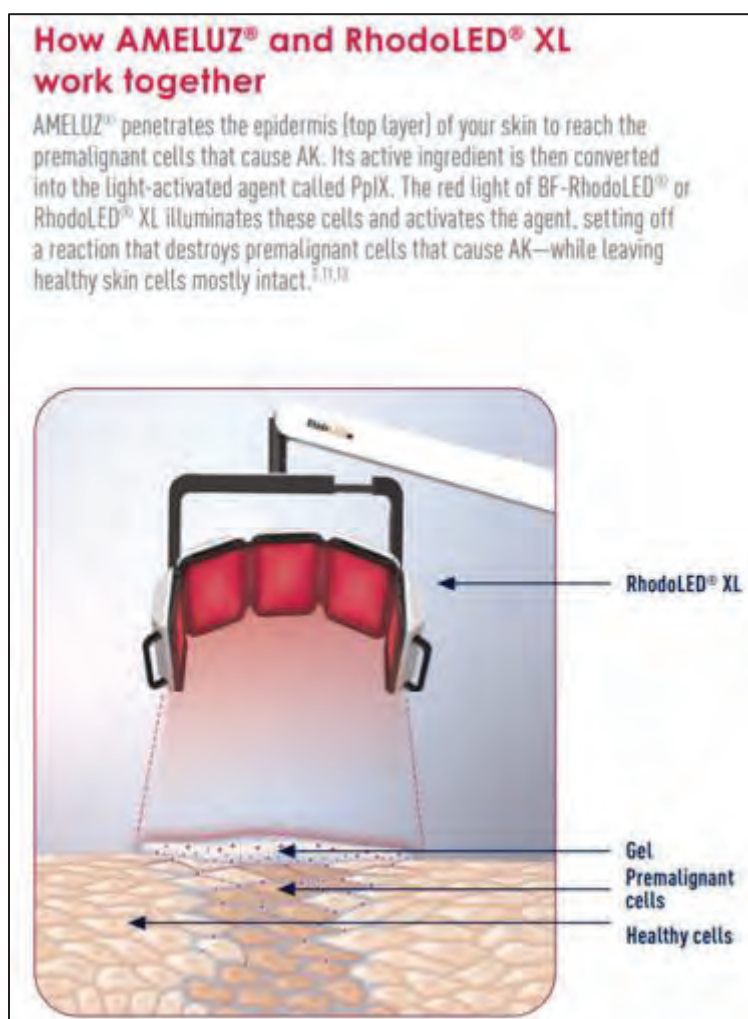
CDX-0018C.182; JX-0078.6–7; CX-0010C.95 (Jokerst), Q512–13.

Additionally, the Ameluz® label instructs infringing uses, including to “[p]osition 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.” CX-1009C.4.



JX-0208C.4.

As a further example, Biofrontera's marketing materials depict the RhodoLED® XL illuminating with five panels to Ameluz®-treated skin:



JX-0104.4.

The treatment process



Your healthcare provider will guide you through therapy with AMELUZ[®] (aminolevulinic acid HCl) topical gel, 10% and RhodoLED[®] XL

IMPORTANT SAFETY INFORMATION (selected)
When using this product:

- **Photosensitivity:** Avoid sun exposure on the treated lesion sites and surrounding skin for approximately 48 hours following treatment.
- **Geriatric Warning:** No overall differences in safety or effectiveness were observed between older (65 years and older) and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

AMELUZ[®]
 [aminolevulinic acid HCl] topical gel, 10%
 & RhodoLED[®] XL

- 1** Your healthcare provider will prepare the skin and apply AMELUZ[®] (application area should not exceed 20 cm²).
- 2** After waiting the recommended time (3 hours) to allow AMELUZ[®] gel to penetrate the targeted cells, your healthcare provider will illuminate the area with RhodoLED[®] XL lamp for 13.5 minutes. Your healthcare provider's staff will provide protective eyewear that must be worn during your RhodoLED[®] XL lamp treatment.




SAFETY
Adverse reactions and the safety of PDT with AMELUZ[®]
 Most common side effects at the application site were:

• skin reddening	• swelling	• scabbing
• pain/burning	• itching	• hardening
• irritation	• scaling of the skin	• blistering

Most side effects occurred during illumination or shortly afterwards, were generally of mild to moderate intensity, and lasted for 1 to 4 days in most cases; in some cases, they persisted for 1 to 2 weeks or even longer.

JX-0104.5. These materials highlight specific features, including five LED panels in a curved configuration and the panels' LED arrangements. JX-0010C (Baldyga), 20:4–32:21, CX-0084C; CX-0096.

Additionally, internal documents and the User Manual demonstrate that Biofrontera intends for customers to use five panels of the RhodoLED[®] XL for full-face PDT illumination.



CDX-0005C.30; CX-0009C.37–38 (Shmuylovich), Q200–02; JX-0105C.5; JX-0086.16; JX-0208C.4.

The User Manual shows the default configuration with five panels activated:



JX-0086.15.

8.4.5 Selecting Active LED Panels

The device has 5 LED panels which are also displayed by the software (Figure 10). The illustrated panels are visible from the back side and the corresponding panel of the device can be identified via the handles, starting from the left. All panels are activated by default and can be deactivated via the software. To deactivate LED panels, press on the illustrated panel. For easier orientation, the panel number can also be found at the backside of the respective panel (Figure 11).



Figure 10: Software illustration of RhodoLED® XL LED panels (all panels are activated)

JX-0086.16 (“[a]ll panels are activated by default” with a graphic of all panels activated). The only illumination area provided in the manual is for all five panels. JX-0086.17, .27. When fewer panels are activated, a dialog box appears which “must be confirmed” for the treatment to start:

8.4.6 Treatment Area

The illumination area of RhodoLED® XL is 9.06 x 11.42 inch (23 cm x 29 cm) when all panels are arranged in the standard curved shape. This usually allows a full-face illumination. However, face and head sizes are subject to strong variations between patients. As a rough guidance, the midlines of the outer two panels marks the outer boundaries of the illumination area (see Figure 13 as guidance).

Note: *The RhodoLED® XL LED panels should only be used in curved shape and not in fully unfolded form. This is necessary to ensure the application of 37 J/cm² during the illumination.*

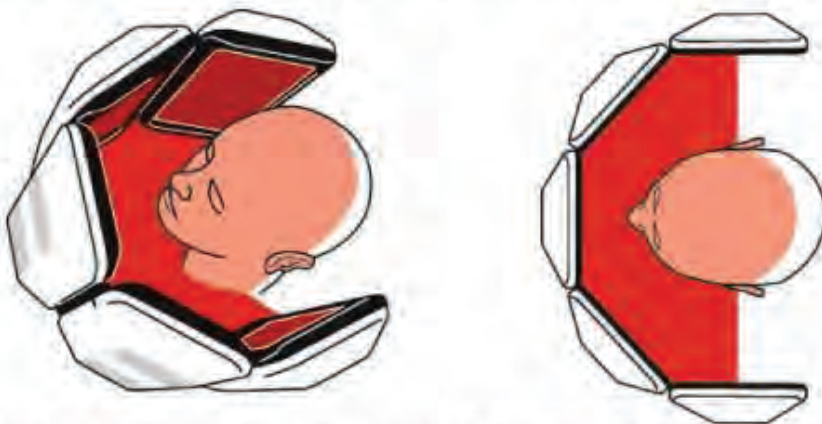


Figure 13: Treatment area of RhodoLED® XL from the side and in top view.

Note: *If 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.*

If a treatment with less than 5 active LED panels is started, a message dialog appears which must be confirmed.

JX-0086.17; JX-0067C.5 (Biofrontera telling FDA that “many patients with AK lesions scattered through face and scalp will require illumination with all five panels.... In the event that an illumination is started with less than 5 active panels, a pop-up notice occurs that reminds the operator that not all panels are active, such that it is ensured that panels have not been deactivated by accident”); CX-0017C.17–18 (Thompson), Q88–92; Tr. (Thompson), 131:3–132:19 (discussing warning language found at JX-0066C.29 when fewer than five panels are activated).

a. Claim 8

Using RhodoLED® XL in accordance with Biofrontera’s User Manual and instructions performs the method of Claim 8.

i. Element 8[p] - Undisputed

Using the RhodoLED® XL in accordance with Biofrontera’s instructions performs this limitation. CX-0010C.111–13 (Jokerst), Q597–603; CX-0009C.26–27 (Shmuylovich), Q135–38; JX-0086.2, .4, .5.

Claim 8 of the '512 Patent – Preamble

A method of photodynamically diagnosing or treating a patient

Construction – the preamble is limiting

Thank you for choosing the RhodoLED® XL LED lamp for your photodynamic therapy. RhodoLED® XL has been developed in accordance with applicable technical standards to provide high energy efficiency as well as constant light emission at the desired wavelength.

Your lamp must be installed and maintained by a qualified Biofrontera technician and used only in accordance with the instructions in this manual. You may request the latest printed version covering this model from Biofrontera at any time.

Our drug Ameluz® and medical device RhodoLED® XL have been approved in combination for photodynamic therapy; the only approved use of our lamp is in combination with Ameluz® gel. This user manual provides important RhodoLED® XL product details, precautions and warnings, and operating instructions. For Ameluz®, please use its US prescribing information. The Ameluz® prescribing information includes information on how to use the gel along with contraindications, warnings and precautions and dosage and administration.

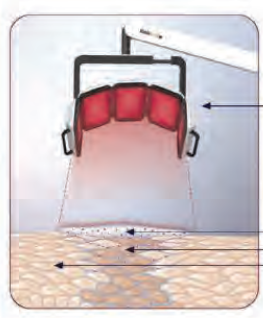
Thorough reading and use of both this user manual and the Ameluz® USPI is required prior to treatment.

Our combination Ameluz®/RhodoLED® XL for photodynamic therapy is only to be used by physicians or healthcare professionals.

JX-0086.2

How AMELUZ® and RhodoLED® XL work together

AMELUZ® penetrates the epidermis (top layer) of your skin to reach the premalignant cells that cause AK. Its active ingredient is then converted into the light-activated agent called PpIX. The red light of BF-RhodoLED® or RhodoLED® XL illuminates these cells and activates the agent, setting off a reaction that destroys premalignant cells that cause AK—while leaving healthy skin cells mostly intact.^{1,10,11}



JX-0104.4

3 Warnings and Precautions

 The RhodoLED® XL has been developed for use in photodynamic therapy in combination with Ameluz® gel (excitation wavelength 635 nm). Any other use or combination of use is prohibited.

JX-0086.5

CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER

CDX-0004C.224

CDX-0004C.224; JX-0086.2, .5; JX-0104.4.

ii. Element 8[a] - Undisputed

Using the RhodoLED® XL in accordance with Biofrontera's instructions performs this limitation. CX-0010C.113–14 (Jokerst), Q604–10; CX-0009C.27–29 (Shmuylovich), Q139–48.

Claim 8 of the '512 Patent – First Element	
administering 5-aminolevulinic acid (ALA) to the patient	
1 Intended Use RhodoLED® XL is a red light-emitting LED lamp, which is used exclusively in combination with Ameluz® gel for lesion-directed and field-directed treatment of actinic keratoses of mild-to-moderate severity on the face and scalp. JX-0086.4	STEP 4) Treat the affected skin area: Application, incubation, and removal of the topical medication according to the USPI of Ameluz®. JX-0086.9
3 Warnings and Precautions  The RhodoLED® XL has been developed for use in photodynamic therapy in combination with Ameluz® gel (excitation wavelength 635 nm). Any other use or combination of use is prohibited. JX-0086.5	Step 2. Application of AMELUZ Apply AMELUZ using glove protected fingertips or a spatula. Use sufficient amount of gel to cover individual lesions or the entire field: • Lesion-directed treatment: Apply gel approximately 1 mm thick to one or more individual AK lesions and include approximately 5 mm of the surrounding healthy skin • Field-directed treatment: Apply gel approximately 1 mm thick to the treatment field. Apply gel to the lesions and the skin in-between the lesions. Additionally, cover approximately 5 mm of the surrounding healthy area. Do not exceed an application area of 60 cm² and do not use more than 6 grams of AMELUZ (3 tubes) at one time. The gel can be applied to healthy skin around the lesions. Avoid application near mucous membranes such as the eyes, nostrils, mouth, and ears (keep a distance of 1 cm from these areas). In case of accidental contact with mucous membranes, thoroughly rinse with water [see Warnings and Precautions (5.7)]. Allow the gel to dry for approximately 10 minutes before applying occlusive dressing.  Figure 2: Drug application CX-1009C.3
How AMELUZ® and RhodoLED® XL work together AMELUZ® penetrates the epidermis (top layer) of your skin to reach the premalignant cells that cause AK. Its active ingredient is then converted into the light-activated agent called PpIX. The red light of BF-RhodoLED® or RhodoLED® XL illuminates these cells and activates the agent, setting off a reaction that destroys premalignant cells that cause AK—while leaving healthy skin cells mostly intact.^{7,10,11} JX-0104.4	CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER CDX-0004C.227

CDX-0004C.227; JX-0086.4, .5, .9; JX-0104.4; CX-1009C.3.

Infringement – Claim 8[a]: administering 5-aminolevulinic acid (ALA) to the patient

AMELUZ- aminolevulinic acid hydrochloride gel Biofrontera Inc.

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use AMELUZ safely and effectively. See full prescribing information for AMELUZ.

AMELUZ® (aminolevulinic acid hydrochloride) topical gel, 10%,
Initial U.S. Approval: 1999

RECENT MAJOR CHANGES

Dosage and Administration, Dosage and Administration Instructions (2.2) 3/2024

INDICATIONS AND USAGE

AMELUZ, a porphyrin precursor, in combination with photodynamic therapy using BF-RhodoLED or RhodoLED XL lamp, is indicated for the lesion-directed and field-directed treatment of actinic keratoses of mild-to-moderate severity on the face and scalp (1).

JX-0208C.1 (Biofrontera Information Sheet for Ameluz®)

7 RhodoLED® XL PDT Summarized Step-by-Step Instruction

These instructions should be used in conjunction with detailed operating instructions below (chapter 8). The section titles and numbers listed next to the instruction refer to the detailed instructions that correspond with each step.

Note: Every user of the RhodoLED® XL must be trained in operating the device. The initial training is provided by Biofrontera during set-up of the RhodoLED® XL. Recurrent training is not mandatory but can be provided by Biofrontera employees or other authorized parties. Before treating a patient with Ameluz®, please ensure that RhodoLED® XL is in good working order.

- STEP 1) Plug in the lamp.
- STEP 2) Turn on the lamp and wait for the home screen to appear (see chapter 8.4.3).
- STEP 3) Check the proper functioning of the RhodoLED® XL.
- STEP 4) Treat the affected skin area: Application, incubation, and removal of the topical medication according to the USPI of Ameluz®.
- STEP 5) Position the patient comfortably and equip the patient with protective eyewear (see chapter 6).
- STEP 6) Select active panels (see chapter 8.4.5).
- STEP 7) Position the lamp and adjust the lamp head over the skin area to be treated (distance 4.9 inch /12.5 cm) (see chapter 8.4.6).
- STEP 8) Put on protective eyewear and make sure anyone remaining in the treatment room also wears protective eyewear (see chapter 6).
- STEP 9) Start treatment by pressing **Start**, the illumination period begins (see chapter 8.4.9). Remind the patient to remain still throughout the illumination period. If audible indicators during treatment are activated, explain the sounds to the patient.

JX-0086.9 (RhodoLED® XL User Manual)

Confidential Business Information Subject to Protective Order

CDX-0005C.22

CDX-0005C.22; JX-0208C.1; JX-0086.9.

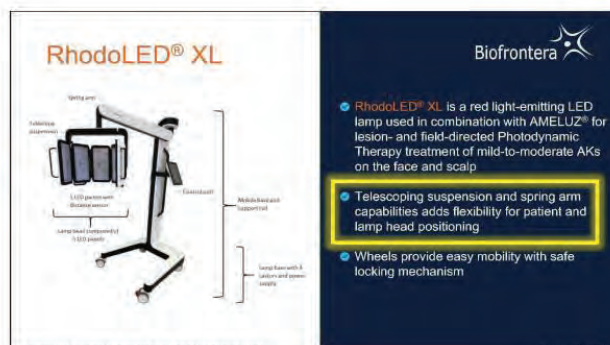
iii. Element 8[b] – Disputed, in part

Using the RhodoLED® XL in accordance with Biofrontera’s instructions performs this limitation.

First, using the RhodoLED® XL in accordance with Biofrontera’s instructions performs the step of positioning an illuminator proximate the patient. CX-0010C.115 (Jokerst), Q614–16; CX-0009C.29–31 (Shmuylovich), Q149–64.



CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER



BF_1411_ITC_00035023

JX-0078C.6

CDX-0004C.229

Infringement – Claim 8[b]: positioning an illuminator proximate to the patient

- STEP 1) Plug in the lamp.
- STEP 2) Turn on the lamp and wait for the home screen to appear (see chapter 8.4.3).
- STEP 3) Check the proper functioning of the RhodoLED® XL.
- STEP 4) Treat the affected skin area: Application, incubation, and removal of the topical medication according to the USPI of Ameluz®.
- STEP 5) Position the patient comfortably and equip the patient with protective eyewear (see chapter 6).
- STEP 6) Select active panels (see chapter 8.4.5).
- STEP 7) Position the lamp and adjust the lamp head over the skin area to be treated (distance 4.9 inch / 12.5 cm) (see chapter 8.4.6).
- STEP 8) Put on protective eyewear and make sure anyone remaining in the treatment room also wears protective eyewear (see chapter 6).
- STEP 9) Start treatment by pressing **Start**, the illumination period begins (see chapter 8.4.9). Remind the patient to remain still throughout the illumination period.
If audio indicators during treatment are activated, explain the sounds to the patient.

JX-0086.17 (RhodoLED® XL User Manual)

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CDX-0005C.25

41

Second, the RhodoLED® XL illuminator comprises at least five panels connected by nested hinges on inner side surfaces of adjacent panels for the same reasons as '512 Patent Element 1[a]. See §V.A.1.a.ii.; CX-0010C.120–21 (Jokerst), Q649.

iv. Elements 8[c] - Disputed

Using the RhodoLED® XL in accordance with Biofrontera's instructions performs this limitation. CX-0010C.116–17 (Jokerst), Q617–21; CX-0009C.31–33 (Shmuylovich), Q165–72.

First, using the RhodoLED® XL in accordance with Biofrontera's instructions performs the step of uniformly illuminating a treatment surface of the patient with light sources disposed on the at least five panels of the illuminator. JX-0086.9 (RhodoLED® XL User Manual); CX-0010C.116 (Jokerst), Q619; CX-0009C.31–32 (Shmuylovich), Q165–70 (explaining the User Manual steps that instruct performing PDT).

7 RhodoLED® XL PDT Summarized Step-by-Step Instruction

These instructions should be used in conjunction with detailed operating instructions below (chapter 8). The section titles and numbers listed next to the instruction refer to the detailed instructions that correspond with each step.

Note: Every user of the RhodoLED® XL must be trained in operating the device. The initial training is provided by Biofrontera during set-up of the RhodoLED® XL. Recurrent training is not mandatory but can be provided by Biofrontera employees or other authorized parties. Before treating a patient with Ameluz®, please ensure that RhodoLED® XL is in good working order.

- STEP 1) Plug in the lamp.
- STEP 2) Turn on the lamp and wait for the home screen to appear (see chapter 8.4.3).
- STEP 3) Check the proper functioning of the RhodoLED® XL.
- STEP 4) Treat the affected skin area: Application, incubation, and removal of the topical medication according to the USPI of Ameluz®.
- STEP 5) Position the patient comfortably and equip the patient with protective eyewear (see chapter 6).
- STEP 6) Select active panels (see chapter 8.4.5).
- STEP 7) Position the lamp and adjust the lamp head over the skin area to be treated (distance 4.9 inch /12.5 cm) (see chapter 8.4.6).
- STEP 8) Put on protective eyewear and make sure anyone remaining in the treatment room also wears protective eyewear (see chapter 6).
- STEP 9) Start treatment by pressing **Start**, the illumination period begins (see chapter 8.4.9).
Remind the patient to remain still throughout the illumination period.
If audible indicators during treatment are activated, explain the sounds to the patient.

JX-0086.9. For example, steps 5, 7, and 9 instruct positioning the patient and the lamp, and starting the illumination. *Id.* The User Manual notes that RhodoLED® XL “emits a uniform, visible light.” JX-0086.7.

Infringement – Claim 8[c]: uniformly illuminating a treatment surface of the patient

4.1 Light emitting diodes (LED)

RhodoLED® XL is a red-light emitting LED lamp, comprised of three main components, the lamp head, an easily adjustable spring arm, and the mobile base with castors for smooth transport. In addition, the lamp has a convenient touchscreen monitor and aids for positioning the lamp head. RhodoLED® XL has 45 LEDs per panel with a total of 5 panels (225 LEDs), which emit a uniform, visible red light. The typical peak wavelength is approximately 635 nm with a half-band width of 16 nm.

JX-0086.7 (RhodoLED® XL User Manual)

- STEP 1) Plug in lamp.
- STEP 2) Turn on the lamp and wait for home screen to appear (see chapter 7.3)
- STEP 3) Check the proper functioning of the BF-RhodoLED®.
- STEP 4) Treat the affected skin area: Application, incubation and removal of the topical medication following the USPI of Ameluz®.
- STEP 5) Position patient comfortably and place protective eyewear on patient (see chapter 5).
- STEP 6) Position the lamp and adjust the lamp head over the skin area to be treated (distance 5-8 cm) (see chapter 7.5.1).
- STEP 7) Put on protective eyewear and make sure anyone remaining in the treatment room also wears protective eyewear (see chapter 5).
- STEP 8) Start treatment by pressing "Treatment" on the home screen, press "Start" on the treatment screen, and press "Start" once again in the profile screen. The illumination period of 10 minutes begins (see chapter 7.5.3).
Remind the patient to remain still throughout the illumination period.

JX-0194C.12 (Ameluz® Full Prescribing Information)

Confidential Business Information Subject to Protective Order

CDX-0005C.27

CDX-0005C.27; JX-0086.7; JX-0194C.12.

It is undisputed that the RhodoLED® XL's illuminator is configured to uniformly illuminate a treatment surface of the patient via the light sources on five panels. See §V.A.1.a.iii. Biofrontera argues only that it does not induce infringement because users may perform a treatment using less than five panels. RX-0011C.24 (Ehrenreich), Q98. However, the default mode of the RhodoLED® XL activates all five panels:

8.4.5 Selecting Active LED Panels

The device has 5 LED panels which are also displayed by the software (Figure 10). The illustrated panels are visible from the back side and the corresponding panel of the device can be identified via the handles, starting from the left. All panels are activated by default and can be deactivated via the software. To deactivate LED panels, press on the illustrated panel. For easier orientation, the panel number can also be found at the backside of the respective panel (Figure 11).



Figure 10: Software illustration of RhodoLED® XL LED panels (all panels are activated)

JX-0086.16; CX-0009C.32 (Shmuylovich), Q168. And if a user attempts to start a treatment with fewer than five panels, a message appears warning the user that not all panels are activated:

Not all panels are activated. Please check whether the surface to be treated is adequately irradiated. If necessary, reposition the patient or activate more panels!	Message before starting a treatment if not all LED units are active
--	---

JX-0066C.29; Tr. (Thompson), 131:20–132:7 (testifying that JX-0066C.29 is the warning a user receives when less than five panels are active); Tr. (Ehrenreich), 517:12–20 (confirming affirmative action is necessary to start treatment with less than five panels); Tr. (Shmuylovich), 181:3–182:19. As Mr. Thompson testified, a warning message is typically included in software to alert the user that they are doing something that is not intended. Tr. (Thompson), 121:18–122:5, 131:3–132:15.

It is undisputed that Biofrontera customers have used all five panels to uniformly illuminate a patient during treatment. Biofrontera produced a promotional video where its customer performs PDT on a patient using Ameluz® and all five RhodoLED® XL panels. JX-0073C; CX-0009C.32

(Shmuylovich), Q168. Dr. Ehrenreich admitted the same. Tr. (Ehrenreich), 518:6–23. As discussed in §V.A.2, above, Biofrontera induces such use.

v. Element 8[d] - Undisputed

Using the RhodoLED® XL in accordance with Biofrontera’s instructions performs this limitation for the same reasons reviewed in connection with Element 1[d]. See §V.A.1.a.v.

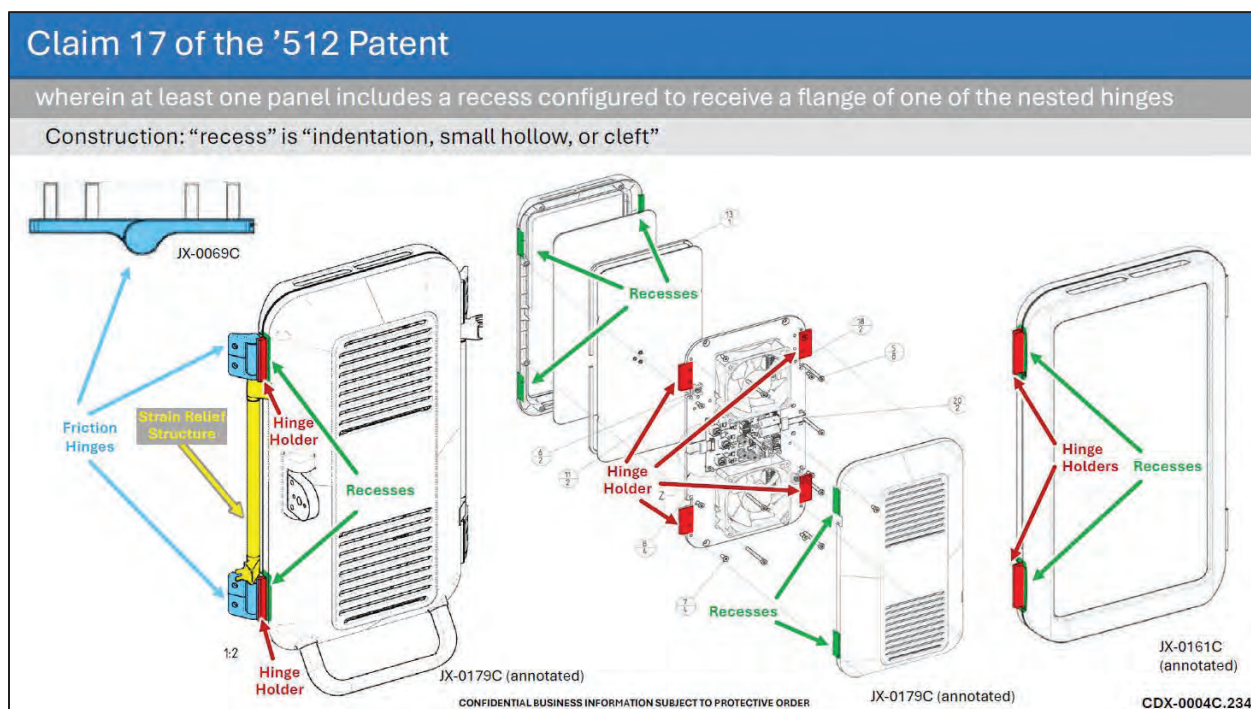
b. Claim 17

i. Element 17[p] – Disputed, in part

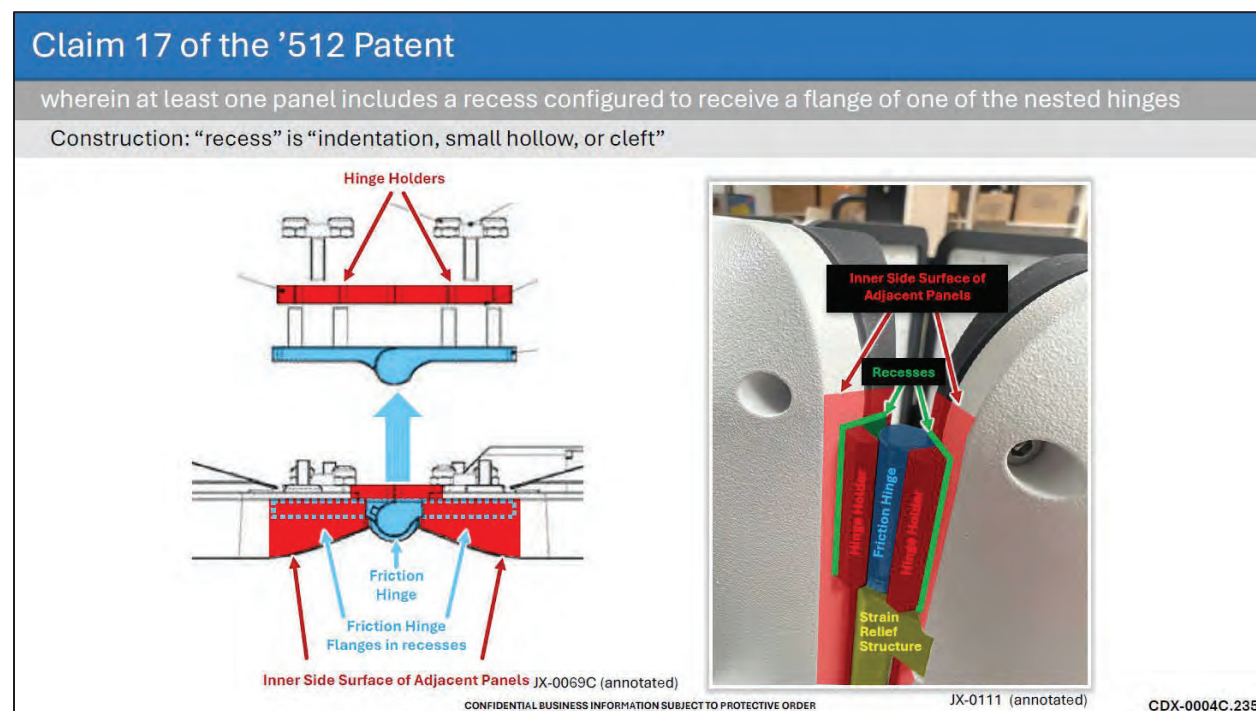
Using RhodoLED® XL in accordance with Biofrontera’s instructions performs the method of Claim 8. See §V.A.2.a.

ii. Element 17[a] - Disputed

The RhodoLED® XL meets this element. CX-0010C.117–19 (Jokerst), Q625–35. **First**, RhodoLED® XL’s friction hinges include a flange, as Biofrontera admits. CX-0022C.2–3 (RFA Response No. 28). **Second**, each panel shell has multiple recesses, as shown in the engineering diagrams below.



CDX-0004C.234; CX-0010C.117–18 (Jokerst), Q626–29; JX-0179C; JX-0161C. When assembled, those recesses define an opening configured to receive a flange of the friction hinge.



CDX-0004C.235; CX-0010C.118 (Jokerst), Q629–32, JX-0069C; JX-0111. Those openings are each a “small hollow” under the construction of “a recess”. CX-0010C.118–19 (Jokerst), Q631–34. Biofrontera’s non-infringement position assumes the claim excludes an opening or a hole, but that is contrary to the construction and embodiments in the specification. *See* JX-0001, 4:63–5:12; CX-0010C.87 (Jokerst), Q475.

c. Claim 18

i. Element 18[p] - Disputed

Using RhodoLED® XL in accordance with Biofrontera’s instructions performs the method of Claim 17. *See* §V.A.2.b.

ii. Element 18[a] - Disputed

As shown in connection with Claim 17, above, the recess is positioned at an inner side surface of the panel. CX-0010C.119–20 (Jokerst), Q641.

B. '028 Patent Asserted Claims

Biofrontera, via RhodoLED® XL, alone or in combination with Ameluz®, directly and/or indirectly infringes '028 Patent Claims 1, 2, 4, 16, 17, and 19–21.

1. Claim 1

a. Element 1[p] - Undisputed

RhodoLED® XL meets this element for the same reasons as '512 Patent Element 1[p]. See §V.A.1.a.i.

b. Element 1[a] - Disputed

As reviewed in connection with '512 Patent Element 1[a], each of the five panels of RhodoLED® XL are connected by one or more hinged structures on inner side surfaces of adjacent panels; specifically, two friction hinges and one strain relief structure are rotatable and connects adjacent panels. CX-0010C.123–26 (Jokerst), Q665–79.

Claim 1 of the '028 Patent – First Element

an illuminator comprising five panels connected by hinged structures on inner side surfaces of adjacent panels

Allgemeintoleranz/ General tolerances		Werkstoff/ Material		Nachbehandlung/ Surface treatment	
Tolerierung ISO 8015					
Oberflächen/ Surface	ISO 1302	Herstellerverfahren/ Technology		Masse/ Mass	
	ISO 13715			1.398 kg	
Bezugs/Drawn	22.07.2021	Name		Prüfverfahren/ Testing method	
Gepr./Ctd		F. Erbe			
Freig./Rls		Projektionskennung/ Project classification		Projektionsmethode/ Projection	
Änderung/ Change		9453			
Dokumentnummer/ Document number		Dok.-art/ Doc.-type		Teil.-No./ Det.-part	
9453 0602		XB		001 05	
Version		Bl.-formel/ Size		Bl.-No.	
		1:2		A1	
Biofrontera					
BF_1411_ITC_00000311					

JX-0179C (annotated)
CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER
CDX-0004C.252

CDX-0004C.252; JX-0179C.1 (annotated). In all other respects, RhodoLED® XL meets this element for the same reasons as '512 Patent Element 1[a]. See §V.A.1.a.ii.

c. Element 1[b] - Undisputed

RhodoLED® XL meets this element for the same reasons as '512 Patent Element 1[b]. See §V.A.1.a.iii.

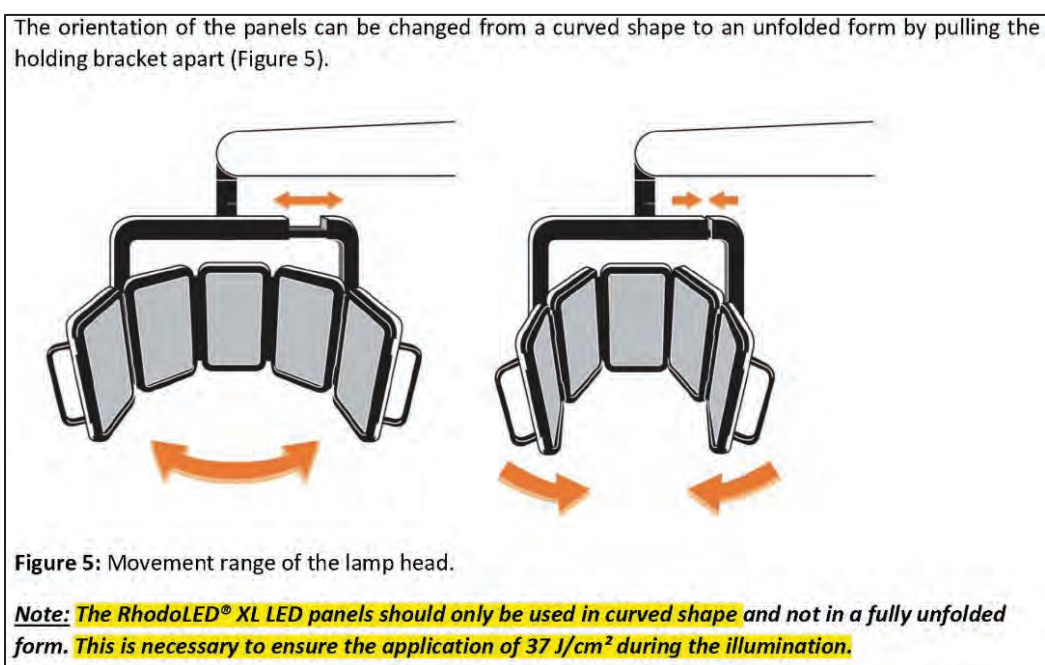
d. Element 1[c] - Undisputed

RhodoLED® XL meets this element for the same reasons as '512 Patent Element 1[c]. See §V.A.1.a.iv.

e. Element 1[d] - Disputed

The five RhodoLED® XL panels are positioned, and capable of being positioned, to allow treatment within approximately four inches of the treatment surface. CX-0010C.127–41 (Jokerst), Q684–751.

When Biofrontera designed RhodoLED® XL, it positioned the device's five panels in a row with hinges in between the panels at the end of the spring arm, allowing the panels to be placed in a curved shape proximate the patient. CX-0010C.127 (Jokerst), Q687. The manual states that the “panels should only be used in [a] curved shape” to ensure the proper light dose:



JX-0086.12. This design permits placing the panels in a curved shape, so that all five panels are within approximately four inches of the treatment surface. CX-0010C.127 (Jokerst), Q687.

RhodoLED® XL is configured to provide treatment at less than or equal to four inches. Biofrontera admits that it will operate when each of the five panels is positioned at a treatment distance of 4.0 inches. CX-0024C.4 (First Suppl. RFA Response No. 18). The manual notes if the panels are too close or too far, they still light up:

8.4.8 Adjustment Light

If the correct treatment distance of 4.9 inch (12.5 cm) is set the LEDs of the panel light up at a low light intensity to allow an easy adjustment of the distance and the target treatment area.

The size of the treatment area is 9.06 x 11.42 inch (23 cm x 29 cm) for all panels in a curved shape.

Note: When starting the treatment, the LED panels that are too close or too far away from the treatment area will nevertheless also light up. To disable an LED panel during the treatment it must be switched off on the display (see Figure 12).

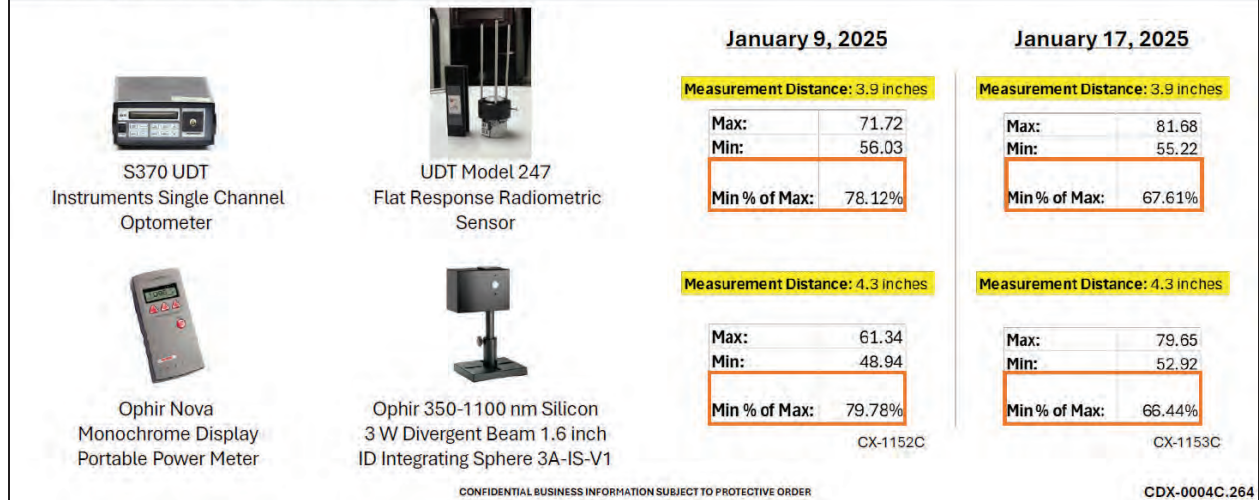
JX-0086.18; CX-0017C.14 (Thompson), Q68; Tr. (Thompson), 128:10–129:5. Biofrontera could have designed the RhodoLED® XL to only illuminate within the recommended range, but *intentionally chose not to*. Tr. (Thompson), 129:9–25. JX-0008C (Luebbert), 163:21–165:13 (Biofrontera designed the device without an automatic shutoff based on distance). Even Biofrontera’s documents reflect that it is “common” for a user to not follow the recommended range. CX-0010C.135 (Jokerst), Q724; JX-0083C.81, .86, .130, .211, .271.

Dr. Jokerst tested RhodoLED® XL to show it uniformly illuminates a treatment surface at 4.3 *and* 3.9 inches:

Claim 1 of the '028 Patent – Fourth Element

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

Construction: “within approximately four inches of the treatment surface” is “less than or equal to approximately four inches from the treatment surface.”



CDX-0004C.264; CX-0010C.69–73, .135 (Jokerst), Q375–95, Q723; CX-1152C; CX-1153C. That testing accords with Biofrontera’s calculations of uniformity at approximately four inches or less. CX-0010C.130–35 (Jokerst), Q700–22; JX-0067C; JX-0082C.3; JX-0083C.272–73; CX-1005C.120; CX-1109C. Biofrontera found that there is likely no effect on the patient if the reduced treatment distance leads to an increased light dose. CX-0010C.136 (Jokerst), Q726–27; JX-0063C.13; JX-0071C.28. No expert has rebutted Dr. Jokerst’s testing or analysis.

As another example, even if infringement requires considering only the recommended treatment distances, RhodoLED® XL’s approved treatment distance includes 4.3 inches:

Claim 1 of the '028 Patent – Fourth Element

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

Construction: “within approximately four inches of the treatment surface” is “less than or equal to approximately four inches from the treatment surface.”



JX-0086.15

The RhodoLED® XL LEDs are calibrated such that the skin being treated receives a light dose of approximately 37 J/cm² under the following conditions:

- illumination time of 13.5 minutes
- Treatment distance of 4.9 ± 0.6 inch ($12.5 \text{ cm} \pm 1.5 \text{ cm}$)

JX-0086.7

8.4.7 Adjusting the Treatment Distance

The correct treatment distance for the RhodoLED® XL is 4.9 ± 0.6 inch ($12.5 \pm 1.5 \text{ cm}$). Each LED panel is equipped with a distance sensor to allow individual adjustment of all panels. The distance sensor is automatically switched on if the panel is switched on. The current distance of each panel is shown on the control unit display above the panel illustration. The following table summarizes the visualization of the treatment distance.

Note: When starting the treatment, the LED panels that are too close or too far away from the treatment area will nevertheless also light up. To disable an LED panel during the treatment it must be switched off on the display (see Figure 12).

JX-0086.17

Typical irradiance	approx. $46 \text{ mW/cm}^2 \pm 20\%$ at 4.9 inch (12.5 cm) distance
Max irradiance	approx. 55 mW/cm^2 at 4.9 inch (12.5 cm) distance
Illuminated area	An area of 9.06×11.42 inch ($23 \text{ cm} \times 29 \text{ cm}$) is illuminated using all panels in curved shape.
Max. deviation of the intensity over the treatment area	Approx. 20 %
Treatment distance	4.9 ± 0.6 inch ($12.5 \text{ cm} \pm 1.5 \text{ cm}$)
	Measuring accuracy $\pm 0.3 \text{ cm}$ (0.1 inch)

JX-0086.27

CDX-0004C.260

CDX-0004C.260; CX-0010C.127–28 (Jokerst), Q685–692; JX-0086.7, .15, .17, .27; JX-0082C.3 (Biofrontera’s treatment range started at 10.5–14.5 cm (4.1–5.7 in), with a safety margin added for the sensor); CX-0010C.128 (Jokerst), Q692 (even when a panel is at 4.3 inches, a correct-distance checkmark is shown, see JX-0086.18 below):

Table 1: Adjusting the treatment distance

Pictogram	Meaning
	Treatment distance is correct for this LED panel (4.9 ± 0.6 inch / $12.5 \pm 1.5 \text{ cm}$), adjustment light is/turns on
	Treatment distance is too small for this LED panel. LED panel must be further away from treatment area, adjustment light is/turns off
	Treatment distance is too large for this LED panel. LED panel must be closer to the treatment area, adjustment light is/turns off
	This LED panel is switched off

4.3 inches meets the construction of “within approximately four inches.” CX-0010C.136–37 (Jokerst), Q728. Terms like “approximately” and “about” must be interpreted in their **technological context**. *Par Pharm., Inc. v. Hospira, Inc.*, 835 F. App’x 578, 584 (Fed. Cir. 2020); *Pall Corp. v. Micron Separations, Inc.*, 66 F.3d 1211, 1217 (Fed. Cir. 1995) (“about” avoids a “strict numerical boundary” and the “range must be interpreted in its technologic and stylistic context”). Dr. Jokerst testified that “approximately” is commonly used in engineering to refer to $\pm 10\%$, absent other information, and here, the Asserted Patents and technology provide additional information and context. CX-0010C.136–37 (Jokerst), Q728; Tr. (Jokerst), 204:18–24.

First, the Asserted Patents provide treatment distances in single-digit whole numbers, conveying that “approximately four inches” includes distances which would round to four inches, such as 3.7 and 4.4 inches (in accordance with the common engineering understanding of “approximately”). CX-0010C.136–37 (Jokerst), Q728. Thus, in the context of the Asserted Patents, the RhodoLED® XL’s listed treatment distance of 4.3 inches is “within approximately four inches.” *Id.*

Second, 4.3 inches is “within approximately four inches” in the context of PDT illuminators, the technology at issue, because PDT treatment distances convey how to place panels in a curved configuration around contoured treatment surfaces, like the human face. Those contoured surfaces have protrusions (such as the nose) on the order of about an inch. CX-0009C.19 (Shmuylovich), Q88; Tr. (Ehrenreich), 527:17–528:7. That degree of approximation is supported by documents both Biofrontera and Sun Pharma considered in designing their PDT illuminators. For example, “The Measure of Man and Woman,” was considered during BLU-U® 4170E development and shows that the nose protrudes about an inch from the face. CX-0009C.18–19

(Shmuylovich), Q83–88; JX-0203.26; CX-0010C.138–39 (Jokerst), Q739–43. Biofrontera used a similar document, [REDACTED] in designing the RhodoLED® XL:

[REDACTED]

CDX-0004C.268; CX-0010C.137–38 (Jokerst), Q732–34 (noting the RhodoLED® XL Design Review Report (JX-0071C.2) references [REDACTED] CX-0009C.18–19 (Shmuylovich), Q83–88.

The devices’ placement instructions account for facial variations. Sun Pharma instructs users to position all surfaces between two and four inches, implying a two-inch range (*i.e.*, 3±1in). JX-0091C.18 (4170E Operating Manual); CX-0010C.137, .139 (Jokerst), Q729–30, Q743; CX-0009C.18 (Shmuylovich), Q82. Biofrontera chose a 1.2-inch range for the RhodoLED® XL (4.9 inches ± 0.6). JX-0086.27, CX-0010C.137–38 (Jokerst), Q731–34; RX-0004C.0030 (Luebbert), Q107–08. Because PDT illuminators have treatment distance ranges of 1–2 inches around a center point to account for physiological variations, “approximately” must encompass that wide degree of variation. CX-0010C.139–40 (Jokerst), Q745. In practice, dermatologists like Dr. Ehrenreich

“don’t use a ruler to measure” the distance from the patient to the treatment surface, they “just eyeball” it. Tr. (Ehrenreich), 528:24–529:5. PDT’s technological context confirms that 4.3 inches, 0.3 inches above 4, is “within approximately four inches.”

Biofrontera relies only on Dr. Ehrenreich, not Dr. Grove, to argue noninfringement of this element. Dr. Ehrenreich has two noninfringement opinions.

First, Dr. Ehrenreich opines that “positioned to allow treatment” is a “method step” that must be performed by someone treating a patient—and Biofrontera does not treat patients. RX-0011C.0007 (Ehrenreich), Q21, Q66, Q68, Q139. However, these are system claims—“wherein the five panels are positioned to allow treatment within approximately four inches” describes a **capability** of the claimed system. See *Finjan, Inc. v. Secure Computing Corp.*, 626 F.3d 1197, 1204 (Fed. Cir. 2010) (“[T]o infringe a claim that recites capability and not actual operation, an accused device ‘need only be capable of operating’ in the described mode.”). Thus, Dr. Ehrenreich’s first opinion fails because it is legally misguided—there is no requirement of **use** to infringe. *R.A.C.C. Indus., Inc. v. Stun-Tech, Inc.*, 1998 WL 834329, at *3 (Fed. Cir. 1998) (“This court has never determined that functional language in a claim converts an apparatus claim into a method of use or hybrid claim.”).

Moreover, though Dr. Ehrenreich never considered the structural aspects of RhodoLED® XL, see RX-0011C.0009 (Ehrenreich), Q30, Dr. Grove did. He agreed with Dr. Jokerst that Biofrontera positions the five panels in a row, connected by hinges, to allow panels to be placed in a curved shape. Tr. (Grove), 433:23–436:4. Indeed, he admitted Biofrontera positions the panels that way because “that curved shape allows each of the panels to be approximately the same distance from the treatment surface.” Tr. (Grove), 436:5–10.

Second, Dr. Ehrenreich opines that the RhodoLED® XL is not configured to allow treatment within approximately four inches of a treatment surface, but that is factually wrong. As explained above, Biofrontera enables using RhodoLED® XL at treatment distances of less than or equal to 4.0 inches, and 4.3 inches meets the construction of “within approximately four inches.”

Dr. Ehrenreich argues that “approximately” implies only a “minimal” or “*de minimus*” variation excluding 4.3 inches. RX-0011C.0037 (Ehrenreich), Q152. Dr. Ehrenreich, however, does not explain what “minimal” or “*de minimus*” means in context or why a variation of just 0.3 inches does not qualify.

DOE: Even if Biofrontera does not literally infringe this element, Biofrontera still infringes under DOE.

Both the purportedly claimed distance range under Biofrontera’s interpretation and the RhodoLED® XL’s recommended treatment distance range perform the same function, because panels positioned in both ranges are capable of illuminating the treatment surface to activate ALA. CX-0010C.140–41 (Jokerst), Q746–51. These distances perform in the same way because RhodoLED® XL panels positioned at those distances deliver an adequate light dose to the treatment area. *Id.* These distances achieve the same result because RhodoLED® XL delivers uniform light at those distances to allow PD or PDT. *Id.* The equivalence of distances such as 4.3 inches and 4.0 inches is further supported by Biofrontera’s own broad treatment range, encompassing 1.2 inches, significantly more than the difference of 0.3 inches between what Biofrontera purports is the maximum claimed distance (4.0 inches plus a “*de minimus*” amount) and the minimum distance Biofrontera recommends (4.3 inches). *Id.* Finally, as discussed above, Biofrontera’s documents detail that decreasing the treatment distance has no adverse or beneficial effects. *Id.*

f. Element 1[e] - Undisputed

RhodoLED® XL meets this element for the same reasons as '512 Patent Element 1[d]. *See* §V.A.1.a.v.

2. Claim 2

a. Element 2[p] - Disputed

RhodoLED® XL infringes Claim 1. *See* §V.B.1.

b. Element 2[a] - Undisputed

RhodoLED® XL meets this element for the same reasons as '512 Patent Claim 3. *See* §V.A.1.b.

3. Claim 4

a. Element 4[p] - Disputed

RhodoLED® XL infringes Claim 1. *See* §V.B.1.

b. Element 4[a] - Undisputed

RhodoLED® XL meets this element for the same reasons as '512 Patent Claim 5. *See* §V.A.1.c.

4. Claim 16

a. Element 16[p] - Undisputed

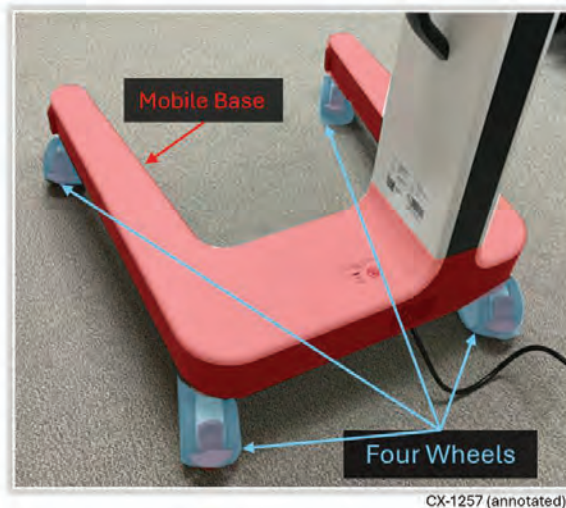
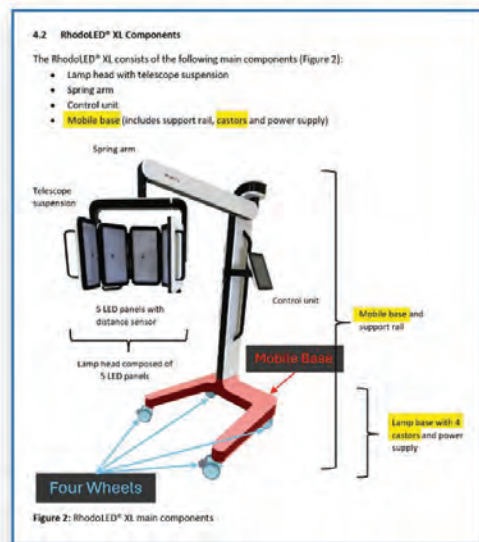
RhodoLED® XL meets this element for the same reasons as '512 Patent Element 1[p]. *See* §V.A.1.a.i.

b. Element 16[a] - Undisputed

RhodoLED® XL meets this limitation. CX-0010C.143 (Jokerst), Q767–69.

Claim 16 of the '028 Patent – First Element

a mobile base supported by at least four wheels



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CDX-0004C.278

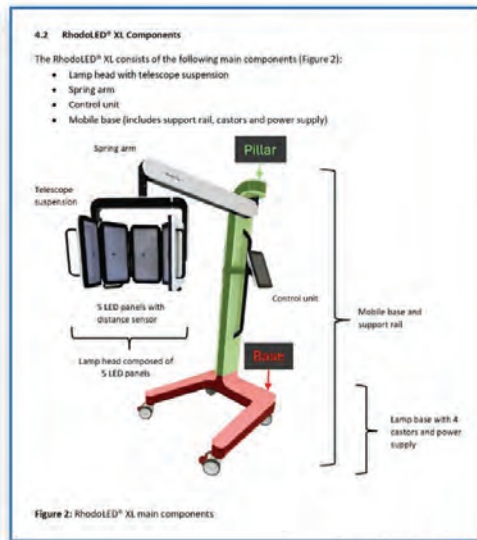
CDX-0004C.278; JX-0086.8; CX-1257.1; CX-0028C.6.

c. Element 16[b] - Undisputed

RhodoLED® XL meets this limitation. CX-0010C.143–44 (Jokerst), Q770–72.

Claim 16 of the '028 Patent – Second Element

a pillar perpendicular to the base



CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER

CDX-0004C.280

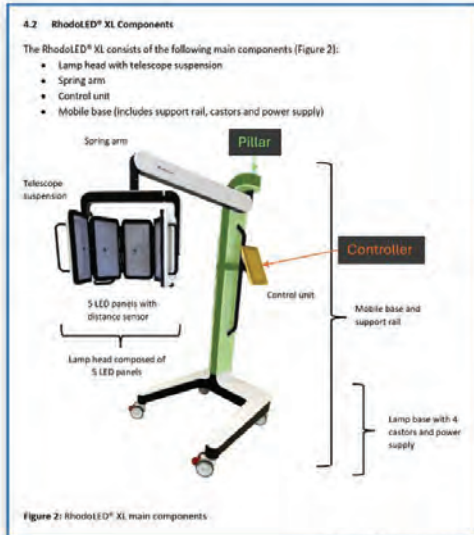
CDX-0004C.280; JX-0086.8; CX-1257; CX-0028C.6.

d. Element 16[c] - Undisputed

RhodoLED® XL meets this limitation. CX-0010C.144–45 (Jokerst), Q773–78.

Claim 16 of the '028 Patent – Third Element

a controller disposed to be supported by the pillar



JX-0086.8 (annotated)

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CDX-0004C.282

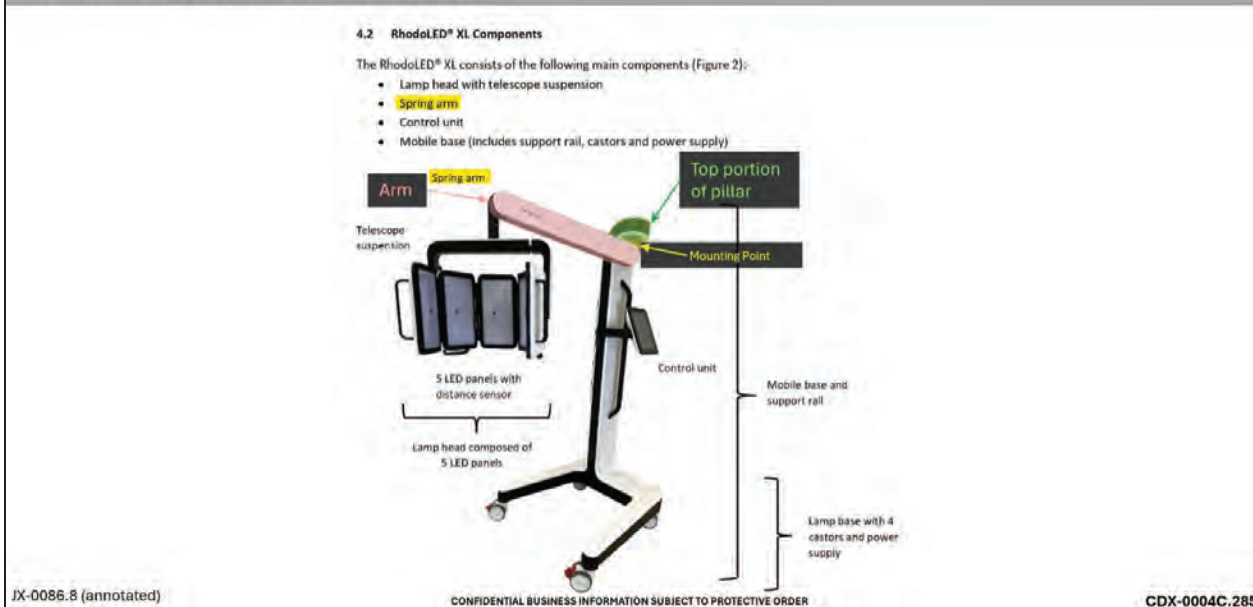
CDX-0004C.282; JX-0086.8; CX-1242; CX-1256; CX-1255C.20–21; JX-0063C.7; CX-0022C.10.

e. Element 16[d] - Undisputed

RhodoLED® XL meets this limitation. CX-0010C.145 (Jokerst), Q779–81.

Claim 16 of the '028 Patent – Fourth Element

an arm mounted to a top portion of the pillar



CDX-0004C.285; JX-0086.8; CX-0022C.10.

f. Element 16[e] - Undisputed

RhodoLED® XL meets this limitation. CX-0010C.145–46 (Jokerst), Q782–88.

Claim 16 of the '028 Patent – Fifth Element

an illuminator connected at an end of the arm

4.2 RhodoLED® XL Components

The RhodoLED® XL consists of the following main components (Figure 2):

- Lamp head with telescope suspension
- Spring arm
- Control unit
- Mobile base (includes support rail, castors and power supply)

JX-0086.8 (annotated)

2 RhodoLED® XL - General Description

RhodoLED® XL is comprised of three main components, the lamp head, an easily adjustable spring arm, and the mobile base with castors for smooth transport. In addition, the lamp has a convenient touchscreen monitor and aids for positioning the lamp head. The device is connected to the mains via a fixed mains supply cable.

JX-0086.4

JX-0086.11

JX-0086.12

CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER

CDX-0004C.287

CDX-0004C.287; JX-0086.4, .8, .11, .12 ; CX-0028C.7.

g. Element 16[f] - Undisputed

RhodoLED® XL meets this limitation. CX-0010C.146–47 (Jokerst), Q789–94.

Claim 16 of the '028 Patent – Sixth Element

the arm being hinged to allow adjustment of a position of the illuminator relative to the base

4.2 RhodoLED® XL Components

The RhodoLED® XL consists of the following main components (Figure 2):

- Lamp head with telescope suspension
- Spring arm
- Control unit
- Mobile base (includes support rail, castors and power supply)

JX-0086.8 (annotated)

2 RhodoLED® XL - General Description

RhodoLED® XL is comprised of three main components, the lamp head, an easily adjustable spring arm, and the mobile base with castors for smooth transport. In addition, the lamp has a convenient touchscreen monitor and aids for positioning the lamp head. The device is connected to the mains via a fixed mains supply cable.

JX-0086.4

8.2 Movement Areas

The swivel range of the spring arm to the left and right of the main axis is $\pm 5^\circ$. The vertical range of the spring arm is 68° . The spring arm with internal gas spring allows seamless adjustment to any height. The lamp head can be rotated by 360° (Figure 4). In addition, the panels can be tilted up to 90° at the holding bracket (Figure 4).

JX-0086.11

JX-0086.11 (annotated)

CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER

CDX-0004C.291

CDX-0004C.291; JX-0224C.3; JX-0086.4, .8, .11; CX-0022C.11.

h. Element 16[g] – Disputed, in part

RhodoLED® XL contains “five panels connected by hinged structures to allow continuous illumination across the five panels.” Claim 16 does not require the hinged structures to be “on inner side surfaces of adjacent panels.” Biofrontera admitted that “the five LED panels of the RhodoLED® XL include hinges that connects [sic] adjacent panels.” CX-0022C.2 (RFA Response No. 27). The hinges allow continuous illumination across the five panels for the same reasons as ’512 Patent Element 20[a]. See §V.A.1.d.ii. This limitation of the element is undisputed. Biofrontera G.R. 14.1, 10 (Element 16[G]).

Biofrontera disputes that “the five panels are individually configurable to control illumination from each of the five panels.” RhodoLED® XL meets this element because “the power output and/or light intensity of each panel can be individually controlled,” as required by the construction. This capability is demonstrated in several features, but overall, each RhodoLED® XL panel has [REDACTED] [REDACTED] CX-0017C.10–11, .15–17 (Thompson), Q40–46, Q77–87; Tr. (Thompson), 106:6–12; 122:21–123:15.

[REDACTED]

[REDACTED]

[REDACTED] [REDACTED] [REDACTED]

[REDACTED]



CDX-0006C.9; JX-0066C.18; JX-0065C.17; CX-1184C; CX-1260 ([REDACTED]).

[REDACTED]

[REDACTED]:

[REDACTED]

[REDACTED] CX-0010C.150–51 (Jokerst), Q809–16; CX-0017C.9 (Thompson), Q35–36; JX-0066C.24; JX-0065C.21.



CDX-0006C.10; JX-0066C.18; JX-0065C.21; CX-1185C. [REDACTED]

[REDACTED] CX-
0017C.9–10 (Thompson), Q37. [REDACTED]

[REDACTED]



CDX-0004C.296; CX-0010C.150–51 (Jokerst), Q810–14; JX-0066C.24; CX-0017C.10 (Thompson), Q40.



See CX-1261 (00:33) ([REDACTED]). Dr. Jokerst performed [REDACTED] on a RhodoLED® XL. CX-0010C.151 (Jokerst), Q813–14.



CX-1122; CX-1123 ([REDACTED]).⁴ [REDACTED]
[REDACTED].



⁴ [REDACTED] JX-0065C.20.

CDX-0004C.297; CX-0010C.150–51 (Jokerst), Q812; JX-0109C.4. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Activating/Deactivating Panels.

Each panel can be individually turned on or off, such that the power output and light intensity for a given panel can be set to either an activated state, where the default power and light intensity is output, or to a deactivated state, where no power and no light intensity is output. CX-0010C.151–53 (Jokerst), Q817–23.

Claim 16 of the '028 Patent – Seventh Element

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

Construction: “the five panels are individually configurable to control illumination from each of the five panels” is “the power output and/or light intensity of each panel can be individually controlled.”

8.4.5 Selecting Active LED Panels

The device has 5 LED panels which are also displayed by the software (Figure 10). The illustrated panels are visible from the back side and the corresponding panel of the device can be identified via the handles, starting from the left. All panels are activated by default and can be deactivated via the software. To deactivate LED panels, press on the illustrated panel. For easier orientation, the panel number can also be found at the backside of the respective panel (Figure 11).



Figure 10: Software illustration of RhodoLED® XL LED panels (all panels are activated)



CX-1267

JX-0086.16



CX-1241

CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER
CDX-0004C.299

CDX-0004C.299; JX-0086.16; CX-1267; CX-1241; CX-1112 (video showing panel deactivation during treatment); [REDACTED]

The ability to individually adjust the LED intensities of the panels is not in dispute. CX-0024C.5 (First Suppl. RFA Response No. 24) ([REDACTED])

[REDACTED]; see also Tr. (Luebbert), 341:13–21 ([REDACTED]). The ability to deactivate individual panels during a treatment session is also not in dispute. CX-0024C.5 (First Suppl. RFA Response No. 19) ([REDACTED]).

Dr. Grove, Biofrontera’s technical expert offers no opinions regarding this element. See, generally, RX-0009C (Grove). Rather, Biofrontera, through its medical expert, argues that this element is not met because: (1) access to the service menus is protected by a password, which is not given to healthcare professionals, RX-0011C.0045–46 (Ehrenreich), Q177–78, Q186, and (2) this element is a method step which Biofrontera does not induce healthcare providers to perform during a treatment. *Id.*, Q176–78. Both arguments fail.

First, the construction requires only that the “power output and/or light intensity of each panel can be individually controlled.” The element describes a capability of the system—the construction does not impose any requirements on who must perform the adjustments or when.

Second, the element is not a method step within the system claim. The preamble of “treating a patient” does not transform this limitation into a method step that must be performed during treatment. *Jazz Pharms., Inc. v. Avadel CNS Pharms., LLC*, 60 F.4th 1373, 1380 (Fed. Cir.

2023) (“That the claimed systems can be used in the course of treating patients suffering from narcolepsy does not alter the fact that these are system claims.”) (citing *MasterMine Software, Inc. v. Microsoft Corp.*, 874 F.3d 1307, 1315–16 (Fed. Cir. 2017) (finding that inclusion of active verbs and other functional language describing capabilities of claimed system does not transform system claim into method claim)); *R.A.C.C. Indus.*, 1998 WL 834329, at *3 (“This court has never determined that functional language in a claim converts an apparatus claim into a method of use or hybrid claim.”). When the RhodoLED® XL is imported and sold, it infringes because it includes five panels whose power output and light intensity can be individually controlled, such that they are individually configurable to control illumination from each of the five panels.

i. Element 16[h](a) - Undisputed

RhodoLED® XL meets this element for the same reasons as '512 Patent Element 1[b]. See §V.A.1.a.iii.

Claim 16 of the '028 Patent – Eighth Element

... the light sources being configured to output light uniformly during at least part of a time when the treatment surface is illuminated ...

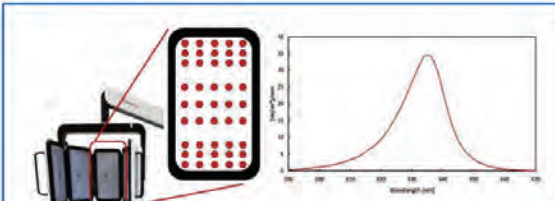


Figure 1: LED panels with LED distribution and emission spectrum of RhodoLED® XL LEDs.

The LEDs are distributed on each panel in a specific way (see Figure 1), such that they are more densely packed towards the upper and lower edges than in the center region of each panel. This distribution optimizes the homogeneity of illumination over the treated skin.

JX-0086.7

13.2 Specification

Type	RhodoLED® XL Medical device class III; Device of protection class 1
Certification	UL certified E513735
Software Version No.	g2.12.00.3739
Service interval	Biofrontera recommends performing service every 2 years
Number of LEDs	225
Typical peak wavelength	635 nm ± 5 nm
Light dose	Approx. 37 J/cm² at 4.9 inch (12.5 cm) distance, 13.5 min
Typical irradiance	approx. 46 mW/cm² ± 20 % at 4.9 inch (12.5 cm) distance
Max irradiance	approx. 55 mW/cm² at 4.9 inch (12.5 cm) distance
Illuminated area	An area of 9.06 x 11.42 inch (23 cm x 29 cm) is illuminated using all panels in curved shape.
Max. deviation of the intensity over the treatment area	Approx. 20 %
Treatment distance	4.9 ± 0.6 inch (12.5 cm ± 1.5 cm) Measuring accuracy ± 0.3 cm (0.1 inch)

JX-0086.27

CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER

CDX-0004C.301

CDX-0004C.301; CDX-0004C.302; JX-0086.7, .27; JX-0165C.1, .2.

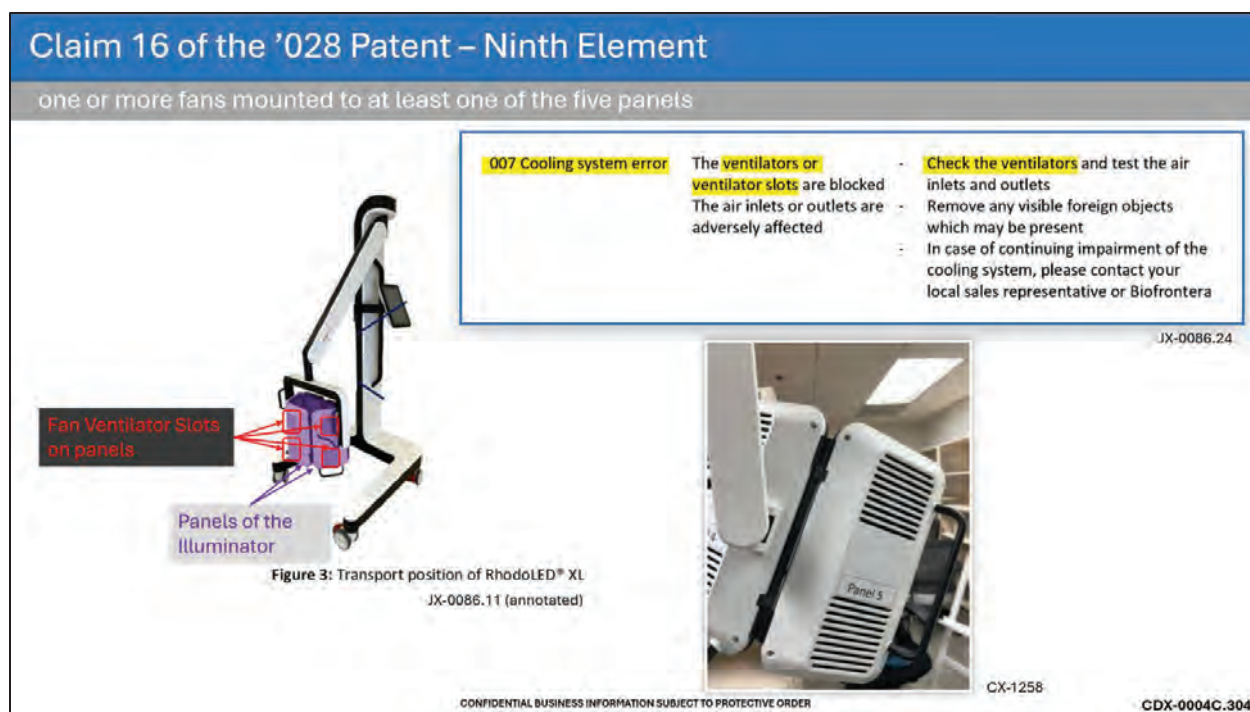
j. Element 16[h](b) - Undisputed

RhodoLED® XL meets this limitation for the same reasons as '512 Patent Element 1[d].

See §V.A.1.a.v.

k. Element 16[i] - Undisputed

RhodoLED® XL meets this limitation. CX-0010C.155–56 (Jokerst), Q831–37.



CDX-0004C.304; JX-0086.11, .24; CX-1258; JX-0178C.7; JX-0223C.18; CX-0028C.8.

5. Claim 17

a. Element 17[p] - Disputed

RhodoLED® XL infringes Claim 16. See §V.B.4.

b. Element 17[a] - Undisputed

RhodoLED® XL meets this element for the same reasons as '512 Patent Element 1[c]. See §V.A.1.a.iv.

6. Claim 19

a. Element 19[p] – Disputed

RhodoLED® XL infringes Claim 16. *See* §V.B.4.

b. Element 19[a] - Undisputed

RhodoLED® XL meets this element for the same reasons as '512 Patent Claim 3. *See* §V.A.1.b.

7. Claim 20

a. Element 20[p] - Undisputed

RhodoLED® XL meets this element for the same reasons as '512 Patent Element 1[p]. *See* §V.A.1.a.i.

b. Element 20[a] – Disputed, in part

Biofrontera disputes the “hinged structures” portion of this element. RhodoLED® XL meets the “hinged structures” portion of the element for the same reasons as '028 Patent Element 1[a]. *See* §V.A.1.a.ii.

Dr. Jokerst testified that RhodoLED® XL meets the “variable irradiance density” portion of the element. CX-0010C.157–58 (Jokerst), Q850.

Claim 20 of the '028 Patent – First Element

... wherein the illuminator is configured to output light at a variable irradiance density during treatment

8.4.8 Adjustment Light

If the correct treatment distance of 4.9 inch (12.5 cm) is set the LEDs of the panel light up at a low light intensity to allow an easy adjustment of the distance and the target treatment area.

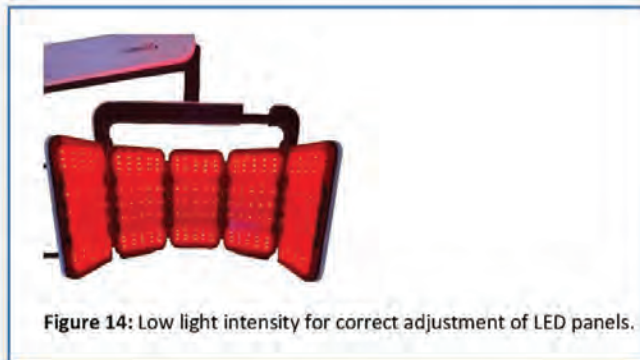


Figure 14: Low light intensity for correct adjustment of LED panels.

JX-0086.18

CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER

CDX-0004C.312

CDX-0004C.312; JX-0086.18; CX-0022C.4; CX-0017C.12–13 (Thompson), Q51–64. This is undisputed. Biofrontera G.R. 14.1, 11 (Element 20[C]).

c. Element 20[b] - Undisputed

RhodoLED® XL meets this element for the same reasons as '512 Patent Element 1[b]. See §V.A.1.a.iii.

d. Element 20[c] - Undisputed

RhodoLED® XL meets this element for the same reasons as '512 Patent Element 1[c]. See §V.A.1.a.iv.

e. Element 20[d] - Disputed

RhodoLED® XL meets this element for the same reasons as '028 Patent Element 1[d]. See §V.A.1.a.v.

f. Element 20[e] - Undisputed

RhodoLED® XL meets this element for the same reasons as '512 Patent Element 1[d]. See §V.A.1.a.v.

8. Claim 21

a. Element 21[p] - Undisputed

RhodoLED® XL meets this element for the same reasons as '512 Patent Element 1[p]. *See* §V.A.1.a.i.

b. Element 21[a] - Disputed

RhodoLED® XL meets this element for the same reasons as '028 Patent Element 1[a]. CX-0010C.160 (Jokerst), Q865–66; *see* §V.A.1.a.ii.

c. Element 21[b] - Undisputed

RhodoLED® XL meets this element for the same reasons as '512 Patent Element 1[b]. *See* §V.A.1.a.iii.

d. Element 21[c] - Undisputed

RhodoLED® XL meets this element for the same reasons as '512 Patent Element 1[c]. *See* §V.A.1.a.iv.

e. Element 21[d] - Disputed

RhodoLED® XL meets this element for the same reasons as '028 Patent Element 1[d]. CX-0010C.160–61 (Jokerst), Q871–72; *see* §V.A.1.a.v.

f. Element 21[e] - Undisputed

RhodoLED® XL meets this element for the same reasons as '028 Patent Element 16[g]. *See* §V.B.4.h.

g. Element 21[f] - Undisputed

RhodoLED® XL meets this element for the same reasons as '512 Patent Element 1[d]. *See* §V.A.1.a.v.

9. Indirect Infringement

Biofrontera indirectly infringes the '028 Patent Asserted Claims, for the reasons reviewed regarding indirect infringement of the '512 Patent. *See* §V.B.2.

Biofrontera argues that it does not instruct healthcare providers to position the panels of the RhodoLED® XL device within approximately four inches of a patient's treatment surface. RX-0011C.0042 (Ehrenreich), Q168. However, these system claims do not require performance of a step. *See* §V.B.1.e. Regardless, direct infringement occurs when the device is used by the healthcare providers. V.B.4.h.

Biofrontera argues that it does not instruct healthcare providers to control illumination from each of the five panels during treatment. RX-0011C.0044 (Ehrenreich), Q176. However, these system claims do not require performance of a step, either before or during treatment. *See* §V.B.4.h. Regardless, direct infringement occurs when the device is used by healthcare providers. *See id.*

VI. VALIDITY

Under 35 U.S.C. §282, each claim of a patent is presumed valid independent of the validity of any other claim(s) in that patent. 35 U.S.C. §282. This presumption is particularly strong when considering a prior art reference that was considered during prosecution of an Asserted Patent. *Glaxo Grp Ltd. v. Apotex, Inc.*, 376 F.3d 1339, 1348 (Fed. Cir. 2004).

The challenger bears the burden of proving invalidity by clear and convincing evidence. *Microsoft Corp. v. i4i Ltd. P'ship*, 564 U.S. 91, 100 (2011). "Obviousness requires more than a mere showing that the prior art includes separate references covering each separate limitation in a claim...." *Unigene Labs., Inc. v. Apotex, Inc.*, 655 F.3d 1352, 1360 (Fed. Cir. 2011).

A. Non-Obviousness

Biofrontera asserts:

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

RX-0006C.18–19, 30 (Grove), Q84, Q140.

Because Biofrontera's primary references, Lundahl and Larsen, are listed on the face of the Asserted Patents, Biofrontera has "the added burden of overcoming the deference that is due" to the PTO who allowed that patents in view of that art. *Shire LLC v. Amneal Pharms., LLC*, 802 F.3d 1301, 1307 (Fed. Cir. 2015). Here, the examiner considered Larsen during prosecution, and the Asserted Patents incorporate Lundahl by reference in the Background section. JX-0004.160; JX-0003.48, .100; RX-0065.1; RX-0057.1.

Biofrontera fails to meet its burden. For example, Biofrontera claims both Larsen and Hente disclose "five panels connected by nested hinges/hinged structures on inner side surfaces." See RX-0006C.0031–37 (Grove), Q145–63. But its expert conceded that (1) Larsen does not show what its hinges look like or describe their physical structure and (2) Hente does not disclose hinges ***in any detail***:

All right. Dr. Grove, I know we don't agree on the location of the hinges in Figure 1 in Larsen, but we can agree that in Figure 1 of Larsen, you can't actually see what Larsen's hinges look like, right?

A. That's correct.

Q. Okay. And in the Larsen specification, Larsen doesn't provide a description of the physical structure of the hinges. Fair?

A. Fair.

Tr. (Grove), 563:1–9.

Q. Okay. And we can agree that Hente does not describe what its hinges actually look like, right?

A. That is also correct.

Q. And Hente does not describe whether its hinges have flanges that extend or whether they are kind of short, stubby flanges. True?

A. Yeah, Hente does not disclose hinges in any detail.

Id. (Grove), 585:5–12.

Without an explanation in either reference as to the structure of the hinges or **how** they connect to the panels, Biofrontera asserts it was simply obvious to place hinges on inner side surfaces. But that is impermissible hindsight, backfilling a lack of disclosure in the art—and ignores that hinges on inner side surfaces were known to create gaps and optical dead zones.

Similarly, Dr. Grove admits that no reference independently discloses that each of the five panels has light sources arranged such that a higher intensity of light is emitted close to the shorter edges: Lundahl does not have five panels and Larsen discloses light sources that are equidistant from each other. Tr. (Grove), 566:1–11, 569:11–14. Moreover, Dr. Grove admits that in Lundahl,

the higher intensity of light is emitted from the *longer edges*. See Tr. (Grove), 565:4–8. Dr. Grove’s analysis thus relies on picking and choosing pieces from the prior art using hindsight: he is “using Lundahl’s spacing and light distribution of the light sources, and then dividing Lundahl’s one-panel device into five panels” pulled from Larsen. Tr. (Grove), 570:15–19. This hindsight is evident because (1) Lundahl’s light distribution *includes* areas of reduced emission outside the center portion, and (2) the higher intensity generated in the center portion was created by more than just tube spacing, it required requiring carefully selected and engineered components. CX-0014C.64, .69, .73 (Jokerst), Q259, Q279, 291. However, Dr. Grove’s combined device ignores Lundahl’s overall light distribution. See, e.g., RDX-0017C.049.

Likewise, Biofrontera claims Lundahl and Larsen disclose or teach the uniform illumination limitation. But Dr. Grove admitted that Larsen does *not* disclose how to achieve uniformity meeting the requirements of 60% of the measured maximum at all points, as required by the construction.

Q. Okay. Now, you just mentioned Lundahl, but Larsen doesn't disclose how to achieve uniformity meeting the requirements of 60 percent of the measured maximum at all points. You agree with that statement? A. Yes, I do. Q. Okay. That teaching is coming from Lundahl, right? A. Yes.
--

Tr. (Grove), 574:16–23. Instead, Dr. Grove relies on Lundahl for this element. *Id.* Dr. Grove agrees that Lundahl discloses spacing its tubes as one teaching among many required to achieve its uniformity, *id.* (Grove), 576:4–578:7 (agreeing that Lundahl discloses achieving uniformity through at least U-shaped tubes, a nine-segmented reflector with precise angles and distances,

differently cooled portions, and light sensors, all in addition to spacing). But Dr. Grove never showed that taking only Lundahl’s spacing of tubes without those other components and applying Larsen’s LEDs would lead to an illuminator configured to “uniformly illuminate a treatment surface” with the tolerance required by the construction. Dr. Grove himself claimed that even with the disclosures of the Asserted Patents and the prior art, it would require “undue experimentation to make and use an illuminator that provides uniform illumination over the full scope of the claims.” *Id.* (Grove), 579:18–25.

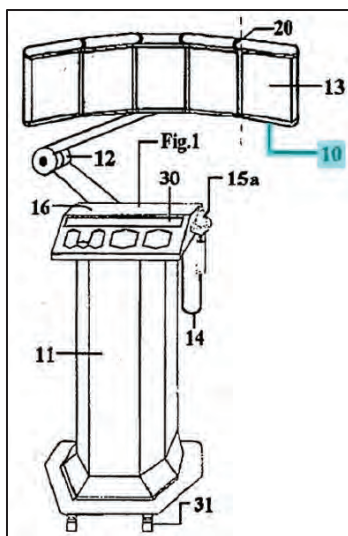
1. “five panels connected by [nested hinges/hinged structures] on inner side surfaces of adjacent panels.”

Claim limitations 1[a], 8[b], 20[a] of the ’512 Patent, and 1[a], 20[a], and 21[a] of the ’028 Patent recite the above language.

a. Lundahl in View of Larsen

Lundahl in view of Larsen does not disclose or render obvious this element. Dr. Grove admitted that Lundahl does not disclose five panels or hinges. Tr. (Grove), 562:15–17, 573:11–13. For this limitation, Biofrontera relies solely on Larsen. Tr. (Grove), 562:18–21.

Larsen does not disclose or render obvious the claimed hinges. CX-0014C.50, .56 (Jokerst), Q196, Q231. In its only disclosure of hinges, Larsen cites Figure 1 and explains that “several applicators 13 are flexibly connected to each other through **hinges 10**.” RX-0057.0012, [0072]; CX-0014C.50 (Jokerst), Q197. As shown in Figure 1 below, element “**10**” points to the **bottom** of applicator 13, **not** the inner side surfaces of adjacent panels. CX-0014C.50 (Jokerst), Q197–98.



RX-0057, Fig. 1, [0027], [0040], [0069], [0071], [0072].

Larsen’s express disclosure of hinges on the bottom of the applicator—not on the inner side surfaces—is corroborated by the prosecution histories of the Asserted Patents and related applications. CX-0014C.50–56 (Jokerst), Q197–231; JX-0004.1731 (Examiner allowing claims of the ’512 Patent over Larsen stating “the art of record neither anticipates nor renders obvious ‘nested hinges on inner side surfaces of adjacent panels’”); RX-0059 (Larsen ’381 Patent); JX-0003.130 (during ’028 Prosecution, Same Examiner recognizing Larsen ’381 Patent discloses “Hinged Structures 10” in reference to same Figure 1); CDX-0018C.64; JX-0003.446–52 (allowing claims of the ’028 Patent over the prior art of record, which included the Larsen ’381 Patent (that contains the same Figure 1 disclosure as the Larsen publication)). Larsen used the same convention in another application, where he identified “individual hinged (27) flat elements (26)” in reference to hinges on the bottom of the panels:

Larsen's Australian Application Also Points To Hinges On The Bottom Of Fig. 1

Figure 1 of Larsen

Dr. Grove's "labeling error" argument conflicts with:

1. Larsen's express disclosure of "Hinges 10" & "Regular Row Arrangements, i.e., 20"
2. The Examiner recognized Hinged Structures 10 (*see Figure 1...*) during prosecution of the '028 Patent
3. Larsen's Australian Application has a nearly identical Figure 1 with bottom hinges
4. The Examiner's decision was based on the fact that the Examiner found no prior art teaching of the claimed invention.

RX-0057.0002, Fig. 1 (annotated)

Figure 3d of the Larsen Australian Application

JX-0189.22, Fig. 3a (annotated)

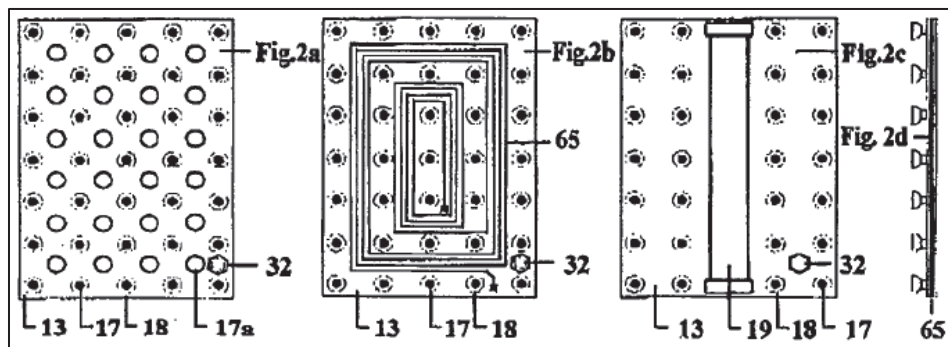
19. Device according to one of the previous claims, wherein the components are housed in:

- a) - a hood-shaped applicator (2),
- b) - a flat applicator (25) consisting of a number of individual hinged (27) flat elements (26) which can be adjusted in angles to each other.

JX-0189.17
CDX-0018C.65

CDX-0018C.65, .67; RX-0057.0002; JX-0189.17, .22 (identifying "27" as "individual hinged"); JX-0191, 8:27–30, 8:41–47 (patent issuing from U.S. Larsen patent application disclosing "applicators 13 are flexibly connected to each other through hinges 10"); Tr. (Jokerst), 761:7–764:19.

Contrary to Biofrontera's assertion, "hinges 10" is not a typo that should read "hinges 20. CX-0014C.50–51 (Jokerst), Q199–201. Larsen identifies element 20 as the regular row arrangements of light sources in applicator 13, as shown below:



RX-0057.0012, [0071] (“According to FIGS. 2*b* and 2*c* **the light sources 17 are placed in regular row arrangements, i.e., 20** equidistant from each other”), [0074], [0079]; CX-0014C.50–51 (Jokerst), Q200–01. The dotted line in Figure 1 indicates a cross-section view, meaning it shows a cut through the object to reveal its internal structure; there is no indication that it identifies hinges on the inner side surfaces of adjacent panels. CX-0014C.55–56 (Jokerst), Q225–30. Instead, the dotted line instructs the reader as to the location of the more detailed views found in Figures 2*a*–2*d* which show the light sources “in regular row arrangements, i.e., 20” as disclosed by Larsen at [0071]. CX-0014C.56 (Jokerst), Q227–30; RX-0057.0011, [0040–0041]. Those figures are details of the applicators, as opposed to other portions of the device shown in Figure 1. CX-0014C.56 (Jokerst), Q227–29.

Finally, a POSITA would not be motivated to place hinges on the inner side surfaces of Larsen’s panels; Larsen’s disclosures would motivate placing hinges **on the bottom**, as placing hinges on the inner side surfaces would impede the panels from being flush and impact uniformity. CX-0014C.57 (Jokerst), Q232–35. There are numerous hinge designs for the bottom, top, or back of panels; and a POSITA would have been discouraged from adding hinges to the front, which would block light, or between the panels, which can create gaps, interfere with wiring, and create alignment issues—all of these issues frustrating the goal of providing uniform illumination. CX-0014C.57–58, .79 (Jokerst), Q234–38, Q310; JX-0015C (Carota), 88:8–89:1; JX-0008C (Luebbert), 84:10–86:9, 129:1–16; CX-0018C.9 (Boyajian), Q40–41; RX-0065.0020, 6:43–57, Fig. 2; Tr. (Jokerst), 765:11–25.

Biofrontera claims that there are a finite number of locations for a POSITA to place hinges, such that it would be obvious to try to place hinges on the inner side surfaces of panels. But that supposition is contrary to law, as there is no reason to select that route as opposed to other

locations. See *In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Pat. Litig.*, 676 F.3d at 1072 (quoting *Ortho–McNeil Pharm., Inc. v. Mylan Labs., Inc.*, 520 F.3d 1358, 1364 (Fed. Cir. 2008)) (“Evidence of obviousness, especially when that evidence is proffered in support of an ‘obvious-to-try’ theory, is insufficient unless it indicates that the possible options skilled artisans would have encountered were ‘finite,’ ‘small,’ or ‘easily traversed,’ and that skilled artisans would have had a reason to select the route that produced the claimed invention.”). Instead, a POSITA would not have had a reason to place the hinges on the sides because it was known to create optical dead spaces. CX-0014C.57–58, 69–70, 79 (Jokerst), Q234–38, Q279, Q310; see Tr. (Jokerst) 765:11–25 (“Q. And so if a [POSITA] were attempting to connect two adjacent panels in the context of a PDT device, would they put a hinge in between the panels? A. So it’s not the first place I would think about putting them...when you put something between the panels, now you’ve got gaps.”).

In sum, Lundahl in view of Larsen does not disclose or render obvious the claimed hinges.

b. Lundahl in View of Larsen Further in View of Hente

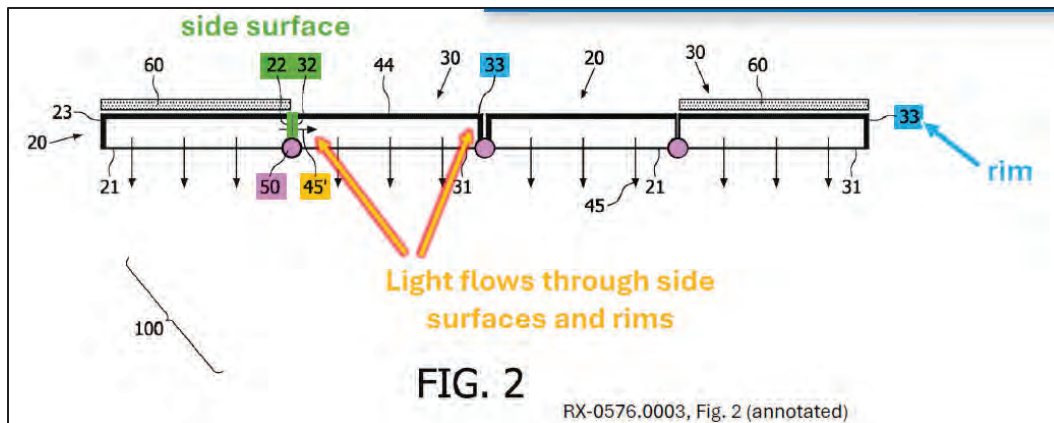
The addition of Hente in Biofrontera’s analysis of the ’512 Patent does not disclose or render obvious this element.

First, Hente is not analogous art. It is not in the same field of endeavor as the Asserted Patents and is not solving the same problem. CX-0014C.124 (Jokerst), Q521; CX-0014C.45–47 (Jokerst), Q172–82. For example, the ’512 Patent is directed to a medical device—“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, 1:17–20. Hente is not a medical device; as Dr. Grove admitted on cross-examination, it does not mention photodynamic therapy or diagnosis. Tr. (Grove), 582:19–21. It does not mention eliminating optical dead spaces. Tr. (Grove), 582:22–24. Dr. Grove even admits that Hente does not discuss the uniformity of light

distribution in the same context as Lundahl. Tr. (Grove), 582:25–583:3. Hente describes the application of a light emitting device to “do-it-yourself-work” for which “a large area lamp is needed to illuminate a workbench or a lathe” and needing “illumination devices for small, limited areas.” RX-0576.0010 at [0002]. A POSITA would not have been motivated to look to a lamp for large area illumination and “do-it-yourself-work” such as “to illuminate a workbench or a lathe” for solving problems associated with “photodynamically diagnosing or treating a patient.” CX-0014C.124 (Jokerst), Q524.

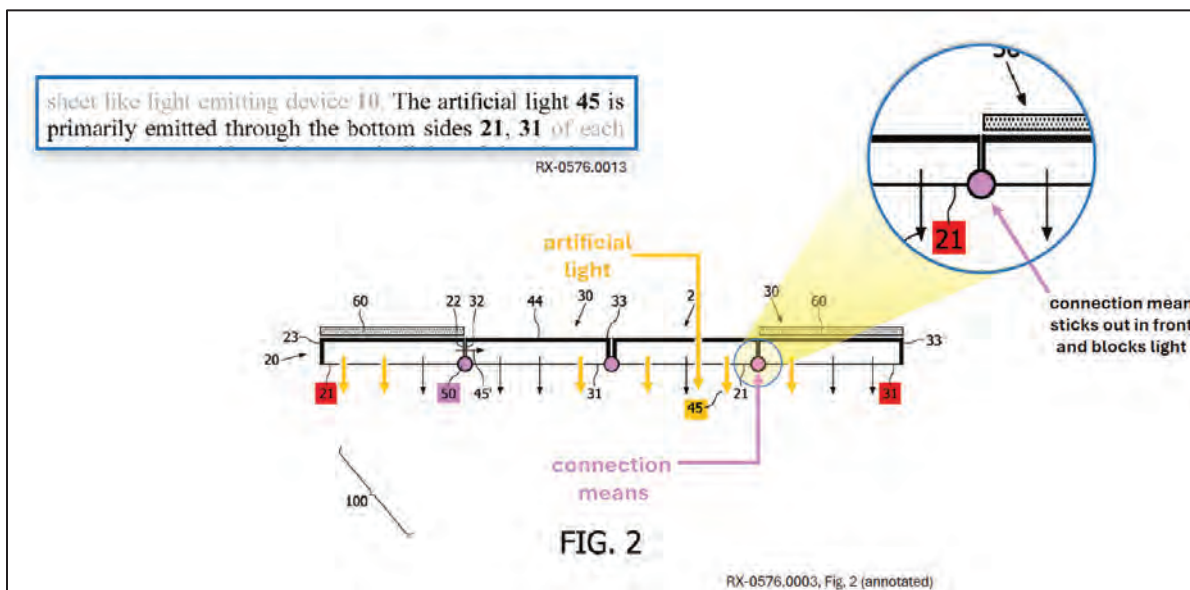
Second, Hente does not disclose “nested hinges on inner side surfaces of adjacent panels.” CX-0014C.86 (Jokerst), Q340. As Dr. Grove admitted, “Hente does not disclose hinges in any detail.” Tr. (Grove), 585:8-12. Hente instead discloses a “connection mean (50),” which may be “a hinge[], a stamping, a cutting or a foil.” RX-0576.0011, .0014, Claim 3, [0015]. The “connection mean 50” is represented generically as a placeholder in the figures; Hente does not distinguish between the various connection means. RX-0576, Figs. 3-4, [0012], [0015], [0033]–[0038]; CX-0014C.86 (Jokerst), Q340; Tr. (Grove) 584:14–17 (agreeing that Hente’s “connection means 50 might be a hinge, a stamping, a cutting, or a foil”). The only locations identified for those hinges are “at the outer ends of each section 20, 30” and “outer rims of the light emitting device respectively sections,” **not** on an inner side surface of adjacent panels. CX-0014C.86 (Jokerst), Q340; RX-0576.0011, .0013, [0037], [0015].

Third, Hente’s disclosures contradict the claim requirements. CX-0014C.87–88 (Jokerst), Q341–45. Hente discloses that light flows through the side surfaces and rims of the sections. RX-0576, [0007], [0008], [0010], [0015], [0017], [0020], [0036], Figs. 1, 2, 3; CX-0014C.87 (Jokerst), Q342.



CDX-0018C.103. If Hente's hinges were located "on the inner side surfaces of adjacent panels," the "artificial light 45" would not be able to "flow through the side surface 22 and the side surface 32"—which would contradict the "aim of the invention." CX-0014C.87–88 (Jokerst), Q341–45.

Fourth, Hente discloses hinges that stick out in front of the light emitting sections, partially obscuring the emitted light, and thus do not *fit* on inner side surfaces. RX-0576.0003, .0012-13, Fig. 2, [0036]; CX-0014C.88 (Jokerst), Q346.



CDX-0018C.107.

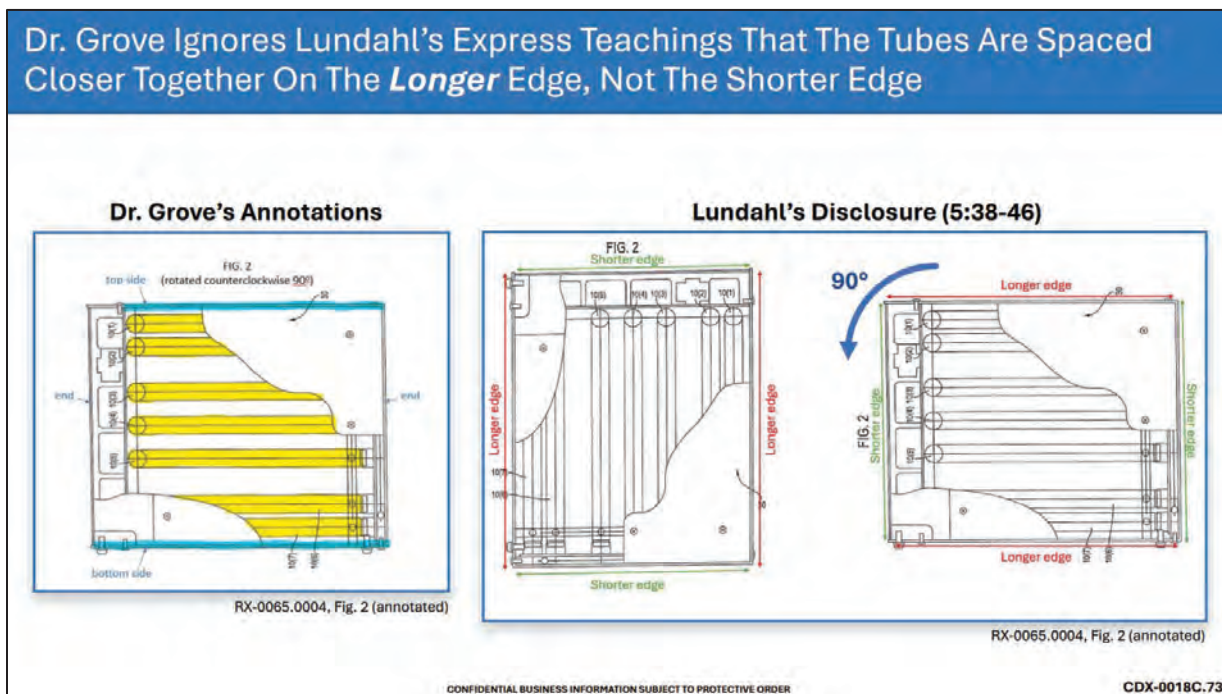
2. “wherein each of the at least five panels has two first edges and two second edges shorter than the two first edges, and the light sources are arranged such that a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges.”

Claim limitations 1[d], 8[d], 20[d] of the '512 Patent, and 1[e], 16[h](b), 20[e], and 21[f] of the '028 Patent recite the above language.

a. **Neither Lundahl Nor Larsen Teaches Or Suggests That The Light Sources Emit A Higher Intensity Close To The Shorter Edges**

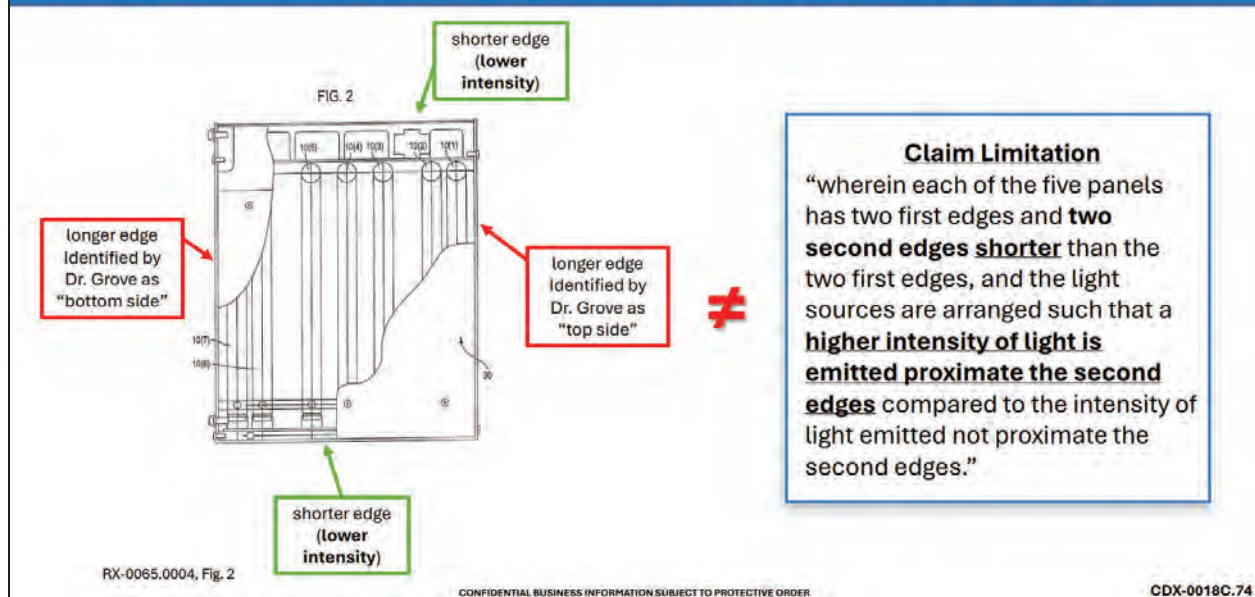
First, neither Larsen nor Lundahl disclose arranging light sources to emit a higher intensity of light close to the *shorter* edges.

Lundahl's more closely spaced fluorescent tubes are at the *longer edges* of Lundahl's panel, *not the shorter edges*. CX-0014C.62–63 (Jokerst), Q249–54; RX-0065, Fig. 2, 5:38–41.



CDX-0018C.73. While Dr. Grove argues Lundahl teaches a higher intensity of light being emitted at the “top” and “bottom” sides, those sides are the longer edges, not the shorter edges required. CX-0014C.60–63 (Jokerst), Q246–55; RX-0065, Fig. 2, 5:38–41.

Dr. Grove Ignores The Requirements Of The Higher Intensity Limitations As A Whole, Which Requires "Higher Intensity" On The Second Shorter Edges



CDX-0018C.74.

Larsen never discloses arranging LEDs or light sources to have a higher intensity proximate the shorter edges either. CX-0014C.64, 66 (Jokerst), Q258–59, Q266–67; RX-0057.0012, [0071]–[0072], Figs. 2a–d; Tr. (Grove), 569:8–570:5 (Dr. Grove admitting that Larsen discloses LEDs in regular row arrangements that are equidistant from each other).

Second, neither reference suggests arranging light sources in accordance with the claims. In fact, just like Lundahl, Larsen Fig. 2c also discloses fluorescent tubes arranged to have lower intensity at the shorter edges because the cathode of the fluorescent tube, having a much lower output than the rest of the tube, is at the shorter edges:

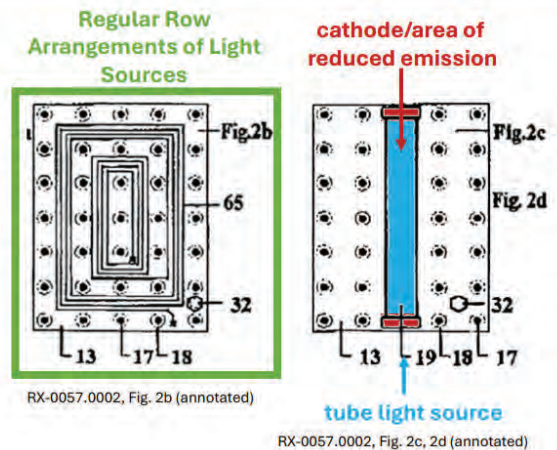
Larsen's Regular Row Arrangements Shown In Figs. 2b & 2c Discourage A "Higher Intensity" Near The Shorter Edges

[0071] According to FIGS. 2b and 2c the light sources 17 are placed in regular row arrangements, i.e., 20 equidistant from each other, whereby, according to FIG. 2c, one appli-

RX-0057.0012 at [0071]

2000 nm. The light source 19 formed as a tube can be selected for radiating blue light or fluorescent light within the wavelength area of 300-450 nm for photodiagnostics (PD). A diagnostic system (PD) containing optics 67 with a

RX-0057.0012 at [0071]



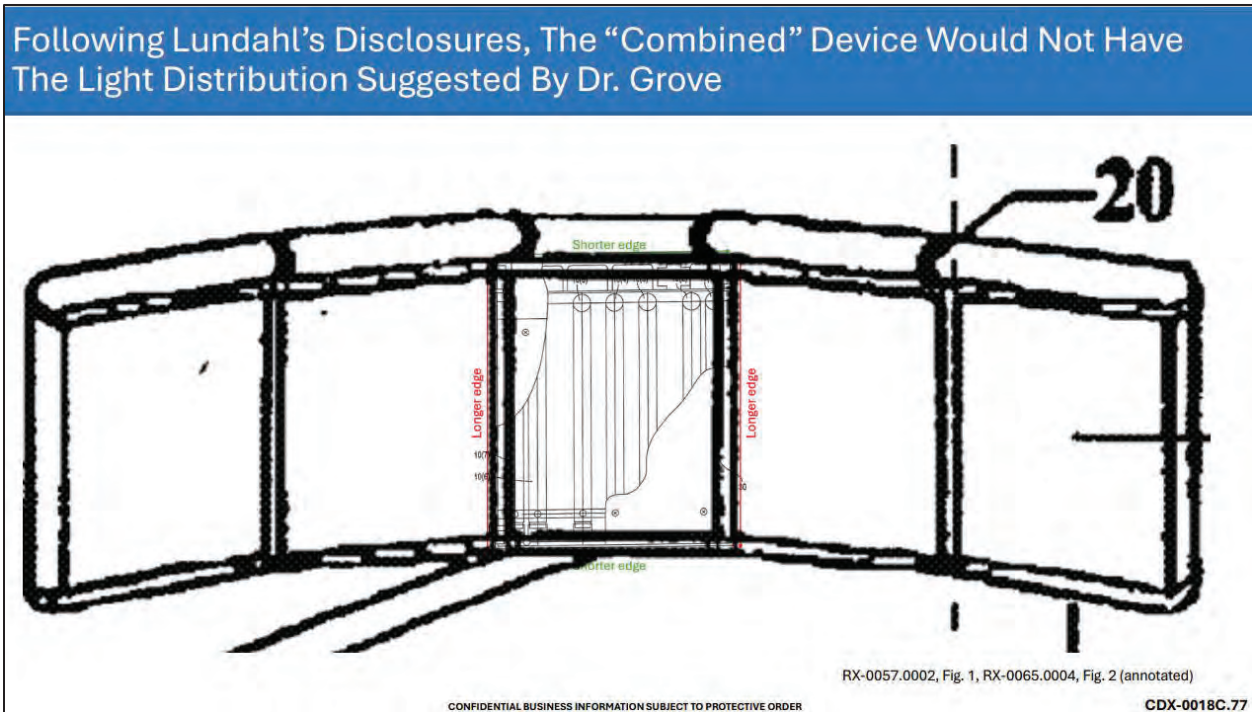
Larsen at Fig. 2b and Fig. 2C

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CDX-0018C.79

CDX-0018C.79; RX-0057.0002, .0012; CX-0014C.64–66 (Jokerst), Q258–67; see *Arctic Cat Inc. v. Bombardier Recreational Prods. Inc.*, 876 F.3d 1350, 1363 (Fed. Cir. 2017) (one must consider evidence that “suggests reasons that a skilled artisan would be discouraged from pursuing such a combination,” even when not rising to the level of teaching away).

If a POSITA actually applied Lundahl’s light distribution to Larsen’s five panels, the “higher intensity” would be emitted on the **longer** edges of the panels in the combined device, with the areas of **reduced** emission on the shorter edges. CX-0014C.63–65 (Jokerst), Q254–60.



CDX-0018C.77; RX-0057.0002, .0004.

There is no teaching in the art to have higher intensity on the shorter edge—Dr. Grove’s choice to apply Lundahl’s teaching of higher intensity on the longer edge to Larsen’s shorter edges can only be explained as impermissible hindsight of working backwards from the Asserted Patents. CX-0014C.64–68 (Jokerst), Q256–74. And even if the vertical spacing were maintained, Dr. Grove fails to consider how changing fluorescent tubes to LEDs would impact the device’s ability to illuminate. CX-0014C.68 (Jokerst), Q273–74.

Biofrontera’s piecemeal reconstruction of the prior art in an attempt to manufacture the claimed invention should be rejected because neither of the references teaches or suggests that the light sources emit a higher intensity close to the shorter edges. *Application of Wesslau*, 353 F.2d 238, 241 (C.C.P.A. 1965) (“no one of the references suggests such a substitution...Such piecemeal reconstruction of the prior art patents...is contrary to the requirements of 35 U.S.C. §103”); *Purdue Pharma L.P. v. Depomed, Inc.*, 643 F. App’x 960, 966 (Fed. Cir. 2016) (improper to use “hindsight

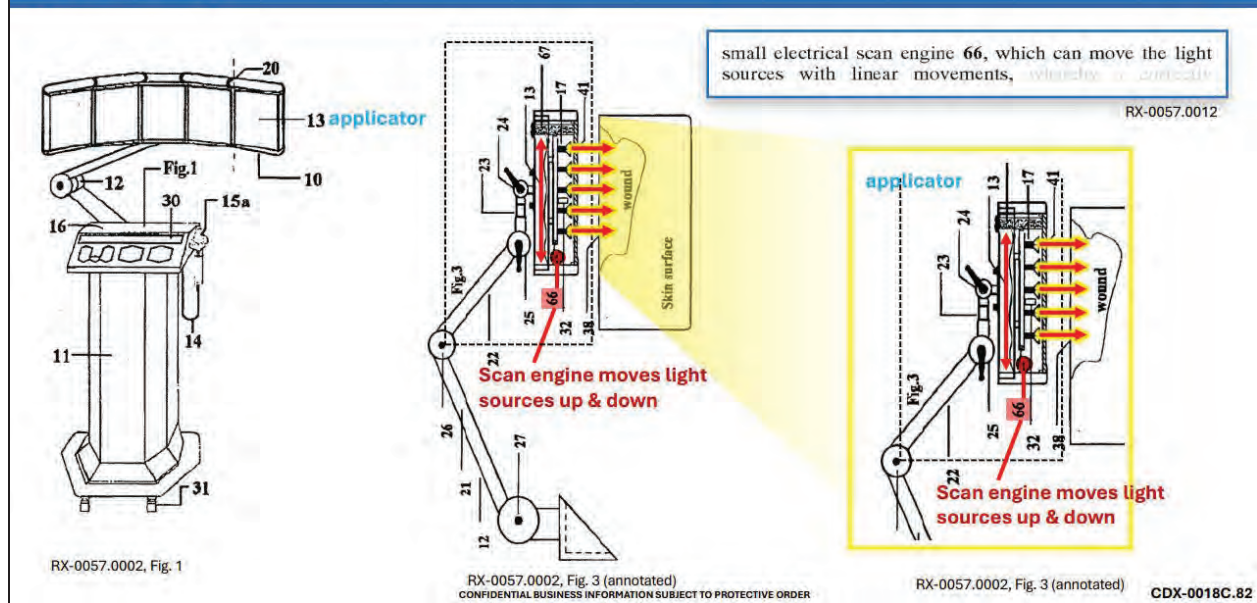
in formulating the problem to be solved”); *In re Kotzab*, 217 F.3d 1365, 1371-1372 (Fed. Cir. 2000) (“the Board fell into the hindsight trap” where there “was no finding as to the specific understanding...that would have motivated one with no knowledge of Kotzab’s invention to make the combination in the manner claimed”).

Because neither Larsen nor Lundahl teaches or suggests this limitation, a POSITA would not arrange light sources such that a higher intensity is emitted near the second edge when combining the references. *See Univ. of Strathclyde*, 17 F.4th at 161 (“Given neither Ashkenazi nor Nitzan teaches or suggests inactivation of *any* bacteria *without* using a photosensitizer, we fail to see why a skilled artisan would opt to entirely omit a photosensitizer when combining these references.”); CX-0014C.63–64 (Jokerst), Q255–58.

b. Larsen’s Scan Engine Further Impedes Any “Higher Intensity” Close To The Shorter Edges

Biofrontera incorporates Larsen’s “scan engine” in its combination as disclosing uniformity (which it does not). RX-0006C.0040 (Grove), Q180. However, that same engine would lead to a higher intensity of light emitted from the center of the panels, not the shorter edges, because the engine moves the lights up and down with linear movements. CX-0014C.68–69 (Jokerst), Q275–78; Tr. (Jokerst), 757:16–758:11 (explaining how the engine moves up and down)

Larsen's Scan Engine Moves The Light Sources Up And Down With "Linear Movements"

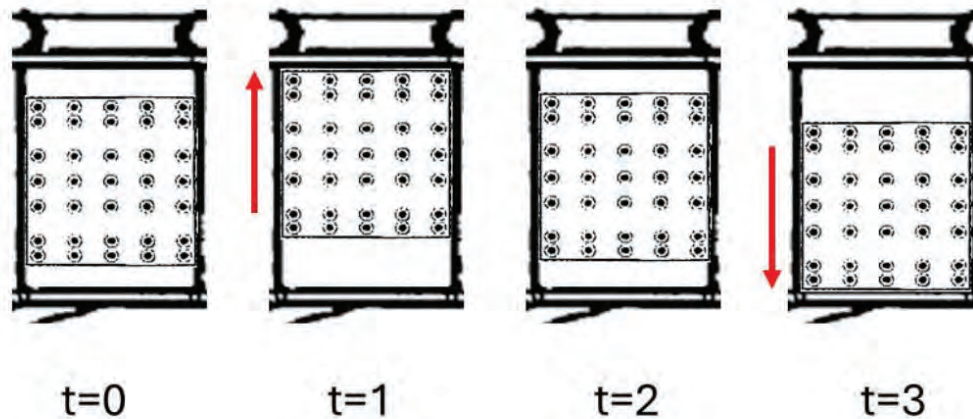


CDX-0018C.82; RX-0057.0002, [0073] (scan engine moves the light sources with "linear movements").

In Dr. Grove's combination, the light intensity emitted from the center of each panel would be greater than the shorter edges:

Dr. Groves Ignores That, Over Time, Larsen's Scan Engine Would Lead To More Light Sources In The Center Portion Than Close To The Shorter Edges

Larsen's scan engine moves the light sources up and down with "linear movements"



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CDX-0018C.83

CDX-0018C.83; CX-0014C.68–69 (Jokerst), Q275–78; Tr. (Jokerst), 758:12–760:13. Therefore, Larsen demonstrates that this limitation is not met.

c. Biofrontera's Combined Device Does Not Disclose Or Render Obvious The "Higher Intensity" Limitation

The combination proposed by Dr. Grove would not meet this limitation. Lundahl discloses areas near the shorter edges that will emit a lower intensity. Lundahl explains the light sources have "*low output area[s]*" (i.e., "*area[s] of reduced emission*"); therefore *[o]nly the more uniform center portion of the tube output is used for patient treatment*," as shown below. CX-0014C.64–65 (Jokerst), Q256–60, CX-0014C.67 (Jokerst), Q270–71; RX-0065.19, 4:66–67, 5:43–46, 6:10–22, Fig. 1; CX-1053C; Tr. (Grove), 561:20–562:4, 752:20–754:25.

Dr. Grove Ignores Lundahl's "Active Emitting Area" & "Areas Of Reduced Emission"—Only The **Center Region** Is Used For Patient Treatment

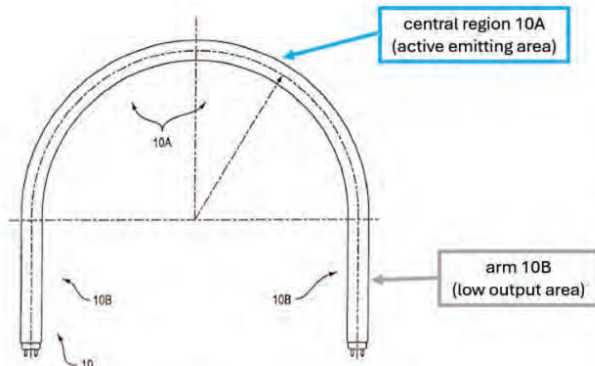


FIG. 4A

RX-0065.0006, Fig. 4A

FIG. 4 is a detail view of the fluorescent tube light source shown in FIG. 1.

RX-0065.0019 at 4:66-67

the tubes have a generally arcuate central region 10A and arms 10B extending from respective ends of the central region.

RX-0065.0020 at 5:43-46

uniform. The output measured in the immediate vicinity of the cathode is typically much lower than the output over the rest of the tube. This occurs because ionized gas in the area

RX-0065.0020 at 6:11-13

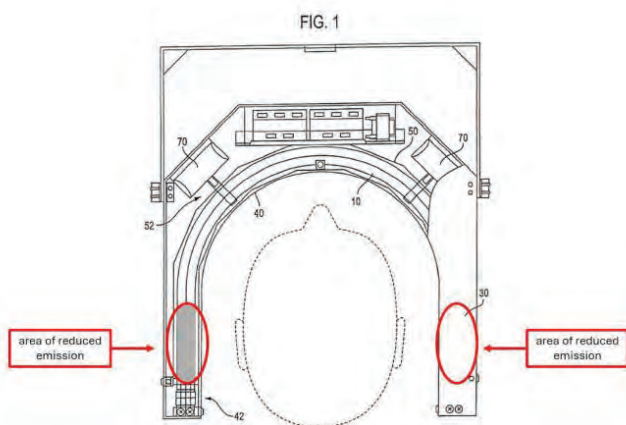
Only the more uniform center portion of the tube output is used for patient treatment. Another advantage of the arrange-

RX-0065.0020 at 6:21-22

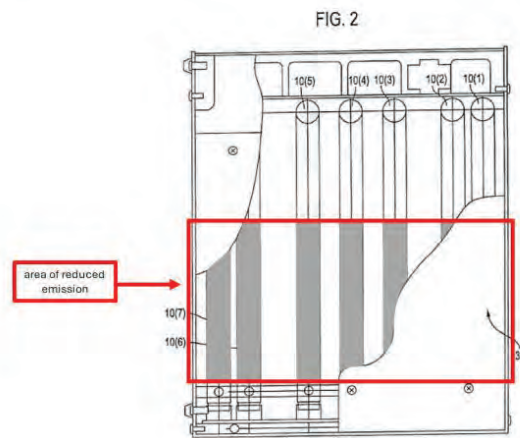
CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER

CDX-0018C.75

Dr. Grove Ignores Lundahl's "Active Emitting Area" & "Areas Of Reduced Emission"—The Areas Of Reduced Emission Are **Not** Used For Patient Treatment



RX-0065.0003, Fig. 1 (annotated)



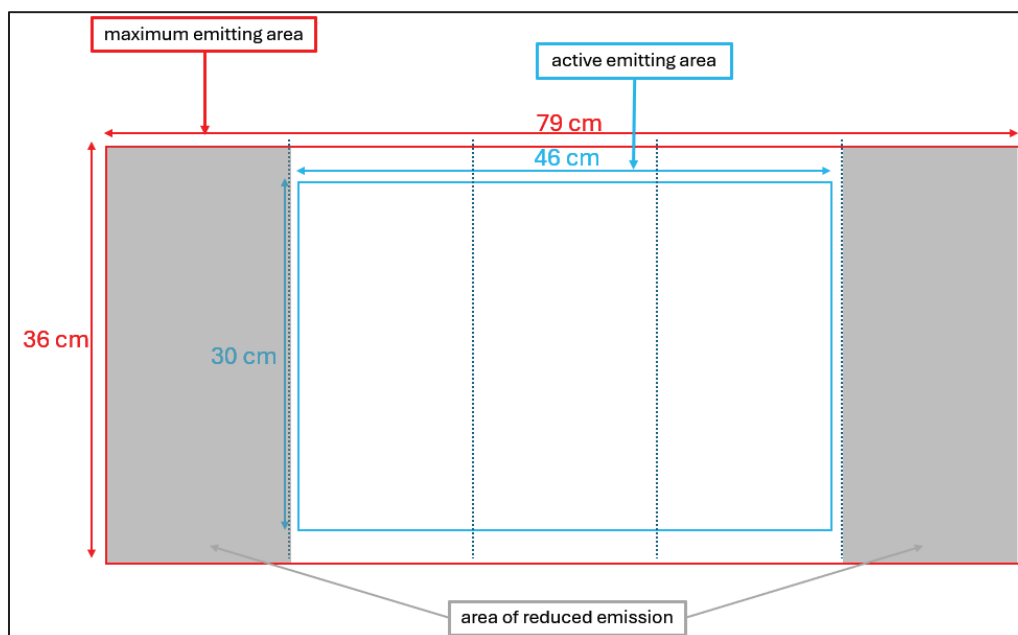
RX-0065.0004, Fig. 2 (annotated)

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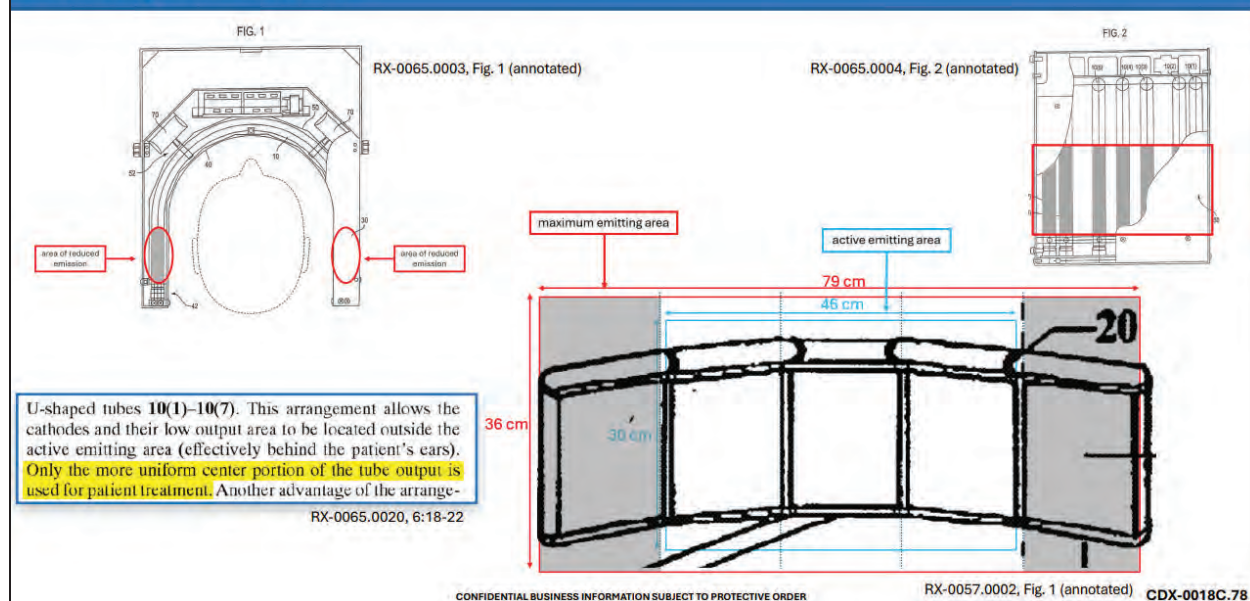
CDX-0018C.76

CDX-0018C.75-76. Therefore, combining Lundahl's light distribution with Larsen's five panels in the manner Dr. Grove proposes leads to higher intensity at the shorter edges only in the center

regions, and **unknown intensity** in the regions shown in gray below. CX-0014C.65–68 (Jokerst), Q262–72; RX-0065.0019, 5:38–46, 6:10–22; CX-1053C; Tr. (Jokerst), 750:21–752:9.



Dr. Grove Reads Out “Wherein *Each* Of The Five Panels...” From The “Higher Intensity” Limitation



CDX-0018C.78; RX-0065.0003-4, .0020; RX-0057.0002.

Applying Lundahl's Disclosure Would Not Lead To "Higher Intensity" On The Shorter Edge Of "Each" Of The Five Panels, As Required By The Claims

This arrangement allows the cathodes and their low output area to be located outside the active emitting area (effectively behind the patient's ears). Only the more uniform center portion of the tube output is used for patient treatment.

RX-0065.0020, 6:18-22

invention, seven 36" U-shaped tubes 10(1)–10(7) provide a maximum visible light-emitting area 36 cm high by 46 cm wide (approximately 2850 cm²), with a minimum therapeutically active area 30 cm high by 46 cm wide (approximately 1350 cm²).

RX-0065.0020, 5:39-43

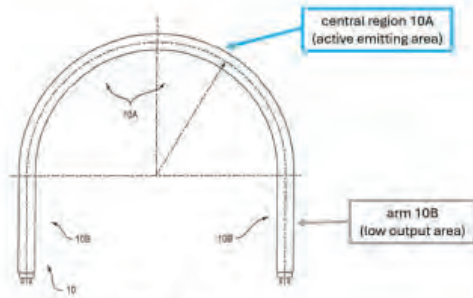
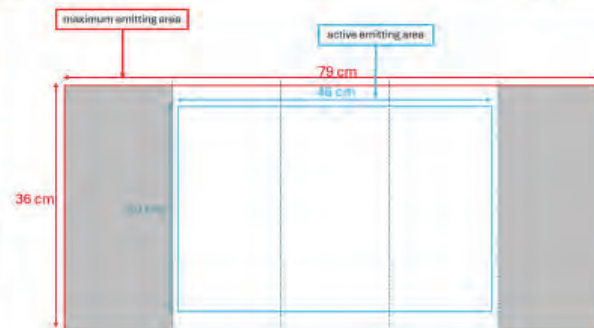


FIG. 4A

RX-0065.0006, Fig. 4A



CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER

CDX-0018C.80

CDX-0018C.80; RX-0065.0020.

Q. Okay. And how, if at all, do the areas of reduced emission impact your opinion as to whether Lundahl discloses a higher intensity of light along the entire longer edge?

A. Well, Lundahl makes no assertions regarding the relative intensity of the tubes in the areas of reduced

emission. So we can't say that there's a higher intensity along even the longer edge in the areas of reduced emission. Lundahl makes no claims about the areas of reduced emission.

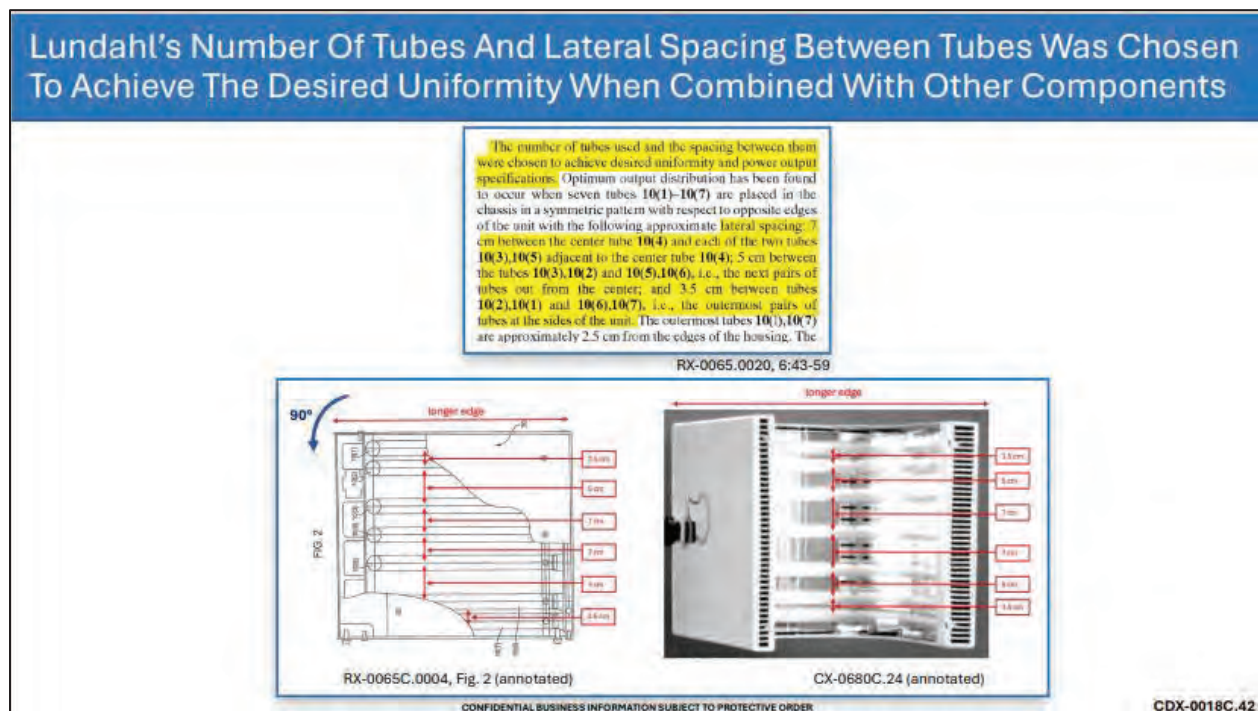
Tr. (Jokerst), 752:20–753:3. Therefore, “*each* of the five panels” would not have a higher intensity of light emitted close to the second edges, as required by the claims.

d. Dr. Grove’s Comparison To RhodoLED® XL Fails

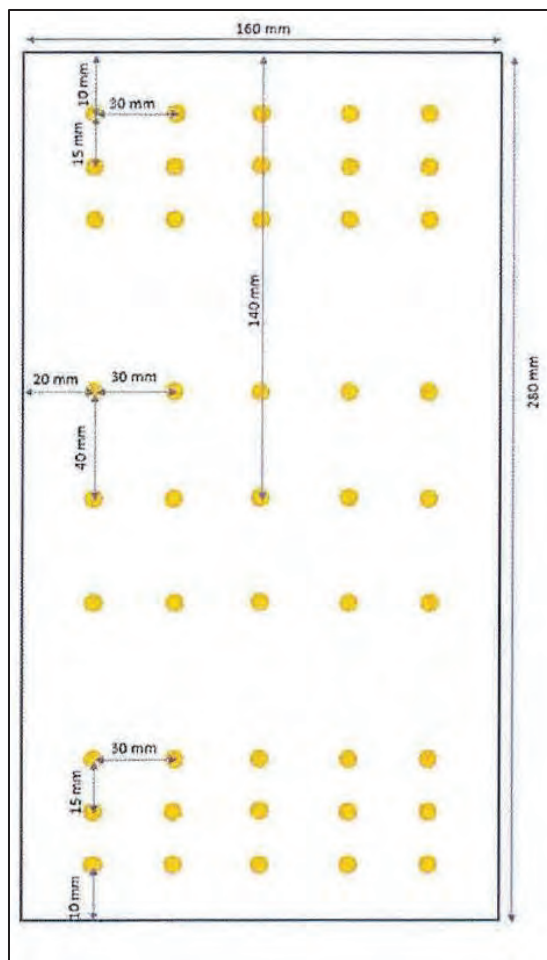
Dr. Grove couches his analysis of “higher intensity” in his combination by claiming that it is “very similar to the light distribution in Biofrontera’s RhodoLED® XL.” RX-0006C.47

(Grove), Q216. First, Dr. Grove’s “finding” the accused product’s light distribution within bits and pieces of the prior art evidences his own hindsight bias, and “cannot constitute clear and convincing evidence of invalidity.” *Zenith Elecs.*, 522 F.3d 1348 at 1363.

Second, Lundahl’s vertical spacing is not “very similar” in the number of rows or spacing of the RhodoLED® XL, as the spacing is significantly smaller in the RhodoLED® XL: the real-world device has 1.5 cm between the top and bottom groups of LEDs, and 4 cm between the center groups, whereas Lundahl’s closest spacing is 3.5 cm, and ranges up to 7 cm:



CDX-0018C.42; CX-0014C.68–70 (Jokerst), Q273–74, Q279; RX-0065.0020, 6:43–57; CX-0680C.24.



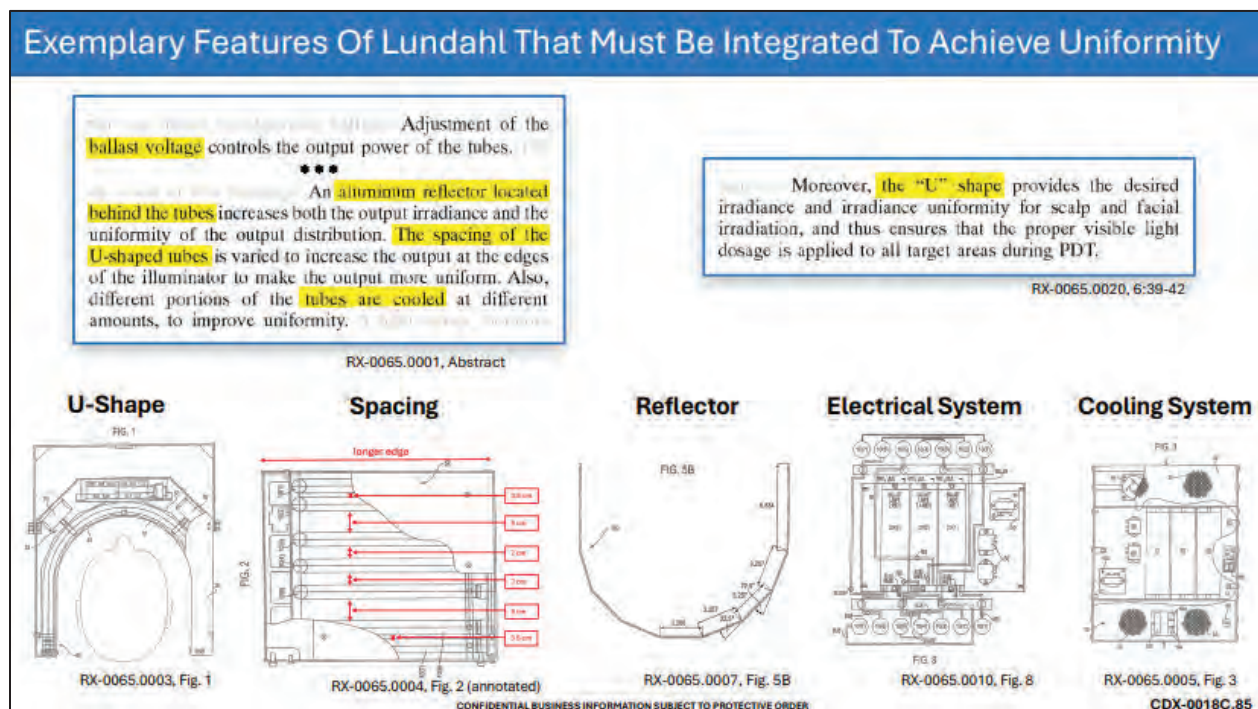
JX-0084C.7.

3. **“the illuminator being configured to uniformly illuminate a treatment surface of the patient via the light sources”/ “uniformly illuminating a treatment surface of the patient”**

Claim limitations 1[b], 8[c], 20[b] of the '512 Patent, and 1[b], 16[h](a), 20[b], and 21[b] of the '028 Patent recite the above language.

Dr. Grove admitted Larsen does not disclose how to achieve the 60% uniformity required by the ALJ's construction. Tr. (Grove), 574:16–20. Instead, Dr. Grove claims Lundahl discloses this degree of uniformity. *Id.*, 574:21–575:2. Lundahl is directed to achieving uniform illumination for a fluorescent tube device with components that were carefully engineered and selected to achieve uniform illumination. CX-0014C.32–40, .72–80 (Jokerst), Q118–55, Q288–

314; RX-0065.0018-19, .0021-22, 2:33–48, 3:22–28, 4:12–22, 4:39–44, 7:10–8:59, 9:13–53; CX-0011C.9–11 (Lundahl), Q26–35; Tr. (Grove), 576:4–578:7. The components that contribute to the irradiance uniformity include the U-shaped tubes, the nine-segmented reflector, the electrical control system, and the cooling system. RX-0065, Abstract, 2:46–67, 3:22–28, 3:62–67, 4:11–22, 4:27–44, 5:22–35, 5:58–61, 6:31–42, 7:10–8:67, 9:14–53, 18:36–40, Figs. 1–9E; CX-0014C.40, .72–73 (Jokerst), Q154–155, Q289–90; CX-0011C.9–11 (Lundahl), Q26–35. Lundahl explains these components require a “much higher degree of precision and integration” to control the “[o]utput spectrum, irradiance, and irradiance uniformity” and “to assure that the properties of the device are suitable to deliver light to the target lesions and drive the photodynamic reaction.” RX-0065.0019, 4:12–22; CX-0011C.9–11 (Lundahl), Q26–35.



CDX-0018C.85; RX-0065.0001, .0003–5, .0007, .0010, .0020.

Dr. Grove assumes that the resulting uniformity achieved through Lundahl’s integrated system would carry through to Dr. Grove’s Lundahl/Larsen combination even after discarding

components from Lundahl that led to that level of uniformity, including replacing fluorescent tubes with LEDs. CX-0014C.71–72 (Jokerst), Q286–87; RX-0006C.0072 (Grove), Q321; Tr. (Grove), 569:8–570:18; *see Unigene Labs.*, 655 F.3d at 1360 (“Obviousness requires more than a mere showing that the prior art includes separate references covering each separate limitation in a claim....”). Specifically, Dr. Grove simply adopts the spacing of Lundahl and the five panels with LEDs from Larsen, and concludes that the device would achieve uniform illumination to the same degree as Lundahl itself. RX-0006C.0072 (Grove), Q321. But Lundahl’s individual reference to the measured output of Lundahl’s preferred embodiment does not inform a POSITA what the measured output would be for the Lundahl system as modified in combination with Larsen. CX-0014C.79 (Jokerst), Q309.

Moreover, Dr. Grove fails to provide evidence that a POSITA would have reasonably expected that combining his references would meet the uniformly illuminate limitation. CX-0014C.115–16 (Jokerst), Q479–86; *see Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1367 (Fed. Cir. 2016) (“The reasonable expectation of success requirement refers to the likelihood of success in combining references to meet ***the limitations of the claimed invention.***”). Dr. Grove never compared the measured maximum over an active emitting area to the measured irradiance at a treatment surface for his combination; indeed, he never presented evidence that the combined device would achieve the same uniformity as Lundahl’s integrated system. CX-0014C.71 (Jokerst), Q286. The absence of any analysis is fatal considering Dr. Grove previously asserted that a POSITA would be required to perform undue experimentation to make and use an illuminator that provides uniform illumination over the full scope of the claims. Tr. (Grove), 579:15–25. Dr. Grove admitted it is well-known that the field of optics and illumination is complex, and in some cases requires extensive measurement and experimentation. Tr. (Grove),

575:3–16.⁵ He even acknowledged that the light output from fluorescent tubes is different from the light output from LEDs, RX-0006C.0048 (Grove), Q218, but still failed to account for how the light output of the LEDs would affect the overall uniformity. CX-0014C.79 (Jokerst), Q310. Merely exchanging Lundahl’s fluorescent tubes with Larsen’s LEDs—while keeping only Lundahl’s tube spacing—would create gaps in areas of the target treatment area and result in **unknown** uniformity. CX-0014C.68–70, .79 (Jokerst), Q273–74, Q279, Q310. Because Dr. Grove failed to address the impact these changes would have on uniformity, Biofrontera cannot show that the combination of Lundahl and Larsen “uniformly illuminate[s] a treatment surface” as construed.

4. “the five panels are individually configurable to control illumination from each of the five panels”

Claim limitations 16[g] and 21[e] of the ’028 Patent recite the above language.

Dr. Grove asserts that Larsen discloses this limitation because Larsen at [0070] teaches that “each of the applicators (13) ‘can be used in the working model according to Fig. 2a to 2c **individually**, side by side (in large numbers) or in combination with an applicator.’” RX-0006C.0053–54 (Grove), Q241. But Larsen only states that “the invented device is adjustable,” not that each of the five applicators is individually configurable to control illumination from each of the five panels. CX-0014C.107 (Jokerst), Q435–37; RX-0057.0012, [0074]. The control mechanism 16 controls the device as a whole, not the output from panels individually. CX-0014C.106–07 (Jokerst), Q434–35; RX-0057.12, [0074].

⁵ This accords with testimony from the inventors of the Asserted Patents, who stated that achieving uniform illumination using LEDs was “one of the more difficult challenges that we had” and was solved through “sizing, spacing, electronic feedback, and the actual mechanical design.” JX-0015C (Carota), 73:20–74:14; JX-0014C (Boyajian), 87:3–89:12, 100:7–12, 100:22–101:15; CX-0014C.76, 79–80 (Jokerst), Q299, Q311–312. Achieving uniform illumination in a five-panel LED system required substantial “trial and error.” JX-0014C (Boyajian), 87:3–89:12; CX-0018C.12 (Boyajian), Q62–63.

Adjustment Of The Control Mechanism 16 Changes The Energy Emitted By Larsen's Entire Device, NOT Each Applicator

[0079] The applicators 13, according to the FIGS. 2a, 2b and 2c are equipped with sensors 32 arranged between the semiconductor and/or laser diodes 17. For therapeutic uses it is typically intended to apply a given amount of energy (Joule/cm²) per irradiated surface of tissue, which can be adjusted at the control mechanism 16. Sensors 32 measure the amount of energy radiated away from the skin surface, which is indicative of the total energy penetrating into the tissue. Taking into account individual variations from patient to patient, the exposure can be determined according to the measurements taken by the sensors 32 so that the correct amount of therapeutic energy (Joule/cm²) reaches the tissue. An 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-0057.0012

CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER

CDX-0018C.136

CDX-0018C.136; RX-0057.0012.

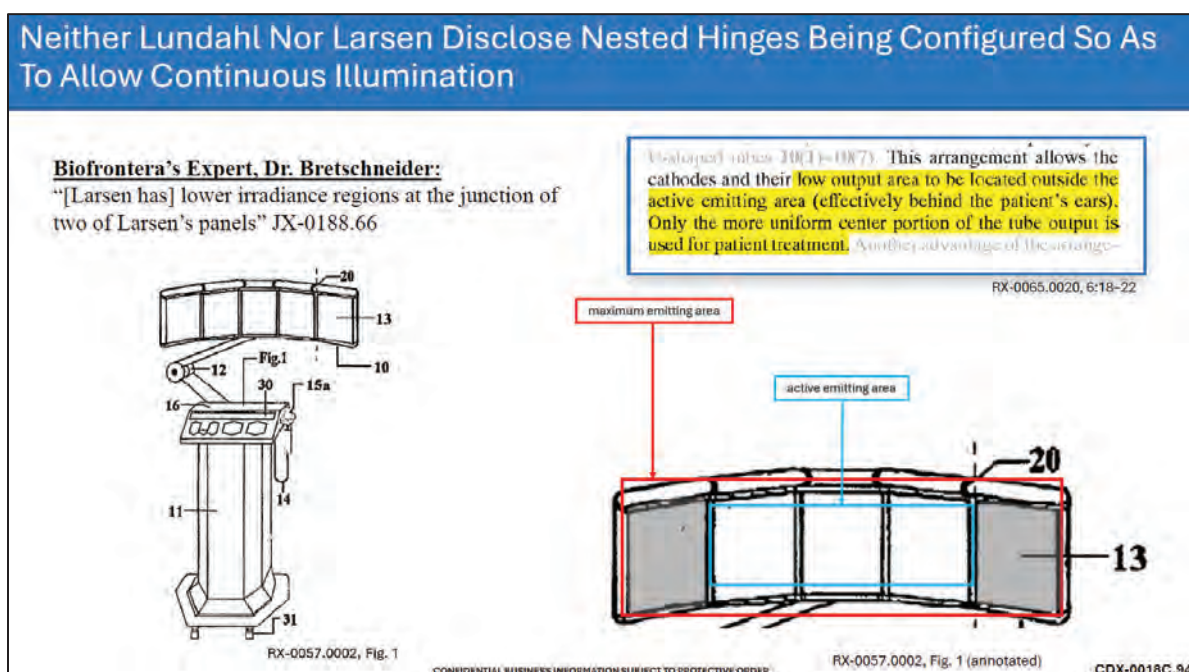
While Larsen references that “the light sources are individually selected” in Claim 5, it never discloses controlling the power output from panels *independently*. Instead, that claim references *selecting* light sources—i.e., switching between the semiconductor diodes and/or laser diodes—for the whole device. CX-0014C.107 (Jokerst), Q435–37; RX-0057.0010, .0012, [0027], [0074].

5. **“the nested hinges being configured so as to allow continuous illumination across the at least five panels”/ “five panels connected by hinged structures to allow continuous illumination across the five panels.”**

Claim limitations 20[a] of the '512 Patent, and 16[g] of the '028 Patent recite the above language.

Lundahl lacks hinges, so Dr. Grove relies on Larsen for this element, pointing to “[t]he orientation of adjacent panels illustrated in Figure 1” as a configuration which would achieve continuous illumination. RX-0006C.0035 (Grove), Q158. But Dr. Grove admitted that “in Figure

1 of Larsen, you can't actually see what Larsen's hinges look like" and "Larsen doesn't provide a description of the physical structure of the hinges." Tr. (Grove), 563:1–9. Accordingly, Larsen cannot teach configuring those hinges "to allow continuous illumination." CX-0014C.81 (Jokerst), Q317–18. Moreover, Biofrontera's expert Dr. Bretschneider explained how Larsen has "lower irradiance regions at the junction of two of Larsen's panels" which contradicts any "continuous illumination across the five panels" teaching. CX-0014C.81 (Jokerst), Q318; JX-0188.66 (Bretschneider Declaration).

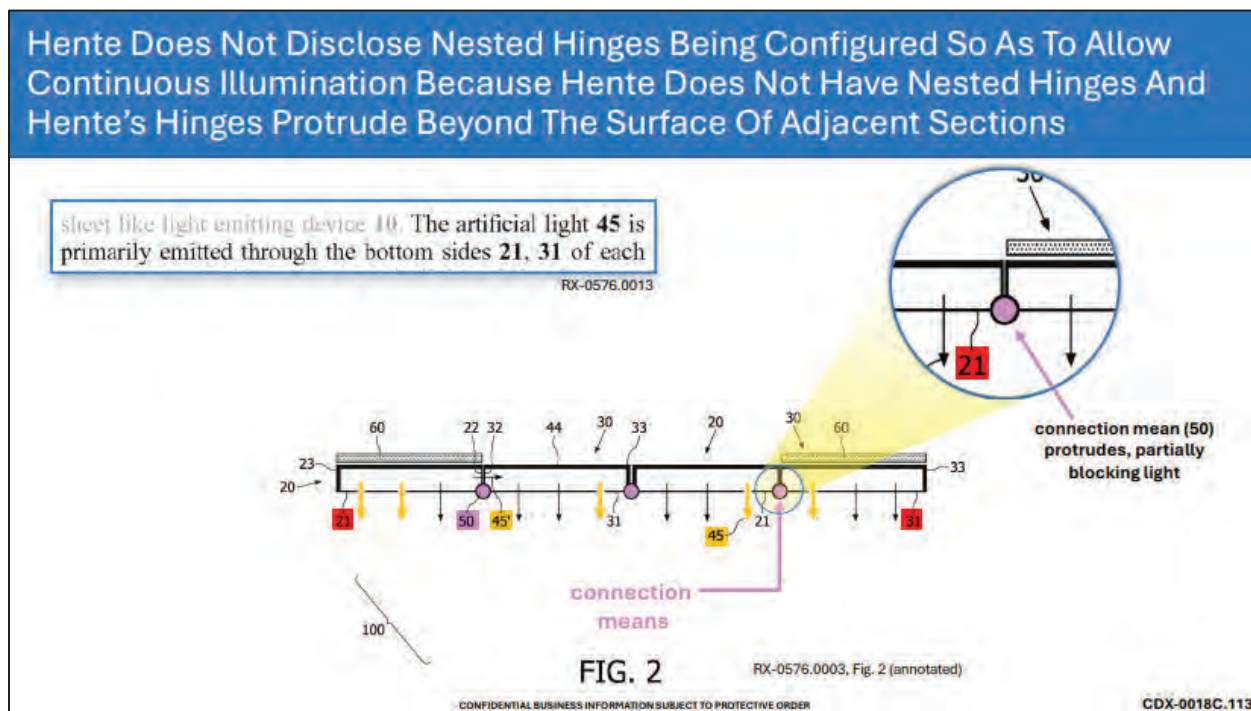


CDX-0018C.94.

Further, Dr. Grove's combined device of Lundahl-Larsen would not provide continuous illumination across all five panels. CX-0014C.82 (Jokerst), Q319–20. Lundahl discloses that "[t]he output measured in the immediate vicinity of the cathode is typically much lower than the output over the rest of the tube" and "[o]nly the more uniform center portion of the tube output is used for patient treatment." RX-0065.0020, 6:10–22. In other words, Lundahl discloses a "low

output area” in its light distribution, such that the light emitted across all five panels cannot be considered “continuously illuminated.” CX-0014C.82 (Jokerst), Q321.

Adding Hente does not cure these deficiencies because its hinges protrude beyond the front of the light emitting sections and partially blocks light—its hinges do not allow for continuous illumination. RX-0576.0003, .0011-13, Fig. 2, [0015], [0036], [0037]; CX-0014C.92 (Jokerst), Q362–64.



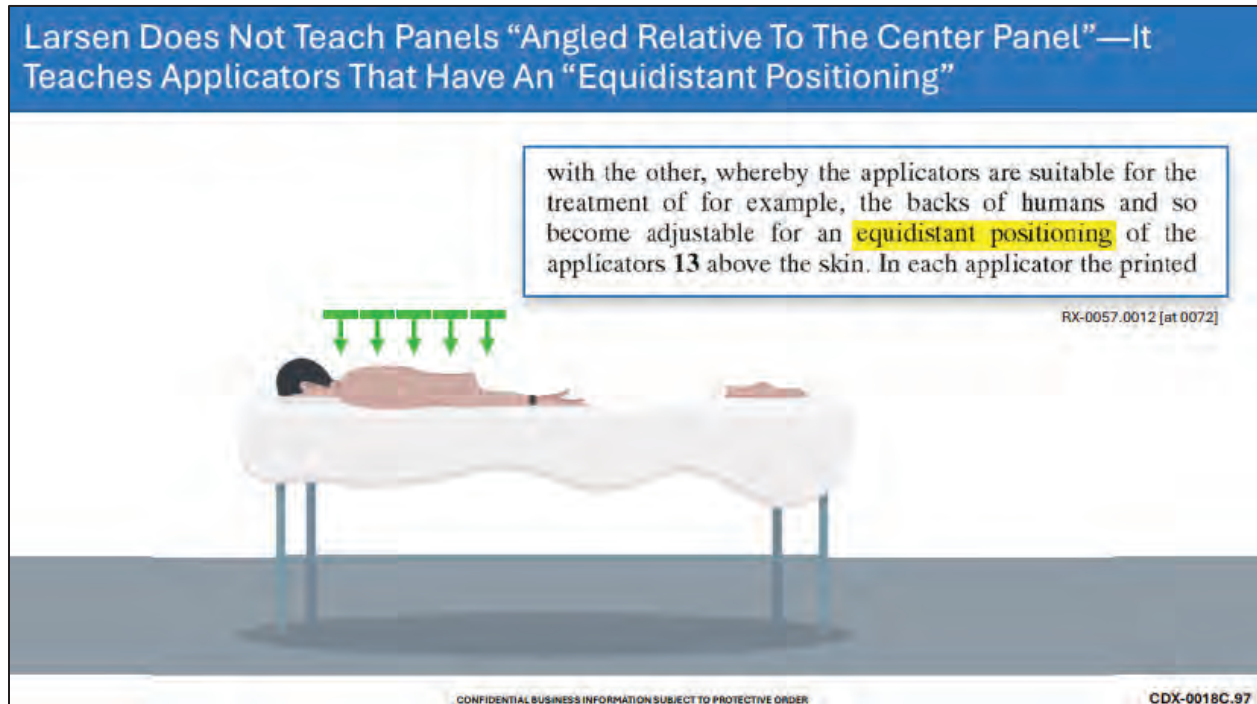
CDX-0018C.113.

6. **“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”**

Claim limitations 1[c] and 20[c] of the '512 Patent, and 1[c], 17, 20[c], and 21[c] of the '028 Patent recite the above language.

Dr. Grove relies on Larsen’s disclosure that its applicators have an “equidistant positioning” above the “backs of humans,” to teach this limitation. RX-0006C.0069 (Grove),

Q315. But Larsen lacks a disclosure of a center panel configured to face the treatment surface, with further angled panels. The “equidistant positioning” above the back teaches only that the panels can be in a *flat* configuration; as Biofrontera’s own expert testified, backs are “closer to being planar.” Tr. (Ehrenreich), 527:12–16. Dr. Jokerst agrees. CX-0014C.84 (Jokerst), Q327–29.



CDX-0018C.97; RX-0057.0012.

7. **“wherein at least one panel includes a recess configured to receive a flange of one of the nested hinges”**

Claim 17 of the ’512 Patent recites the above language.

Hente does not disclose this limitation. As Dr. Grove admitted, there is no description in Hente of the hinges or flanges—when asked about the type of flanges disclosed in Hente, Dr. Grove freely offered on cross-examination that “Hente does not disclose hinges *in any detail*.”

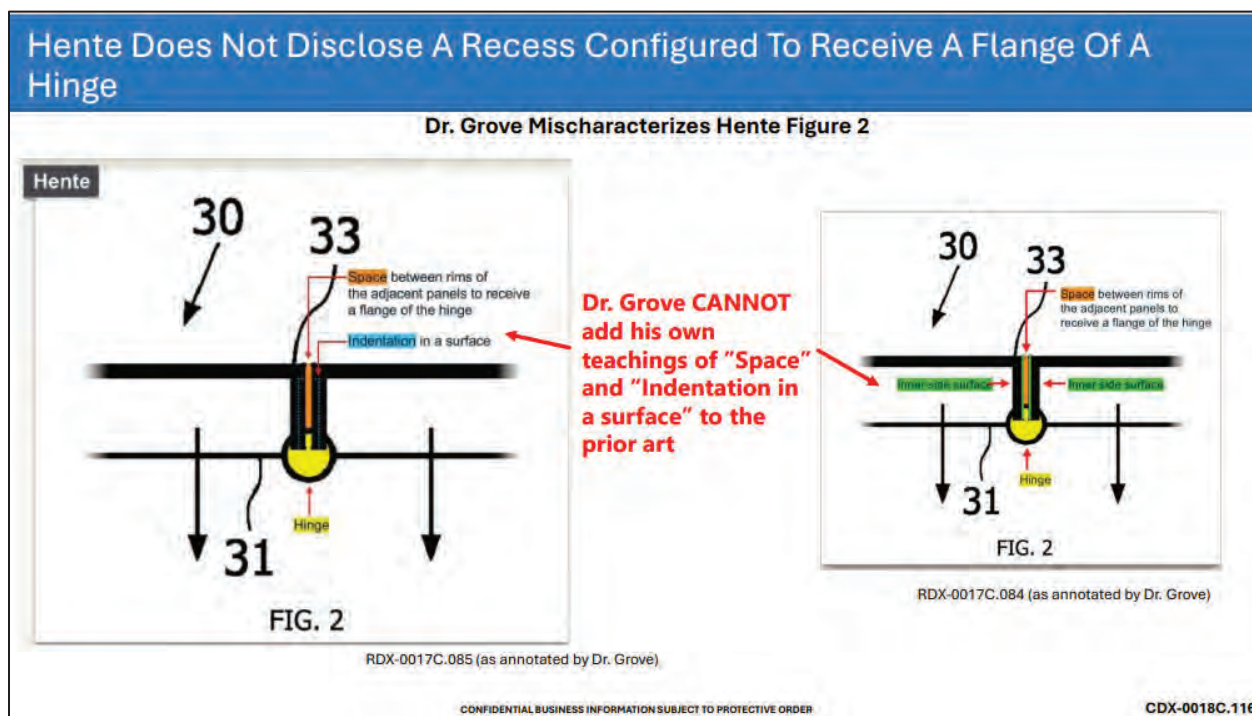
Q. Okay. And we can agree that Hente does not describe what its hinges actually look like, right?

A. That is also correct.

Q. And Hente does not describe whether its hinges have flanges that extend or whether they are kind of short, stubby flanges. True?

A. Yeah, Hente does not disclose hinges in any detail.

Tr. (Grove), 585:5–12. Instead, Dr. Grove *invents* with no support in the reference a “space between the rims of adjacent panels of Hente to receive a flange of the hinge,” (contradicting his statement that Hente’s sections are “nearly flush.”) CX-0014C.95 (Jokerst), Q375.

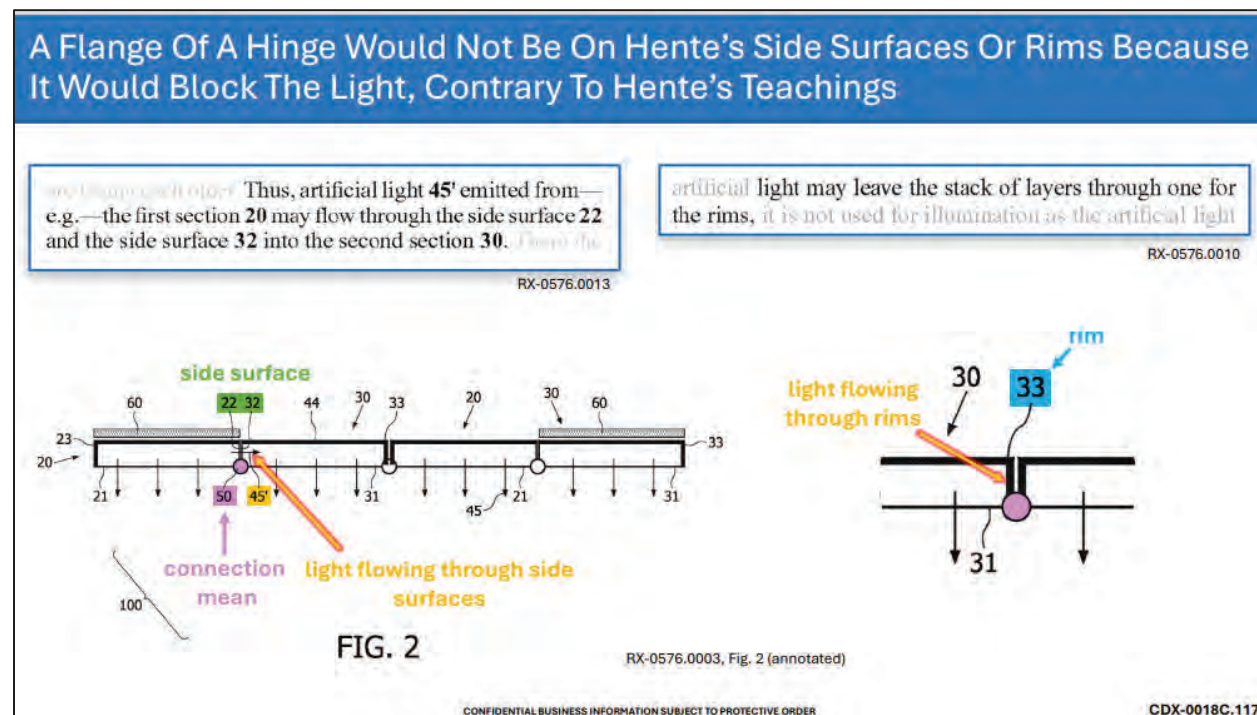


CDX-0018C.116; RDX-0017C.084–85.

Moreover, a POSITA would be discouraged from placing the flange on an inner side surface because it would block the light that Hente teaches flows through the side surfaces of the sections. CX-0014C.95 (Jokerst), Q376. If the flange was located “on an inner side surface,” the

artificial light 45' would not be able to “flow through the side surface 22 and the side surface 32.”

RX-0576.0003, Fig. 2; CX-0014C.95 (Jokerst), Q376.



CDX-0018C.117.

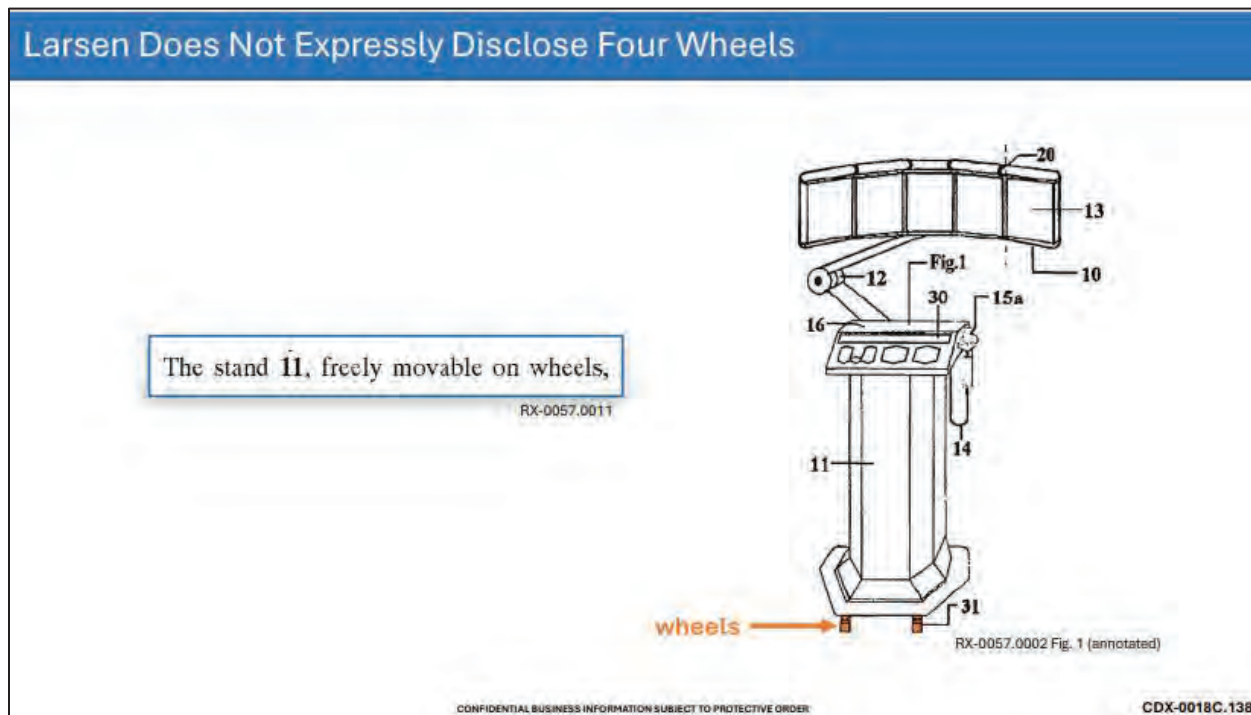
8. “wherein the recess is positioned at an inner side surface of the at least one panel”

Claim 18 of the '512 Patent recites the above language.

As discussed in Claim 17, the only “evidence” Dr. Grove offers for the location of a “recess” in Hente is his own annotated picture of Hente where he draws an indentation. CX-0014C.97 (Jokerst), Q388. Dr. Grove admitted Hente itself does not disclose a recess or an indentation. Tr. (Grove), 586:5–18. Dr. Grove’s conclusory and unsupported opinions are insufficient to support alleged obviousness. *KSR*, 550 U.S. at 418 (“Rejections on obviousness grounds cannot be sustained by mere conclusory statements...”).

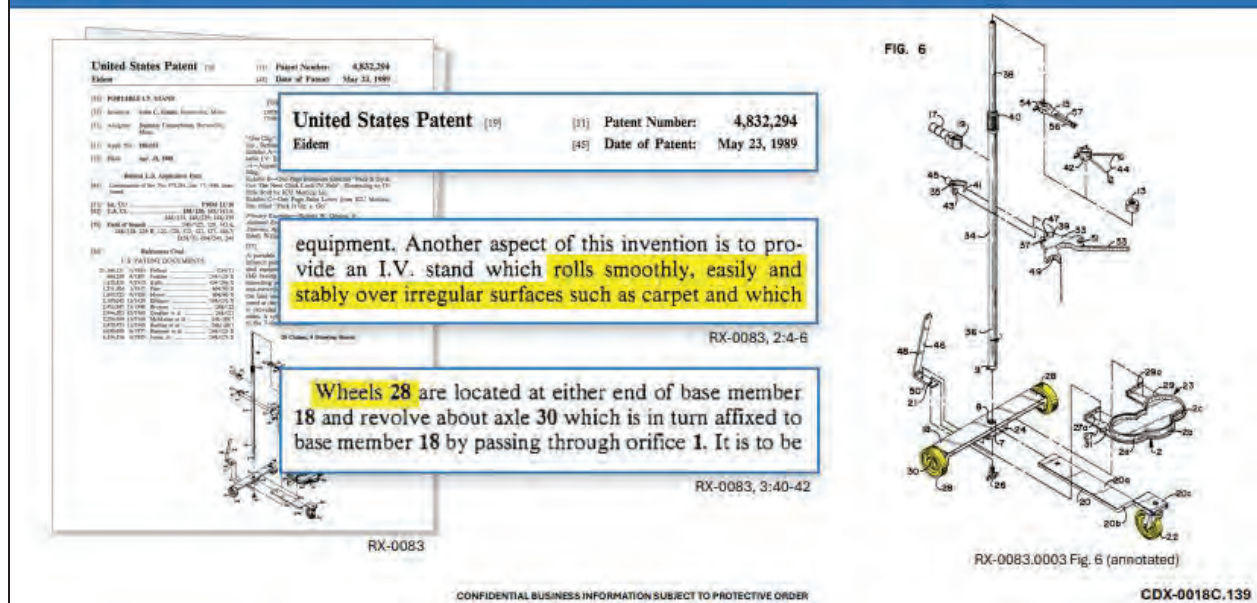
9. “a mobile base supported by at least four wheels.”

Claim limitation 16[a] of the '028 Patent recites the above claim language. Dr. Grove relies on Larsen, but there is no express disclosure in Larsen of **four** wheels—Dr. Grove points to Figure 1, but shows two wheels. CX-0014C.109 (Jokerst), Q446–47; RX-0057.0002, Fig. 1.



CDX-0018C.138. Nor is there inherent disclosure, because a POSITA would have understood that the device is stable and freely moveable on only three wheels. CX-0014C.109–10 (Jokerst), Q448–52; CX-1028.

Larsen Does Not Inherently Disclose Four Wheels And Four Wheels Is Not Obvious



CDX-0018C.139; RX-0083.

10. Lack of Motivation to Modify or Combine

Biofrontera never demonstrated that a POSITA would have had a reason to modify or combine the prior art references to achieve the claimed invention or a reasonable expectation of success in doing so. CX-0014C.50–56, .111–12 (Jokerst), Q195–228, Q459–563.

a. No Motivation To Combine Lundahl And Larsen

Dr. Grove has failed to show that a POSITA would have been motivated to modify Lundahl to incorporate Larsen's panels. CX-0014C.112 (Jokerst), Q461–63. First, a POSITA would not have been motivated to look to Larsen to address the precise issues of uniformity Lundahl already solves, and Larsen lacks any disclosure of the high degree of uniformity needed for certain PDT treatments. CX-0014C.112–13 (Jokerst), Q464–66; RX-0065, 1:14–17, 6:39–45, 15:22–27. Second, a POSITA would have been discouraged from modifying Lundahl's ideal U-shaped tube

configuration to incorporate Larsen’s five panels because such modification would create unwanted gaps. CX-0014C.113–14 (Jokerst), Q467–71.

Lundahl criticizes “flat emitting surface[s]” that “would not deliver a uniform light dose to all contours of the face simultaneously.” RX-0065.0019, 4:29–31. Lundahl “ameliorate[d] this problem” with 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.” *Id.*, 4:33–38. A single curved structure like Lundahl’s did not have the issues that were a known concern with connected panel designs. JX-0008C (Luebbert), 199:12–200:14; JX-0014C (Boyajian), 100:22–102:4; JX-0015C (Carota), 88:15–89:1.⁶

Dr. Grove argues that a POSITA would have been motivated to “incorporate Larsen’s solution of disposing light sources, specifically LEDs, on the surface of the light applicators to Lundahl’s device.” RX-0006C.0073–74 (Grove), Q327. Dr. Grove, however, does not properly apply Larsen’s teachings, but instead cherry-picks Larsen’s LEDs (together with the five panels) but modifies the “regular row arrangements” of Larsen to arrange them according to the “the uneven spacing” of Lundahl’s fluorescent tubes, without explanation for the modification. RX-0006C.0074 (Grove), Q328; CX-0014C. 117–18 (Jokerst), Q491–97; Tr. (Grove), 570:15–19.

Further, Biofrontera failed to show a reasonable expectation of success in combining Lundahl’s device with Larsen’s panels to arrive at the claimed invention. CX-0014C.115 (Jokerst), Q479. As discussed, there is no evidence of reasonable expectation of success that modifying Lundahl’s device with Larsen’s five panels would uniformly illuminate a treatment

⁶ The Asserted Patents themselves explains that “conventional adjustable illuminators” suffered from the problem of “a ‘gap’ between the light sources” that “can cause optical ‘dead space’ in certain portions of the target treatment area,” and that an object of the present invention was to “reduce or eliminate these dead spaces and provide for a more uniform light distribution.” JX-0001, 2:5–20, 2:50–62.

surface as construed. Further, a POSITA would have understood that modifying Lundahl's single U-shaped structure to incorporate Larsen's five panels would have created unwanted gaps that would not deliver a uniform light dose. CX-0014C.116–17 (Jokerst), Q481–89. As the inventors noted, “[h]aving separate panels is not easy.... Uniformity is a big challenge.” CX-0014C.116–17 (Jokerst), Q481–89; JX-0014C (Boyajian), 99:15–100:12. In fact, it was “one of the more difficult challenges.” CX-0014C.117 (Jokerst), Q489; JX-0015C (Carota), 73:20–74:5. Even Biofrontera's CEO, Dr. Luebbert, acknowledge this challenge, admitting that there were “issues that are caused by...gaps between individual connected panels.” CX-0014C.116 (Jokerst), Q481; JX-0008C (Luebbert), 200:10–12. Biofrontera and Dr. Grove do not discuss how the combined modified device meets the “uniformly illuminate” claim limitation. CX-0014C.116–17 (Jokerst), Q484–89. They simply look at Lundahl and Larsen individually. Any expectation that the device would meet this claim limitation is contradicted by the express teachings of Lundahl that all of its components were carefully engineered and selected to achieve uniform illumination. RX-0065.0020, 6:10–22; CX-0014C.72–75, .116–17 (Jokerst), Q288–94, Q486–90; *see* §VI.A.3.

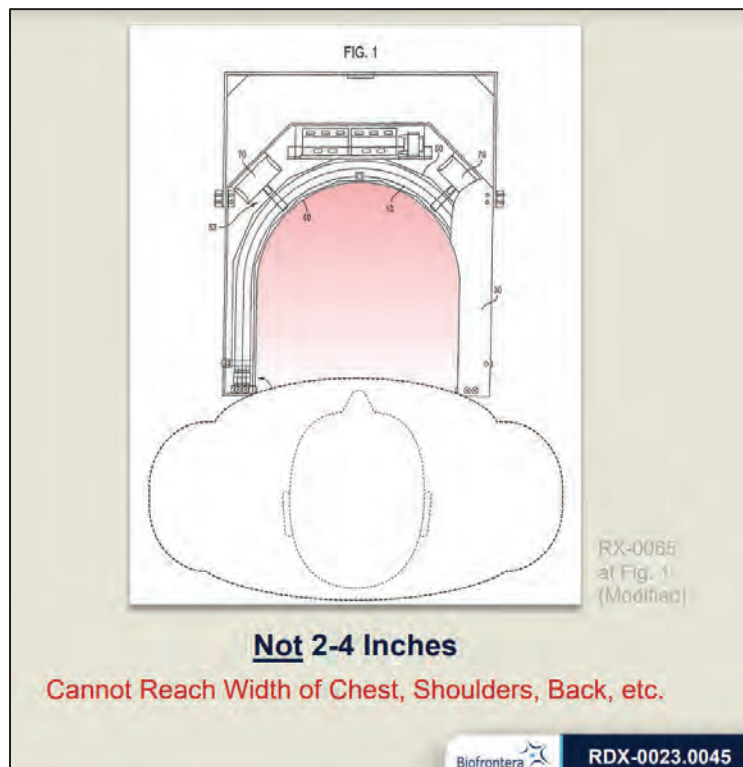
Converting from fluorescent tubes to LEDs for a phototherapy device that requires uniform illumination of a treatment surface was not a “routine design process.” CX-0014C.120 (Jokerst), Q503–05. This is particularly the case when designing an illuminator capable of use in PDT because of the importance of the uniformity and power requirements. CX-0014C.120 (Jokerst), Q503–05. These conclusions find support in the inventors' testimony, which confirms that attaining uniformity when developing an LED system after a first-generation fluorescent system was not a routine design process. CX-0014C.120 (Jokerst), Q506; JX-0014C (Boyajian), 88:5–89:12, 99:15–100:12; JX-0015C (Carota), 73:20–74:5, 76:20–77:9, 106:13–107:4.

b. No Motivation To Modify BLU-U® 4170

Dr. Grove further relies on Dr. Ehrenreich’s assertion that a POSITA would “have been motivated to modify the prior art phototherapy lamps, like the BLU-U.” RX-0007C.0033 (Ehrenreich), Q159. According to Biofrontera, this motivation stemmed from an “important issue” of trying to use the device to treat the “chest and back” which were “often” too big for the fixed U shape.

But physicians ran into another issue, another important issue, when they wanted to treat other parts of the patient's body, such as the chest and back. And as we can clearly see up on the screen, often the surfaces are too big to fit within the fixed U shape. So inflexibility of the U-shaped design presented a readily apparent and known problem prior to 2015.

Tr. (Biofrontera’s Opening), 35:17–23.



RDX-0023.0045.

But none of the alleged difficulties with BLU-U® 4170 would have motivated a POSITA to change the BLU-U® device. CX-0013C.53 (Shmuylovich), Q197. Dr. Ehrenreich asserts that the fixed U-shape requires “jury-rigging” to position a patient for treatment of the arms, but that would somehow be solved with a flexible panel arrangement. RX-0007C.0033 (Ehrenreich), Q159. But he admitted on cross-examination that he uses the 4170 to treat arms, and has no plans to stop:

Q. And in terms of your own use of the BLU-U 4170 device, you're still using the BLU-U 4170 to treat arms and hands in your practice, right? A. Yes, I do. Q. You have no plans to stop using the older BLU-U device to treat arms and hands, right? A. Not at the moment.
--

Tr. (Ehrenreich), 640:10–16. Moreover, he clarified that treating the chest and back with BLU-U® was “uncommon” and that the size of patient’s body parts never prevented him from doing a PDT treatment—contrary to Biofrontera’s counsel claim that a too-large chest was an “important” problem that happens “often.”

Q. And you mentioned this earlier, you do use the BLU-U to treat patients' chests, but it's on the rare occasion, right, Doctor?

A. Right. It's uncommon compared to the other uses.

Q. It's quite rare, right, Doctor?

A. I don't know what "quite rare" means, but it's -- I think the numbers we gave before are that about 90 percent on the face and head, about 10-ish percent on the face and arms, and a smattering of other uses is about right.

Q. And the other uses, that would include chest and back?

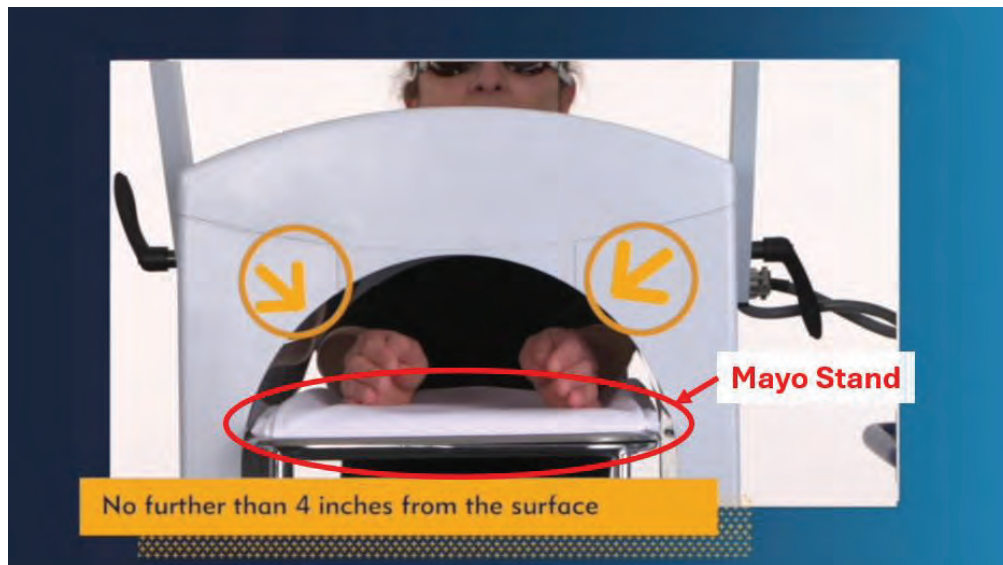
A. Chest and back, et cetera, shoulders.

Q. Thank you. Now, switching to talking about the size of the patient, it's your testimony that the size of someone's body parts has never prevented you from doing a PDT treatment. True?

A. True.

Tr. (Ehrenreich), 648:1–17.

BLU-U® 4170 was designed to treat patients with larger or smaller heads. CX-0013C.57 (Shmuylovich), Q221–25; CX-0169; CX-1053C; CX-0305C; JX-0203. Dr. Heather Roberts, an expert who testified on Sun Pharma's behalf in the parallel IPR proceeding, stated that she used BLU-U® 4170 to treat patients' faces, necks, arms, hands, chests, and backs for AK. CX-1063.15. The fact that Dr. Ehrenreich and Dr. Roberts use the U-shaped device to treat patients and body parts of varying shapes and sizes shows that any "jury-rigging" is a normal scenario, not a motivation to modify. CX-0013C.55 (Shmuylovich), Q210; CX-1330C.69, 69:12–18. Even the new BLU-U® 4170E with its flexible panels encourages using a Mayo stand to treat the upper extremities at the proper distances for uniformity. Tr. (Ehrenreich), 642:9–647:8.



CX-1355, 3:15 (annotated).



CX-1351, 1:42 (annotated).

c. No Motivation To Combine Lundahl, Larsen, And Hente

A POSITA would not look to Hente to further modify Lundahl with Larsen absent hindsight because Hente is not analogous art. CX-0014C.123–24 (Jokerst), Q519–21.

As previously discussed, Hente is not in the same field of endeavor as the Asserted Patents and is not solving the same problem. CX-0014C.124 (Jokerst), Q521–24. Dr. Grove admitted on both cross-examination and re-direct that “Hente does not ever mention photodynamic therapy” and that he is “not relying on Hente for teachings related to PDT”:

Q. Okay. Now, you agree that Hente does not ever mention photodynamic therapy or diagnosis, right? A. That's correct.

Tr. (Grove), 582:19-21

Q. Are you relying on Hente for teachings related to PDT? A. Nothing related to PDT, no.
--

Tr. (Grove), 587:9-11

Dr. Grove fails to explain how or why a POSITA would have incorporated Hente’s hinges into Lundahl (as modified by Larsen), given the numerous differences between the features of the devices that make them incompatible. CX-0014C.124–25 (Jokerst), Q526–27. For example, LEDs such as those used in the Asserted Patents are Lambertian light sources considered to be point sources in arrays, whereas OLEDs are diffuse area sources. CX-1056.2. Hente is directed to a different problem of a workbench light that needed to allow light to leave through the side surfaces. RX-0576.0010, [0008]. Hente does not connect multiple adjacent panels, where each panel incorporates LEDs, because each of the sections that Hente connects are, themselves, individual OLEDs. CX-0014C.124 (Jokerst), Q525; RX-0576, Fig. 2, [0003], [0036].

A POSITA would also not have been motivated to combine Hente with Lundal and Larsen because the specifications of Hente’s device utilizing OLEDs are significantly smaller than the specifications of a PDT device utilizing LEDs. CX-0014C.125 (Jokerst), Q529–30; RX-0576, Fig.

2, [0009], [0033]. A POSITA would not have been motivated to utilize Hente's hinges in the combined modified device of Lundahl and Larsen because the hinges suitable for a very thin stretchable device like Hente's—no greater than 1mm thick, would not be suitable for connecting rigid panels in the alleged combined PDT device of Lundahl and Larsen. CX-0014C.126 (Jokerst), Q531–33; RX-0576, Fig. 2, [0003], [0009], [0033], [0036].

Biofrontera has not explained why a POSITA would have looked to Hente to solve a problem that Biofrontera argues Lundahl (as modified by Larsen) already solves. CX-0014C.126 (Jokerst), Q534. In any event, Hente does not purport to solve the problem of “uniform illumination” and never discloses uniformly illuminating any surface, especially not a treatment surface of a patient. CX-0014C.126 (Jokerst), Q535–36. Biofrontera's arguments to the contrary are all grounded in hindsight. CX-0014C.127 (Jokerst), Q539–41.

d. No Motivation To Combine Lundahl, Larsen, Hente, And Perutz

Likewise, Perutz is not analogous art, as it is not from the same field of invention and is not solving the same problem as the Asserted Patents. CX-0014C.48, 129 (Jokerst), Q183–87, Q551. Perutz is directed to “display panel systems utilized for exhibiting at trade shows, promotional events and the like.” RX-0607, 1:7–9, 4:11–14, Fig. 1. Perutz never discloses an illuminator or light sources. CX-0014C.129 (Jokerst), Q552.

Moreover, a POSITA would not have had a reasonable expectation of success in combining Perutz's hinges (for thick, rigid display panels) with Hente's hinges (for 1mm thin OLED sections), or that hinges that would hold up Perutz's display boards or Larsen's panels could be applied successfully to Hente's thin OLEDs. CX-0014C.130–31 (Jokerst), Q555–56. A POSITA would also have been discouraged from adding Perutz's teaching of hinges at an inner side surface of the display panels, because such hinges would block the light emitted from Hente's side surfaces

and rims, contrary to Hente's teachings for every one of its embodiments. CX-0014C.131 (Jokerst), Q556.

11. Objective Indicia of Nonobviousness

a. Commercial Success

RhodoLED® XL has enjoyed commercial success, which stems from its patented features. CX-0014C.133–36 (Jokerst), Q570–79. The RhodoLED® XL is coextensive with the Asserted Patents, entitling Sun Pharma to a presumption of nexus. See §V. Biofrontera markets RhodoLED® XL's larger illumination area as its main advantage over RhodoLED®, which is made possible by the patented five-panel design:

Benefits of RhodoLED® XL over RhodoLED®

Biofrontera Announces the Launch of a New, FDA-Approved Red Light Source, the RhodoLED® XL Lamp
June 24, 2024 5 min read

In comparison to Biofrontera's existing lamp, the RhodoLED XL offers a larger illumination area with five panels compared to one, and additional features such as positioning sensors to ensure the patient receives the optimal energy delivery from the LED array.

JX-0046.2

Biofrontera Inc. (BFRI) Q3 2024 Earnings Call Transcript
Nov 14, 2024 3:02 PM ET Biofrontera Inc. (BFRI) Stock, BFRW Stock

tissue and even the bone. The fourth point I mentioned is the launch of our RhodoLED XL lamp. This lamp offers an alternative for doctors who wish to treat larger skin regions with Ameluz PDT.

CX-0183.4

Biofrontera
Source: Biofrontera Inc.
December 23, 2024 09:30 ET

The RhodoLED XL was approved by the FDA for use in combination with Ameluz® in 2022 and was launched in June of this year. Since then, it has seen rapid adoption by offices who had previously used Ameluz and those who are new to the product, with 100 now being installed since launch. The main difference between the company's existing BF RhodoLED lamp and the new RhodoLED XL is the number of LED panels which allows a larger surface area to be illuminated during a single PDT treatment with Ameluz®.

CX-0356

CX-0356.1

Confidential Business Information Subject to Protective Order

CDX-0015C.19

CDX-0015C.19; JX-0046.2; CX-0356.1; CX-0183.4

The RhodoLED® XL has been outperforming the nonpracticing RhodoLED® device since its launch, which according to Biofrontera's CEO Mr. Luebbert is itself a successful product. Tr. (Luebbert), 332:1–12 (testifying that he considered RhodoLED® XL to be a successful product.)

Biofrontera placed a total of 100 units by December 2024, in the 6-month period since the RhodoLED® XL launched in June 2024. CX-0356; JX-0229C; CX-1342; CX-1307; CX-0012C.24 (Vander Veen), Q132; CX-1353. In comparison, Biofrontera only placed 72 RhodoLED® units in the entire 2024 year. CX-0012C.24 (Vander Veen), Q130; CX-1307. Biofrontera CFO Mr. Frederick Leffler testified that he expects enough RhodoLED® XL sales to [REDACTED]. CX-1335C, 139:4–21; Tr. (Leffler), 410:11–15 (Mr. Leffler testifying that Q3 2024 revenue was up from Q3 2023 revenue by \$600,000 because of RhodoLED® XL sales).

RhodoLED® XL also outperformed Sun Pharma’s nonpracticing BLU-U® 4170D device, showing that its success stems from the patented features. [REDACTED]

[REDACTED] CX-0012C.29 (Vander Veen), Q165; RX-0004C.0035 (Luebbert), Q127; JX-0008C (Luebbert), 140:19–141:4; CX-0013C.61–62 (Shmuylovich), Q241–51. Indeed, Biofrontera Inc.’s CEO admitted that “launching the XL has been a success for the company.” Tr. (Luebbert), 316:23–317:6; *id.*, 284:2–8, 316:10–13: (“Q. So do you agree with Biofrontera’s position in this case that RhodoLED XL has not even sold anywhere near what was projected? A. No.”).

The patented features are plainly the driving force behind RhodoLED® XL’s commercial success. Biofrontera’s press releases and industry reviews both acknowledge the principal advantage of RhodoLED® XL is the five-panel design with a larger illumination area allowing for treatment in a single session. CX-0356.1 (noting the “main difference between the company’s existing BF-RhodoLED lamp and the new RhodoLED XL is the number of LED panels which allows a larger surface area to be illuminated during a single PDT treatment with Ameluz®”); CX-

0014C.141–143 (Jokerst), Q602–609; JX-0008C (Luebbert), 139:18–21; CX-1335C, 55:1–4; CX-1331C, 136:10–17; CX-1336C, 90:2–11; CX-1331C, 105:13–22; JX-0078. RhodoLED® XL is priced at \$18,500, while RhodoLED® is priced at \$7,500; increased sales at a higher price point further support the nexus between patented features and RhodoLED® XL’s commercial success, as healthcare providers invest in a device for increased efficiency of treatment, which is a product of the **patented** features. Tr. (Leffler), 412:22–413:10; CX-0012C.28 (Vander Veen), Q153–154; CX-1329C, 188:1–5; 185:10–190:3; CX-0013C.62 (Shmuylovich), Q248.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

b. Industry Praise

RhodoLED® XL has received industry praise for the patented features. Tr. (Luebbert), 316:14–22 (testifying that “[w]e got very positive response about the lamp [RhodoLED® XL] from the doctors using the lamp”). The industry praise for the RhodoLED® XL is directly tied to the patented features. CX-1249 (RhodoLED® XL “revolutionize[s] photodynamic therapy for actinic keratoses...by being highly maneuverable and **capable of accommodating various patient treatment positions**”); CX-1225.3 (RhodoLED® XL “represents a significant advancement in the treatment of PDT” and “is designed to be simple to maneuver and **able to accommodate various patient treatment positions...**”); JX-0177.4 (Dr. Ted Lain praising RhodoLED® XL for its “**multi-panel lamp head** [that] fits nicely over a patient’s face or scalp for the short treatment, while providing better coverage”); CX-0356.1 (customer stating they “were thoroughly impressed by the lamp’s...exceptional **maneuverability and adjustability**, which made it ideal for Photodynamic

Therapy (PDT) treatments...The **larger illumination area** has significantly increased our patient throughput while also enhancing the overall quality of care and patient experience”); Tr. (Luebbert), 336:2–8 (admitting that “[i]n the 2015 to 2016 time frame...there was an unmet need for a PDT lamp with a larger treatment area in the market.”); JX-0009C (Lyons), 90:6–11; JX-0010C (Baldyga), 44:9–45:11; CX-0014C.143–45 (Jokerst), Q610–19.

Customer Perception of the RhodoLED® XL

Q. What is your understanding of what the benefit of five panels are?

A. My benefit or from a provider's point of view?

Q. From the provider's point of view.

A. Feedback that I received is they like having the five panels versus the one panel.

Q. And why is that?

A. When treating a patient.

Q. Can you give me anything more as to why they think having five panels is a benefit?

A. One of the benefits is you can treat a patient's full face with one treatment. On our original lamp you cannot do that.

Biofrontera Inc. Announces 100 RhodoLED® XL Machines Now Placed in US Market

After a three-month evaluation of the RhodoLED XL, Dr. Aaron Hoover of Front Range Dermatology, Colorado was so impressed with its performance that his practice decided to purchase not one but two units, including the 100th installed RhodoLED XL lamp. "We were thoroughly impressed by the lamp's robust yet elegant design, as well as its exceptional maneuverability and adjustability, which made it ideal for Photodynamic Therapy (PDT) treatments in our offices," Dr. Hoover explained. "The larger illumination area has significantly increased our patient throughput while also enhancing the overall quality of care and patient experience." Dr. Hoover also noted the high level of

CX-1329C (Baldyga Dep. Tr.) at 58:15–59:6

Confidential Business Information Subject to Protective Order

CX-0356
CDX-0015C.22

CDX-0015C.22; CX-1329C, 58:15–59:6; CX-0356.

Similarly, industry praise for the newly-launched BLU-U® 4170E has highlighted the patented features. CX-1346–47. For example, a *Dermatology Times* article on the 4170E launch quoted a dermatologist saying, “The approval of the new illuminator is advancing the technology and treatment of field therapy of AK’s with PDT.” CX-1346.2. Under “Technological Advancements,” it lists, “a 5-panel shape for increased flexibility” and “an optimized LED arrangement.” *Id.* “The next-generation LED BLU-U device represents a step forward in photodynamic therapy.” CX-1346.4. Mr. Lundahl testified that the marketing feedback on the

BLU-U® 4170E has been very positive, with one doctor saying “we’d hit a home run with this light source.” CX-0011C.34–35 (Lundahl), Q161–64; JX-0094C.2.

c. Copying

Biofrontera was well aware of Sun Pharma’s patented technology and copied its features in developing the RhodoLED® XL.

On October 15, 2015, Sun Pharma filed the ’902 Provisional application disclosing the five-panel illuminator and other key features of the claimed illuminator. JX-0001; JX-0002; CX-0018C.10 (Boyajian), Q48. Biofrontera began developing the RhodoLED® XL in 2017, after Sun Pharma’s patent applications—including those disclosing the novel features of the asserted inventions—had been published. CX-0014C.147 (Jokerst), Q628; RX-0002C.0019 (Foguet), Q44; RX-0004C.0016 (Luebbert), Q62–64. Biofrontera was not only monitoring Sun Pharma’s IP portfolio at the time (CX-0014C.147 (Jokerst), Q629; JX-0011C (Foguet), 41:24–42:2), it was specifically aware of Sun Pharma’s patents relating to a five-panel LED illumination device during development of the RhodoLED® XL. Tr., 326:2–10; JX-0008C (Luebbert), 61:5–9, 61:18. By February 10, 2022, Biofrontera submitted an Information Disclosure Statement to the PTO during prosecution of U.S. App. No. 17/071,496, which cited Sun Pharma’s ’616 Patent Application Publication. CX-1229; CX-0014C.147 (Jokerst), Q632. This publication, from the same family as the Asserted Patents, discloses the novel inventive features—including the five-panel curved illuminator with hinged side panels, a mobile base with spring arm and pillar, and LED placement for enhanced intensity and uniformity. CX-0014C.146 (Jokerst), Q624. Biofrontera was also aware of the ’028 Patent by at least April 2024, when it filed an IPR challenging the patent before launching the RhodoLED® XL. Tr. (Luebbert), 326:23–327:8. The objective evidence demonstrates that Biofrontera saw value in Sun Pharma’s patented invention that it could not independently create.

B. Enablement

The preamble of the Asserted Claims includes “photodynamically diagnosing or treating a patient.” Biofrontera, through Dr. Ehrenreich, asserts that the Asserted Claims are not enabled because “undue experimentation would have been required to use the claimed illuminator to photodynamically diagnose a patient across the full scope of the asserted claims.” RX-0007C.0042. Biofrontera does not assert that a POSITA would be unable to build an illuminator with the structural components of the claims; indeed, Biofrontera’s expert *expressly opined* that a POSITA would *not* require undue experimentation to practice the claims when photodynamically treating a patient. RX-0007C.0043, Q209; Tr. (Ehrenreich), 616:8–19.

Biofrontera failed to establish by clear and convincing evidence that the Asserted Claims are invalid for lack of enablement, because a POSITA reading the Asserted Patents would understand how to use the claimed illuminator for photodynamically diagnosing a patient—that is, apply a photoactivatable agent and then turn on the claimed illuminator to uniformly illuminate the treatment surface—without undue experimentation. CX-0013C.18 (Shmuylovich), Q55.

While Biofrontera posits that PD was poorly understood for certain conditions, RX-0007C.0051, Q245, the scope of the Asserted Claims do not require an enabling disclosure of diagnosing specific conditions not known to be amenable to PD—the claims do not recite any disease or condition. CX-0013C.22–23 (Shmuylovich), Q75–78.

1. Nature Of The Invention And Breadth Of The Claims

The system Asserted Claims recite an improved illuminator with specific, structural characteristics that make it suitable for use in PD or PDT and the method claims recite steps for using that improved illuminator with ALA for PD or PDT. The Asserted Patents clearly disclose the breadth of those claims. JX-0001, 1:17–20 (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”), 9:44–48 (“The invention thus provides a method for photodynamically diagnosing...a patient, which includes providing the adjustable illuminator described above, placing the patient in the illuminator, and illuminating the patient to diagnose...the patient”); JX-0002, 9:48–52; CX-0013C.18–25 (Shmuylovich), Q56–85.

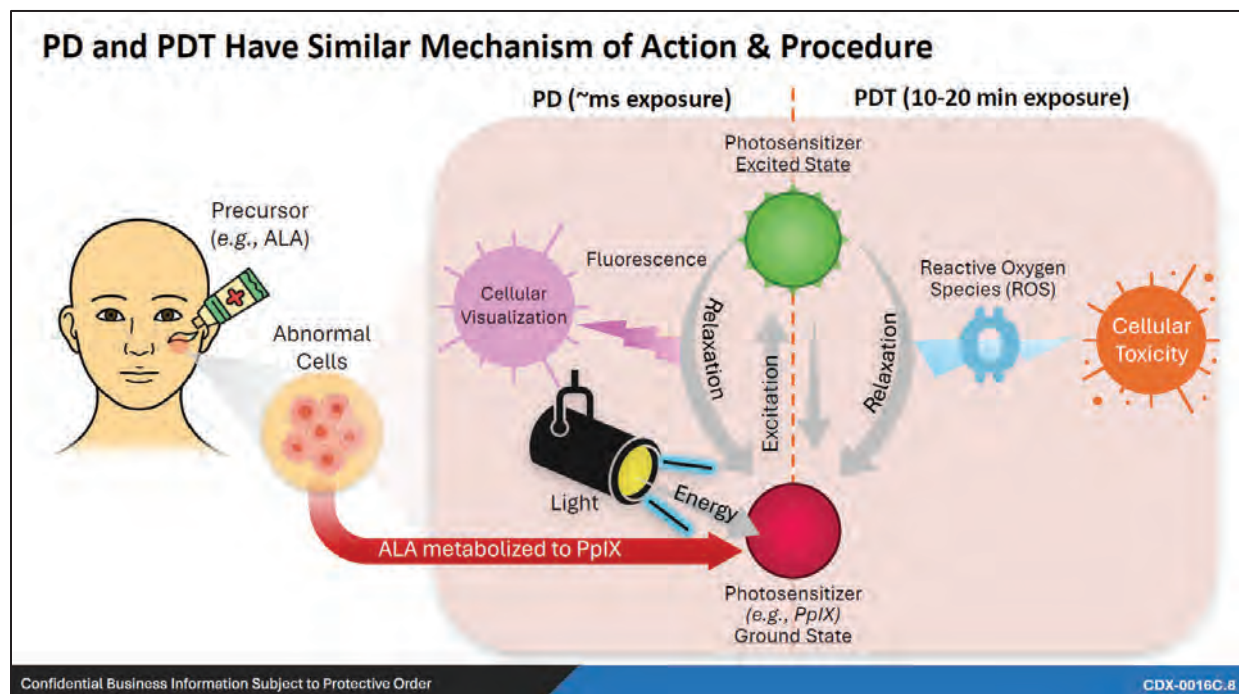
The Asserted Claims relate to photodynamic diagnosis of **dermatological** conditions, as the claimed five-panel illuminator is used in PDT or PD by illuminating the **exterior** of a patient, as opposed to internal body parts. JX-0001, 9:44–52; CX-0013C.22–23 (Shmuylovich), Q75–78.

2. Amount Of Direction Provided By The Patents And Existence Of Working Examples

There is no dispute that the specification teaches a POSITA to **make** the claimed illuminator, which is suitable for use in PD. The specification also teaches a POSITA how to **use** that illuminator to photodynamically diagnose a patient. CX-0013C.27 (Shmuylovich), Q94. The specification includes many disclosures about using the claimed illuminator for PD, including a general procedure for performing PD with an illuminator. JX-0001, 1:34–45, 2:50–54; CX-0013C.25–28 (Shmuylovich), Q86–97. That procedure is applicable to any dermatological condition amenable to PD. CX-0013C.26 (Shmuylovich), Q90. The specification also incorporates by reference several patents specifically for the techniques, methods, compositions, and devices related to both PDT and PD. CX-0013C.28 (Shmuylovich), Q97; JX-0001, 1:48–55.

The specification further includes procedures for conducting PDT using the claimed illuminator. JX-0001 at 8:64–9:52; CX-0013C.26–27 (Shmuylovich), Q91. Biofrontera apparently agrees that those procedures enable a POSITA to perform PDT using the claimed illuminator. RX-0007C.0043 (Ehrenreich), Q209; CX-0013C.16 (Shmuylovich), Q47; Tr. (Ehrenreich), 616:3–19 (Dr. Ehrenreich admitting that undue experimentation would not be required to practice the PDT aspect of the Asserted Claims). Those procedures also direct a

POSITA how to photodynamically diagnose using the illuminator, as the difference between PD and PDT for these steps is simply the length of illumination time—what the specification refers to as the “prescribed time”—and the act of detecting fluorescence. JX-0001, 1:39–43 (changes caused by exposing photosensitizing agent to light “allow the agent to then selectively locate...the target tissue”); CX-0013C.27 (Shmuylovich), Q93; Tr. (Shmuylovich), 705:4–707:25, *id.* (Shmuylovich), 708:23–709:6. The “prescribed period” of illumination required for PD is nearly instantaneous, whereas tissue destruction requires minutes of illumination, as the specification describes. JX-0001, 8:64–9:52; CX-0013C.27 (Shmuylovich), Q93; Tr., (Shmuylovich), 697:19–699:5, 701:2–8. Therefore, those steps disclosed for PDT inform a POSITA how to perform PD. CX-0013C.27 (Shmuylovich), Q92–93; CX-1081.1; Tr. (Shmuylovich), 703:14–704:19.



CDX-0016C.8. The specification reiterates the overlapping steps for PD/PDT:

The invention thus provides a method for photodynamically diagnosing or treating a contoured surface of a patient, which includes providing the adjustable illuminator described above, placing the patient in the illuminator, and illuminating the patient to diagnose or treat the patient.

JX-0001, 9:44–48.

The specification appropriately directs a POSITA regarding the novel aspects of the inventions, including how to build the claimed illuminator and how to use that illuminator in PD and PDT. CX-0013C.28 (Shmuylovich), Q97. The specification makes clear that one can use the claimed illuminator to uniformly illuminate a patient’s treatment area during both PD and PDT, using the standard procedures for PD and PDT at the time. CX-0013C.28 (Shmuylovich), Q97. The general mechanics and procedures for PD using such illuminators were understood in the art. CX-0013C.28 (Shmuylovich), Q97. For example, the specification discloses emitting “light at an appropriate wavelength ... to activate the particular photoactivatable agent used in treatment or diagnosis.” JX-0001, 3:66–4:2.

3. Level Of Skill In The Art

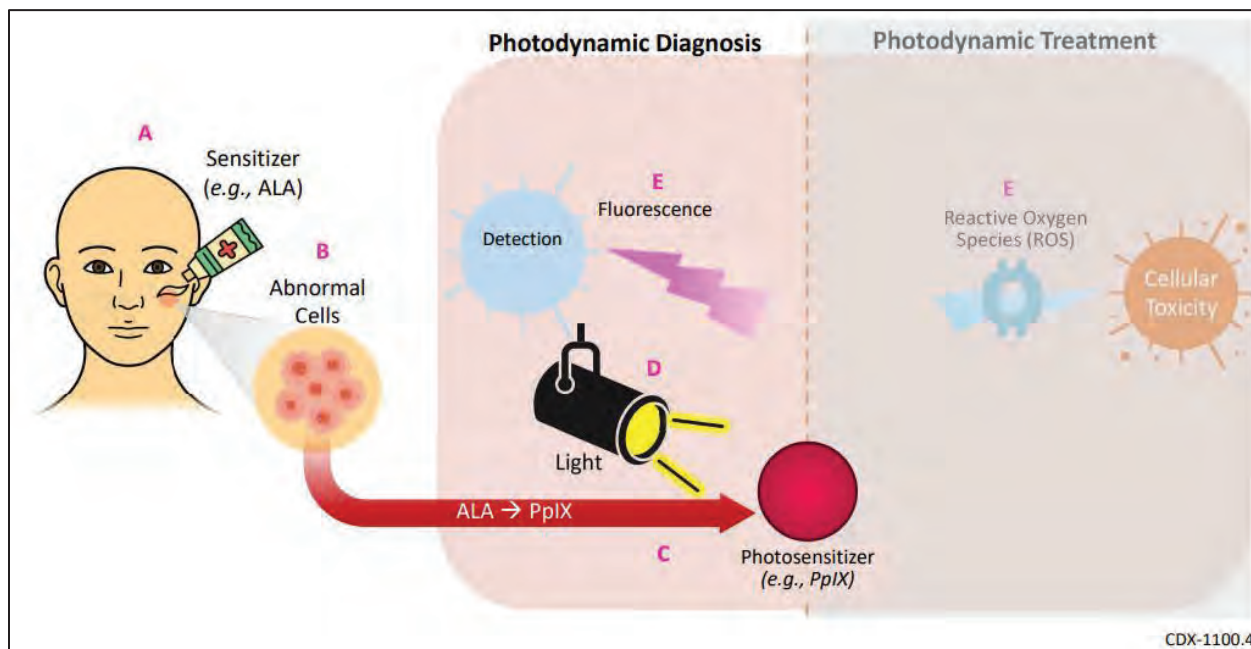
The level of skill in the art is high, particularly with respect to PD of dermatological conditions using various photosensitizing agents. CX-0013C.28–29 (Shmuylovich), Q98–103; RX-0007C.0049–50 (Ehrenreich), Q239.

4. State Of The Prior Art And Predictability Of The Field

Both parties agree that the general concepts of PD were well-understood by 2015. CX-0013C.30 (Shmuylovich), Q106; RX-0007C.0051, Q245; Tr. (Ehrenreich), 617:3–6. While the Asserted Patents disclose a novel illuminator that is configured to output a uniform light across five panels, it was also known in the art at the time of the asserted patents that illuminators could be used for both photodynamic therapy and diagnosis. Tr. (Ehrenreich), 621:5–624:2 (reviewing disclosures in RX-0065), 374:8–377:5; Tr. (Foguet), 374:16–375:8 (admitting her patent disclosed a PDT light that “may further be capable to induce red fluorescence of accumulated porphyrins”). Both sides’ expert agree that it was known that applying a fluorophore/photosensitizer, exposing

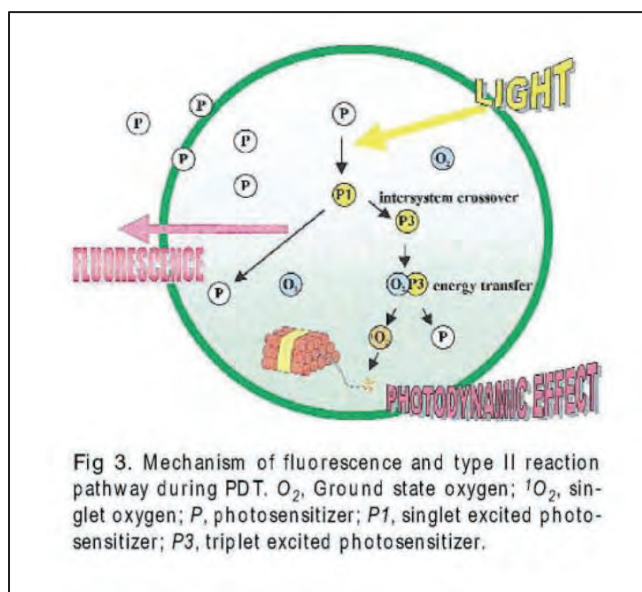
it to light, and detecting resulting fluorescence could identify abnormal tissue, including certain cancers. CX-0013C.29–40 (Shmuylovich), Q104–48; Tr. (Ehrenreich), 617:3–618:1.

The knowledge of PD by those skilled in the art is not in dispute. CX-0011C.15 (Lundahl), Q60; CX-0013C.30 (Shmuylovich), Q107. Dr. Foguet admitted on cross-examination that it was known before 2015 that “irradiation of a photosensitizer could give rise to a characteristic fluorescence radiation which could be used for diagnostic purposes.” Tr. (Foguet), 370:4–14. Biofrontera’s expert admits that “photodynamic diagnosis was generally known as of the priority date of the asserted patents.” Tr. (Ehrenreich), 617:4–6. Biofrontera’s expert, Dr. Ehrenreich, testified in reference to CDX-1100.4 that PD involves applying a photosensitizer like ALA (Step A), its accumulation in abnormal cells (Step B), conversion to PpIX (Step C), and illumination with light of the appropriate wavelength (Step D) will induce fluorescence that is detectable by human eye or a camera (Step E). Tr. (Ehrenreich), 617:7–618:16.

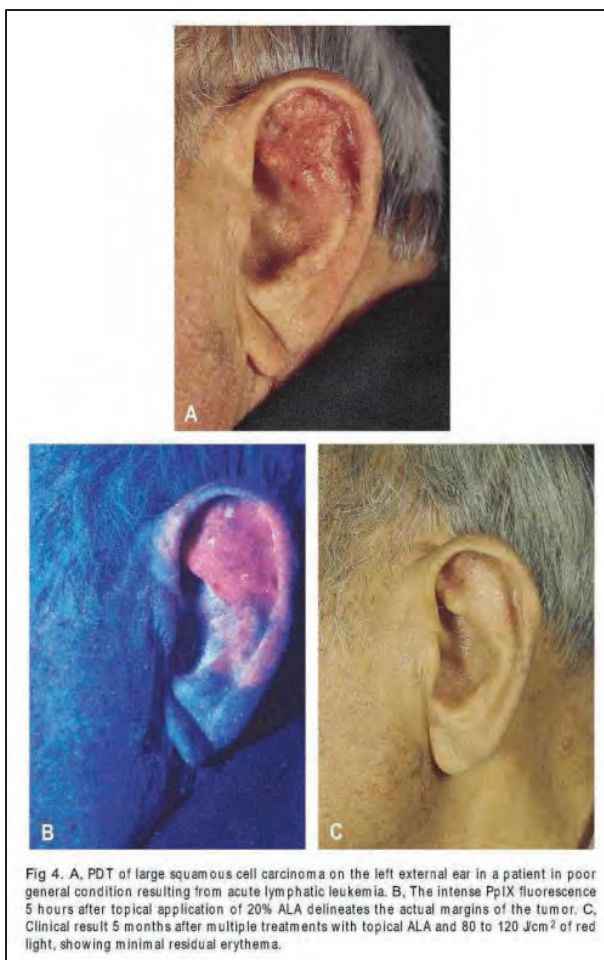


CDX-1100.4.

A POSITA using a known photosensitizer and the claimed illuminator would understand how to configure the device to match the photosensitizer's absorption spectrum. CX-0013C.30 (Shmuylovich), Q109; Tr. (Ehrenreich), 612:25–613:8. Dr. Ehrenreich admitted that “if a dermatologist is using an agent known to absorb light at a particular wavelength, that dermatologist can use an illuminator that emits light at a wavelength generally near the peak to excite the agent.” Tr. (Ehrenreich), 615:3–8. There is nothing in the use of the claimed illuminator for PD that would confound a POSITA as compared to other illuminators used in PD at the time of the invention. CX-0013C.31 (Shmuylovich), Q110, CX-0013C.35 (Shmuylovich), Q125; JX-0001, 1:48–60; RX-0622.0018, 1:23–31; CX-1085.2–3. Once built according to the Asserted Patents, the illuminator's use in PD would be readily understood by POSITAs based on the state of the art and the patent disclosures. CX-0013C.30–37 (Shmuylovich), Q106–36; CX-0342; CX-0343; CX-1076; CX-1081; CX-1084; CX-1085; RX-0622; Tr. (Shmuylovich), 708:23–709:6.



CX-0343.7.



CX-0343.11; CX-0342.2 (providing exemplary instructions for a “technique of PDD”); JX-0015C (Carota), 93:6–16, 94:10–95:8; JX-0011C (Foguet), 189:22–191:17; RX-0007C.0050 (Ehrenreich), Q239 (recognizing knowledge at the time of the patents for diagnosing certain conditions using known photosensitizing agents); Tr. (Foguet), 373:17–25 (disclosed example of PD using 405nm light).

5. Quantity Of Experimentation Needed To Make Or Use The Invention

The knowledge of a POSITA, combined with the disclosures of the Asserted Patents and the state of the art at the time would enable a POSITA to practice the full scope of the claims without undue experimentation. CX-0013C.40–47 (Shmuylovich), Q149–75. None of the parameters identified by Biofrontera qualify as undue experimentation to practice the scope of the

claims, including selecting the 1) wavelength to use for PDT, 2) type and amount of photosensitizer to use, and 3) light dose and fluence. CX-0013C.40 (Shmuylovich), Q150; Tr. (Shmuylovich), 705:4–706:19.

A POSITA would understand that PDT and PD require a photosensitizer or fluorophore, and a light source. CX-0013C.40–41 (Shmuylovich), Q152; Tr. (Shmuylovich), 705:4–706:19. Photosensitizers have well-studied absorption and emission spectra, with known particular wavelengths for efficient activation. CX-0013C.40–41 (Shmuylovich), Q152. So, a POSITA seeking to use the claimed methods and systems with a particular photosensitizer could easily look up which wavelengths of light to use to excite that photosensitizer for fluorescence activity. CX-0013C.40–41 (Shmuylovich), Q152, CX-0013C.46–47 (Shmuylovich), Q172 (example of ALA); Tr. (Shmuylovich), 705:22–706:19 (“Depending on which fluorophore you have, you know which wavelength you need...But if you had another fluorophore, it is pretty simple to either look up the fluorescence peaks or just measure them.”).

A POSITA would not need to test every visible wavelength to determine the appropriate one for PD. CX-0013C.41 (Shmuylovich), Q153. In any event, testing absorption spectra for fluorophores is routine, CX-0013C.40–41 (Shmuylovich), Q152; CX-0013C.47 (Shmuylovich), Q175, and testing at 10 nm intervals is unnecessary. CX-0013C.46–47 (Shmuylovich), Q172; Tr. (Shmuylovich), 706:2–3 (appropriate wavelength depends on the known properties of the fluorophore); CX-0013C.41 (Shmuylovich), Q153. Moreover, types of photosensitizers, their activation wavelengths, administration routes, and dosages were well-known in the art by 2015. CX-0013C.43–45 (Shmuylovich), Q160–66; CX-1084.6. Topical application was standard for PD of dermatological indications, and effective photosensitizer doses were documented and could be adjusted as needed for patient specific factors. CX-0013C.44 (Shmuylovich), Q165. Biofrontera

also incorrectly claims that light dose requires experimentation, but visualizing fluorescence takes seconds of light exposure. CX-0013C.45 (Shmuylovich), Q168–69. Photobleaching is not a factor that requires undue effort to enable PD. CX-0013C.45 (Shmuylovich), Q170. Photosensitizers fluoresce within milliseconds, but observation or imaging can occur over several seconds to minutes—turning off the light isn’t time-critical for PD. Tr. (Shmuylovich), 713:2–16.

C. Written Description

Biofrontera and Dr. Ehrenreich assert that the claims are invalid for lack of written description because the specification does not “convey to a POSITA with reasonable clarity that the inventors possessed methods and systems for photodynamically diagnosing any dermatological condition.” RX-0007C.0074 (Ehrenreich), Q346. That is not the case.

As discussed, the Asserted Claims claim an illuminator with specific structural requirements that a POSITA would understand can be used to diagnose dermatological conditions amenable to PD, as well as the use of that improved illuminator in a PD procedure. CX-0013C.49 (Shmuylovich), Q183–84. The specification discloses that the claimed illuminator can be used for PD. CX-0013C.50 (Shmuylovich), Q186–87; JX-0001, 1:19–20, 2:50–54. It expressly describes methods for locating target tissue by application of a photoactivable agent like ALA followed by illumination. CX-0013C.50 (Shmuylovich), Q188; JX-0001, 1:34–47. It further discloses using ALA with the claimed illuminator and concludes: “The invention thus provides a method for photodynamically diagnosing or treating a contoured surface of a patient, which includes providing the adjustable illuminator described above, placing the patient in the illuminator, and illuminating the patient to diagnose or treat the patient.” CX-0013C.50 (Shmuylovich), Q189; JX-0001, 9:44–48. Finally, the specification discloses the illuminator can be used to diagnose dermatological conditions. CX-0013C.50 (Shmuylovich), Q189; JX-0001, 1:27–33; 9:48–52.

The specification explains the use of photosensitizers, including ALA, for PD of dermatological conditions. CX-0013C.49 (Shmuylovich), Q183; JX-0001, 1:43–47, 9:1–52. Photosensitizers, their prodrugs, and their formulations were well-known in the art. CX-1084. The Asserted Patents include examples of wavelengths for use in PD, such as activating ALA with blue or red light for optimal PpIX activity. CX-0013C.49, .51 (Shmuylovich), Q183, Q191. More generally, the LEDs can be configured to “emit light at an appropriate wavelength according to the intended treatment or to activate the particular photoactivatable agent used in...diagnosis.” CX-0013C.42 (Shmuylovich), Q159; JX-0001, 3:66–4:2.

Therefore, a POSITA would understand the inventors possessed the claimed inventions, *i.e.*, a novel illuminator for PD that can be used with photosensitizers or their prodrugs that were well-known to a POSITA in 2015, at an appropriate wavelength for their activation. CX-0013C.52 (Shmuylovich), Q192.

Biofrontera is incorrect when it argues the specification does not “disclose structural features common to members of the claimed genus.” CX-0013C.52 (Shmuylovich), Q194. Biofrontera contends that the claimed illuminator is the “genus” and implementations of the claimed illuminator adapted for use in a PD procedure for a specific condition are the “species.” This is error, because each member of the genus will have the same structural components—namely five panels connected by inner side surface hinges, with the claimed arrangement of light sources. *Id.* To the extent different LED wavelengths are needed for different agents, matching the LED emission with the agent and embodiments of the illuminator with different wavelengths is disclosed in the specification. *Id.*; JX-0001, 3:66–4:13.

VII. DOMESTIC INDUSTRY TECHNICAL PRONG

BLU-U® 4170E, individually or in combination with Levulan®, practices each of the system DI Claims and healthcare providers practice each of the method DI Claims when they use BLU-U® 4170E in combination with Levulan® following Sun Pharma’s instructions.

Biofrontera offers no expert testimony in response: neither Dr. Grove nor Dr. Ehrenreich offer any DI opinions. *See generally* RX-0009C (Grove); RX-0011C (Ehrenreich). Biofrontera concedes that the device has the structural elements of the claims, but disputes that the device “has been used to ‘diagnose or treat a patient’ as required by the limiting preamble of each independent claim or has been used to practice the method claims...” Biofrontera G.R. 14.1, 2–7. Appendix A lists the “disputed” limitations for the 4170E.

First, there is no requirement for the device to be **used** to treat patients to practice system claims—it is undisputed that the device **existed** at the time of the filing of the complaint. CX-0603C (510(k) submission for BLU-U® 4170E dated May 13, 2024, with testing data from 4170E device). [REDACTED]

[REDACTED]

[REDACTED] That un rebutted testimony suffices as “there is no Commission requirement that sworn witness testimony directed to the domestic industry requirement cannot be credited without further corroboration by underlying documentation.” *Certain Raised Garden Beds*, Inv. No. 337-TA-1334, EDIS Doc. ID. 817237, Comm’n Op. (Apr. 1, 2024) at 45.

A. ’512 Patent DI Claims

BLU-U® 4170E, individually or in combination with Levulan®, practices ’512 Patent Claims 1, 2, 4, 5, 8, 19, and 20.

1. System Claims

a. Claim 1

i. Element 1[p] - Disputed⁷

BLU-U® 4170E practices this element. CX-0010C.23–24 (Jokerst), Q85–91. For example, the Operating Manual describes how the device is indicated for the treatment of AK, and is intended to provide phototherapeutic light to the body as a “Photodynamic Therapy Illuminator.” JX-0091C.4, .7.

Claim 1 of the '512 Patent – Preamble

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

Construction – the preamble is limiting



JX-0091C

The **BLU-U® Blue Light Photodynamic Therapy Illuminator Model 4170E**, in combination with the **Levulan® Kerastick® (aminolevulinic acid HCl) for Topical Solution, 20%**, is indicated for the treatment of minimally to moderately thick actinic keratoses (AK) of the face, scalp or upper extremities.

JX-0091C.4

The **BLU-U® Blue Light Photodynamic Therapy Illuminator Model 4170E** is intended to provide phototherapeutic light to the body. The **BLU-U® 4170E** is generally indicated to treat dermatological indications. The **BLU-U® 4170E** is specifically indicated to treat moderate inflammatory acne vulgaris.

JX-0091C.4

The **BLU-U®** is a compact light source designed to provide a uniform distribution of blue light to areas of the patient's face, scalp or upper extremities for the use stated above. It is comprised of 5 individual LED panels connected by hinges. The panels are covered by a protective shield, the center panel directs cooling airflow to the patient to improve comfort during the treatment.

JX-0091C.7

CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER CDX-0004C.24

CDX-0004C.24; CX-0010C.23–24 (Jokerst), Q86-91; JX-0091C, .4, .7; CX-0011C.14–15 (Lundahl), Q53–59 (describing how the Operating Manual instructs users how to treat AK with PDT using 4170E in combination with Levulan®).

Thus, BLU-U® 4170E is a system for photodynamically treating a patient.

⁷ See Appendix A.

ii. **Element 1[a] - Undisputed**

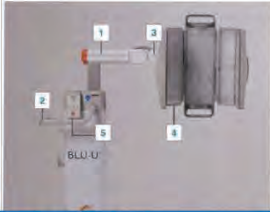
4170E practices this element. CX-0010C.24–26 (Jokerst), Q92–103.

Claim 1 of the '512 Patent – First Element

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

OPERATING MANUAL
BLU-U® Blue Light Photodynamic Therapy Illuminator, Model 4170E

Product Diagram:



- ① Adjustable height positioning of the unit for treatment flexibility.
- ② Large locking casters and post handle for easier mobility.
- ③ A pivoting arm for compact storage and easy movement within the treatment facility.
- ④ **Five Panel LED treatment array**



Description:

The BLU-U® is a compact light source designed to provide a uniform distribution of blue light to areas of the patient's face, scalp or upper extremities for the use stated above. **It is comprised of 5 individual LED panels** connected by hinges. The panels are covered by a protective shield, the center panel directs cooling airflow to the patient to improve comfort during the treatment.

JX-0091C.7

CX-1038C

CDX-0004C.27

CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER

CDX-0004C.27; JX-0091C.7; CX-1038C.

CDX-0004C.28; CX-1243C.1, .4.

iii. Element 1[b] - Undisputed

4170E practices this element. CX-0010C.26–29 (Jokerst), Q104–26.

Claim 1 of the '512 Patent – Second Element

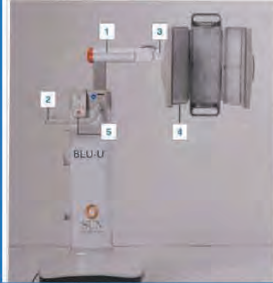
light sources disposed on surfaces of the at least five panels, the illuminator being configured to uniformly illuminate a treatment surface of the patient via the light sources



CX-1038C

OPERATING MANUAL
BLU-U® Blue Light Photodynamic Therapy Illuminator, Model 4170E

Product Diagram:



- ① Adjustable height positioning of the unit for treatment flexibility.
- ② Large locking casters and post handle for easier mobility.
- ③ A pivoting arm for compact storage and easy movement within the treatment facility.
- ④ **Five Panel LED treatment array.**
- ⑤ Control Panel / User Interface.

Description:

The BLU-U® is a compact light source designed to provide a uniform distribution of blue light to areas of the patient's face, scalp or upper extremities for the use stated above. **It is comprised of 5 individual LED panels** connected by hinges. The panels are covered by a protective shield, the center panel directs cooling airflow to the patient to improve comfort during the treatment.

JX-0091C.7
CDX-0004C.31

CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER

CDX-0004C.31; JX-0091C.7; CX-1038C.



CDX-0004C.37; CX-1216C.3, .4; CX-1021C.

iv. Element 1[c] - Undisputed

4170E practices this element. CX-0010C.30 (Jokerst), Q127–33.

Claim 1 of the '512 Patent – Third Element

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



JX-0183C.2

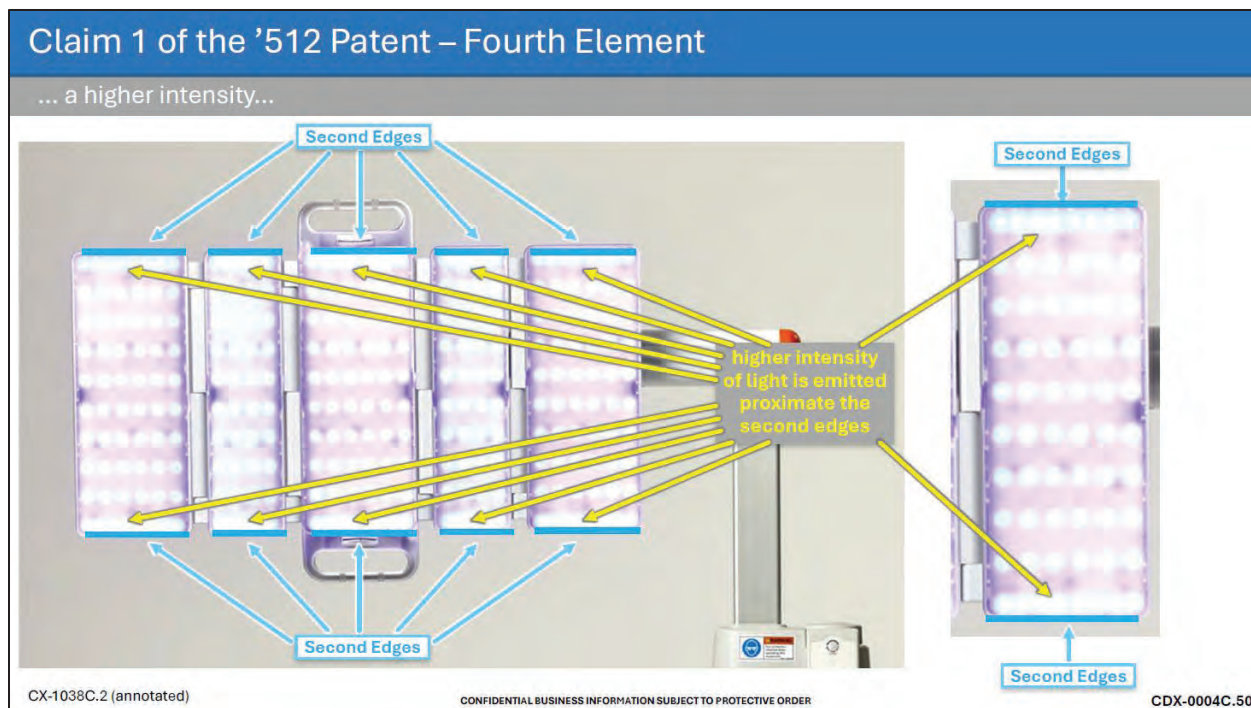
CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER

CDX-0004C.41

CDX-0004C.41; JX-0183C.2.

v. Element 1[d] - Undisputed

4170E practices this element. CX-0010C.30–33 (Jokerst), Q134–48.



CDX-0004C.50; CX-1038C.2.

b. Claim 2

i. Element 2[p] - Disputed

4170E practices Claim 1. See §VII.A.1.a.

ii. Element 2[a] - Disputed

4170E practices this element. CX-0010C.34–36 (Jokerst), Q155–61. The Operating Manual instructs users to use 4170E at treatment distances of two-to-four inches. JX-0091C.18–20. Sun Pharma tests 4170E to ensure it meets internal standards for uniformity, including that the measured power output at any point on the active emitting surface shall not be less than 60% of the maximum when measured over all operational distances, including at two and four inches from the panels to the treatment surface. CX-1021C; CX-1216C.3.



CDX-0004C.55; CX-1021C; CX-1216C.3; CX-0010C.35 (Jokerst), Q157–60; CX-0011C.15–19 (Lundahl), Q62–77 (explaining that 4170E is uniform at two-to-four inches), Q76–77.

c. Claim 4

i. Element 4[p] - Disputed

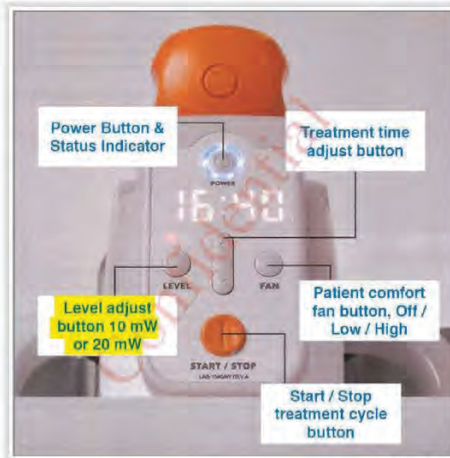
4170E practices Claim 1. *See* §VII.A.1.a.

ii. Element 4[a] - Undisputed

4170E practices this element. CX-0010C.36–37 (Jokerst), Q162-68.

Claim 4 of the '512 Patent

wherein the illuminator is configured to output light at an irradiance density of 10 mW/cm² to 30 mW/cm²



JX-0091C.8

Power Button & Status Indicator:

The system **Power Button** is used to load the pre-programmed treatment cycle. The system will automatically load the 10 mW power level at initial power up and will reset to 10mW power level after the completion of any treatment cycle, and will display time as 16:40. The 20mW power level setting can be selected by pressing the Level button, this will change the time displayed to 8:20.

Level Button:

The **Level Button** is used to toggle between 2 power settings, 10mW & 20mW. The power level can be selected after pressing the power button to load one of the pre-programmed cycles. The timer will automatically set the correct time for the power level chosen.

- The power level selected will be displayed above the level button as 10 or 20.

JX-0091C.10

Power Output	10 mW/cm² ± 10% – Use with Levulan Kerastick 10 or 20 mW/cm² ± 10% – Light alone treatment of acne Maximum Output: 22 mW/cm², continuous Output Wavelength: 417 nm + 5 nm Output Uniformity: 30%
Light Dose	Timer defaults to 16 minutes, 40 seconds to deliver 10 J/cm² at 10mW/cm² or 8 minutes, 20 seconds to deliver 10 J/cm² at 20 mW/cm²

JX-0091C.6

CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER

CDX-0004C.58

CDX-0004C.58; JX-0091C.6, .8, .10.

d. Claim 5

i. Element 5[p] - Disputed

4170E practices Claim 1. See §VII.A.1.a.

ii. Element 5[a] - Undisputed

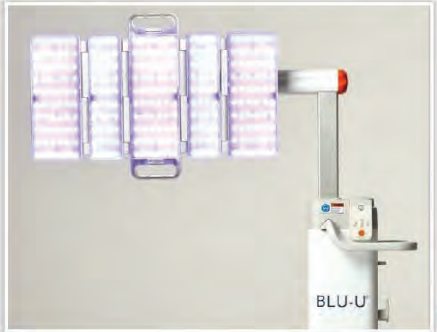
4170E practices this element. CX-0010C.37 (Jokerst), Q169–73.

Claim 5 of the '512 Patent

wherein a plurality of the light sources are configured to emit light having a wavelength in a range of 400 nm to 700 nm



JX-0183C.2



BLU-U CX-1038C

Power Output	10 mW/cm ² ± 10% – Use with Levulan Kerastick 10 or 20 mW/cm ² ± 10% – Light alone treatment of acne Maximum Output: 22 mW/cm ² , continuous Output Wavelength: 417 nm ± 5 nm Output Uniformity: 30%
---------------------	--

CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER

JX-0091C.6

CDX-0004C.61

CDX-0004C.61; JX-0183C.2; CX-1038C; JX-0091C.6.

e. Claim 20

i. Element 20[p] - Disputed

4170E practices this element for the same reasons as '512 Patent Element 1[p]. See §VII.A.1.a.i.

ii. Element 20[a] - Undisputed

4170E practices this element for the same reasons as '512 Patent Element 1[a]. CX-0010C.44 (Jokerst), Q212–15; see §VII.A.1.a.ii.

Claim 20 of the '512 Patent – First Element

... the nested hinges being configured so as to allow continuous illumination across the at least five panels



CX-1041C.2



CX-1213C.2

CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER

CDX-0004C.84

CDX-0004C.84; CX-1041C.2; CX-1213C.2; CX-1246C.1, CX-1247.1.

iii. Element 20[b] – Undisputed

4170E practices this element for the same reasons as '512 Patent Element 1[b]. See §VII.A.1.a.iii.

iv. Element 20[c] - Undisputed

4170E practices this element for the same reasons as '512 Patent Element 1[c]. See §VII.A.1.a.iv.

v. Element 20[d] – Undisputed

4170E practices this element for the same reasons as '512 Patent Element 1[d]. See §VII.A.1.a.v.

2. Method Claims

Healthcare providers following Sun Pharma's instructions in 4170E Operating Manual, JX-0091C, practice the method DI Claims. Sun Pharma's medical expert, Dr. Shmuylovich, testified that healthcare professionals will refer to and follow Sun Pharma's instructions for

performing PDT using Levulan® and 4170E, as found in the Levulan® prescribing information and 4170E Operating Manual. CX-0009C.15–16 (Shmuylovich), Q62–68; JX-0197C; JX-0091C. Sun Pharma intends for healthcare professionals to follow those instructions when using 4170E and Levulan® for PDT of AK. CX-0009C.22 (Shmuylovich), Q105; CX-0011C.14 (Lundahl), Q52–53.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

a. Claim 8

i. Element 8[p] - Disputed

Using 4170E in combination with Levulan® in accordance with Sun Pharma’s instructions performs this limitation. CX-0010C.38–39 (Jokerst), Q178–82; CX-0009C.16–17 (Shmuylovich), Q74–75. As discussed for Element 1[p], §VII.A.1.a.i, 4170E is indicated for the treatment of minimally to moderately thick AK of the face, scalp, or upper extremities and intended to provide phototherapeutic light to the body. *See* JX-0091C.4, .7; CX-0011C.14–15 (Lundahl), Q55, Q59; *see also* CDX-0005C.13.

ii. Element 8[a] – Undisputed

Using 4170E following Sun Pharma’s instructions performs this limitation. CX-0010C.39–40 (Jokerst), Q183–89; CX-0009C.17 (Shmuylovich), Q76–78.

Claim 8 of the '512 Patent – First Element

administering 5-aminolevulinic acid (ALA) to the patient

LEVULAN® KERASTICK™ (aminolevulinic acid HCl) for Topical Solution, 20%, contains the hydrochloride salt of 5-aminolevulinic acid (ALA), an endogenous 5-carbon aminoketone.

JX-0212.2

The LEVULAN KERASTICK for Topical Solution plus blue light illumination using the BLU-U Blue Light Photodynamic Therapy Illuminator is indicated for the treatment of non-hyperkeratotic actinic keratoses of the face or scalp.

JX-0212.7

Indications for Use:

The BLU-U® Blue Light Photodynamic Therapy Illuminator Model 4170E, in combination with the Levulan® Kerastick® (aminolevulinic acid HCl) for Topical Solution, 20%, is indicated for the treatment of minimally to moderately thick actinic keratoses (AK) of the face, scalp or upper extremities.



WARNING: The BLU-U® Blue Light Photodynamic Therapy Illuminator, in combination with the Levulan® Kerastick® for Topical Solution, 20% is indicated for the treatment of minimally to moderately thick actinic keratoses of the face, scalp or upper extremities. Use only the 10 mW/cm² power setting in conjunction with Levulan Kerastick to deliver 10 J/cm². Refer to the Levulan® Kerastick® for Topical Solution, 20% Package Physician Insert for additional information. Do not use this device with other photosensitizing drugs.

CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER

JX-0091C.4 CDX-0004C.67

CDX-0004C.67; JX-0091C.4; JX-0212.2, .7; JX-0197C.12–13.

iii. Element 8[b] - Disputed

Using 4170E following Sun Pharma's instructions performs this limitation. CX-0010C.40–41 (Jokerst), Q190–93; CX-0009C.17–19 (Shmuylovich), Q79–89.

First, 4170E comprises an illuminator comprising at least five panels connected by nested hinges on inner side surfaces of adjacent panels for the same reasons as Element 1[a]. See §VII.A.1.a.ii.

Second, the Operating Manual explains the procedures for treating lesions on the face, scalp, and upper extremities, where 4170E must be positioned such that the entire surface area to be treated lies between two and four inches from 4170E's surface. JX-0091C.18–20.

Claim 8 of the '512 Patent – Second Element

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



JX-0183C.2

Procedure for Treating Lesions on the Face:

1. Remove the system Head from the stowed position by pressing the release button on the Arm and raising the Arm into the locked treatment position. If not already configured, adjust the Head Panel rotation to place the Head into the "U" shape for treatment. Unlock the Vertical Column and adjust the column height, slide the locking lever into the locked position after the correct treatment height is attained. Adjust Head tilt and rotation to optimize the position of the system for treatment.
2. Position the BLU-U® around the patient's head so the entire surface area to be treated lies between 2" and 4" from the BLU-U® surface:
 - a.) The patient's nose should be **no closer than 2"** from the surface and
 - b.) The patient's forehead and cheeks should be **no further than 4"** from the surface and
 - c.) The sides of the patient's face and the patient's ears should be **no closer than 2"** from the BLU-U® surface

JX-0091C.18

CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER

CDX-0004C.70

CDX-0004C.70; CX-0010C.40–41 (Jokerst), Q192–93; JX-0183C.2; JX-0091C.18.

Technical Domestic Industry – Claim 8[b]: 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

OPERATING MANUAL BLU-U® Blue Light Photodynamic Therapy Illuminator, Model 4170E

Procedure for Treating Lesions on the Face:

1. Remove the system Head from the stowed position by pressing the release button on the Arm and raising the Arm into the locked treatment position. If not already configured, adjust the Head Panel rotation to place the Head into the "U" shape for treatment. Unlock the Vertical Column and adjust the column height, slide the locking lever into the locked position after the correct treatment height is attained. Adjust Head tilt and rotation to optimize the position of the system for treatment.
2. Position the BLU-U® around the patient's head so the entire surface area to be treated lies between 2" and 4" from the BLU-U® surface:
 - a.) The patient's nose should be **no closer than 2"** from the surface and
 - b.) The patient's forehead and cheeks should be **no further than 4"** from the surface and
 - c.) The sides of the patient's face and the patient's ears should be **no closer than 2"** from the BLU-U® surface

Note:

The patient's hair should not cover or shadow the area to be treated. If needed, the patient's hair may be restrained with a headband or similar item, being careful not to cover the area to be treated. However, the patient's hair may be closer than 2" to the surface of the BLU-U® without any deleterious effects.

JX-0091C.18 (BLU-U® 4170E Operating Manual)

OPERATING MANUAL BLU-U® Blue Light Photodynamic Therapy Illuminator, Model 4170E

Procedure for Treating Lesions on the Scalp:

1. Remove the system Head from the stowed position by pressing the release button on the Arm and raising the Arm into the locked treatment position. If not already configured, adjust the Head Panel rotation to place the Head into the "U" shape for treatment. Unlock the Vertical Column and adjust the column height, slide the locking lever into the locked position after the correct treatment height is attained. Adjust Head tilt and rotation to optimize the position of the system for treatment.
2. Position the BLU-U® around the patient's head so the entire surface area to be treated lies between 2" and 4" from the BLU-U® surface:
 - a.) The patient's scalp should be **no closer than 2"** from the surface and
 - b.) The patient's scalp should be **no further than 4"** from the surface and
 - c.) The sides of the patient's face and the patient's ears should be **no closer than 2"** from the BLU-U® surface

Note:

The patient's hair should not cover or shadow the area to be treated. If needed, the patient's hair may be restrained with a headband or similar item, being careful not to cover the area to be treated. However, the patient's hair may be closer than 2" to the surface of the BLU-U® without any deleterious effects.

JX-0091C.19 (BLU-U® 4170E Operating Manual)

Confidential Business Information Subject to Protective Order

CDX-0005C.16

CDX-0005C.16; CX-0009C.17–18 (Shmuylovich), Q80; JX-0091C.18, .19.

Thus, this element is practiced by using 4170E following Sun Pharma's instructions.

iv. Elements 8[c]–[d] - Undisputed

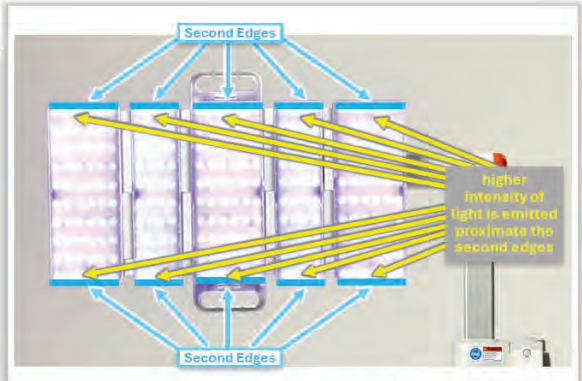
Using 4170E following Sun Pharma's instructions performs this limitation. See CX-0010C.41 (Jokerst), Q194–97; CX-0009C.19–20 (Shmuylovich), Q90–94.

Claim 8 of the '512 Patent – Third Element

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

Procedure for Treating Lesions on the Face:

1. Remove the system Head from the stowed position by pressing the release button on the Arm and raising the Arm into the locked treatment position. If not already configured, adjust the Head Panel rotation to place the Head into the "U" shape for treatment. Unlock the Vertical Column and adjust the column height, slide the locking lever into the locked position after the correct treatment height is attained. Adjust Head tilt and rotation to optimize the position of the system for treatment.
2. Position the BLU-U® around the patient's head so the entire surface area to be treated lies between 2" and 4" from the BLU-U® surface.
 - a.) The patient's nose should be **no closer** than 2" from the surface and
 - b.) The patient's forehead and cheeks should be **no further** than 4" from the surface and
 - c.) The sides of the patient's face and the patient's ears should be **no closer** than 2" from the BLU-U® surface



The diagram shows a top-down view of the BLU-U treatment head. It consists of a central rectangular panel flanked by two side panels. Yellow arrows point from the central panel towards the edges, indicating light emission. Blue arrows point to the outer edges of the side panels, labeled 'Second Edges'. A text box on the right states: 'higher intensity of light is emitted proximate the second edges'.

JX-0091C.18 CX-1038C.2 (annotated)

CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER CDX-0004C.72

CDX-0004C.72; JX-0091C.18–19; CX-1038C.2. These elements are met for the same reasons as Elements 1[b] and 1[d]. See §VII.A.1.a.iii; §VII.A.1.a.v.

b. Claim 19

i. Element 19[p] - Disputed

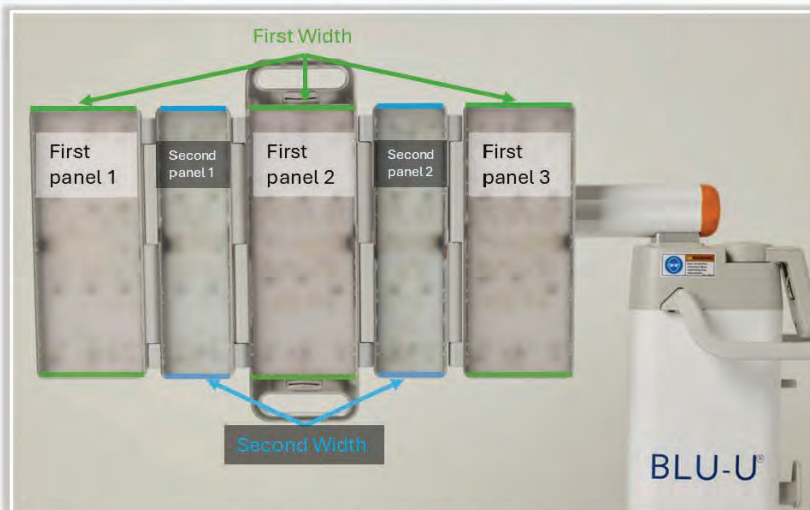
Using 4170E performs the method of Claim 8. See §VII.A.2.a.

ii. Element 19[a] – Undisputed

4170E practices this element. CX-0010C.42 (Jokerst), Q200–02.

Claim 19 of the '512 Patent – First Element

wherein the illuminator comprises at least three first panels having first widths, at least two second panels having second widths, wherein each of the second widths of the at least two second panels is narrower than each of the first widths of the at least three first panels



CX-1041C.2 (annotated)

CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER

CDX-0004C.76

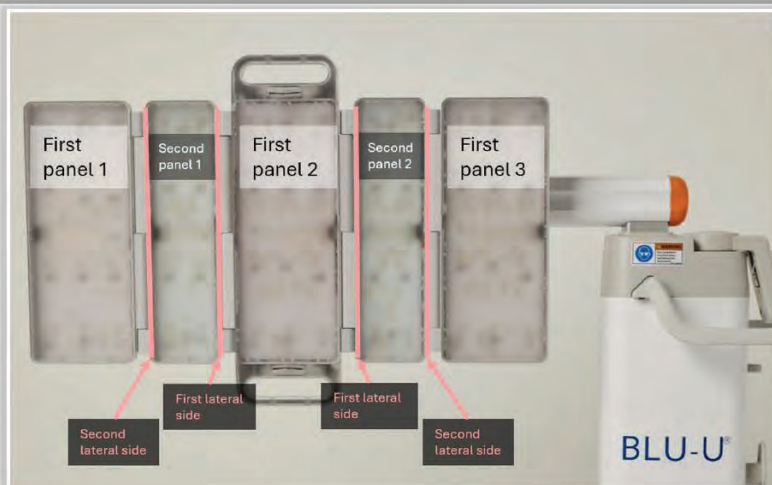
CDX-0004C.76; CX-1041C.2.

iii. Element 19[b] - Undisputed

4170E practices this element. CX-0010C.42–43 (Jokerst), Q203–06.

Claim 19 of the '512 Patent – Second Element

wherein the at least three first panels and the at least two second panels are connected in an alternating manner such that each of the at least two second panels has a first lateral side connected to a respective one of the at least three first panels and a second lateral side connected to another respective one of the at least three first panels.



CX-1041C.2 (annotated)

CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER

CDX-0004C.78

CDX-0004C.78; CX-1041C.2.

B. '028 Patent DI Claims

BLU-U® 4170E, individually or in combination with Levulan®, practices '028 Patent Claims 1, 3, 4, 5, 7, 9, 16–18, and 21.

1. System Claims

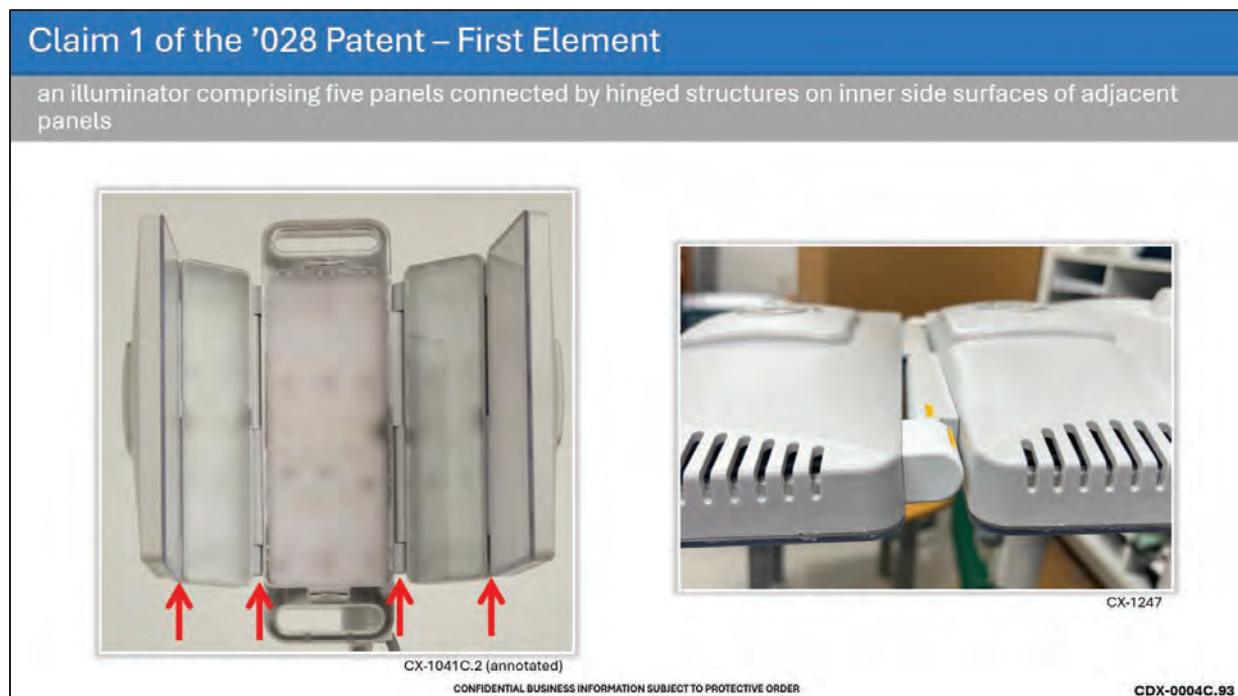
a. Claim 1

i. Element 1[p] - Disputed

4170E comprises this element for the same reasons as '512 Patent Element 1[p]. *See* §VII.A.1.a.i.

ii. Element 1[a] - Undisputed

4170E comprises this element for the same reasons as '512 Patent Element 1[a]. *See* §VII.A.1.a.ii.



CDX-0004C.93; CX-1243C; CX-1041C.2; CX-1247; CX-1213C.2.

iii. Element 1[b] - Undisputed

4170E comprises this element for the same reasons as '512 Patent Element 1[b]. *See* §VII.A.1.a.iii.

iv. Element 1[c] - Undisputed

4170E comprises this element for the same reasons as '512 Patent Element 1[c]. *See* §VII.B.1.a.iv.

v. Element 1[d] - Disputed

4170E comprises wherein the five panels are positioned to allow treatment within approximately four inches of the treatment surface. CX-0010C.47–48 (Jokerst), Q237–42. 4170E was designed such that the five panels are positioned to allow treatment within approximately four inches of the treatment surface, where the five panels are at the end of 4170E's pivoting arm and connected by hinges; that enables the panels to assume a circular, curved configuration where the panels are positioned less than or equal to approximately four inches from the treatment surface.



JX-0183C; see JX-0091C.7 (describing how the “Five Panel LED treatment array” connects to the end of the pivoting arm); CX-1038C.2; JX-0091C.13; CX-1243C.1.

The Operating Manual requires placing 4170E such that the entire surface area to be treated lies between two and four inches from 4170E’s surface.

Claim 1 of the '028 Patent – Fourth Element

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

Construction: “within approximately four inches of the treatment surface” is “less than or equal to approximately four inches from the treatment surface.”

Procedure for Treating Lesions on the Face:

1. Remove the system Head from the stowed position by pressing the release button on the Arm and raising the Arm into the locked treatment position. If not already configured, adjust the Head Panel rotation to place the Head into the “U” shape for treatment. Unlock the Vertical Column and adjust the column height, slide the locking lever into the locked position after the correct treatment height is attained. Adjust Head tilt and rotation to optimize the position of the system for treatment.
2. Position the BLU-U[®] around the patient’s head so the entire surface area to be treated lies between 2” and 4” from the BLU-U[®] surface:
 - a.) The patient’s nose should be no closer than 2” from the surface and
 - b.) The patient’s forehead and cheeks should be no further than 4” from the surface and
 - c.) The sides of the patient’s face and the patient’s ears should be no closer than 2” from the BLU-U[®] surface

JX-0091C.18

Procedure for Treating Lesions on the Scalp:

1. Remove the system Head from the stowed position by pressing the release button on the Arm and raising the Arm into the locked treatment position. If not already configured, adjust the Head Panel rotation to place the Head into the “U” shape for treatment. Unlock the Vertical Column and adjust the column height, slide the locking lever into the locked position after the correct treatment height is attained. Adjust Head tilt and rotation to optimize the position of the system for treatment.
2. Position the BLU-U[®] around the patient’s head so the entire surface area to be treated lies between 2” and 4” from the BLU-U[®] surface:
 - a.) The patient’s scalp should be no closer than 2” from the surface and
 - b.) The patient’s scalp should be no further than 4” from the surface and
 - c.) The sides of the patient’s face and the patient’s ears should be no closer than 2” from the BLU-U[®] surface

JX-0091C.19

Procedure for Treating Lesions on the Upper Extremities:

1. Remove the system Head from the stowed position by pressing the release button on the Arm and raising the Arm into the locked treatment position. If not already configured, adjust the Head Panel rotation to place the Head into the “U” shape for treatment. Unlock the Vertical Column and adjust the column height, slide the locking lever into the locked position after the correct treatment height is attained. Adjust Head tilt and rotation to optimize the position of the system for treatment.
2. Position the BLU-U[®] around the patient’s upper extremities so the entire surface area to be treated lies between 2” and 4” from the BLU-U[®] surface:
 - a.) The patient’s upper extremities should be no closer than 2” from the surface and
 - d.) The patient’s upper extremities should be no further than 4” from the surface

JX-0091C.20

CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER

CDX-0004C.97

CDX-0004C.97; JX-0091C.18–20.

vi. Element 1[e] - Undisputed

4170E practices this element for the same reasons as ’512 Patent Element 1[d]. See §VII.A.1.a.v.

b. Claim 3

i. Element 3[p] - Disputed

4170E practices Claim 1. See §VII.B.1.a.

ii. Element 3[a] - Undisputed

4170E comprises this element for the same reasons as ’512 Patent Claim 4. See §VII.A.1.c.

c. **Claim 4**

i. **Element 4[p] - Disputed**

4170E practices Claim 1. *See* §VII.B.1.a.

ii. **Element 4[a] - Undisputed**

4170E comprises this limitation for the same reasons as '512 Patent Claim 5. *See* §VII.A.1.d.

d. **Claim 16**

i. **Element 16[p] - Disputed**

4170E comprises this element for the same reasons as '512 Patent Element 1[p]. *See* §VII.A.1.a.i.

ii. **Element 16[a] - Undisputed**

4170E comprises this element. CX-0010C.55 (Jokerst), Q282–84.

Claim 16 of the '028 Patent – First Element

... a mobile base supported by at least four wheels

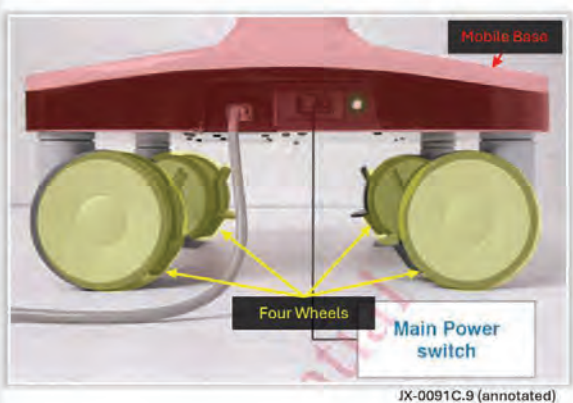
Product Diagram:



- ① Adjustable height positioning of the unit for treatment flexibility.
- ② Large locking casters and post handle for easier mobility.
- ③ A pivoting arm for compact storage and easy movement within the treatment facility.
- ④ Five Panel LED treatment array.
- ⑤ Control Panel / User Interface.

Description:

The BLU-U® is a compact light source designed to provide a uniform distribution of blue light to areas of the patient's face, scalp or upper extremities for the use stated above. It is comprised of 5 individual LED panels connected by hinges. The panels are covered by a protective shield, the center panel directs cooling airflow to the patient to improve comfort during the treatment. The BLU-U® is mounted on a floor-stand (Base), which permits rapid positioning as well as adjustment for patient height. The control panel / user interface is also affixed to the floor stand.



JX-0091C.9 (annotated)

JX-0091C.7

CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER

CDX-0004C.117

CDX-0004C.117; JX-0091C.7, .9.

iii. **Element 16[b] - Undisputed**

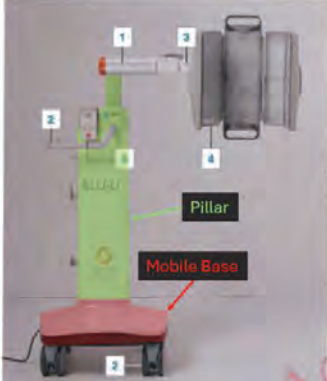
4170E comprises this element. CX-0010C.55–56 (Jokerst), Q285–87.

Claim 16 of the '028 Patent – Second Element

a pillar perpendicular to the base

OPERATING MANUAL
BLU-U® Blue Light Photodynamic Therapy Illuminator, Model 4170E

Product Diagram:



- ① Adjustable height positioning of the unit for treatment flexibility.
- ② Large locking casters and post handle for easier mobility.
- ③ A pivoting arm for compact storage and easy movement within the treatment facility.
- ④ Five Panel LED treatment array.
- ⑤ Control Panel / User Interface.

Pillar

Mobile Base



Pillar

Mobile Base

JX-0091C.7 (annotated) JX-0091C.24 (annotated)

CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER CDX-0004C.119

CDX-0004C.119; JX-0091C.7, .24.

iv. **Element 16[c] - Undisputed**

4170E comprises this element. CX-0010C.56 (Jokerst), Q288–90.

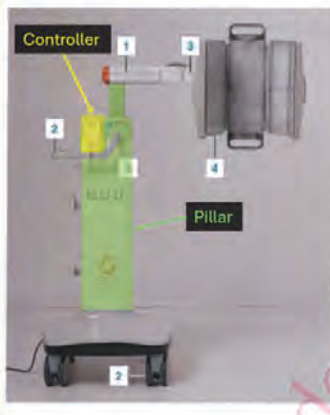
Claim 16 of the '028 Patent – Third Element

a controller disposed to be supported by the pillar

OPERATING MANUAL

BLU-U® Blue Light Photodynamic Therapy Illuminator, Model 4170E

Product Diagram:



- ① Adjustable height positioning of the unit for treatment flexibility.
- ② Large locking casters and post handle for easier mobility.
- ③ A pivoting arm for compact storage and easy movement within the treatment facility.
- ④ Five Panel LED treatment array.
- ⑤ Control Panel / User Interface.

JX-0091C.7 (annotated)

CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER

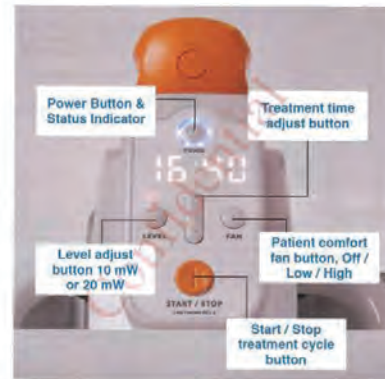
OPERATING MANUAL

BLU-U® Blue Light Photodynamic Therapy Illuminator, Model 4170E

Controls:

Controls for the BLU-U® are located on the **User Interface**. See the image below.

Caution – Use of controls or adjustments or performance of procedures other than those specified herein could result in improper operation of the system.



JX-0091C.8

CDX-0004C.121

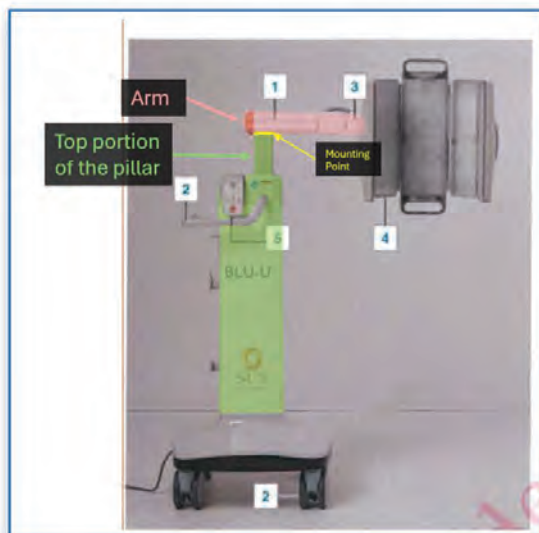
CDX-0004C.121; JX-0091C.7, .8.

v. Element 16[d] - Undisputed

4170E comprises this element. CX-0010C.56–57 (Jokerst), Q291–93.

Claim 16 of the '028 Patent – Fourth Element

an arm mounted to a top portion of the pillar



JX-0091C.7 (annotated)

CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER

Horizontal Arm Adjustment:



JX-0091C.13

CDX-0004C.123

CDX-0004C.123; JX-0091C.7, .13.

vi. Element 16[e] - Undisputed

4170E comprises this element. CX-0010C.57 (Jokerst), Q294–98.

Claim 16 of the '028 Patent – Fifth Element

an illuminator connected at an end of the arm

Product Diagram:



- ① Adjustable height positioning of the unit for treatment flexibility.
- ② Large locking casters and post handle for easier mobility.
- ③ A pivoting arm for compact storage and easy movement within the treatment facility.
- ④ Five Panel LED treatment array.
- ⑤ Control Panel / User Interface.

Description:

The BLU-U® is a compact light source designed to provide a uniform distribution of blue light to areas of the patient's face, scalp or upper extremities for the use stated above. It is comprised of 5 individual LED panels connected by hinges. The panels are covered by a protective shield, the center panel directs cooling airflow to the patient to improve comfort during the treatment.

The BLU-U® is mounted on a floor-stand (Base), which permits rapid positioning as well as adjustment for patient height. The control panel / user interface is also affixed to the floor stand.



JX-0091C.7

CX-1038C.2

CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER

CDX-0004C.125

CDX-0004C.125; JX-0091C.7, CX-1038C.2.

vii. Element 16[f] - Undisputed

4170E comprises this element. CX-0010C.57–58 (Jokerst), Q299–301.

Claim 16 of the '028 Patent – Sixth Element

the arm being hinged to allow adjustment of a position of the illuminator relative to the base

Horizontal Arm Adjustment:

The horizontal Arm assembly can be folded to stow the Arm & Head for storage and transit or extended to put the system into the treatment position. The lock for the horizontal arm is located approximately at the midpoint on the Arm assembly as shown in the image below (grey button). To unlock the Arm, put slight pressure on the arm towards the post assembly while pressing the release button, then lift the Arm. While lifting the arm, release the release button and the Arm will automatically lock in place once raised into the use position. To lower the Arm, pull the arm up slightly while pressing the release button, then lower the Arm to the stowed position, the Arm will automatically lock in place once in the fully stowed position.



JX-0091C.13 (annotated)



CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER

CDX-0004C.127

CDX-0004C.127; JX-0091C.13.

viii. Element 16[g]

4170E comprises this limitation. CX-0010C.58–60 (Jokerst), Q302–13.

(a) an illuminator comprising five panels connected by hinged structures - Undisputed

4170E comprises this limitation for the same reasons as '512 Patent Element 1[a]. See

§VII.A.1.a.ii.

(b) an illuminator comprising five panels connected by hinged structures to allow continuous illumination across the five panels - Undisputed

4170E comprises this limitation for the same reasons as '512 Patent Element 20[a]. See

§VII.A.1.e.ii.

(c) wherein the five panels are individually configurable to control illumination from each of the five panels - Disputed

4170E comprises this limitation. CX-0010C.58–60 (Jokerst), Q306–13. The power output and/or light intensity of each panel can be individually controlled, as each panel has addressable LEDs whose power output and light intensities are individually controlled, and each panel sets its power configuration independently:



CDX-0004C.130; CX-1244C; *see* CX-1266C.14; CX-0017C.18–21 (Thompson), Q93–109 (reviewing how each panel sets its power configuration); CX-1248C.1; CX-0011C.22–23 (Lundahl), Q84–91.

ix. Elements 16[h](a)–16[h](b) - Undisputed

4170E comprises this element. CX-0010C.60–61 (Jokerst), Q314–19.



CDX-0004C.132; CX-1215C.6–7.

x. Element 16[i] - Undisputed

4170E comprises this element. CX-0010C.61–62 (Jokerst), Q320–25.



CDX-0004C.134; CX-1017C.11; JX-0091C.7, .8, .10.

e. Claim 17

i. Element 17[p] - Disputed

4170E practices Claim 16. See §VII.B.1.d.

ii. Element 17[a] - Undisputed

4170E comprises this limitation for the same reasons as '512 Patent Element 1[c]. See §VII.A.1.a.iv.

f. Claim 18

i. Element 18[p] - Disputed

4170E practices Claim 16. See §VII.B.1.d.

ii. Element 18[a] - Undisputed

4170E comprises this limitation. CX-0010C.62–63 (Jokerst), Q328–31.

Claim 18 of the '028 Patent

wherein the light sources are configured to output blue light during at least part of the time when the treatment surface is illuminated.



JX-0183C.2



BLU-U CX-1038C

Power Output	10 mW/cm ² ± 10% – Use with Levulan Kerastick 10 or 20 mW/cm ² ± 10% – Light alone treatment of acne Maximum Output: 22 mW/cm ² , continuous Output Wavelength: 417 nm ± 5 nm Output Uniformity: 30%
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CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER
JX-0091C.6
CDX-0004C.138

CDX-0004C.138; JX-0183C.2; JX-0091C.6; CX-1038C.

g. Claim 21

i. Element 21[p] - Disputed

4170E comprises this element for the same reasons as '512 Patent Element 1[p]. *See* §VII.A.1.a.i.

ii. Element 21[a] - Undisputed

4170E comprises this element for the same reasons as '512 Patent Element 1[a]. *See* §VII.A.1.a.ii.

iii. Element 21[b] - Undisputed

4170E comprises this element for the same reasons as '512 Patent Element 1[b]. *See* §VII.A.1.a.iii.

iv. Element 21[c] - Undisputed

4170E comprises this element for the same reasons as '512 Patent Element 1[c]. *See* §VII.A.1.a.iv.

v. Element 21[d] - Disputed

4170E comprises this limitation for the same reasons as '512 Patent Element 1[d]. *See* §VII.A.1.a.v.

vi. Element 21[e] - Disputed

4170E comprises this element for the same reasons as '028 Patent Element 16[g]. *See* §VII.B.1.d.viii.

vii. Element 21[f] - Undisputed

4170E comprises this limitation for the same reasons as '512 Patent Element 1[d]. *See* §VII.A.1.a.v.

2. Method Claims

a. Claim 5

i. Element 5[p] - Disputed

Using 4170E following Sun Pharma's instructions performs this element for the same reasons as '512 Patent Element 8[p]. *See* §VII.A.2.a.i.

ii. Element 5[a] - Undisputed

Using 4170E following Sun Pharma's instructions performs this element for the same reasons as '512 Patent Element 8[a]. *See* §VII.A.2.a.ii.

iii. Element 5[b] – Disputed

(a) positioning an illuminator proximate to the patient - Disputed

Using 4170E following Sun Pharma's instructions performs this element for the same reasons as '512 Patent Element 8[b]. *See* §VII.A.2.a.iii.

(b) the illuminator comprising five panels connected by hinged structures on inner side surfaces of adjacent panels - Undisputed

4170E practices this limitation for the same reasons as '028 Patent Element 1[a]. *See* §VII.A.1.a.ii.

iv. Element 5[c]

(a) uniformly illuminating a treatment surface of the patient with light sources disposed on the five panels of the illuminator - Undisputed

Using 4170E following Sun Pharma's instructions performs this limitation for the same reasons as '512 Patent Element 8[c]. *See* §VII.A.2.a.iv.

(b) the five panels being positioned to allow treatment within approximately four inches of the treatment surface - Disputed

Using 4170E following Sun Pharma's instructions performs this limitation. CX-0010C.52 (Jokerst), Q264; JX-0091C.18–20 (requiring positioning between two and four inches); CX-0011C.36 (Lundahl), Q171 (confirming use following the manual to treat a patient in the U.S. with a two-to-four inches treatment distance).

v. Element 5[d] - Undisputed

Using 4170E following Sun Pharma's instructions performs this element for the same reasons as '512 Patent Element 8[d]. *See* §VII.A.2.a.iv.

b. Claim 7

i. Element 7[p] - Disputed

Using 4170E device in accordance with Sun Pharma's Operating Manual and instructions practices Claim 5. *See* §VII.A.1.d.

ii. Element 7[a] - Undisputed

4170E comprises this element. CX-0010C.53 (Jokerst), Q268–70.

c. Claim 9

i. Element 9[p] - Disputed

Using 4170E following Sun Pharma's instructions practices Claim 5. *See* §VII.B.2.a.

ii. Element 9[a] - Undisputed

4170E comprises this limitation for the same reasons as '512 Patent Claim 19[b]. *See* §VII.A.2.b.

VIII. REMEDY AND BONDING

The ID should recommend an LEO and CDO, and a 100% bond.

A. LEO and CDO

Respondents do not dispute that an LEO and a CDO are appropriate remedies.

An LEO is appropriate if a violation is found. *See Certain Icemaking Machines and Components Thereof*, Inv. No. 337-TA-1369, Final Determination (Feb. 27, 2025).

Moreover, a CDO is appropriate because Respondents maintain a commercially significant U.S. inventory of RhodoLED® XL. Biofrontera held [REDACTED] RhodoLED® XL units in U.S. inventory as of November 30, 2024, with an additional [REDACTED]. *See* Tr., 421:8–25; CX-0608C (Jan. 2, 2025 Joint Stipulation of Importation and Inventory).⁸ With estimated sales of [REDACTED] units in 2025, Biofrontera held [REDACTED] months’ worth of sales of RhodoLED® XL in inventory as of November 30, 2024, which is commercially significant. *See* CX-0016C.50 (Vander Veen), Q325–28; CX-1334C, 49:6–16; CX-1335C, 139:4–21; CX-1329C, 79:17–80:5. This is especially true because Biofrontera sells from its inventory. *See* CX-1336C, 106:9–25.

B. Bond

A 100 percent bond is appropriate where a price comparison is impractical and there is no established royalty rate. *Certain Flash Memory Circuits and Prods. Containing Same*, Inv. No. 337-TA-382, Comm’n Op. at 26–27 (July 1997). The ID should recommend a 100% bond.

There is no established royalty rate for the Asserted Patents. CX-0016C.51–52 (Vander Veen), Q330, Q334.

Moreover, a price comparison is impractical. Sun Pharma’s list price for the 4170E is [REDACTED]. Tr. (Vander Veen), 269:24–270:13. Biofrontera’s alleged prices—the \$18,500 sticker price, [REDACTED] average price, and [REDACTED] “floor price”—are all illusory. First, Biofrontera admits it has never sold a single unit at the sticker price. RX-0003C.0007 (Leffler), Q44. Second, neither

⁸ *See also* RX-0003C.7 (Leffler), Q38 (Biofrontera had 160 units in U.S. inventory as of April 18, 2025).

the average price nor the “floor price” account for Biofrontera’s aggressive trade-in discounts on RhodoLED® XL. CX-0012C.28 (Vander Veen), Q156–58; Tr. (Vander Veen), 291:11–292:7. Indeed, Biofrontera’s net revenue for a given unit is routinely well below [REDACTED] (the purported floor price), net of trade-in discounts. Indeed, Biofrontera’s net revenue for a RhodoLED® XL sale is frequently well below the [REDACTED] “floor price.” See JX-0079C, “Sales” tab col. V; JX-0229C, “Sales_10.1 thru 11.30” tab col. X; Tr. (Vander Veen), 276:6–15, 291:11–292:7. Third, Biofrontera sells refurbished units considerably below the “floor price.” Tr. (Vander Veen), 291:11–292:7, 300:17–22; Tr. (Leffler), 417:12–22; RX-0003C.10 (Leffler), Q55; JX-0229C, “Sales_10.1 thru 11.30” tab row 45. Fourth, the majority of RhodoLED® XL placements in the U.S.—over 55% as of December 2024—are leased for [REDACTED] for up to six months. RX-0003C.6 (Leffler), Q30; CX-0016C.51 (Vander Veen), Q331. And there is no requirement for a customer to buy the product at the end of the lease. Tr. (Vander Veen), 289:20–24. Thus, a lease customer can compete with Sun Pharma for up to 6 months for [REDACTED]. CX-0016C.51 (Vander Veen), Q331. Fifth, and finally, there is nothing stopping Biofrontera from changing its “floor price” or increasing the trade-in discounts it offers. CX-0016C.51 (Vander Veen), Q332 (Biofrontera is likely to lower prices in the face of competition from Sun Pharma); Tr. (Vander Veen), 276:6–15.

IX. CONCLUSION

Biofrontera has violated Section 337 and remedial orders should issue.

CERTIFICATE OF COMPLIANCE

The undersigned certifies that the foregoing contains 24,986 words, excluding words in the tables of contents, exhibits, table of authorities, figures, signature blocks, certification of compliance, and certificate of service, as calculated by the word count feature of Microsoft Word Office 365 software used to prepare this brief.

Dated: July 21, 2025

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APPENDIX A – LISTING OF CLAIMS⁹

Sun Pharma Claim #	Limitation	Infringement Dispute?	Technical Prong of DI Dispute?
<u>U.S. Patent No. 11,446,512</u>			
Claim 1			
1[p]	A system for photodynamically diagnosing or treating a patient, comprising:	Undisputed	Disputed
1[a]	an illuminator comprising at least five panels connected by nested hinges on inner side surfaces of adjacent panels,	Disputed	Undisputed
1[b]	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,	Undisputed	Undisputed
1[c]	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,	Undisputed	Undisputed
1[d]	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.	Undisputed	Undisputed
Claim 2			
2[p]– 2[a]	The system of claim 1, wherein the illuminator is configured to uniformly illuminate the treatment surface when the treatment surface is at a distance of two to four inches from the illuminator.	n/a	Disputed

⁹ Claim element breakdown follows Sun Pharma’s GR 14.1. Identification of disputed limitations from Biofrontera’s GR 14.1 for infringement and technical prong of DI. An asterisk (*) denotes that Biofrontera disputes the independent claim only.

Claim 3			
3[p]– 3[a]	The system of claim 1, wherein the illuminator is configured to output red light at a dose of about 30 J/cm ² to about 150 J/cm ² .	Undisputed*	n/a
Claim 4			
4[p]– 4[a]	The system of claim 1, wherein the illuminator is configured to output light at an irradiance density of 10mW/cm ² to 30 mW/cm ² .	n/a	Undisputed*
Claim 5			
5[p]– 5[a]	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.	Undisputed*	Undisputed*
Claim 8			
8[p]	A method of photodynamically diagnosing or treating a patient, comprising:	Undisputed	Disputed
8[a]	administering 5-aminolevulinic acid (ALA) to the patient;	Undisputed	Undisputed
8[b]	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	Disputed	Disputed
8[c]	uniformly illuminating a treatment surface of the patient with light sources disposed on the at least five panels of the illuminator,	Disputed	Undisputed
8[d]	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.	Undisputed	Undisputed
Claim 17			
17[p]– 17[a]	The method of claim 8, wherein at least one panel includes a recess configured to receive a flange of one of the nested hinges.	Disputed	n/a
Claim 18			
18[p]– 18[a]	The method of claim 17, wherein the recess is positioned at an inner side surface of the at least one panel.	Disputed	n/a

Claim 19			
19[p]– 19[a]	The method of claim 8, wherein the illuminator comprises at least three first panels having first widths, at least two second panels having second widths, wherein each of the second widths of the at least two second panels is narrower than each of the first widths of the at least three first panels; and	n/a	Undisputed*
19[b]	wherein the at least three first panels and the at least two second panels are connected in an alternating manner such that each of the at least two second panels has a first lateral side connected to a respective one of the at least three first panels and a second lateral side connected to another respective one of the at least three first panels.	n/a	Undisputed*
Claim 20			
20[p]	A system for photodynamically diagnosing or treating a patient, comprising:	Undisputed	Disputed
20[a]	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,	Disputed	Undisputed
20[b]	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,	Undisputed	Undisputed
20[c]	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,	Undisputed	Undisputed
20[d]	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.	Undisputed	Undisputed

<u>U.S. Patent No. 11,697,028</u>			
Claim 1			
1[p]	A system for photodynamically diagnosing or treating a patient, comprising:	Undisputed	Disputed
1[a]	an illuminator comprising five panels connected by hinged structures on inner side surfaces of adjacent panels; and	Disputed	Undisputed
1[b]	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,	Undisputed	Undisputed
1[c]	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,	Undisputed	Undisputed
1[d]	wherein the five panels are positioned to allow treatment within approximately four inches of the treatment surface, and	Disputed	Disputed
1[e]	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.	Undisputed	Undisputed
Claim 2			
2[p]– 2[a]	The system of claim 1, wherein the illuminator is configured to output red light at a dose of 30 J/cm ² to 150 J/cm ² .	Undisputed*	n/a
Claim 3			
3[p], 3[a]	The system of claim 1, wherein the illuminator is configured to output light at an irradiance density of 10 mW/cm ² to 30 mW/cm ² .	n/a	Undisputed*
Claim 4			
4[p]– 4[a]	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.	Undisputed*	Undisputed*
Claim 5			
5[p]	A method of photodynamically diagnosing or treating a patient, comprising:	n/a	Disputed

5[a]	administering 5-aminolevulinic acid (ALA) to the patient;	n/a	Undisputed
5[b]	positioning an illuminator proximate to the patient,	n/a	Disputed
5[b]	the illuminator comprising five panels connected by hinged structures on inner side surfaces of adjacent panels; and	n/a	Undisputed
5[c]	uniformly illuminating a treatment surface of the patient with light sources disposed on the five panels of the illuminator,	n/a	Undisputed
5[c]	the five panels being positioned to allow treatment within approximately four inches of the treatment surface,	n/a	Disputed
5[d]	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.	n/a	Undisputed
Claim 7			
7[p]– 7[a]	The method of claim 5, wherein the illuminating comprises outputting blue light during at least part of the time when the treatment surface is illuminated.	n/a	Undisputed*
Claim 9			
9[p]– 9[a]	The method of claim 5, wherein: the illuminator comprises at least three first panels having first widths, at least two second panels having second widths, wherein each of the second widths of the at least two second panels is narrower than each of the first widths of the at least three first panels; and	n/a	Undisputed*
9[b]	the at least three first panels and the at least two second panels are connected in an alternating manner such that each of the at least two second panels has a first lateral side connected to a respective one of the at least three first panels and a second lateral side connected to another respective one of the at least three first panels.	n/a	Undisputed*
Claim 16			
16[p]	A system for photodynamically diagnosing or treating a patient, comprising:	Undisputed	Disputed

16[a]	a mobile base supported by at least four wheels;	Undisputed	Undisputed
16[b]	a pillar perpendicular to the base;	Undisputed	Undisputed
16[c]	a controller disposed to be supported by the pillar;	Undisputed	Undisputed
16[d]	an arm mounted to a top portion of the pillar; and	Undisputed	Undisputed
16[e]	an illuminator connected at an end of the arm,	Undisputed	Undisputed
16[f]	the arm being hinged to allow adjustment of a position of the illuminator relative to the base,	Undisputed	Undisputed
16[g]	the illuminator comprising:	Undisputed	Undisputed
	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,	Disputed in part	Disputed in part
16[h](a)	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,	Undisputed	Undisputed
16[h](b)	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	Undisputed	Undisputed
16[i]	one or more fans mounted to at least one of the five panels.	Undisputed	Undisputed
Claim 17			
17[p]– 17[a]	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.	Undisputed*	Undisputed*
Claim 18			
18[p]– 18[a]	The system of claim 16, wherein the light sources are configured to output blue light	n/a	Undisputed*

	during at least part of the time when the treatment surface is illuminated.		
Claim 19			
19[p]– 19[a]	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.	Undisputed*	n/a
Claim 20			
20[p]	A system for photodynamically diagnosing or treating a patient, comprising:	Undisputed	Disputed
20[a]	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	Disputed	n/a
20[b]	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,	Undisputed	n/a
20[c]	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,	Undisputed	n/a
20[d]	wherein the five panels are positioned to allow treatment within approximately four inches of the treatment surface, and	Disputed	n/a
20[e]	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.	Undisputed	n/a
Claim 21			
21[p]	A system for photodynamically diagnosing or treating a patient, comprising:	Undisputed	Disputed
21[a]	an illuminator comprising five panels connected by hinged structures on inner side surfaces of adjacent panels; and	Disputed	Undisputed
21[b]	light sources disposed on surfaces of the five panels, the illuminator being configured to uniformly illuminate a	Undisputed	Undisputed

	treatment surface of the patient via the light sources,		
21[c]	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,	Undisputed	Undisputed
21[d]	wherein the five panels are positioned to allow treatment within approximately four inches of the treatment surface,	Disputed	Disputed
21[e]	wherein the five panels are individually configurable to control illumination from each of the five panels, and	Disputed	Disputed
21[f]	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.	Undisputed	Undisputed

CERTIFICATE OF SERVICE

I hereby certify that on July 28, 2025, copies of the foregoing were filed and served upon the following as indicated:

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