

PATENT TRIAL AND APPEAL BOARD
UNITED STATES PATENT AND TRADEMARK OFFICE

**Biofrontera Inc., Biofrontera Bioscience GmbH, Biofrontera Pharma
GmbH, and Biofrontera AG**

v.

Sun Pharmaceutical Industries, Inc.

December 3, 2025

IPR2024-01312 U.S. Patent No. 11,697,028



Outline

- A** Overview of the '028 Patent
- B Overview of the Prior Art
- C Disputed Issues
- D Motion to Exclude Evidence

Related Matters

B. Related Matters (37 C.F.R. § 42.8(b)(2))

The '028 Patent is involved in three matters that may affect or be affected by this proceeding:

PTAB IPR Parallel Petition

BioFrontera Inc., Biofrontera Bioscience GMBH, Biofrontera Pharma GMBH, and Biofrontera AG v. Dusa Pharmaceuticals, Inc., IPR2024-00874 (petition filed on April 30, 2024).

ITC COMPLAINT

In Re Certain Photodynamic Therapy Systems, Components Thereof, And Pharmaceutical Products Used In Combination With The Same, Investigation No. 337-TA-1411 (complaint filed on June 25, 2024). *See* Ex.1020.

Pet., 6



IPR2024-00874
Patent 11,697,028 B2

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that the Petition is *denied*, and no trial is instituted.

IPR2024-00874, Paper 9 at 21



In the Matter of

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

Inv. No. 337-TA-1411

INITIAL DETERMINATION ON VIOLATION OF SECTION 337 AND
RECOMMENDED DETERMINATION ON REMEDY AND BOND

Administrative Law Judge Bryan F. Moore

(September 30, 2025)

EX2090, 1

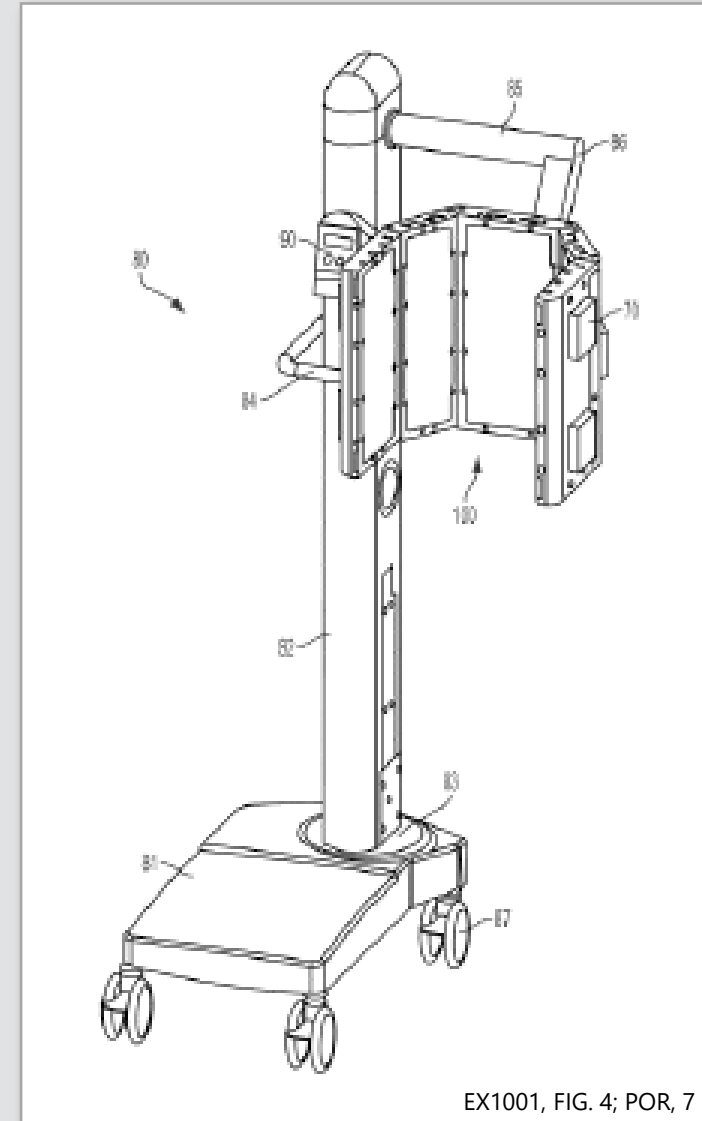
The PDT Device Of The '028 Patent

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

EX1001, 1:26-35; Pet., 22

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.

EX1001, 1:19-22; POR, 4



EX1001, FIG. 4; POR, 7

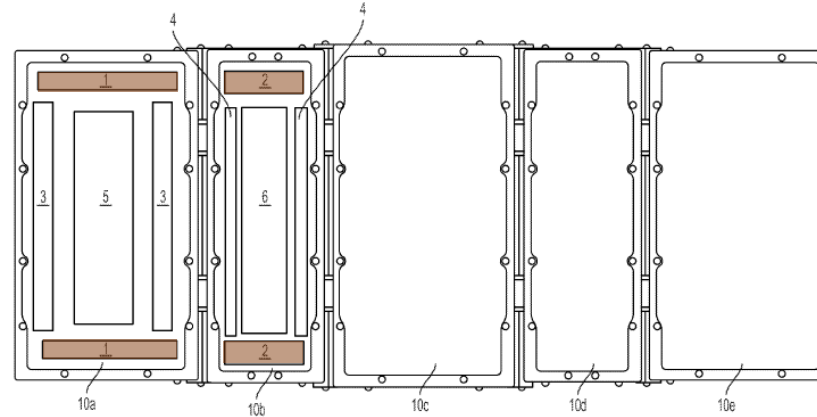
The PDT Device Of The '028 Patent

Therefore, it is an object of some embodiments of the present invention to reduce or eliminate these dead spaces and **provide for a more uniform light distribution** in an adjustable illuminator designed for PDT or PD of a variety of targeted areas.

EX1001, 2:52-56; POR, 1

In one embodiment, **the measured output over the active emitting area** (over the entire active emitting area) **is within 60% of the measured maximum** (over the entire active emitting area) measured with a cosine response detector over all operation distances. More preferably, the measured output over the emitting area is within 70% of the measured maximum over a distance of two and four inches. Even more preferably, the measured output over the emitting area is within 80% of the measured maximum over a distance of two and four inches.

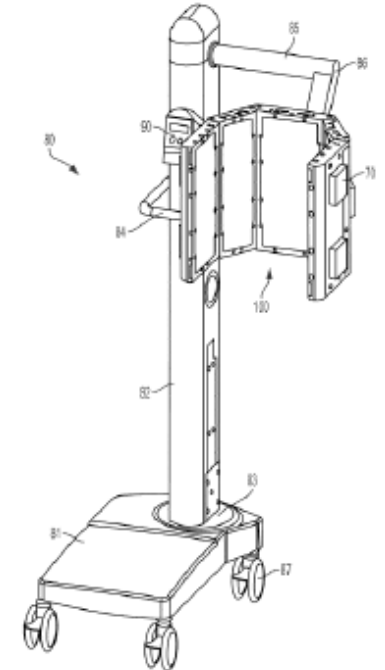
EX1001, 8:58-67; POR, 7



EX1001, FIG. 5 (annotated); POR, 6

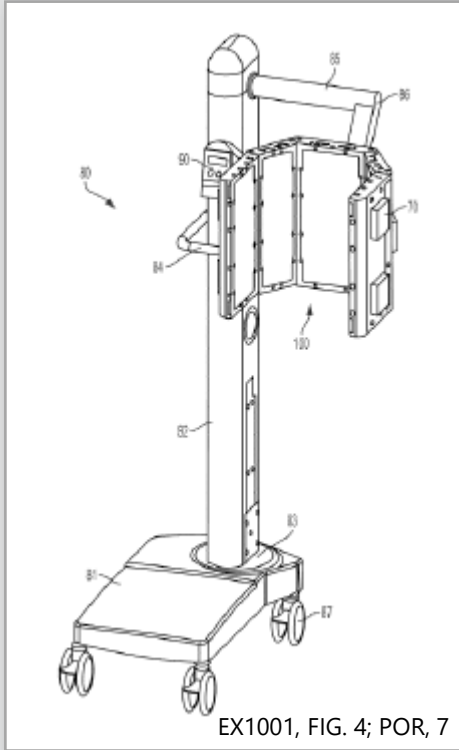
An example in which the LED arrays **60** may be individually configured is shown in FIG. 5. Here, the LED arrays **60** are divided into three general areas, which may be described as “addressable strings.” Areas **1**, **3**, and **5** correspond to an addressable string configuration that may be included in the wider panels **10a**, **10c**, and **10e**, while areas **2**, **4**, and **6** correspond to an addressable string configuration that may be included in the narrower panels **10b** and **10d**. The current to each area is adjusted in order to adjust the intensity of light emitting from each of the areas. For example, **a higher current may be supplied to areas 1 and 2** than the current supplied to areas **3 and 4** such that **areas 1 and 2 emit a higher intensity of light** than areas **3 and 4**. Similarly, a higher current may be supplied to areas **3 and 4** than the current supplied to areas **5 and 6**. Thus, a higher intensity of light is emitted overall from the edges, which may allow for a reduction in any fall-off effect.

EX1001 6:24-40; POR, 6



EX1001, FIG. 4; POR, 7

The PDT Device Of The '028 Patent

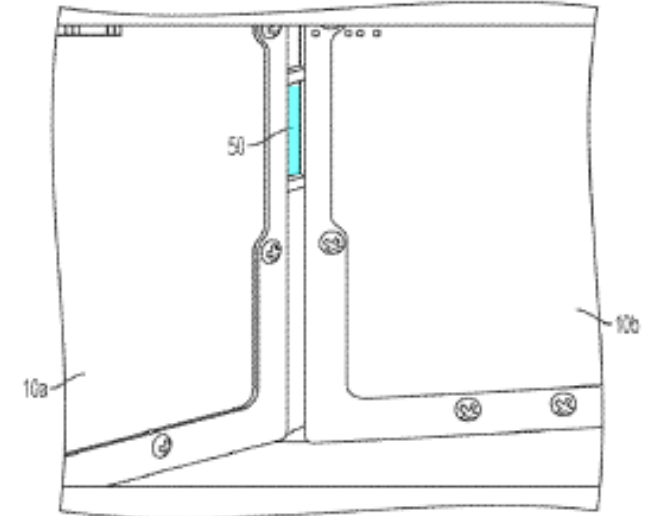


Furthermore, to further reduce or eliminate optical dead spaces, the panels are preferably coupled together using nested hinges, thereby reducing the area in which no light source is present on the illuminator. In order to even further reduce or eliminate optical dead spaces, it is preferable that the light sources on each of the panels are individually configurable to provide specific power output to certain areas of the light sources on the panels to compensate for decreased uniformity. For example, the power outputted to each individual diode in an array of light emitting diodes (LED) may be individually adjusted.

EX1001, 3:11-21; POR, 4

The optical dead space that can occur at or near the hinges of conventional adjustable illuminators reduces the uniformity of the light along the treatment area, thereby reducing the effectiveness of PDT for these specific treatments.

EX1001, 2:41-44; POR, 4



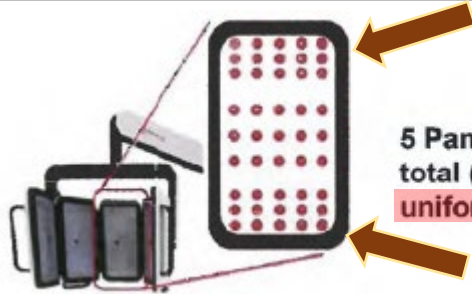
As shown in further detail in FIGS. 3A-3B, between the tabs 23 are the nested hinges 50, which are mounted to the inner side surfaces of adjacent panels (e.g., 10a, 10b) to allow for rotation of the panels.

EX1001, 4:65-5:1, FIG. 3A (annotated); POR, 5

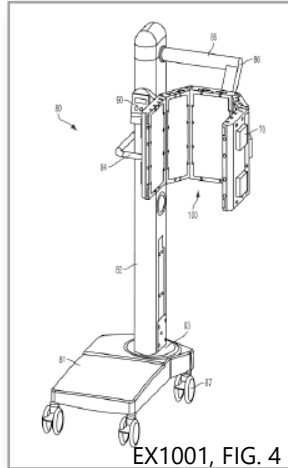
Petitioner's RhodoLED® XL



Biofrontera RhodoLED XL®



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



"We are honored to be the first to integrate the XL lamp into our practice," Cleaver said. "The advanced features and versatility of this device represent a considerable upgrade on what has been available until now and will allow us to provide our patients with the highest standard of care."

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 satisfaction among both staff and patients with the outcomes of using Ameluz PDT in conjunction with the RhodoLED XL. "Additionally, the Biofrontera team made the purchase and transition to the XL an entirely seamless process for us," he added.

This innovative device represents a significant advancement in the treatment of PDT with state-of-the-art engineering, robust but sleek construction and an intuitive user interface. It is designed to be simple to maneuver and able to accommodate various patient treatment positions in order to optimize ease of use.

POR, 72-78; EX2040, 7; EX2045, 1; EX2046, 1; EX2054, 1

Five Independent Claims Of The '028 Patent

1. A system for photodynamically diagnosing or treating a patient, comprising:
an illuminator comprising five panels connected by hinged structures on inner side surfaces of adjacent panels; and
light sources disposed on surfaces of the five panels, the illuminator being configured to uniformly illuminate a treatment surface of the patient via the light sources, one of the five panels being positioned as a center panel configured to face the treatment surface, and two or more of the five panels being configured to be angled relative to the center panel,
wherein the five panels are positioned to allow treatment within approximately four inches of the treatment surface, and
wherein each of the five panels has two first edges and two second edges shorter than the two first edges, and the light sources are arranged such that a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges.

EX1001, claim 1

5. A method of photodynamically diagnosing or treating a patient, comprising:
administering 5-aminolevulinic acid (ALA) to the patient;
positioning an illuminator proximate to the patient, the illuminator comprising five panels connected by hinged structures on inner side surfaces of adjacent panels; and
uniformly illuminating a treatment surface of the patient with light sources disposed on the five panels of the illuminator, the five panels being positioned to allow treatment within approximately four inches of the treatment surface,
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.

EX1001, claim 5

16. A system for photodynamically diagnosing or treating a patient, comprising:
a mobile base supported by at least four wheels;
a pillar perpendicular to the base;
a controller disposed to be supported by the pillar;
an arm mounted to a top portion of the pillar; and
an illuminator connected at an end of the arm, the arm being hinged to allow adjustment of a position of the illuminator relative to the base, the illuminator comprising:
five panels connected by hinged structures to allow continuous illumination across the five panels, wherein the five panels are individually configurable to control illumination from each of the five panels,
light sources disposed on surfaces of the five panels, the illuminator being configured to uniformly illuminate a treatment surface of the patient via the light sources, the light sources being configured to output light uniformly during at least part of a time when the treatment surface is illuminated, each of the five panels having two first edges and two second edges shorter than the two first edges, the light sources arranged such that a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges, and
one or more fans mounted to at least one of the five panels.

EX1001, claim 16

Five Independent Claims Of The '028 Patent

20. A system for photodynamically diagnosing or treating a patient, comprising:
an illuminator comprising five panels connected by hinged structures on inner side surfaces of adjacent panels, wherein the illuminator is configured to output light at a variable irradiance density during treatment; and
light sources disposed on surfaces of the five panels, the illuminator being configured to uniformly illuminate a treatment surface of the patient via the light sources, one of the five panels being positioned as a center panel configured to face the treatment surface, and two or more of the five panels being configured to be angled relative to the center panel,
wherein the five panels are positioned to allow treatment within approximately four inches of the treatment surface, and
wherein each of the five panels has two first edges and two second edges shorter than the two first edges, and the light sources are arranged such that a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges.

EX1001, claim 20

21. A system for photodynamically diagnosing or treating a patient, comprising:
an illuminator comprising five panels connected by hinged structures on inner side surfaces of adjacent panels; and
light sources disposed on surfaces of the five panels, the illuminator being configured to uniformly illuminate a treatment surface of the patient via the light sources, one of the five panels being positioned as a center panel configured to face the treatment surface, and two or more of the five panels being configured to be angled relative to the center panel,
wherein the five panels are positioned to allow treatment within approximately four inches of the treatment surface,
wherein the five panels are individually configurable to control illumination from each of the five panels, and
wherein each of the five panels has two first edges and two second edges shorter than the two first edges, and the light sources are arranged such that a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges.

EX1001, claim 21

Outline

- A Overview of the '028 Patent
- B Overview of the Prior Art**
- C Disputed Issues
- D Motion to Exclude Evidence

Petitioner Presents Two Obviousness Grounds

Ground	Challenged Claims	References
1	1, 2, 4-6, 16, 17, 19-21	Lundahl and Larsen
2	1, 2, 4-6, 16, 17, 19-21	Lundahl, Larsen, and Bansal

Petitioner Affirmatively Dropped Ground 2

Ground	Challenged Claims	References
1	1, 2, 4-6, 16, 17, 19-21	Lundahl and Larsen
~~2~~	~~1, 2, 4-6, 16, 17, 19-21~~	~~Lundahl, Larsen, and Bansal~~

Pet.,9

² Petitioner no longer intends to pursue Ground 2 in view of the Board’s findings in IPR2024-00874.

Reply, 2

Having considered the arguments and evidence on the record, we agree with Patent Owner that Petitioner **has not sufficiently shown for institution that Bansal** teaches or suggests arranging light sources “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,” as required by the challenged claims.

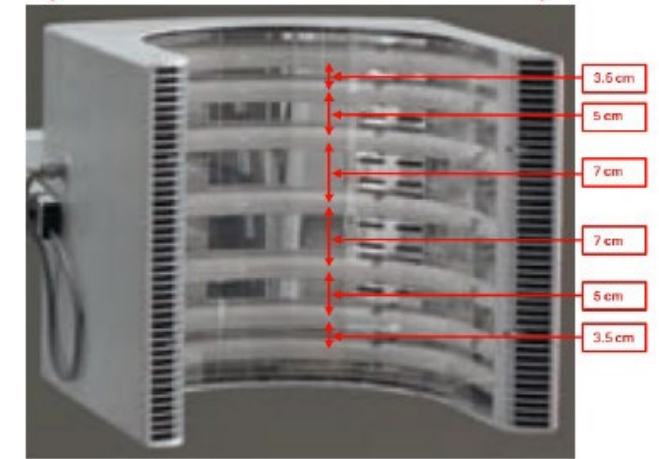
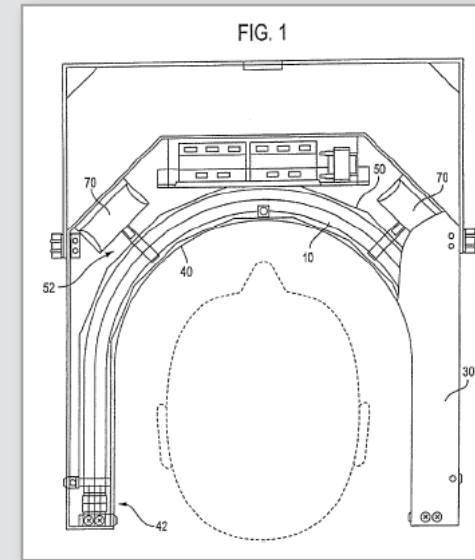
Accordingly, we determine that Petitioner **has not shown a reasonable likelihood** of prevailing in its obviousness challenge of independent claims 1, 5, 16, 20, or 21, or dependent claims 2, 4, 6–8, and 17–19 over **Larsen, Bansal,** and Jones.

IPR2024-00874, DI, 17-18; POR, 2-3

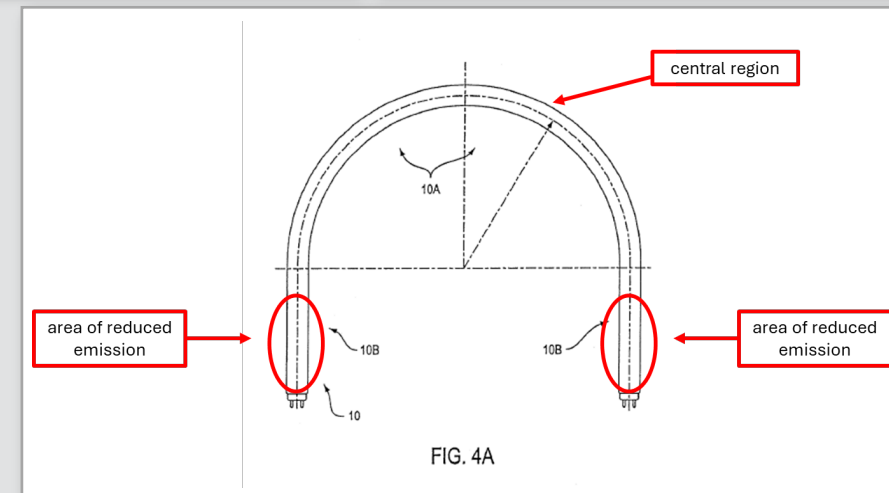
Lundahl's Fluorescent Tubes Have An Inconsistent Light Output That Is "Not Inherently Uniform"

- Single panel with U-shaped fluorescent tube
- Uniform center portion of the tube is used for patient treatment

The output from a fluorescent tube is not inherently 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 near the cathode does not emit as much UV to excite the phosphor. This area of reduced emission is known as the Faraday dark space. To avoid uniformity problems, one embodiment of the present invention utilizes a plurality of U-shaped tubes 10(1)–10(7). 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.



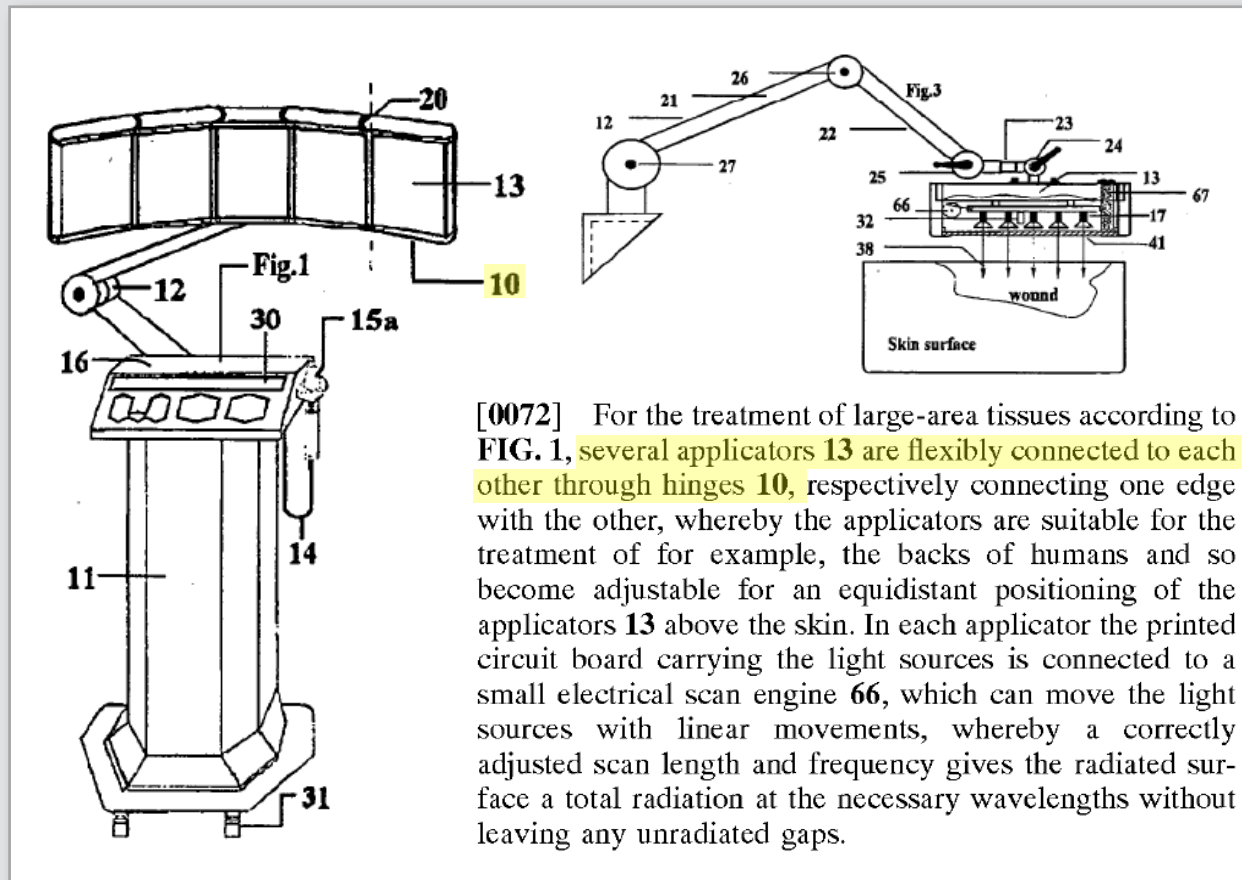
EX1023, 29 (annotated); POR, 25



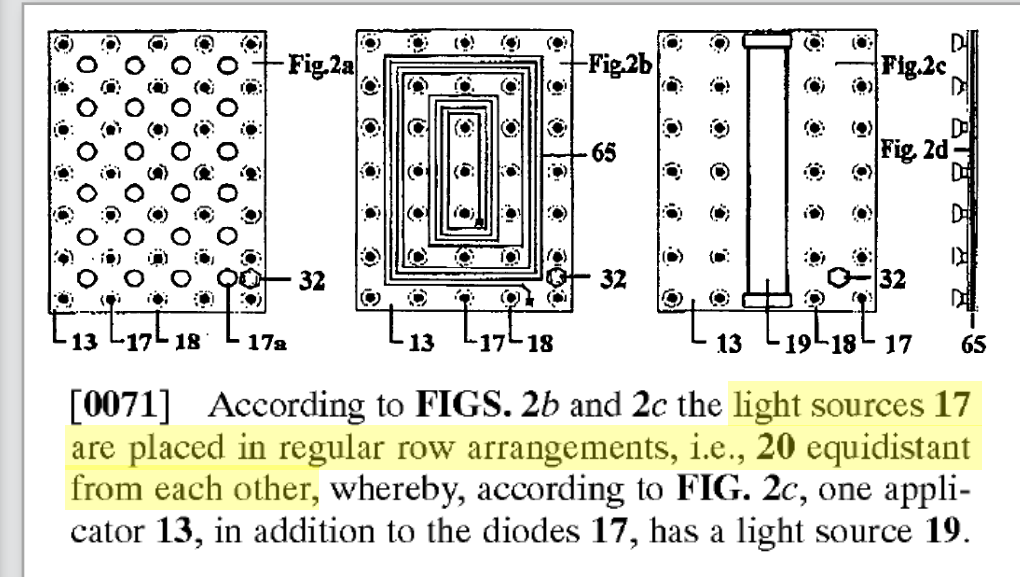
EX1014, 5:43-46, 6:10-22, 9:43-54, FIGS. 1, 2, 4A; POR, 11-13, 44

Larsen Uses Panels Having LEDs Arranged In “Regular Row Arrangements” With Hinges 10 On The Bottom Edge Of The Panels

- Five panels with LEDs arranged in regular row arrangement 20
- Panels connected by hinges 10



[0072] For the treatment of large-area tissues according to FIG. 1, several applicators 13 are flexibly connected to each other through hinges 10, respectively connecting one edge with the other, whereby the applicators are suitable for the treatment of for example, the backs of humans and so become adjustable for an equidistant positioning of the applicators 13 above the skin. In each applicator the printed circuit board carrying the light sources is connected to a small electrical scan engine 66, which can move the light sources with linear movements, whereby a correctly adjusted scan length and frequency gives the radiated surface a total radiation at the necessary wavelengths without leaving any unradiated gaps.

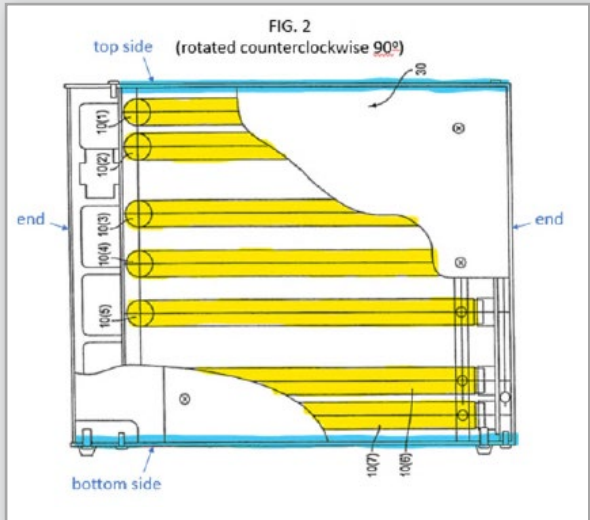


[0071] According to FIGS. 2b and 2c the light sources 17 are placed in regular row arrangements, i.e., 20 equidistant from each other, whereby, according to FIG. 2c, one applicator 13, in addition to the diodes 17, has a light source 19.

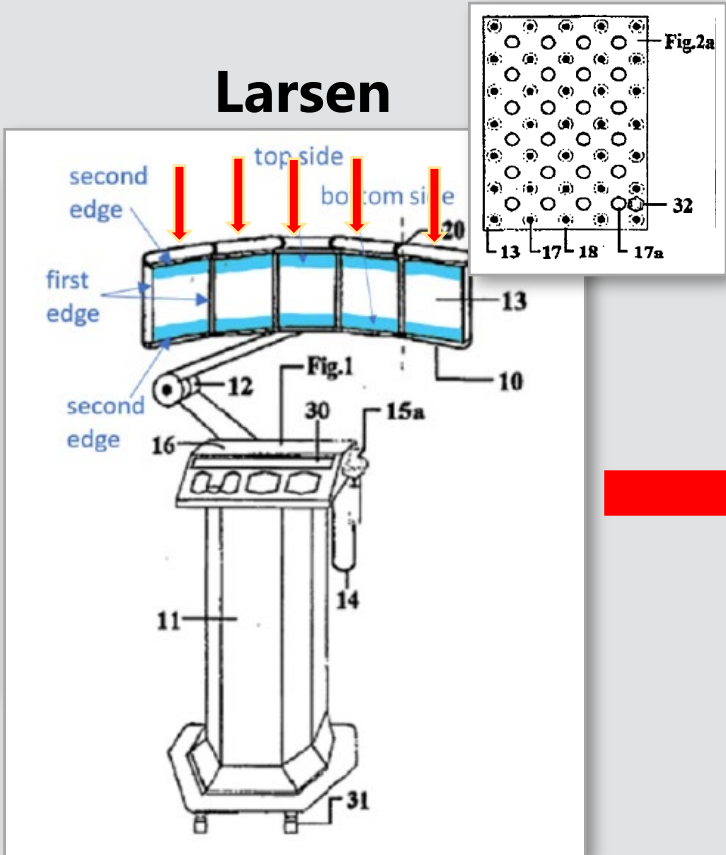
EX1004, [0027], [0040], [0069], [0071], [0072], FIGS. 1-3; POR, 14-15

Petitioner's Proposed Combination Modifies Lundahl's Single Panel Into Larsen's Five Discrete Panels

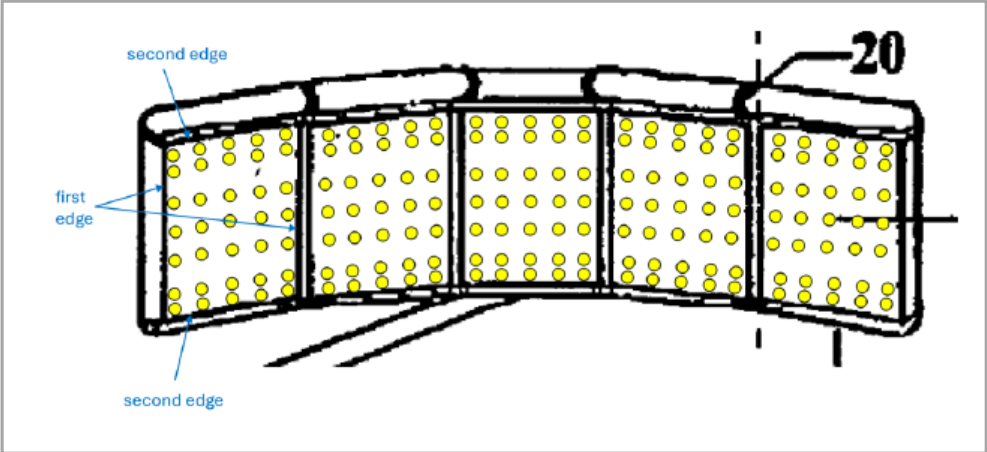
Lundahl



Larsen



Lundahl + Larsen



Pet., 38-42, 45-49; EX1015, ¶¶173-179; POR, 34-38; EX2036, 151:17-152:6

Lundahl Purportedly Combinable With Larsen With A Reasonable Expectation of Success



Dr. Grove

Petitioner's Expert

131. POSITA would have had a reasonable expectation of success in combining Lundahl with Larsen, because both references describe similar illuminators and the conversion from fluorescent tubes to LEDs was a routine practice prior to 2015.

Pet., 31-32 (citing EX1015, ¶¶128, 131)

Outline

- A** Overview of the '028 Patent
- B** Overview of the Prior Art
- C** Disputed Issues
- D** Motion to Exclude Evidence

The Disputed Issues

- 1 Combination does not meet required **uniform illumination**
- 2 No higher intensity of light emitted near the shorter edges of each panel
- 3 No hinged structures on the inner side surfaces
- 4 Each panel's light output is **not individually configurable**
- 5 Combination does not produce **continuous illumination**
- 6 Objective indicia of non-obviousness confirm inventiveness

The Disputed Issues

- 1 Combination does not meet required **uniform illumination**
- 2 No higher intensity of light emitted near the shorter edges of each panel
- 3 No hinged structures on the inner side surfaces
- 4 Each panel's light output is not individually configurable
- 5 Combination does not produce continuous illumination
- 6 Objective indicia of non-obviousness confirm inventiveness

“Uniformly Illuminate/Illuminating” Recited In All Challenged Claims

1. A system for photodynamically diagnosing or treating a patient, comprising:
an illuminator comprising five panels connected by hinged structures on inner side surfaces of adjacent panels; and
light sources disposed on surfaces of the five panels, the illuminator being configured to **uniformly illuminate a treatment surface** of the patient via the light sources, one of the five panels being positioned as a center panel configured to face the treatment surface, and two or more of the five panels being configured to be angled relative to the center panel,
wherein the five panels are positioned to allow treatment within approximately four inches of the treatment surface, and
wherein each of the five panels has two first edges and two second edges shorter than the two first edges, and the light sources are arranged such that a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges.

EX1001, claim 1

5. A method of photodynamically diagnosing or treating a patient, comprising:
administering 5-aminolevulinic acid (ALA) to the patient;
positioning an illuminator proximate to the patient, the illuminator comprising five panels connected by hinged structures on inner side surfaces of adjacent panels; and
uniformly illuminating a treatment surface of the patient with light sources disposed on the five panels of the illuminator, the five panels being positioned to allow treatment within approximately four inches of the treatment surface,
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.

EX1001, claim 5

16. A system for photodynamically diagnosing or treating a patient, comprising:
a mobile base supported by at least four wheels;
a pillar perpendicular to the base;
a controller disposed to be supported by the pillar;
an arm mounted to a top portion of the pillar; and
an illuminator connected at an end of the arm, the arm being hinged to allow adjustment of a position of the illuminator relative to the base, the illuminator comprising:
five panels connected by hinged structures to allow continuous illumination across the five panels, wherein the five panels are individually configurable to control illumination from each of the five panels,
light sources disposed on surfaces of the five panels, the illuminator being configured to **uniformly illuminate a treatment surface** of the patient via the light sources, the light sources being configured to output light uniformly during at least part of a time when the treatment surface is illuminated, each of the five panels having two first edges and two second edges shorter than the two first edges, the light sources arranged such that a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges, and
one or more fans mounted to at least one of the five panels.

EX1001, claim 16

"Uniformly Illuminate/Illuminating" Recited In All Challenged Claims

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

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

light sources disposed on surfaces of the five panels, the illuminator being configured to **uniformly illuminate a treatment surface** of the patient via the light sources, one of the five panels being positioned as a center panel configured to face the treatment surface, and two or more of the five panels being configured to be angled relative to the center panel,

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

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

EX1001, claim 20

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

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

light sources disposed on surfaces of the five panels, the illuminator being configured to **uniformly illuminate a treatment surface** of the patient via the light sources, one of the five panels being positioned as a center panel configured to face the treatment surface, and two or more of the five panels being configured to be angled relative to the center panel,

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

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

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

EX1001, claim 21

Petition Did Not Propose Any Claim Construction: Took “A View ... Consistent With Patent Owner’s Infringement Allegations”

- Petition never proposed a construction for “**uniformly illuminate/illuminating,**” but “t[ook] a view ... consistent with Patent Owner’s infringement allegations”
- Parties and the ALJ agreed that the construction requires “***measured irradiance ... is at least within 60% of the measured maximum***”

D. Claim Construction

For the purposes of this IPR, Petitioner has taken a view of the scope of the claims consistent with Patent Owner’s infringement allegations. See e.g., Ex.1019.

In view of Patent Owner’s infringement allegations, Petitioner does not believe any term needs to be construed to determine the claims are rendered obvious over the prior art cited herein. *Wellman, Inc. v. Eastman Chem. Co.*, 642 F.3d 1355, 1361 (Fed.Cir.2011) (“claim terms need only be construed to the extent necessary to resolve the controversy”) (internal quotations removed). Petitioner does not agree the accused products infringe the ’028 Patent and reserves the right to present its own interpretation of the claim scope of the ’028 Patent in the related ITC, district court litigation or later in this IPR proceeding, including claim scope that disagrees with Patent Owner’s infringement allegations and/or claim scope that fails to meet statutory requirements under 35 U.S.C. §112.

Pet., 12-13

CLAIM TERM	RELEVANT CLAIMS	PARTIES’ AGREED CONSTRUCTION
“uniformly illuminate treatment surface”	’028 patent: claims 1, 16, 20, 21 ’512 patent: claims 1, 2, 20	“irradiating light over the active emitting area such that the measured irradiance at a treatment surface of the patent is at least within 60% of the measured maximum”
“uniformly illuminating treatment surface”	’028 patent: claim 5 ’512 patent: claim 8	“irradiating light over the active emitting area such that the measured irradiance at a treatment surface of the patent is at least within 60% of the measured maximum”

EX2033, 13; POR, 18



I hereby adopt the parties’ proposed constructions and shall construe the terms set forth above according to their agreed-to definitions.

EX2033, 13; POR, 18

"Uniformly Illuminate/Illuminating" Limitations Require Measured Irradiance Within At Least 60% Of The Measured Maximum

- Petitioner's expert, Dr. Grove, purports that he applied this understanding of the agreed-upon construction



Dr. Grove
Petitioner's Expert

Q: So in this proceeding on the 1312 IPR, you understood the "**uniformly illuminate**" claim terms...to mean "irradiating light over the active emitting area such that the measured irradiance at a treatment surface of the patient is at least within 60 percent of the measured maximum," correct?

A: That's my understanding, yes.

“Uniformly Illuminate/Illuminating” Limitations Require Measured Irradiance Within At Least 60% Of The Measured Maximum

- Dr. Grove never calculated whether the claimed “at least 60% of the measured maximum” can be met by the combination



Dr. Grove
Petitioner's Expert

Q: ... And you haven't calculated the intensity of light received at the treatment surface in the example you're providing in figure – in paragraph 15. True?

A: I have not calculated it mathematically, but from the drawing it's easy to estimate a degree of uniformity.

Q. Okay. You have not provided an estimate of the degree of uniformity for illustrations you've provided in your declaration; right?

A. No, I have not.

Biofrontera Failed To Demonstrate The Proposed Modifications Would Meet The Required Degree Of **Uniform Illumination**



Biofrontera's

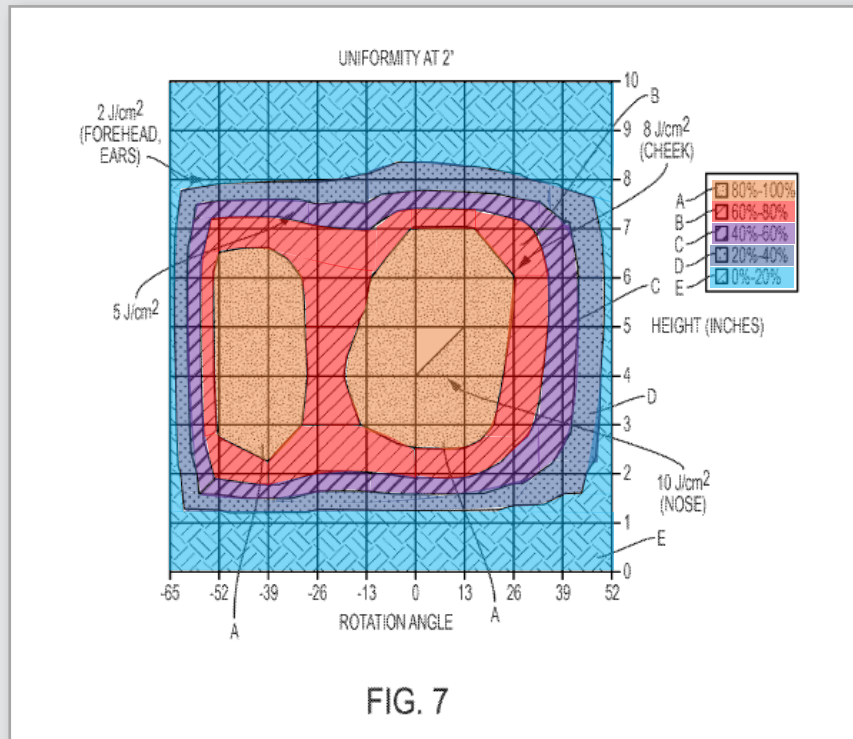
"uniformity" analysis is based on the wrong assumption that spacing LEDs according to Lundahl's fluorescent tube spacing leads to the claimed 60% uniformity. Biofrontera offers only speculation in support because it did no analysis and provided no evidence showing spacing alone is enough. CX-0014C (Jokerst RWS) at Q/A 309-13, 503-06. I am not persuaded by Biofrontera's reliance on a single conclusory statement that it would "adapt[] an existing device to achieve the same goal." *Juniper Networks*, 2024 WL 3517862, at *6.¹⁰

EX2090, 108; Paper 42, 2

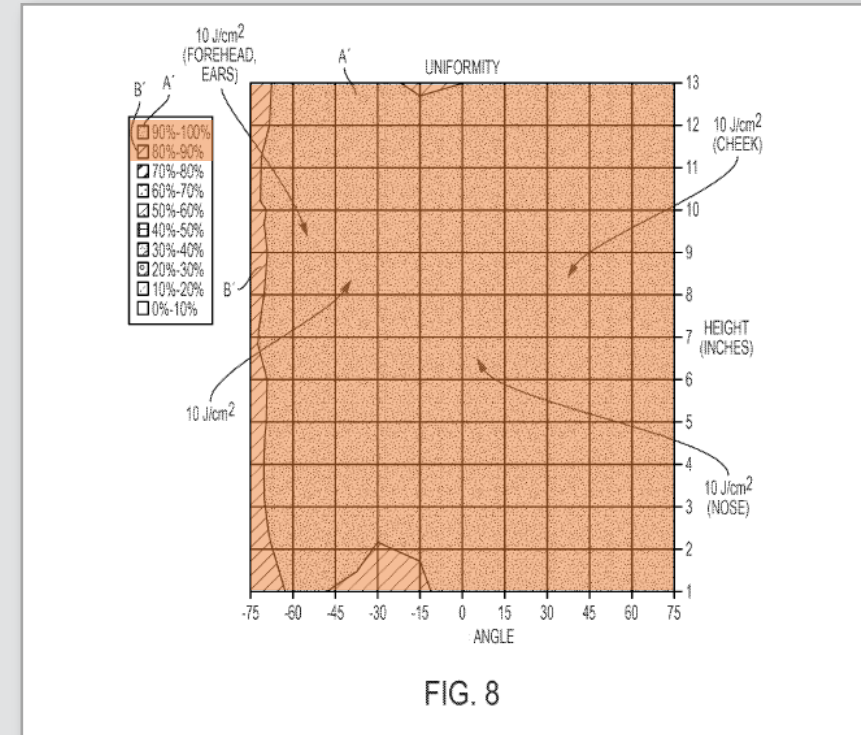
“Uniformly Illuminate/Illuminating” Limitations Require Measured Irradiance Within At Least 60% Of The Measured Maximum

- Conventional illuminators achieved gap-free illumination (*i.e.*, no unlit spaces) without achieving illumination with intensities that were at least within 60% of the measured maximum
- '028 Patent solved this exact problem

Conventional Illuminator



'028 Patent



EX1001, 8:17-67, FIGS. 7-8 (annotated); Sur-Reply, 11-12

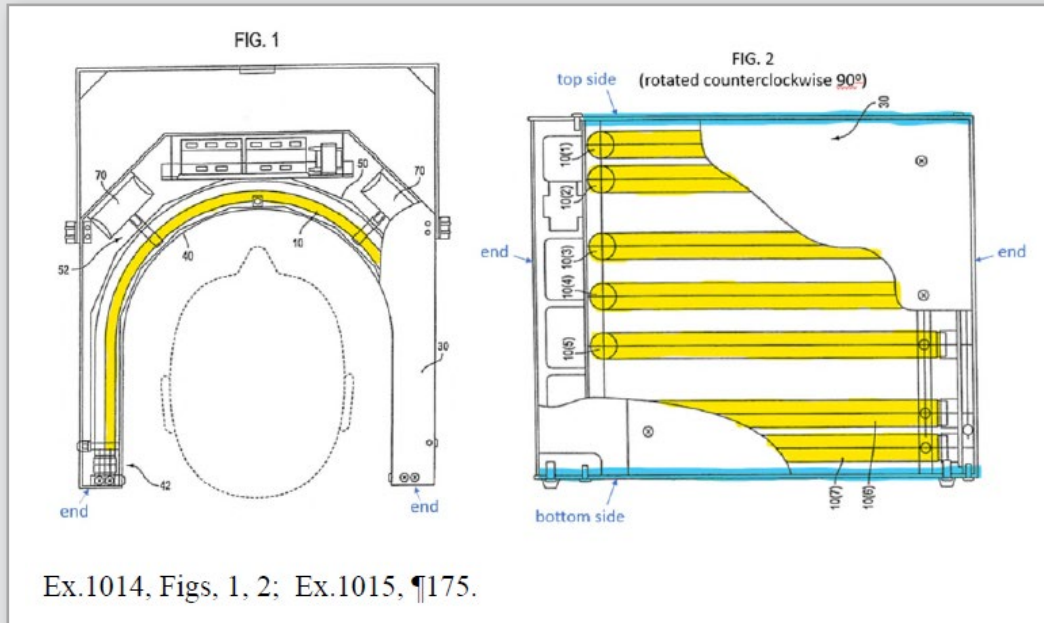
Five Additional Reasons Why The Proposed Combination Fails To Meet “Uniformly Illuminate/Illuminating”

1. Modifying Lundahl into five separate panels creates gaps between them, negatively impacting uniform illumination
2. Arranging Larsen’s LEDs using Lundahl’s uneven spacing creates optical dead spaces – not uniform illumination
3. Achieving uniform illumination by replacing Lundahl’s fluorescent tubes with Larsen’s LEDs is a big challenge
4. POSITA would not have had a reasonable expectation of success in achieving the required degree of uniform illumination
5. At best, Petitioner merely addresses teachings of Lundahl and Larsen separately and fails to render obvious “uniformly illuminate/illuminating”

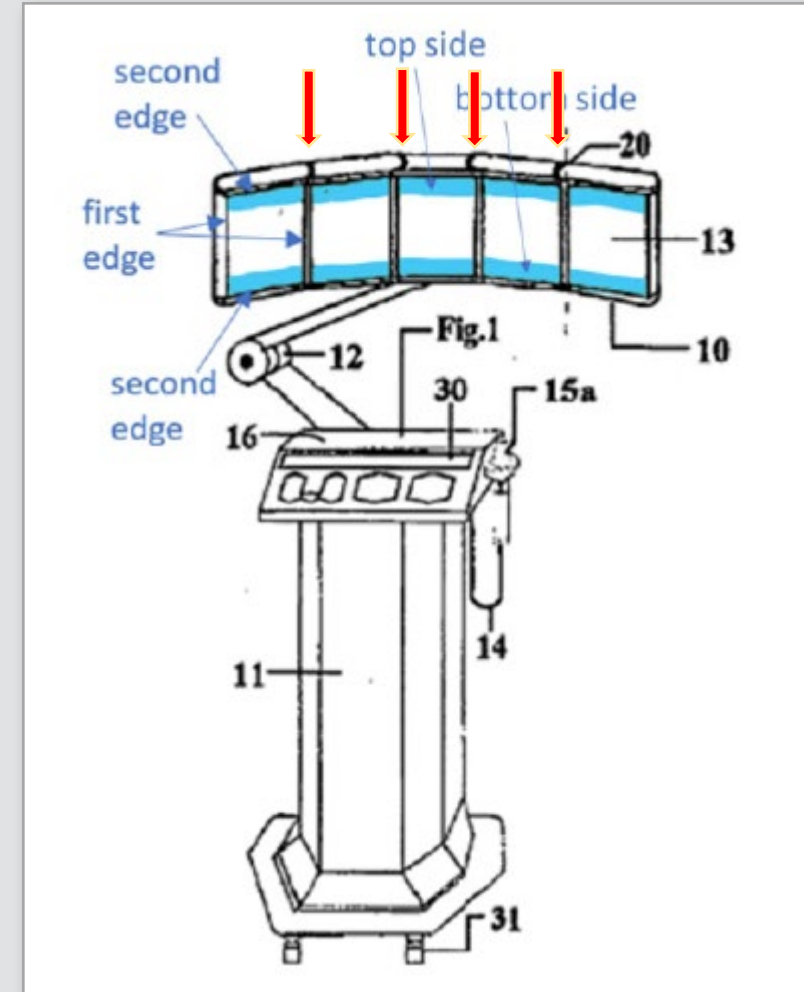
POR, 20-33; Sur-Reply, 5-19

1. Modifying Lundahl Into Five Separate Panels Creates Gaps Between Them, Negatively Impacting **Uniform Illumination**

Lundahl

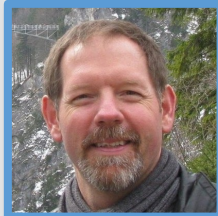
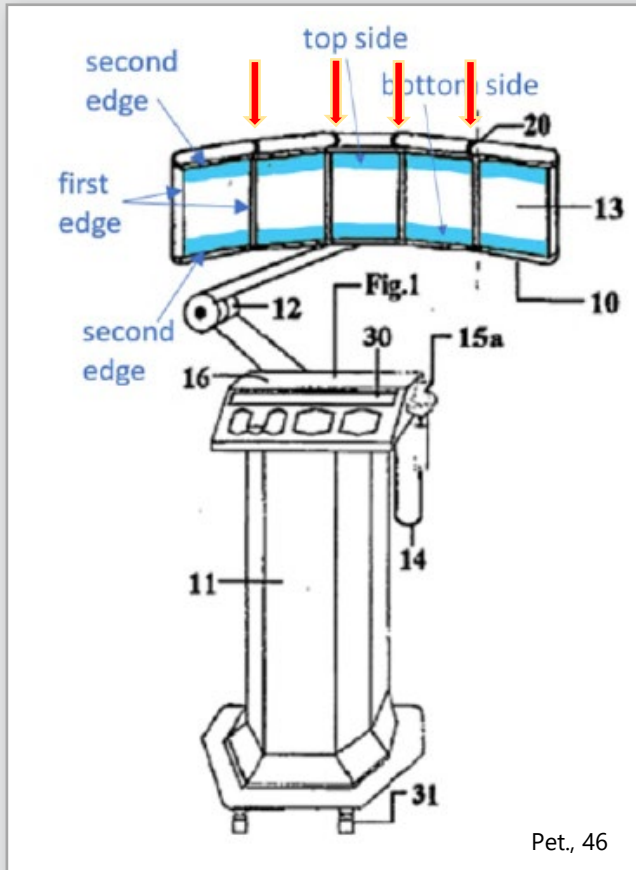


Larsen



1. Modifying Lundahl Into Five Separate Panels Creates Gaps Between Them, Negatively Impacting **Uniform Illumination**

Larsen



Dr. Bretschneider
Petitioner's Expert



Hermann Luebbert
Petitioner's CEO



Mark Carota
Inventor of '028 Patent

- there are "**lower irradiance regions** *at the junction of two of Larsen's panels.*"

EX2082, 1151; POR, 24, 29; Sur-Reply, 1, 10

- "[There are] issues [with **illumination homogeneity**] that are **caused by...the gaps** between individual connected panels."

EX2088, 199:12-200:14; Sur-Reply, 10

- Explained the "difficulty" in achieving **uniform illumination** "because of the **gap between the lights at the place where there was a hinge.**"

EX2052, 88:8-89:1; POR, 24; Sur-Reply, 10

1. Modifying Lundahl Into Five Separate Panels Creates Gaps Between Them, Negatively Impacting **Uniform Illumination**



Biofrontera also ignores the optical dead spaces created by breaking Lundahl's device into five panels. CX-0014C (Jokerst RWS) at Q/A 310-13. Dr. Luebbert, Biofrontera's CEO, testified that multiple-panel illuminators had known issues in homogeneity because of "gaps between individual connected panels" that are not present in a "single curved structure." JX-0008C (Luebbert Dep. Tr.) at 199:12-200:14. Neither Lundahl nor Larsen teaches how to maintain uniformity when introducing multi-panel gaps. CX-0014C (Jokerst RWS) at Q/A 297-98, 470; JX-0188.66 (Biofrontera's expert confirming Larsen has "lower irradiance regions at the junction of two of Larsen's panels.").

EX2090, 107; Paper 42, 2



Biofrontera acknowledges hinged panels would introduce gaps but argues it cannot defeat a motivation to increase flexibility. However, Biofrontera's citation of *Medichem, S.A. v. Rolabo, S.L.*, 437 F.3d 1157, 1165 (Fed. Cir. 2006) omits the next sentence, "the benefits, both lost and gained, should be weighed against one another." Moreover, introducing gaps would destroy Lundahl's goal of uniform illumination, undermining any motivation for flexibility.

EX2090, 120; Paper 42, 3

2. Arranging Larsen's LEDs Using Lundahl's Uneven Spacing Creates Optical Dead Spaces – Not **Uniform Illumination**

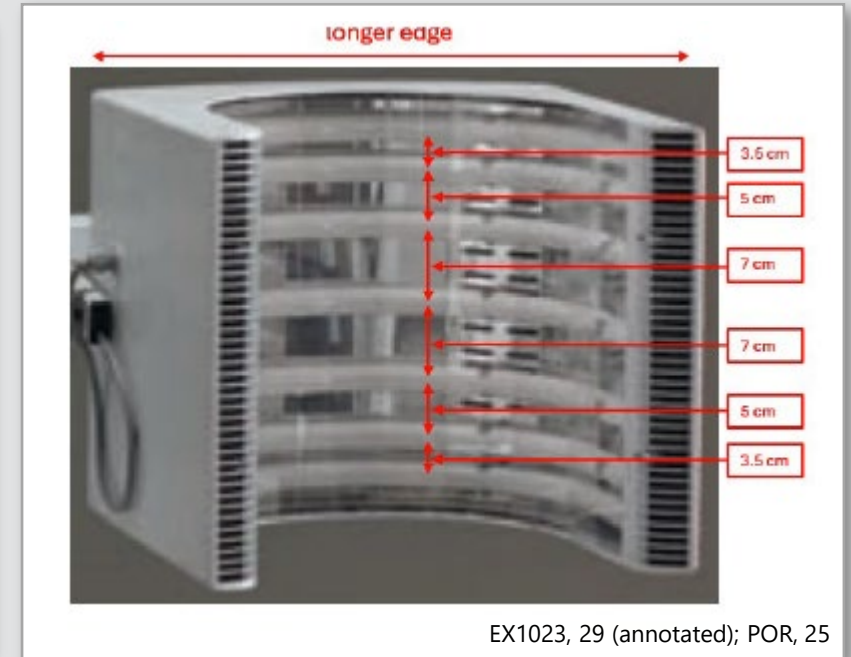
- Dr. Grove incorporated "***the uneven spacing of light sources of Lundahl***" in his proposed combination
 - Will address Petitioner's improper attempts to further expand on this in our MTEE



Dr. Grove
Petitioner's Expert

179. The annotated figure above demonstrates a rendering whereby the hinged panels and LEDs taught by Larsen are incorporated into the device of Lundahl, while maintaining the same light distribution pattern Lundahl utilized for the fluorescent bulbs, as shown in Fig. 2 above and the accompanying disclosure. A POSITA would have found it obvious and would have been motivated with a reasonable expectation of success to incorporate the uneven spacing of light sources of Lundahl to increase the intensity of light emitted from the second edges (e.g., extending along the top and bottom sides of the panel arrangement) of the panels of Larson compared to regions not proximate to the second edges.

EX1015, ¶1179



EX1023, 29 (annotated); POR, 25

EX1015, ¶¶1176-179; EX1014, 6:48-57, Fig. 2; EX2036, 149:24-150:4; EX2087, 38:18-40:10; EX1031, 570:15-19; POR, 24-26; Sur-Reply, 8-10

2. Arranging Larsen's LEDs Using Lundahl's Uneven Spacing Creates Optical Dead Spaces – Not **Uniform Illumination**

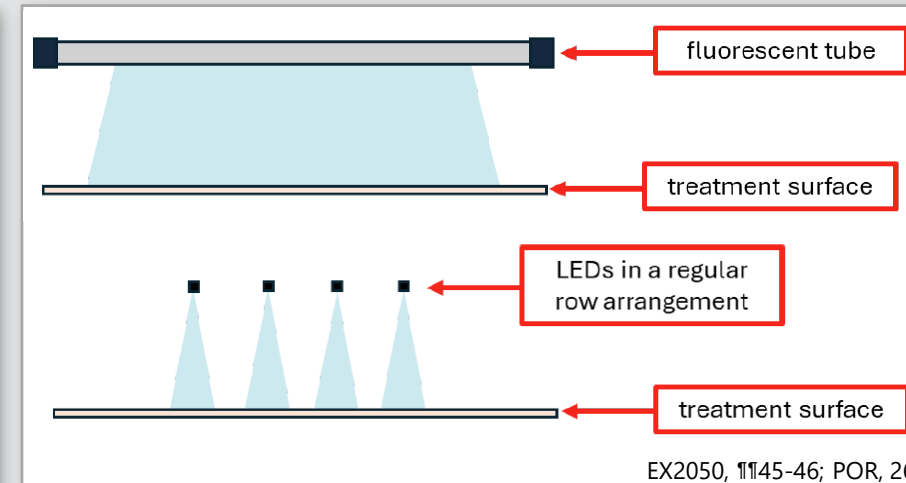
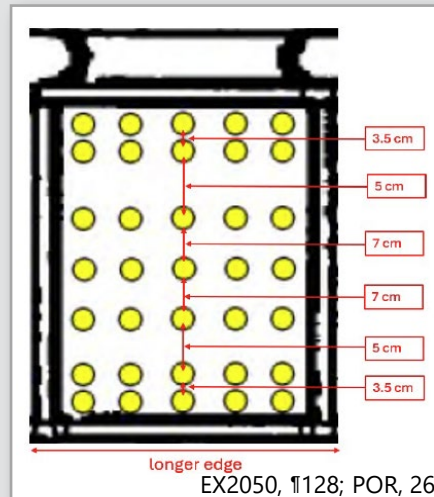
- Larsen's LEDs arranged with **Lundahl's uneven spacing** of fluorescent tubes create "gaps (optical dead spaces)" and do not lead to **uniform illumination**



Dr. Jokerst
Patent Owner's Expert

128. Spacing LEDs as taught by Lundahl's spacing of light sources would create gaps ("optical dead spaces") in areas of the target treatment area that would impact the uniform illumination, because LEDs and fluorescent tubes do not have the same light output characteristics, as explained in Section VII.

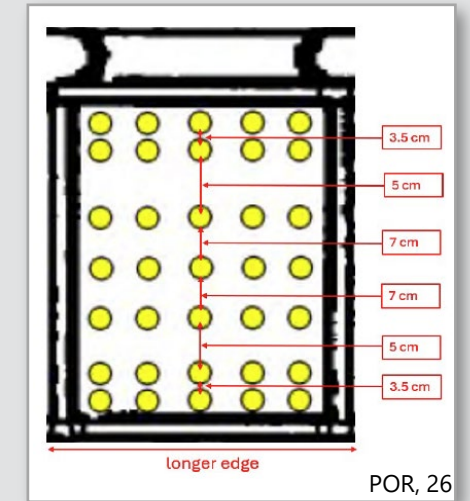
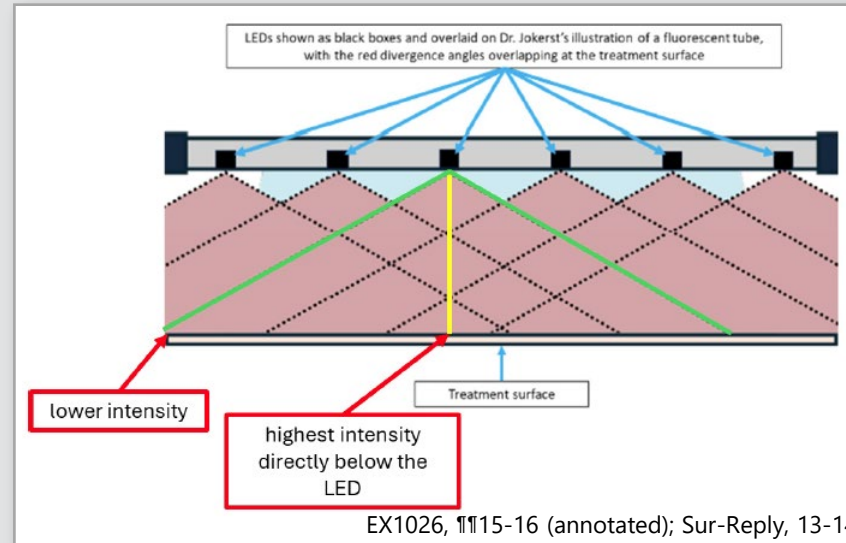
EX2050, ¶128; POR, 26



EX1015, ¶¶176-179; EX2050, ¶¶127-128; EX1014, 6:48-57, Fig. 2; EX1023, 29; POR, 24-26

2. Arranging Larsen's LEDs Using Lundahl's Uneven Spacing Creates Optical Dead Spaces – Not **Uniform Illumination**

- LED outputs highest intensity directly below the LED and can lead to optical dead spaces between the LEDs



Dr. Grove
Petitioner's Expert

Q: ... The intensity of light can be different at each angle from the LED, right?

A: Yes, *It is, in fact, different at each angle with the highest intensity directly below, if you will, the LED. And then the intensity decreases as you move one side or the other, looking back toward the LED.*

EX2087, 29:1-30:8; Sur-Reply, 13-14

EX1015, ¶¶176-179; EX2050, ¶¶127-128; EX1014, 6:48-57, Fig. 2; EX1023, 29; POR, 24-26; Sur-Reply, 8-15

2. Arranging Larsen's LEDs Using Lundahl's Uneven Spacing Creates Optical Dead Spaces – Not **Uniform Illumination**



That

theory assumes that (1) Lundahl's vertical spacing of fluorescent tubes is unrelated to fluorescent technology, and (2) LEDs illuminate uniformly with that same spacing. These assumptions are not persuasive, as the different light sources have different optical emission properties. One cannot assume identical illumination given Lundahl's spacing but different light sources. Fluorescent tubes are continuous, diffuse light sources, whereas LEDs are directional point-source with Lambertian outputs. Thus, switching to LEDs would create gaps and would completely change the light distribution pattern emitted from the illuminator. CX-0014C (Jokerst RWS) at Q/A 273-74, 310, 506.

EX2090, 105-106; Paper 42, 3

3. Achieving **Uniform Illumination** By Replacing Lundahl's Fluorescent Tubes With Larsen's LEDs Is A Big Challenge

- Fluorescent tubes and LEDs have "different light output characteristics" making **uniform illumination** a "big challenge"



Dr. Grove
Petitioner's Expert

Q: Fluorescent tubes have different light output characteristics than LEDs; right?

A: Yes, absolutely.

EX2087, 46:21-47:1; Sur-Reply, 16



Thomas Boyajian
Inventor of '028 Patent

Q: What were some of the challenges?

A: ... As I mentioned before, LEDs don't act like fluorescents. Having separate panels is not easy. Not easy. Uniformity is a big challenge.

EX2053, 100:7-12; POR, 33

POR, 24-26; Sur-Reply, 15-18

3. Achieving **Uniform Illumination** By Replacing Lundahl's Fluorescent Tubes With Larsen's LEDs Is A Big Challenge



That

theory assumes that (1) Lundahl's vertical spacing of fluorescent tubes is unrelated to fluorescent technology, and (2) LEDs illuminate uniformly with that same spacing. These assumptions are not persuasive, as the different light sources have different optical emission properties. One cannot assume identical illumination given Lundahl's spacing but different light sources. Fluorescent tubes are continuous, diffuse light sources, whereas LEDs are directional point-source with Lambertian outputs. Thus, switching to LEDs would create gaps and would completely change the light distribution pattern emitted from the illuminator. CX-0014C (Jokerst RWS) at Q/A 273-74, 310, 506.

EX2090, 105-106; Paper 42, 3

4. A POSITA Would Not Have Had A Reasonable Expectation Of Success In Achieving The Required Degree Of **Uniform Illumination**

- Petitioner's expert argued that a "POSA would be required to perform **undue experimentation** to make and use an illuminator that provides '**uniform illumination**' over the full scope of the claims."



Dr. Grove
Petitioner's Expert

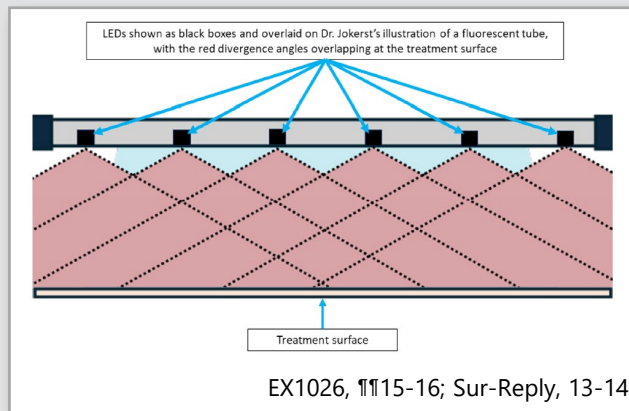
186. Additionally, I understand that an invention must be enabled, meaning that the patentee is required to provide guidance and teach a POSA how to practice the full scope of the claims without undue experimentation. I understand that the relevant statutory requirement is that "[t]he specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains . . . to make and use the same." It is also my understanding that factors considered in determining whether a disclosure would require "undue experimentation" to make and use the claims include the following: (1) breadth of the claims; (2) the quantity of experimentation necessary, (3) the amount of direction or guidance presented, (4) the presence or absence of working examples, (5) the nature of the invention, (6) the state of the prior art, (7) the relative skill of those in the art, and (8) the predictability or unpredictability of the art. Importantly, it is further my understanding that the scope of enablement must be commensurate with the full scope of the claims. I have considered these factors, and it is my opinion that a POSA would be required to perform undue experimentation to make and use an illuminator that provides "uniform illumination" over the full scope of the claims.

4. A POSITA Would Not Have Had A Reasonable Expectation Of Success In Achieving The Required Degree Of **Uniform Illumination**

- Petitioner's expert's simplified drawing is based on a flat surface



Dr. Grove
Petitioner's Expert



Q: ... the drawing that you're providing your opinion on in your declaration, that drawing shows a flat treatment surface; right?

A: Yes.

Q: And in the PDT context, the treatment surface such as a face is often not a flat surface; right?

A: True.

Q: It's your opinion that the amount of experimentation and testing necessary to achieve a specific design goal increases when the treatment surface is not flat, right?

A: In general, that's true, yes.

EX2087, 55:4-20; Sur-Reply, 16.

EX2034, ¶¶186, 191; EX2084, Sur-Reply, 15-16

4. A POSITA Would Not Have Had A Reasonable Expectation Of Success In Achieving The Required Degree Of **Uniform Illumination**



Biofrontera fails to show a reasonable expectation that its combination of Lundahl and Larsen would meet the uniform illumination limitation as discussed above. Biofrontera asserts that its “modifications to Lundahl’s device are simple and straightforward,” RIB at 79, but that ignores the challenges of achieving uniform illumination using LEDs and hinged panels, as discussed above.¹³ Its expert previously claimed achieving uniformity would require “undue experimentation.” Tr. (Grove) at 579:15-25.

EX2090, 122; Paper 42, 4



Fundamentally, however, Dr. Grove never measured any irradiance values for the resultant combination, and, thus, Biofrontera cannot prove the combination maintained the measured uniformity of Lundahl’s integrated fluorescent system. Biofrontera has not shown sufficiently that a skilled artisan would reasonably expect success in achieving the claimed uniformity given those modifications all affect uniformity. CX-0014C (Jokerst RWS) at Q/A 235, 294, 479-89. There is no reasonable expectation of success where an expert merely relies on the theory that “the prior art combinations were simple and would have led to predictable results,” and there is contrary expert testimony. *Juniper Networks, Inc. v. Correct Transmission, LLC*, 2024 WL 3517862, at *6 (Fed. Cir. July 24, 2024).

EX2090, 104-105; Paper 42, 4

5. At Best, Petitioner Merely Addresses Teachings of Lundahl And Larsen Separately And Fails To Render Obvious “Uniformly Illuminate/Illuminating”



Unigene Labs., Inc. v. Apotex, Inc., 655 F.3d 1352, 1360
(Fed. Cir. 2011)

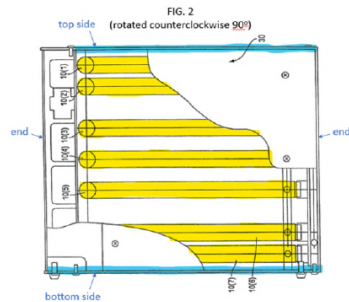
“Obviousness requires more than a mere showing that the prior art includes separate references covering each separate limitations in a claim”

5. At Best, Petitioner Merely Addresses Teachings of Lundahl And Larsen Separately And Fails To Render Obvious “Uniformly Illuminate/Illuminating”

- Petitioner addresses only the **individual** teachings of Lundahl and Larsen

Claim 1(c): “the illuminator being configured to uniformly illuminate a treatment surface of the patient via the light sources,”

Lundahl teaches uniform illumination of the head of a patient via photodynamic therapy. Lundahl states “[t]he present invention is directed to photodynamic therapy using an illuminator that provides a uniform distribution of visible light.” Ex.1014, at 1:9-11. To achieve this uniformity Lundahl utilizes the light distribution pattern illustrated in Figure 2 (which has been rotated 90° to better illustrate):



Ex.1014, Fig. 2; Ex.1015, ¶160. Lundahl explains that “[t]o avoid uniformity problems, one embodiment, of the present invention utilizes a plurality of U-shaped tubes 10(1)-10(7)....[An] advantage of the arrangement is that uniformity can also be adjusted by varying the lateral spacing of the tubes (relative horizontal spacing as shown in FIG. 2). This is important since it is necessary to compensate for the fact that the output from a flat plane emitting light source drops near the edges. Varying the lateral spacing of the tubes creates the same effect as folding the edges of a larger illuminator in on itself, thus emulating an infinite plane emitter with a compact unit.” Ex.1014, 6:16-30; Ex.1015, ¶161.

Lundahl states that the spacing of lights and greater density of lighting near the top and bottom of the panel provide for uniform illumination, stating “[t]he number of tubes used and the spacing between them were chosen to achieve desired uniformity and power output specifications...The present invention provides a highly uniform output irradiance without the use of an additional diffusing element.” Ex.1014, 6:43-57; Ex.1015, ¶162.

Larsen teaches that its panels (applicators) are configured to uniformly illuminate a treatment surface of the patient via the light sources. Larsen teaches that “[i]n each applicator the printed circuit board carrying the light sources is connected to a small electrical scan engine 66, which can move the light sources with linear movements, whereby a correctly adjusted scan length and frequency gives the radiated surface a total radiation at the necessary wavelengths without leaving any unirradiated gaps.” Ex.1004, [0072]. During prosecution of Application No. 16/791,004 (the “’004 Application”), which is the direct parent of the ‘028 Patent, the Examiner reviewed this same disclosure of Larsen and confirmed that it taught “the illuminator being configured to uniformly illuminate a treatment surface of the patient via the light sources.” Ex.1010, ¶23 (citing Ex.1004, [0072]); Ex.1015, ¶163.

Larsen also teaches that its applicators “permit[] an even and gap-free radiation of the surface with multiple wavelengths of light.” Ex.1004, [0028]. An “even and gap-free radiation of the surface” would uniformly illuminate the

treatment surface. Ex.1015, ¶163. Larsen also describes measurements taken by sensors 32 that measure “the amount of energy radiated away from the skin surface, which is indicative of the total energy penetrating into the tissue.” Ex.1004, [0079]. Larsen teaches that “[t]aking 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.” *Id.* POSITA would have understood that Larsen’s applicator is configured to uniformly illuminate a treatment surface of the patient. Ex.1015, ¶164.

Thus, Lundahl and Larsen teaches the limitations of claim 1(c). Ex.1015, ¶165.

5. At Best, Petitioner Merely Addresses Teachings of Lundahl And Larsen Separately And Fails To Render Obvious “Uniformly Illuminate/Illuminating”



Biofrontera admits that the claims require uniform illumination “via the light sources” which are “disposed on the surfaces of the five panels.” RIB at 30. However, throughout its analysis, Biofrontera relies on separate disclosures from Lundahl (lacking five panels) and Larsen (lacking uniform illumination) for pieces of this limitation and never demonstrates that the combination—Lundahl’s light distribution with Larsen’s five LED panels—teaches the whole “uniformly illuminate” limitation. *Unigene Labs., Inc. v. Apotex, Inc.*, 655 F.3d 1352, 1360 (Fed. Cir. 2011) (“Obviousness requires more than a mere showing that the prior art includes separate references covering each separate limitation in a claim....”). Biofrontera’s analysis fails to sufficiently show that it is free of improper hindsight.

EX2090, 103; Paper 42, 4-5

The Disputed Issues

- 1 Combination does not meet required uniform illumination
- 2 No higher intensity of light emitted near the shorter edges of each panel
- 3 No hinged structures on the inner side surfaces
- 4 Each panel's light output is not individually configurable
- 5 Combination does not produce continuous illumination
- 6 Objective indicia of non-obviousness confirm inventiveness

"Higher Intensity Near Shorter Edges" Recited In All Challenged Claims

1. A system for photodynamically diagnosing or treating a patient, comprising:
an illuminator comprising five panels connected by hinged structures on inner side surfaces of adjacent panels; and
light sources disposed on surfaces of the five panels, the illuminator being configured to uniformly illuminate a treatment surface of the patient via the light sources, one of the five panels being positioned as a center panel configured to face the treatment surface, and two or more of the five panels being configured to be angled relative to the center panel,
wherein the five panels are positioned to allow treatment within approximately four inches of the treatment surface, and
wherein each of the five panels has two first edges and two second edges shorter than the two first edges, and the light sources are arranged such that a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges.

EX1001, claim 1

5. A method of photodynamically diagnosing or treating a patient, comprising:
administering 5-aminolevulinic acid (ALA) to the patient;
positioning an illuminator proximate to the patient, the illuminator comprising five panels connected by hinged structures on inner side surfaces of adjacent panels; and
uniformly illuminating a treatment surface of the patient with light sources disposed on the five panels of the illuminator, the five panels being positioned to allow treatment within approximately four inches of the treatment surface,
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.

EX1001, claim 5

16. A system for photodynamically diagnosing or treating a patient, comprising:
a mobile base supported by at least four wheels;
a pillar perpendicular to the base;
a controller disposed to be supported by the pillar;
an arm mounted to a top portion of the pillar; and
an illuminator connected at an end of the arm, the arm being hinged to allow adjustment of a position of the illuminator relative to the base, the illuminator comprising:
five panels connected by hinged structures to allow continuous illumination across the five panels, wherein the five panels are individually configurable to control illumination from each of the five panels,
light sources disposed on surfaces of the five panels, the illuminator being configured to uniformly illuminate a treatment surface of the patient via the light sources, the light sources being configured to output light uniformly during at least part of a time when the treatment surface is illuminated, each of the five panels having two first edges and two second edges shorter than the two first edges, the light sources arranged such that a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges, and
one or more fans mounted to at least one of the five panels.

EX1001, claim 16

"Higher Intensity Near Shorter Edges" Recited In All Challenged Claims

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

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

light sources disposed on surfaces of the five panels, the illuminator being configured to uniformly illuminate a treatment surface of the patient via the light sources, one of the five panels being positioned as a center panel configured to face the treatment surface, and two or more of the five panels being configured to be angled relative to the center panel,

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

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

EX1001, claim 20

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

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

light sources disposed on surfaces of the five panels, the illuminator being configured to uniformly illuminate a treatment surface of the patient via the light sources, one of the five panels being positioned as a center panel configured to face the treatment surface, and two or more of the five panels being configured to be angled relative to the center panel,

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

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

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

EX1001, claim 21

Three Reasons Why The Proposed Combination Fails To Meet Or Suggest Higher Intensity of Light Proximate Shorter Edge Limitations

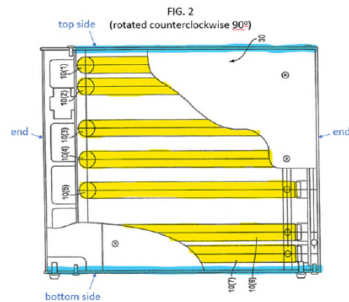
1. Proposed combination leads to higher intensity near the center of the panel – not “proximate the second edges”
2. Proposed combination would have placed more light sources near the longer edges – not “proximate the second edges”
3. Proposed combination does not meet the claimed higher intensity “proximate the second edges” in “each of the five panels”

1. Petitioner's Proposed Combination Also Included Larsen's Scan Engine To Meet The "Uniformly Illuminate" Limitation

- Petition also relied on **Larsen's "scan engine"** to meet the "uniformly illuminate" limitation

Claim 1(c): "the illuminator being configured to **uniformly illuminate** a treatment surface of the patient via the light sources,"

Lundahl teaches **uniform illumination** of the head of a patient via photodynamic therapy. Lundahl states "[t]he present invention is directed to photodynamic therapy using an illuminator that provides a uniform distribution of visible light." Ex.1014, at 1:9-11. To achieve this **uniformity**, Lundahl utilizes the light distribution pattern illustrated in Figure 2 (which has been rotated 90° to better illustrate):



Ex.1014, Fig. 2; Ex.1015, ¶160. Lundahl explains that "[t]o avoid uniformity problems, one embodiment, of the present invention utilizes a plurality of U-shaped tubes 10(1)-10(7)...[An] advantage of the arrangement is that uniformity can also be adjusted by varying the lateral spacing of the tubes (relative horizontal spacing as shown in FIG. 2). This is important since it is necessary to compensate for the fact that the output from a flat plane emitting light source drops near the edges. Varying the lateral spacing of the tubes creates the same effect as folding the edges of a larger illuminator in on itself, thus emulating an infinite plane emitter with a compact unit." Ex.1014, 6:16-30; Ex.1015, ¶161.

Lundahl states that the spacing of lights and greater density of lighting near the top and bottom of the panel provide for **uniform illumination**, stating "[t]he number of tubes used and the spacing between them were chosen to achieve desired uniformity and power output specifications...The present invention provides a highly uniform output irradiance without the use of an additional diffusing element." Ex.1014, 6:43-57; Ex.1015, ¶162.

Larsen teaches that its panels (applicators) are configured to **uniformly illuminate** a treatment surface of the patient via the light sources. Larsen teaches that "[i]n each applicator the printed circuit board carrying the light sources is connected to a **small electrical scan engine 66, which can move the light sources with linear movements**, whereby a correctly adjusted scan length and frequency gives the radiated surface a total radiation at the necessary wavelengths without leaving any unirradiated gaps." Ex.1004, [0072]. During prosecution of Application No. 16/791,004 (the "'004 Application"), which is the direct parent of the '028 Patent, the Examiner reviewed this same disclosure of Larsen and confirmed that it taught "the illuminator being configured to **uniformly illuminate** a treatment surface of the patient via the light sources." Ex.1010, ¶23 (citing Ex.1004, [0072]); Ex.1015, ¶163.

Larsen also teaches that its applicators "**permit[] an even and gap-free radiation** of the surface with multiple wavelengths of light." Ex.1004, [0028]. An "even and gap-free radiation of the surface" would **uniformly illuminate** the

treatment surface. Ex.1015, ¶163. Larsen also describes measurements taken by sensors 32 that measure "the amount of energy radiated away from the skin surface, which is indicative of the total energy penetrating into the tissue." Ex.1004, [0079]. Larsen teaches that "[t]aking 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." *Id.* POSITA would have understood that Larsen's applicator is configured to **uniformly illuminate** a treatment surface of the patient. Ex.1015, ¶164.

Thus, Lundahl and Larsen teaches the limitations of claim 1(c). Ex.1015, ¶165.

1. Petitioner's Proposed Combination Also Included Larsen's Scan Engine To Meet The "**Uniformly Illuminate**" Limitation

- Petitioner cannot argue it "merely cited the scan engine for the proposition that Larsen also taught the benefits of uniform light distribution"



Application of Wesslau, 353 F.2d 238, 241 (C.C.P.A. 1965)

“It is impermissible within the framework of section 103 to pick and choose from any one reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art.”

1. Larsen's Scan Engine Would Lead To Higher Intensity Of Light Emitted From The Center Of The Panels, Not "Proximate The Second Edges"

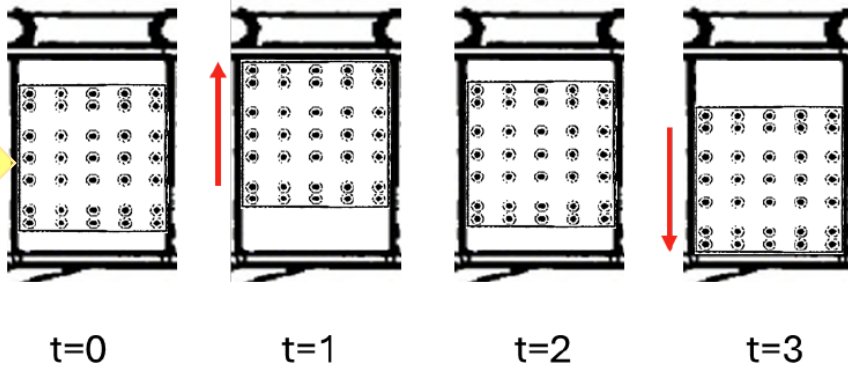


Dr. Jokerst
PO's Expert

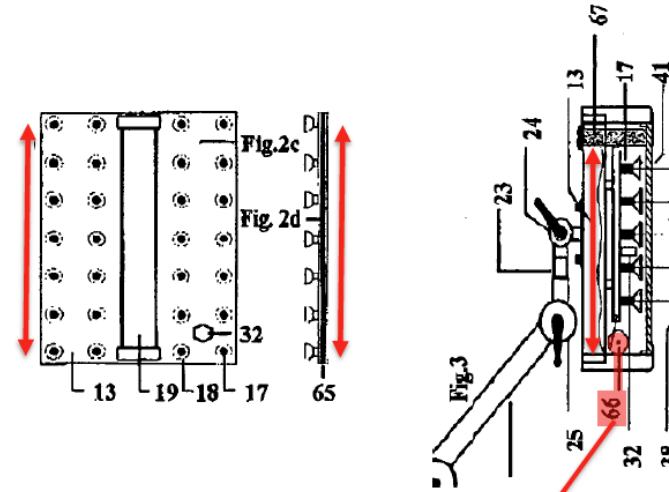
Declaration)), ¶154; IPR2024-00874, Petition, 18. As seen in the time lapse from $t=0$ to $t=3$, *there would be more light sources in the center portion of each panel than at the shorter edges of each panel.* Therefore, a POSITA would have

[0072]

In each applicator the printed circuit board carrying the light sources is connected to a small electrical scan engine 66, which can move the light sources with linear movements, whereby a correctly adjusted scan length and frequency gives the radiated surface a total radiation at the necessary wavelengths without leaving any unradiated gaps.



EX1015, ¶¶178-179; EX1004, [0072]; POR, 41; EX2050, ¶152



scan engine 66 moves the light sources up and down with "linear movements"

EX1004, FIGS. 2c-d and FIG. 3; POR, 40; EX2050, ¶151

EX1015, ¶¶178-179; EX1004, [0072], FIGS. 2c-d, 3; EX2082, ¶154; EX2050, ¶¶150; POR, 38-41; Sur-Reply, 21-23

1. Larsen's Scan Engine Would Lead To Higher Intensity Of Light Emitted From The Center Of The Panels, Not "Proximate The Second Edges"



Additionally,

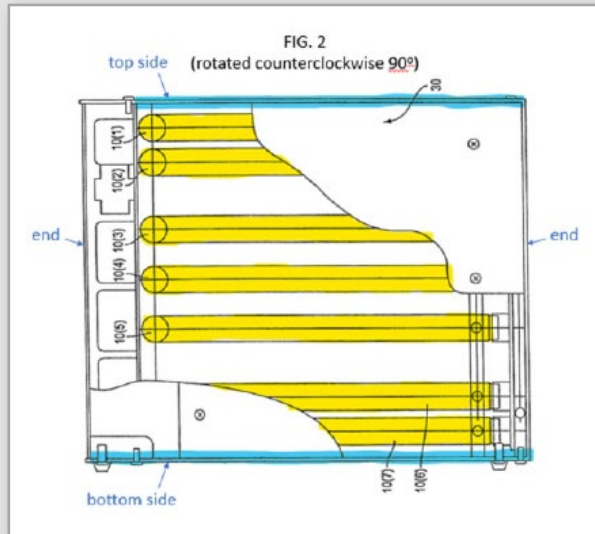
incorporating Larsen's scan engine in the Lundahl/Larsen combination would lead to higher intensity of light emitted from the center of the panels, not near the second shorter edges as claimed. *See* CIB at 90-92.¹¹

EX2090, 114; Paper 42, 6

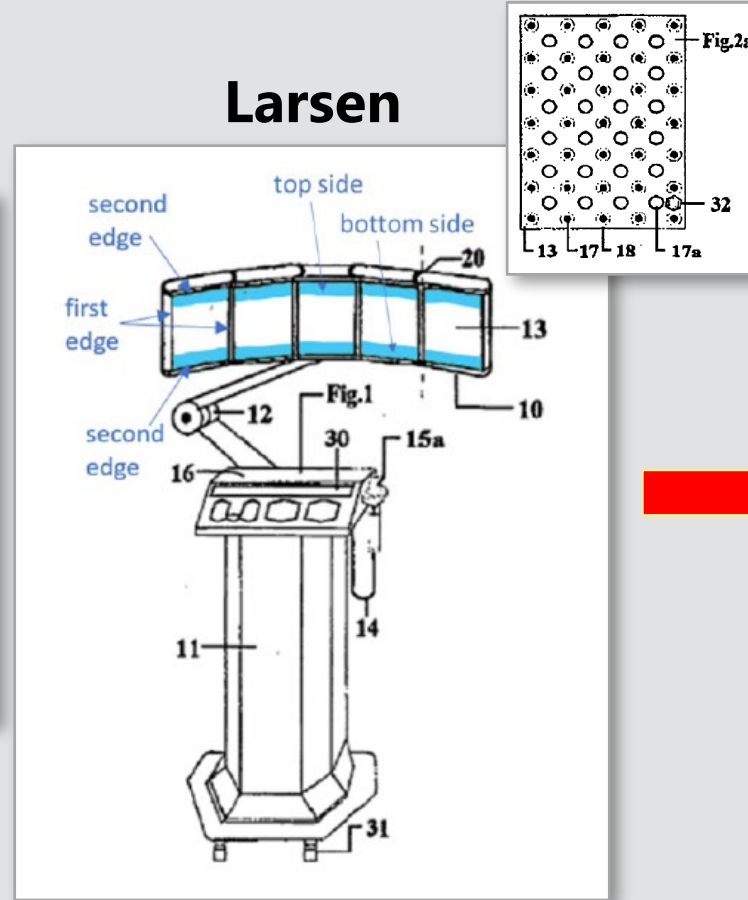
2. Neither Lundahl Nor Larsen Teaches Or Suggest Higher Intensity "Proximate The Second Edges"

- Petitioner's proposed combination is based on hindsight reconstruction

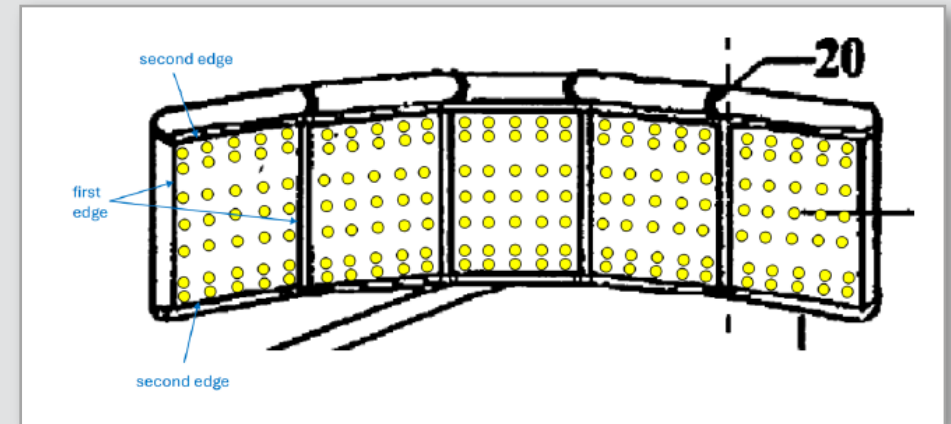
Lundahl



Larsen



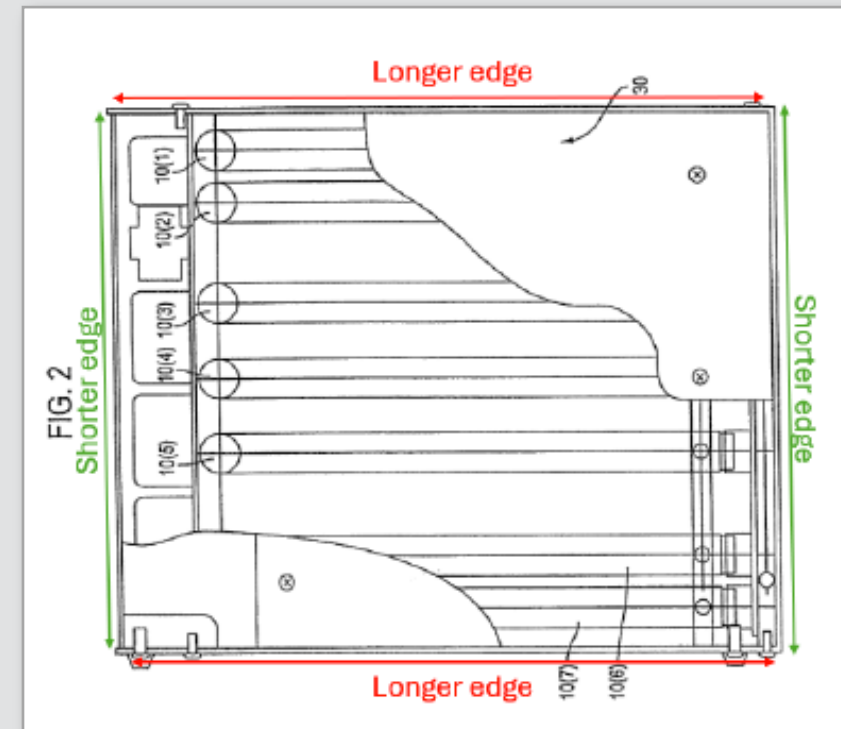
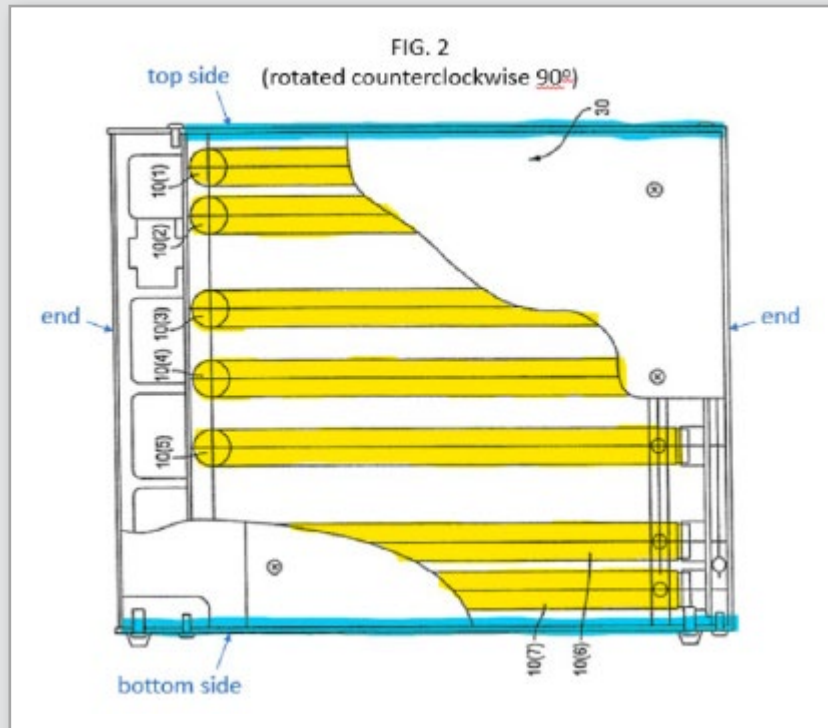
Lundahl + Larsen



Pet., 38-42, 45-49; EX1015, ¶¶173-179; POR, 34-38; EX2036, 151:17-152:6

2. Neither Lundahl Nor Larsen Teaches Or Suggest Higher Intensity "Proximate The Second Edges"

- Lundahl's panel has the fluorescent tubes more closely spaced at the ***longer edges***, not the ***shorter edges***



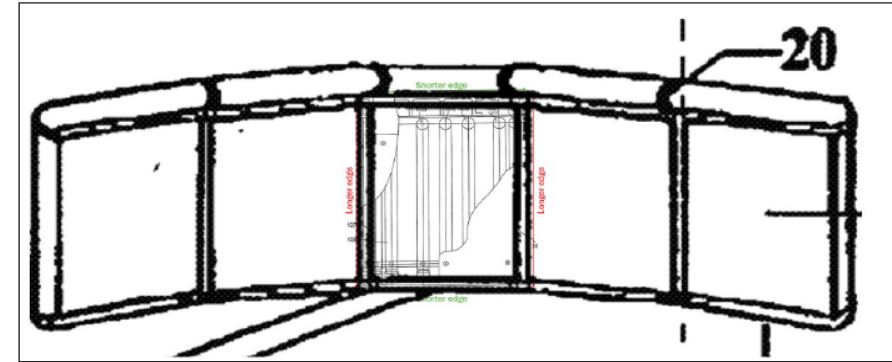
EX1014, FIG. 2, 6:10-22; POR, 42-47

2. Proposed Combination Would “Yield[] A Higher Intensity Of Light On The Longer Edges Of Each Panel” – Not “Proximate The Second Edges”

- ALJ agreed that the combination “requires improper hindsight”



It is undisputed that neither Larson nor Lundahl teaches the full limitation. Instead, Biofrontera argues that Lundahl teaches “arranging light sources in a higher density near the top and bottom edges of its device” and applies that to each of Larsen’s panels. RIB at 57. However, the “top and bottom edges” that Biofrontera alleges emit a higher intensity of light, are the longer edges, not the shorter second edges, as required by the claims. CX-0014C (Jokerst RWS) at Q/A 249-55. Applying Lundahl’s light distribution to Larsen’s five panels yields a higher intensity of light on the longer edges of each panel. CX-0014C (Jokerst RWS) at Q/A 258-59.

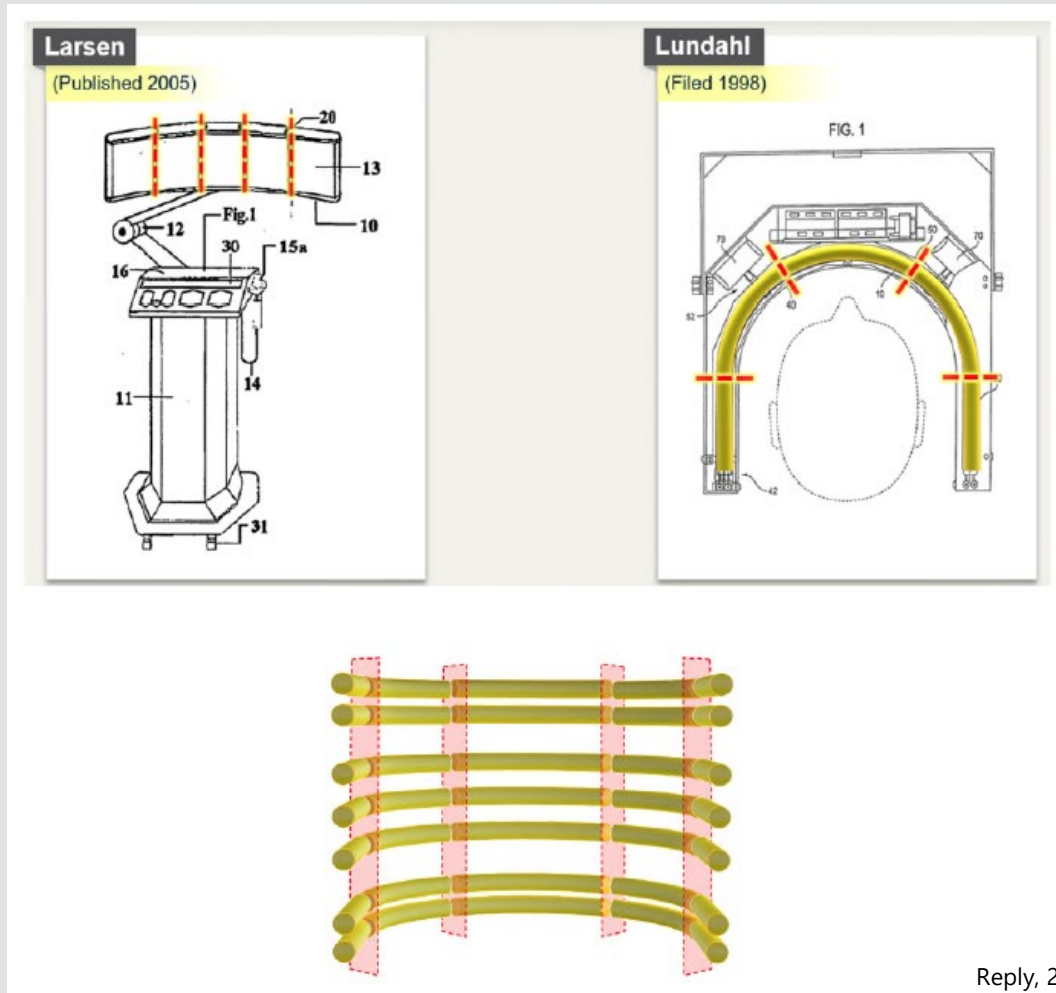


Biofrontera asserts that Lundahl discloses “a higher intensity of light is emitted proximate the second [shorter] edges,” because Sun asserted the RhodoLED®-XL met this claim limitation. RIB at 57 n.6. As discussed above, the LED spacing of the RhodoLED®-XL is very different. Moreover, Biofrontera is wrong to rely on the spacing in Figure 2 of Lundahl because that is not the spacing that provides Lundahl’s uniformity—Figure 2’s distances between the three center tubes are not evenly spaced. CX-0014C (Jokerst RWS) at Q/A 279. The specification’s precise measurements lead to uniformity. RX-0065 at 6:16-30, 6:43-45. They are not only “exemplary values” as argued by Biofrontera. CX-0014C (Jokerst RWS) at Q/A 142. In sum, Biofrontera’s reading of Lundahl requires improper hindsight, and, thus, “cannot constitute clear and convincing evidence of invalidity.” *Zenith Elecs. Corp. v. PDI Comm’n Sys., Inc.*, 522 F.3d 1348, 1363 (Fed. Cir. 2008).

EX2090, 109-110; Paper 42, 5-6

3. Proposed Combination Does Not Meet Higher Intensity “Proximate The Second Edges” In “Each Of the Five Panels”

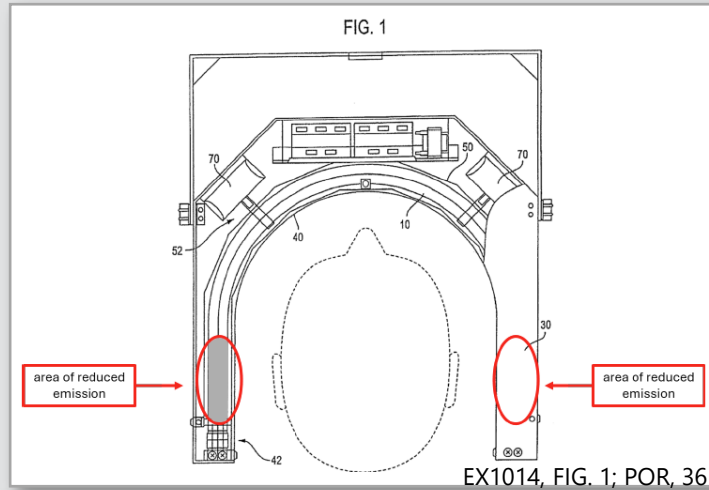
- Petitioner proposed breaking up Lundahl’s single panel into five discrete panels



Reply, 20

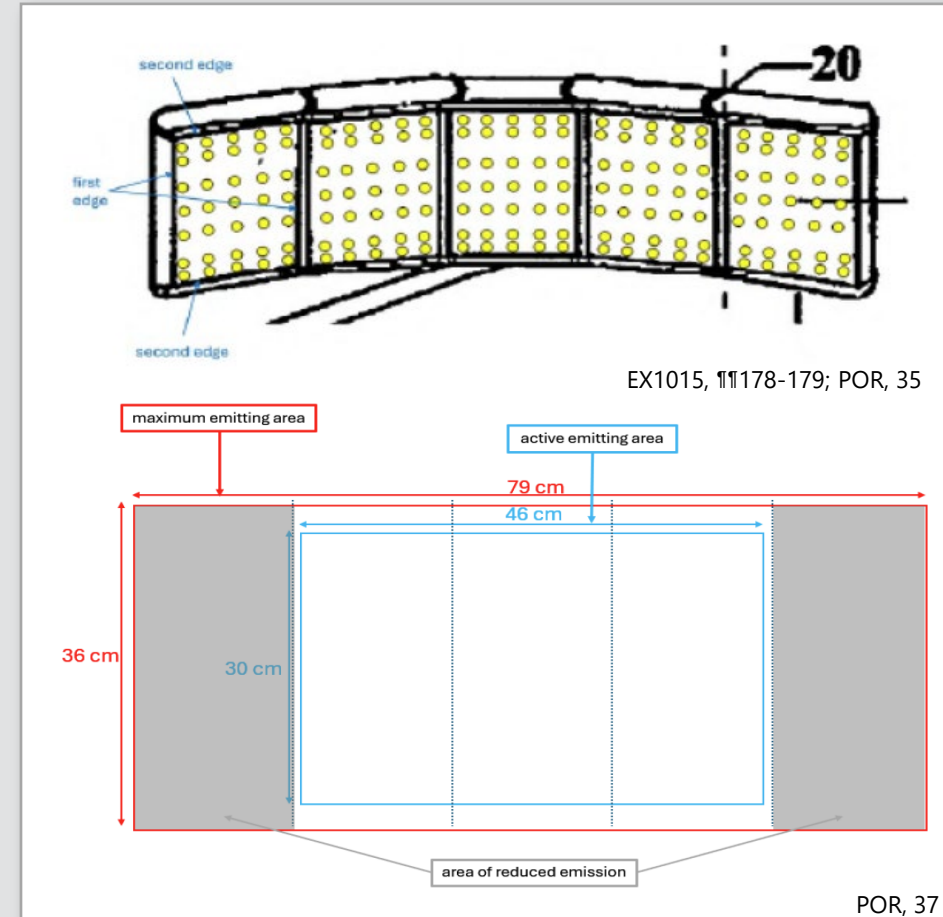
3. Proposed Combination Does Not Meet Higher Intensity “Proximate The Second Edges” In “Each Of the Five Panels”

- Even in the proposed combination, the two outermost panels would have reduced emission compared to the active emitting area



The output from a fluorescent tube is not inherently 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 near the cathode does not emit as much UV to excite the phosphor. This area of reduced emission is known as the Faraday dark space. To avoid uniformity problems, one embodiment of the present invention utilizes a plurality of U-shaped tubes 10(1)–10(7). This arrangement allows the cathodes and their low output area to be located outside the active emitting area (effectively behind the patient's ears).

EX1014, 6:10-22; POR, 35



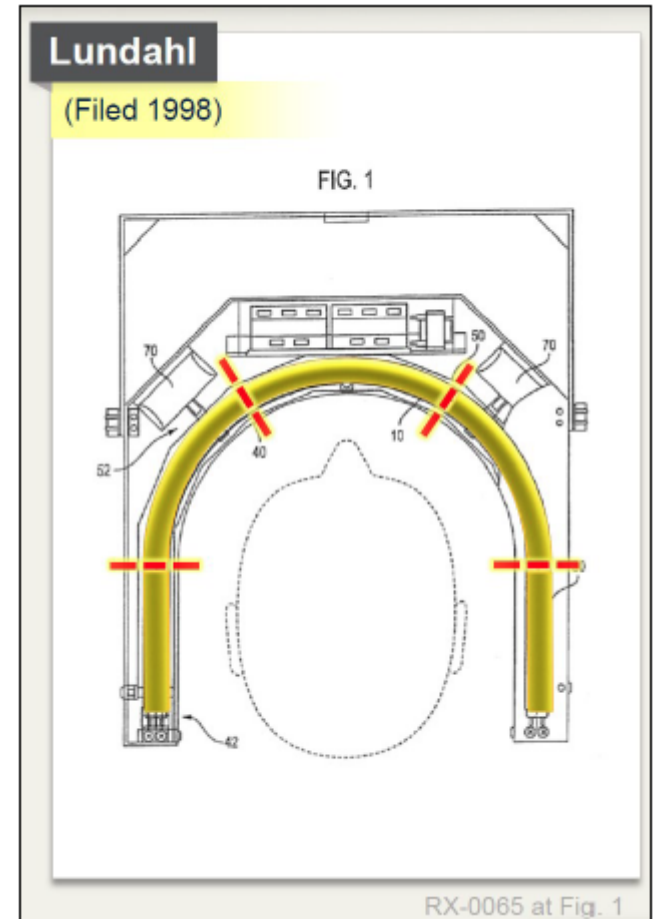
EX1014, FIGS. 1, 4A, 6:10-22, 5:38-46; EX2037; EX2036, 151:17-152:6; POR, 34-38; Sur-Reply, 20-21

3. Proposed Combination Does Not Meet Higher Intensity “Proximate The Second Edges” In “Each Of the Five Panels”



Biofrontera asserts Lundahl would be broken up into five panels, including the straight arms on the left and right:

RIB at 60. But Lundahl’s curved center is the only portion with higher intensity at the top and bottom as “[o]nly the more uniform center portion of the tube output is used for patient treatment.” RX-0065 at 6:10-22. Nor is this just a matter of tube spacing, as Lundahl tuned the cooling system to increase output in the “generally arcuate region.” *Id.* at 3:8-21. Biofrontera cites Dr. Jokerst’s testimony explaining this point. Tr. (Jokerst) at 740:25-741:5 (answering Lundahl teaches a higher intensity, “in the curved region, which would be near the forehead and chin...”); CX-0014C (Jokerst RWS) at Q/A 256-60, 270-71. Combining Lundahl’s light distribution with Larsen’s five panels yields higher intensity at the shorter edges only in the center of the device, not on each of the five panels. CX-0014C (Jokerst RWS) at Q/A 262-72; CX-1053C; Tr. (Jokerst) at 750:21-752:9.



The Disputed Issues

- 1 Combination does not meet required uniform illumination
- 2 No higher intensity of light emitted near the shorter edges of each panel
- 3 No hinged structures on the inner side surfaces
- 4 Each panel's light output is not individually configurable
- 5 Combination does not produce continuous illumination
- 6 Objective indicia of non-obviousness confirm inventiveness

No “Hinged Structures *On The Inner Side Surfaces*”

1. A system for photodynamically diagnosing or treating a patient, comprising:
an illuminator comprising five panels connected by hinged structures on inner side surfaces of adjacent panels; and
light sources disposed on surfaces of the five panels, the illuminator being configured to uniformly illuminate a treatment surface of the patient via the light sources, one of the five panels being positioned as a center panel configured to face the treatment surface, and two or more of the five panels being configured to be angled relative to the center panel,
wherein the five panels are positioned to allow treatment within approximately four inches of the treatment surface, and
wherein each of the five panels has two first edges and two second edges shorter than the two first edges, and the light sources are arranged such that a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges.

EX1001, claim 1

5. A method of photodynamically diagnosing or treating a patient, comprising:
administering 5-aminolevulinic acid (ALA) to the patient;
positioning an illuminator proximate to the patient, the illuminator comprising five panels connected by hinged structures on inner side surfaces of adjacent panels; and
uniformly illuminating a treatment surface of the patient with light sources disposed on the five panels of the illuminator, the five panels being positioned to allow treatment within approximately four inches of the treatment surface,
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.

EX1001, claim 5

16. A system for photodynamically diagnosing or treating a patient, comprising:
a mobile base supported by at least four wheels;
a pillar perpendicular to the base;
a controller disposed to be supported by the pillar;
an arm mounted to a top portion of the pillar; and
an illuminator connected at an end of the arm, the arm being hinged to allow adjustment of a position of the illuminator relative to the base, the illuminator comprising:
five panels connected by hinged structures to allow continuous illumination across the five panels, wherein the five panels are individually configurable to control illumination from each of the five panels,
light sources disposed on surfaces of the five panels, the illuminator being configured to uniformly illuminate a treatment surface of the patient via the light sources, the light sources being configured to output light uniformly during at least part of a time when the treatment surface is illuminated, each of the five panels having two first edges and two second edges shorter than the two first edges, the light sources arranged such that a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges, and
one or more fans mounted to at least one of the five panels.

EX1001, claim 16

No “Hinged Structures *On The Inner Side Surfaces*”

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

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

light sources disposed on surfaces of the five panels, the illuminator being configured to uniformly illuminate a treatment surface of the patient via the light sources, one of the five panels being positioned as a center panel configured to face the treatment surface, and two or more of the five panels being configured to be angled relative to the center panel,

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

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

EX1001, claim 20

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

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

light sources disposed on surfaces of the five panels, the illuminator being configured to uniformly illuminate a treatment surface of the patient via the light sources, one of the five panels being positioned as a center panel configured to face the treatment surface, and two or more of the five panels being configured to be angled relative to the center panel,

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

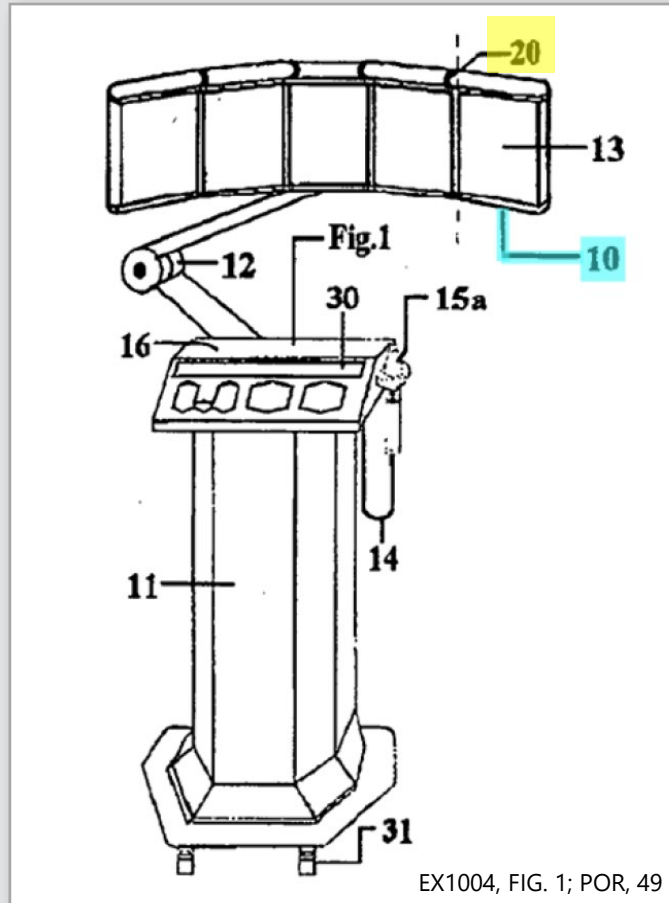
wherein the five panels are individually configurable to control illumination from each of the five panels, and

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

EX1001, claim 21

Larsen Discloses Hinges 10 Only At The Bottom Of Adjacent Panels

- Petition argues hinges are shown as **element 20** in Figure 1
- Figure 1 shows **hinges 10** on the bottom of the panel – ***not the inner side surface***



Petition

Larsen discloses that “several applicators 13 are flexibly connected to each other through hinges” (the hinges are indicated as **element 10** in the specification, but shown as **element 20** in Figure 1). Ex.1004, [0072]. As shown in Figure 1, the

[0072] For the treatment of large-area tissues according to **FIG. 1**, several applicators **13** are flexibly connected to each other through **hinges 10**, respectively connecting one edge with the other, whereby the applicators are suitable for the treatment of for example, the backs of humans and so become adjustable for an equidistant positioning of the applicators **13** above the skin.

"Hinges 10" Is Not A Typo And Element 20 Is the Regular Row Arrangement Of Light Sources

- Dr. Grove contradicts Petitioner's argument that hinges "are shown as element 20 in Figure 1"



Dr. Grove
Petitioner's Expert

Q: So paragraph 71 says (as read):
According to Figures 2b and 2c the light sources 17 are placed in regular row arrangements, i.e., 20 equidistant from each other. Do you see that?

A: Yes, I do.

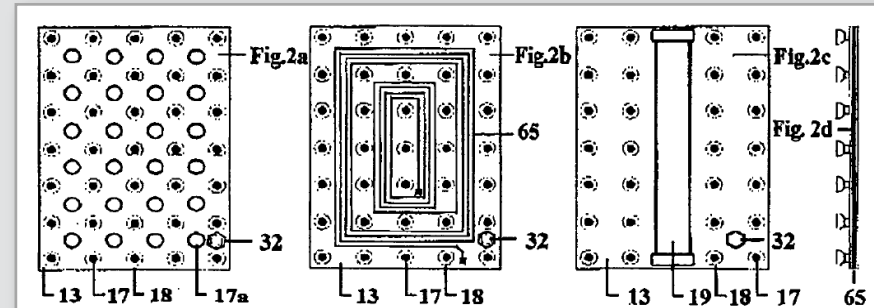
Q: And that sentence is referring to Figure 2b, correct?

A: ...It's not clear to me what 20 is referring to, unless it's simply referring to rows of light sources. In which case if it's referring to rows of light sources as is shown in, for example, Figure 2a, then I understand what 20 means.

EX2084, 143:18-144:15; POR, 50

Petition

Larsen discloses that "several applicators 13 are flexibly connected to each other through hinges" (the hinges are indicated as element 10 in the specification, but shown as element 20 in Figure 1). Ex.1004, [0072]. As shown in Figure 1, the



[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 applicator 13, in addition to the diodes 17, has a light source 19.

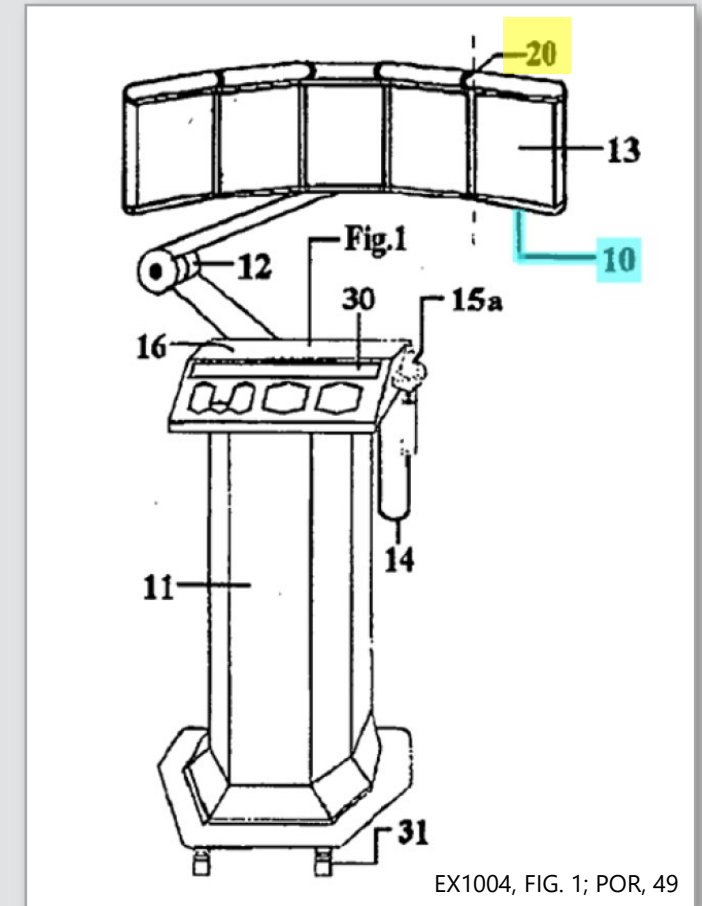
EX1004, FIG. 2a-d, [0071]; Pet., 36-37; POR, 49-52; Sur-Reply, 2-3

Larsen Discloses Hinges 10 Only At The Bottom Of Adjacent Panels



I find that Larsen does not disclose or render obvious the claimed hinges. CX-0014C (Jokerst RWS) at Q/A 196, 231. As an initial matter, 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 at [0072]; CX-0014C (Jokerst RWS) at Q/A 197. 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 (Jokerst RWS) at Q/A 197-98.

EX2090, 94; Paper 42, 7



"Hinges 10" Is Not A Typo And Element 20 Is the Regular Row Arrangement Of Light Sources



Contrary to Biofrontera's arguments, element 20

refers not to the location "between the panels." Rather, it is the location of the "regular row arrangement" of light sources, which are "mounted in" the applicators 13. CX-0014C (Jokerst RWS) at Q/A 159, 197-201. While Dr. Jokerst agreed there is no label "20" in Figures 2b-c, a skilled artisan would not expect there to be because Figure 1's dotted line indicates a more detailed view shown in those figures. RX-0057 at [0041] (Figs. 2a-2d "illustrate details of the machine applicator"); CX-0014C (Jokerst RWS) at Q/A 225-30. Figure 2d shows a cross-sectional view with the light sources "in regular row arrangements, i.e., 20." *Id.* Figures 2a-2d are reproduced below.

EX2090, 97; Paper 42, 7-8



In sum, I find that there is no persuasive evidence that one of ordinary skill would recognize the label "10" as a typographical error and disregard it and mentally "correct" Larsen by assuming label "20" refers to the location of the hinges as on the inner side surface of the panel.

My conclusion is further supported especially given that Dr. Grove admitted that "Larsen does not describe in any detail the hinges..." Tr. (Grove) at 563:1-20, and "Hente does not disclose hinges in any detail," Tr. (Grove) at 585:8-12.

EX2090, 99; Paper 42, 8

Petitioners Backup Obviousness Argument Is Not Supported By Evidence

- Petitioner does not identify a single reference demonstrating “hinged structure on inner side surfaces of adjacent panels” was known in the art
 - Petitioner cites only Dr. Grove’s declaration that verbatim regurgitates the Petition
 - Will address Petitioner’s improper attempts to further expand on this in our MTEE

Even if the Board determines that Larsen’s hinges are not expressly (or inherently) disclosed on the inner side surfaces of the panels, POSITA would have found it obvious and would have been motivated with a reasonable expectation of success to locate Larsen’s hinges on the inner side surfaces of adjacent panels.

Ex.1015, ¶154. First, Figure 1 of Larsen shows that the inner edges of each of the panels (13) are nearly flush with each other. This disclosure would have motivated POSITA to place the hinges on the inner side surfaces of Larsen’s panels in order to facilitate this nearly flush arrangement. *Id.* Such a modification would have involved

nothing more than the use of a known prior art element according to known methods to yield predictable results. *Id.* Second, there were finite number of known, predictable solutions for Larsen’s panels to be “flexibly connected to each other through hinges,” and POSITA would have found it obvious to try placing the hinges on the inner side surfaces of the panels. *Id.* And POSITA would have had a reasonable expectation of success, since POSITA would have known that hinges located on the inside surfaces of the applicator would allow them to be positioned in a nearly flush arrangement as shown in Figure 1. Ex.1015, ¶¶154-155.

Thus, Larsen teaches the limitations of claim 1(a). Ex.1015, ¶156.

Pet., 37-38

Pet., 37-38 ; POR, 53-56; Sur-Reply, 3-5

Petitioners Backup Obviousness Argument Is Not Supported By Evidence



back of the panels.” CX-0014C (Jokerst RWS) at Q/A 236. Biofrontera fails to identify a single illuminator with hinges on inner side surfaces of panels—the only references of record with that arrangement are the Asserted Patents. Before 2015, persons of ordinary skill designing PDT illuminators to output uniform light were discouraged from placing hinge between the LED panels because that arrangement was thought to negatively impact the illuminator’s uniformity by creating gaps between the panels, interfering with the panels’ wiring, and causing panel alignment issues. CX-0014C (Jokerst RWS) at Q/A 233-37; Tr. (Jokerst) at 765:3-25; JX-0008C (Luebbert Dep. Tr.) at 82:7-11, 84:10-86:9; *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).

EX2090, 100; Paper 42, 8

A POSITA Would Have Been Discouraged From Putting Hinges 10 On Inner Side Surfaces Of Adjacent Panels



Biofrontera also argues that there are only a “finite number of identified, predictable solutions” for connecting panels that make this limitation obvious. RIB at 44-45. However, Dr. Jokerst testified that “[a] person of ordinary skill would have understood that there were numerous designs to connect the panels of a PDT device flexibly, including without hinges or with different hinge designs, including overlay hinges, strap hinges, and knife hinges, on the top, bottom, and back of the panels.” CX-0014C (Jokerst RWS) at Q/A 236. Biofrontera fails to identify a single illuminator with hinges on inner side surfaces of panels—the only references of record with that arrangement are the Asserted Patents. Before 2015, persons of ordinary skill designing PDT illuminators to output uniform light were discouraged from placing hinge between the LED panels because that arrangement was thought to negatively impact the illuminator’s uniformity by creating gaps between the panels, interfering with the panels’ wiring, and causing panel alignment issues. CX-0014C (Jokerst RWS) at Q/A 233-37; Tr. (Jokerst) at 765:3-25; JX-0008C (Luebbert Dep. Tr.) at 82:7-11, 84:10-86:9; *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).

EX2090, 100-101; Paper 42, 8

The Disputed Issues

- 1 Combination does not meet required uniform illumination
- 2 No higher intensity of light emitted near the shorter edges of each panel
- 3 No hinged structures on the inner side surfaces
- 4 Each panel's light output is **not individually configurable**
- 5 Combination does not produce continuous illumination
- 6 Objective indicia of non-obviousness confirm inventiveness

"Individually Configurable" Recited In Claims 16, 17, 19, And 21

1. A system for photodynamically diagnosing or treating a patient, comprising:
an illuminator comprising five panels connected by hinged structures on inner side surfaces of adjacent panels; and
light sources disposed on surfaces of the five panels, the illuminator being configured to uniformly illuminate a treatment surface of the patient via the light sources, one of the five panels being positioned as a center panel configured to face the treatment surface, and two or more of the five panels being configured to be angled relative to the center panel,
wherein the five panels are positioned to allow treatment within approximately four inches of the treatment surface, and
wherein each of the five panels has two first edges and two second edges shorter than the two first edges, and the light sources are arranged such that a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges.

EX1001, claim 1

5. A method of photodynamically diagnosing or treating a patient, comprising:
administering 5-aminolevulinic acid (ALA) to the patient;
positioning an illuminator proximate to the patient, the illuminator comprising five panels connected by hinged structures on inner side surfaces of adjacent panels; and
uniformly illuminating a treatment surface of the patient with light sources disposed on the five panels of the illuminator, the five panels being positioned to allow treatment within approximately four inches of the treatment surface,
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.

EX1001, claim 5

16. A system for photodynamically diagnosing or treating a patient, comprising:
a mobile base supported by at least four wheels;
a pillar perpendicular to the base;
a controller disposed to be supported by the pillar;
an arm mounted to a top portion of the pillar; and
an illuminator connected at an end of the arm, the arm being hinged to allow adjustment of a position of the illuminator relative to the base, the illuminator comprising:
five panels connected by hinged structures to allow continuous illumination across the five panels, wherein the five panels are individually configurable to control illumination from each of the five panels,
light sources disposed on surfaces of the five panels, the illuminator being configured to uniformly illuminate a treatment surface of the patient via the light sources, the light sources being configured to output light uniformly during at least part of a time when the treatment surface is illuminated, each of the five panels having two first edges and two second edges shorter than the two first edges, the light sources arranged such that a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges, and
one or more fans mounted to at least one of the five panels.

EX1001, claim 16

"Individually Configurable" Recited In Claims 16, 17, 19, And 21

20. A system for photodynamically diagnosing or treating a patient, comprising:
an illuminator comprising five panels connected by hinged structures on inner side surfaces of adjacent panels, wherein the illuminator is configured to output light at a variable irradiance density during treatment; and
light sources disposed on surfaces of the five panels, the illuminator being configured to uniformly illuminate a treatment surface of the patient via the light sources, one of the five panels being positioned as a center panel configured to face the treatment surface, and two or more of the five panels being configured to be angled relative to the center panel,
wherein the five panels are positioned to allow treatment within approximately four inches of the treatment surface, and
wherein each of the five panels has two first edges and two second edges shorter than the two first edges, and the light sources are arranged such that a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges.

EX1001, claim 20

21. A system for photodynamically diagnosing or treating a patient, comprising:
an illuminator comprising five panels connected by hinged structures on inner side surfaces of adjacent panels; and
light sources disposed on surfaces of the five panels, the illuminator being configured to uniformly illuminate a treatment surface of the patient via the light sources, one of the five panels being positioned as a center panel configured to face the treatment surface, and two or more of the five panels being configured to be angled relative to the center panel,
wherein the five panels are positioned to allow treatment within approximately four inches of the treatment surface,
wherein the five panels are individually configurable to control illumination from each of the five panels, and
wherein each of the five panels has two first edges and two second edges shorter than the two first edges, and the light sources are arranged such that a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges.

EX1001, claim 21

Petition Did Not Propose Any Claim Construction: Took “A View ... Consistent With Patent Owner’s Infringement Allegations”

- Petition never proposed a construction for “the five panels are individually configurable to control illumination from each of the five panels,” but “t[ook] a view ... consistent with Patent Owner’s infringement allegations”
- ALJ construed the term as “the power output and/or light intensity of each panel can be individually controlled”

D. Claim Construction

For the purposes of this IPR, Petitioner has taken a view of the scope of the claims consistent with Patent Owner’s infringement allegations. See e.g., Ex.1019.

In view of Patent Owner’s infringement allegations, Petitioner does not believe any term needs to be construed to determine the claims are rendered obvious over the prior art cited herein. *Wellman, Inc. v. Eastman Chem. Co.*, 642 F.3d 1355, 1361 (Fed.Cir.2011) (“claim terms need only be construed to the extent necessary to resolve the controversy”) (internal quotations removed). Petitioner does not agree the accused products infringe the ’028 Patent and reserves the right to present its own interpretation of the claim scope of the ’028 Patent in the related ITC, district court litigation or later in this IPR proceeding, including claim scope that disagrees with Patent Owner’s infringement allegations and/or claim scope that fails to meet statutory requirements under 35 U.S.C. §112.

Pet., 12-13

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

EX2033, 35-40; POR, 18

construction). The Board should apply this same construction because Petitioner “[f]or purposes of this IPR” took a “view of the scope of the claims consistent with Patent Owner’s infringement allegations.” Petition, 12, 63-65. Larsen does not

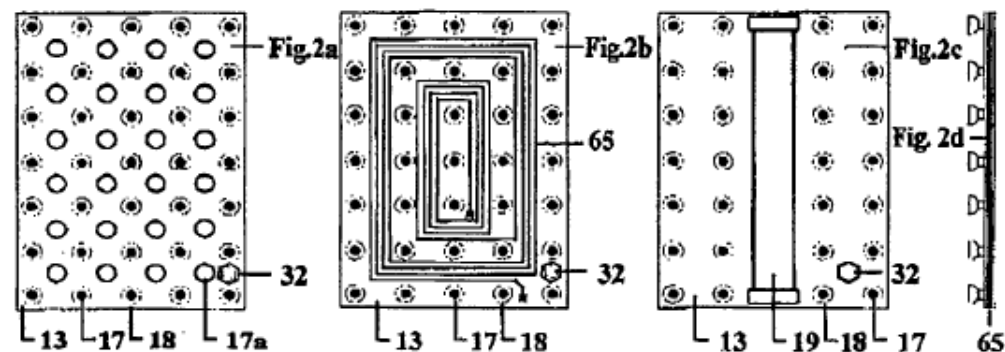
POR, 57

Larsen Does Not Disclose That Each Of The Five Panels Can Be Individually Configurable

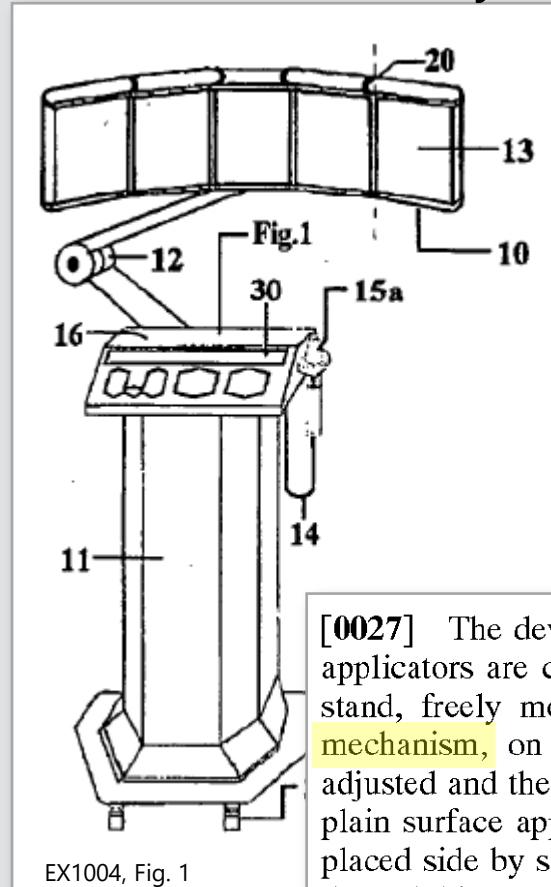
- Larsen discloses **printed circuit boards** can be used individually – but only a **single control mechanism 16** for the entire device

[0070] The FIGS. 2a, 2b and 2c show plain surfaced printed circuit boards with light sources mounted in the applicators 13. These 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. Furthermore the printed circuit boards on which the light sources are mounted can favourably be produced as multilayer, also containing the electromagnetic field transmitter coils 65 shown in FIG. 2d. According to FIG. 2a, the applicators 13

EX1004, [0070]



EX1004, Figs. 2a-d



EX1004, Fig. 1

[0027] The device consists of a stand, to which machine applicators are connected by means of a jointed arm. The stand, freely moveable on wheels, consists of a control mechanism, on which the desired therapy data can be adjusted and the device can be switched ON and OFF. The plain surface applicators can consist of several applicators placed side by side and flexibly connected with each other through hinges, whereby the applicators are suitable for the treatment of large-area tissues such as the human back.

EX1004, [0027]

POR, 57-63

Larsen Does Not Disclose That Each Of The Five Panels Can Be Individually Configurable

- Larsen discloses a ***single switch-select control mechanism*** that activates either semiconductor diodes or laser diodes ***across all panels, not*** controlling individual LEDs

[0074] With the help of the control mechanism 16, the invented device is adjustable within a relatively large range with reference to duration, amplitude and frequency of surge of current, so that the semiconductor diodes 17, 17a and 18, as well as laser 17 diodes with the same realisation as semiconductor diode 17, can be used as light sources. For that purpose the control mechanism is equipped with a switch select system for operating different types of semiconductor diodes 17 and/or with laser diodes.

EX1004, [0074]; POR, 59-61

1. A device for the (PDT) photodynamic therapy and electromagnetic field stimulation of light sensitive substances and human cells, comprising:

light sources with suitable strength, suitable wavelength, a light conductor, an applicator, an optic lens, a polarization filter, an electromagnetic field transmitter coil, and a control and power unit, characterized by the following:

the light source consists of at least one semiconductor diode and/or at least one laser diode,

5. A device according to claim 1, wherein the light sources are individually selected—switched ON or OFF.

EX1004, claims 1, 5; Sur-Reply, 24

EX1004, claim 5, [0074], [0079]; POR, 57-63; Sur-Reply, 23-25

Larsen Does Not Disclose That Each Of The Five Panels Can Be Individually Controlled



individual panels. CX-0014C (Jokerst RWS) at Q/A 436-37. “Individually” in claim 5 does not refer to panels, and Biofrontera has no support to show that the output from each panel can be individually controlled. *Id.* at Q/A 441. Moreover, Larsen states that “[w]ith the help of the control mechanism 16, the invented device is adjustable.” RX-0057 at [0074]. The entire device is adjustable, not that each of the five applicators is individually configurable to control illumination from each panel.

Biofrontera has not shown by clear and convincing evidence that Larsen discloses the individually configurable limitation.

EX2090, 115; Paper 42, 9-10

EX2011 Does Not Support That Larsen Discloses The “Individually Configurable” Limitation

- Petitioner’s attempt to rely on EX2011 fails
 - EX2011 does not relate to Larsen and is contrary to Larsen’s express disclosure of adjusting “the invented device” as a whole
 - EX2011 not part of Ground as presented in the Petition

An Introduction to Light-emitting Diodes

C. Michael Bourget

Orbital Technologies Corporation, Electrical Engineering, 1212 Fourier Drive, Madison, WI 53717

Additional index words. controlled environment, lighting, efficiency, fluorescent, HID, light source

Abstract. Light-emitting diodes (LEDs) are semiconductor devices that produce noncoherent, narrow-spectrum light when forward voltage is applied. LEDs range in wavelength from the UVC band to infrared (IR) and are available in packages ranging from milliwatts to more than 10 W. The first LED was an IR-emitting device and was patented in 1961. In 1962, the first practical visible spectrum LED was developed. The first high-power (1-W) LEDs were developed in the late 1990s. LEDs create light through a semiconductor process rather than with a superheated element, ionized gas, or an arc discharge as in traditional light sources. The wavelength of the light emitted is determined by the materials used to form the semiconductor junction. LEDs produce more light per electrical watt than incandescent lamps with the latest devices rivaling fluorescent tubes in energy efficiency. They are solid-state devices, which are much more robust than any glass-envelope lamp and contain no hazardous materials like fluorescent lamps. LEDs also have a much longer lifetime than incandescent, fluorescent, and high-density discharge lamps (U.S. Dept. of Energy). Although LEDs possess many advantages over traditional light sources, a total system approach must be considered when designing an LED-based lighting system. LEDs do not radiate heat directly, but do produce heat that must be removed to ensure maximum performance and lifetime. LEDs require a constant-current DC power source rather than a standard AC line voltage. Finally, because LEDs are directional light sources, external optics may be necessary to produce the desired light distribution. A properly designed LED light system is capable of providing performance and a lifetime well beyond any traditional lighting source.

Reply, 27; EX2011; Sur-Reply, 25

The Disputed Issues

- 1 Combination does not meet required uniform illumination
- 2 No higher intensity of light emitted near the shorter edges of each panel
- 3 No hinged structures on the inner side surfaces
- 4 Each panel's light output is not individually configurable
- 5 Combination does not produce **continuous illumination**
- 6 Objective indicia of non-obviousness confirm inventiveness

"Continuous Illumination" Recited In Claims 16, 17, And 19

1. A system for photodynamically diagnosing or treating a patient, comprising:
an illuminator comprising five panels connected by hinged structures on inner side surfaces of adjacent panels; and
light sources disposed on surfaces of the five panels, the illuminator being configured to uniformly illuminate a treatment surface of the patient via the light sources, one of the five panels being positioned as a center panel configured to face the treatment surface, and two or more of the five panels being configured to be angled relative to the center panel,
wherein the five panels are positioned to allow treatment within approximately four inches of the treatment surface, and
wherein each of the five panels has two first edges and two second edges shorter than the two first edges, and the light sources are arranged such that a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges.

EX1001, claim 1

5. A method of photodynamically diagnosing or treating a patient, comprising:
administering 5-aminolevulinic acid (ALA) to the patient;
positioning an illuminator proximate to the patient, the illuminator comprising five panels connected by hinged structures on inner side surfaces of adjacent panels; and
uniformly illuminating a treatment surface of the patient with light sources disposed on the five panels of the illuminator, the five panels being positioned to allow treatment within approximately four inches of the treatment surface,
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.

EX1001, claim 5

16. A system for photodynamically diagnosing or treating a patient, comprising:
a mobile base supported by at least four wheels;
a pillar perpendicular to the base;
a controller disposed to be supported by the pillar;
an arm mounted to a top portion of the pillar; and
an illuminator connected at an end of the arm, the arm being hinged to allow adjustment of a position of the illuminator relative to the base, the illuminator comprising:
five panels connected by hinged structures to allow continuous illumination across the five panels, wherein the five panels are individually configurable to control illumination from each of the five panels, light sources disposed on surfaces of the five panels, the illuminator being configured to uniformly illuminate a treatment surface of the patient via the light sources, the light sources being configured to output light uniformly during at least part of a time when the treatment surface is illuminated, each of the five panels having two first edges and two second edges shorter than the two first edges, the light sources arranged such that a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges, and
one or more fans mounted to at least one of the five panels.

EX1001, claim 16

"Continuous Illumination" Recited In Claims 16, 17, And 19

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

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

- light sources disposed on surfaces of the five panels, the illuminator being configured to uniformly illuminate a treatment surface of the patient via the light sources, one of the five panels being positioned as a center panel configured to face the treatment surface, and two or more of the five panels being configured to be angled relative to the center panel,

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

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

EX1001, claim 20

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

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

- light sources disposed on surfaces of the five panels, the illuminator being configured to uniformly illuminate a treatment surface of the patient via the light sources, one of the five panels being positioned as a center panel configured to face the treatment surface, and two or more of the five panels being configured to be angled relative to the center panel,

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

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

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

EX1001, claim 21

Petitioner's Expert Admitted That Larsen Does Not Provide **Continuous Illumination** Across The Five Panels

- Petitioner's own expert admitted that Larsen does not provide **continuous illumination** across the five panels.



Dr. Bretschneider
Petitioner's Expert

- There are "**lower irradiance regions at the junction of two of Larsen's panels.**"
- Larsen's 'scan engine can only move lights linearly in one direction at a time, **which would only decrease unirradiated gaps on the portion of the treatment surface towards which the light sources are being moved.**

Petitioner's Expert Admitted That Larsen Does Not Provide Continuous Illumination Across The Five Panels



Because “Larsen doesn’t provide a description of the physical structure of the hinges...,”

Tr. (Grove) at 563:1-23, Larsen cannot teach those hinges “allow continuous illumination across the five panels.” CX-0014C (Jokerst RWS) at Q/A 317-19. Moreover, Biofrontera’s expert confirmed Larsen cannot have “continuous illumination” because it has “lower irradiance regions at the junction of two of Larsen’s panels.” JX-0188.66.

EX2090, 102-103; Paper 42, 10

The Disputed Issues

- 1 Combination does not meet required uniform illumination
- 2 No higher intensity of light emitted near the shorter edges of each panel
- 3 No hinges on inner side surfaces
- 4 Each panel's light output is not individually configurable
- 5 Combination does not produce continuous illumination
- 6 Objective indicia of non-obviousness confirm inventiveness**

ALJ Moore Did Not Address Objective Indicia



Secondary considerations of nonobviousness may rebut a prima facie case of obviousness.

Merck Sharp & Dohme Corp. v. Hospira, Inc., 874 F.3d 724, 733 (Fed. Cir. 2017) (“[once it is established] a prima facie case [of obviousness is shown] we turn to [a party’s] attempt to rebut this prima facie case with secondary considerations of nonobviousness.”) (quoting *Muniauction, Inc. v. Thomson Corp.*, 532 F.3d 1318, 1327 (Fed. Cir. 2008)). Here, where Respondents have not made out a prima facie case of obviousness, there is no showing to rebut. Accordingly, I need not consider any secondary considerations of nonobviousness.

EX2090, 124; Paper 42, 1

There Is Nexus Between The 028 Patent Claims And The Commercial Success of The RhodoLED® -XL

- Because the RhodoLED® -XL is coextensive with the Challenged Claims, a presumption of nexus applies.



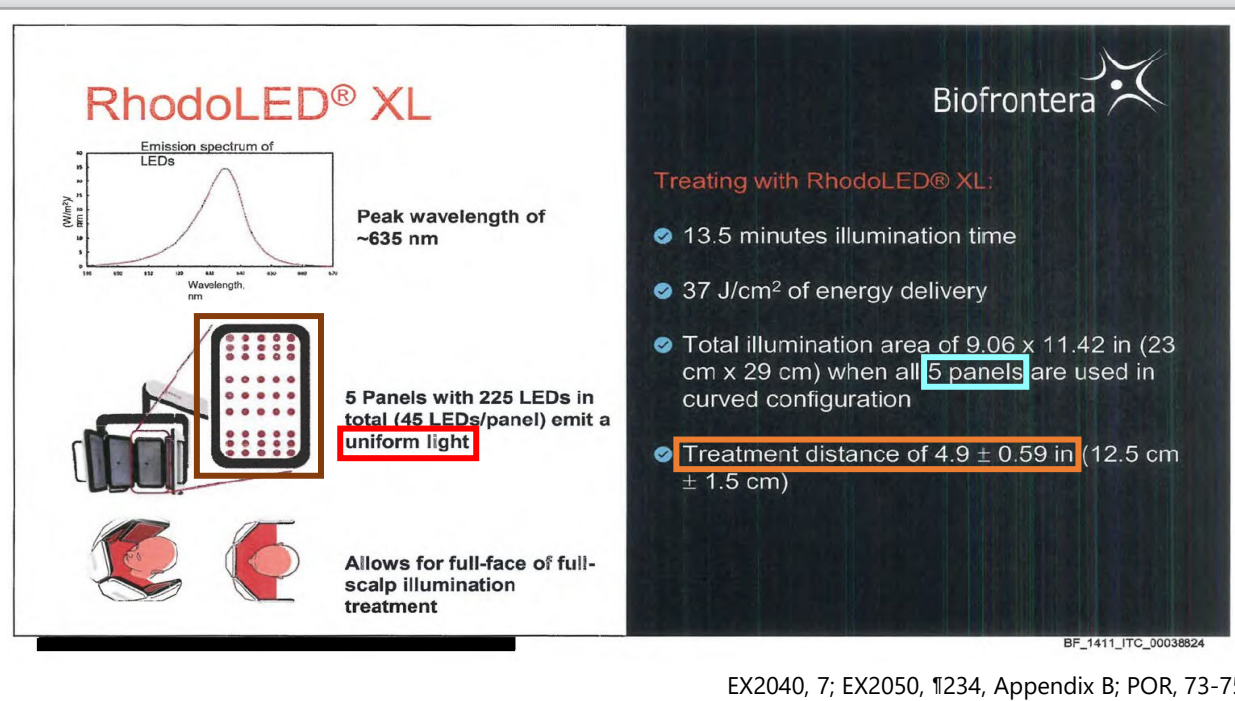
***WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1329-30 (Fed. Cir. 2016).**

“there is a presumption of nexus for objective considerations when the patentee shows that the asserted objective evidence is tied to a specific product and that product ‘is the invention disclosed and claimed in the patent.’”

The RhodoLED® -XL Is Coextensive With The Claims Of The '028 Patent

1. A system for photodynamically diagnosing or treating a patient, comprising:
 an illuminator comprising five panels connected by hinged structures on inner side surfaces of adjacent panels; and
 light sources disposed on surfaces of the five panels, the illuminator being configured to uniformly illuminate a treatment surface of the patient via the light sources, one of the five panels being positioned as a center panel configured to face the treatment surface, and two or more of the five panels being configured to be angled relative to the center panel,
 wherein the five panels are positioned to allow treatment within approximately four inches of the treatment surface, and
 wherein each of the five panels has two first edges and two second edges shorter than the two first edges, and the light sources are arranged such that a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges.

EX1001, claim 1



EX2040, 7; EX2050, 1234, Appendix B; POR, 73-75

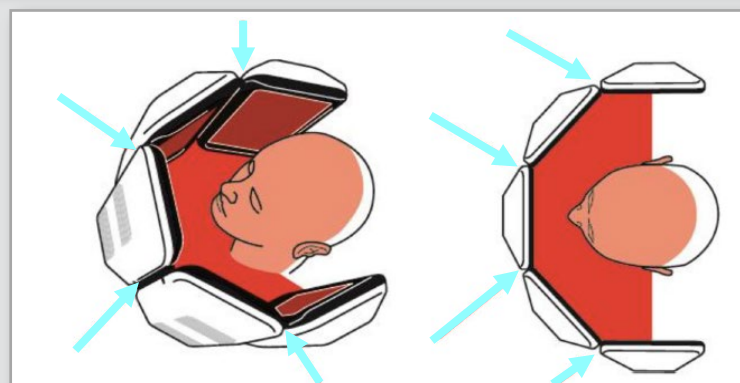


Figure 13: Treatment area of RhodoLED® XL from the side and in top view.

EX2043, Fig. 13; EX2050, Appendix B; POR, 73-75

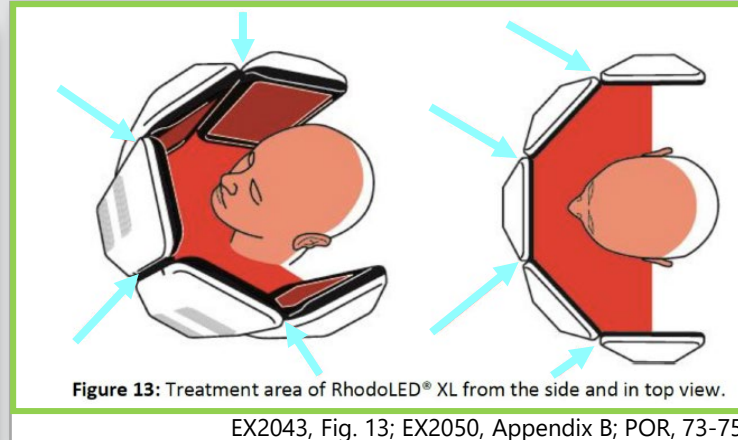
The RhodoLED® -XL Is Coextensive With The Claims Of The '028 Patent

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

a mobile base supported by at least four wheels;
a pillar perpendicular to the base;
a controller disposed to be supported by the pillar;
an arm mounted to a top portion of the pillar;
and an illuminator connected at an end of the arm, the arm being hinged to allow adjustment of a position of the illuminator relative to the base, the illuminator comprising:

five panels connected by hinged structures to allow continuous illumination across the five panels, wherein the five panels are individually configurable to control illumination from each of the five panels, light sources disposed on surfaces of the five panels, the illuminator being configured to uniformly illuminate a treatment surface of the patient via the light sources, the light sources being configured to output light uniformly during at least part of a time when the treatment surface is illuminated, each of the five panels having two first edges and two second edges shorter than the two first edges, the light sources arranged such that a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges, and one or more fans mounted to at least one of the five panels.

EX1001 ('028 Patent), claim 16



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)

EX2043, 16; EX2050, ¶1, Appendix B; POR, 73-75

Biofrontera Markets the RhodoLED® -XL By Emphasizing The Claimed Features



Mark Baldyga
Petitioner's VP

Q: And another one of the features that was advertised with the customer was that the RhodoLED XL includes five panels with this particular LED arrangement that we see here; right?

A: Right.

Q: And those panels in a **uniformed light**, that's also one of the points you communicated to the customer; right?

A: Right.

EX2039, 45:7-15; POR, 74, 77

RhodoLED® XL

Emission spectrum of LEDs

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:

- ✓ 13.5 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)

BF_1411_ITC_00038824

EX2040, 7; EX2050, 11234, Appendix B; POR, 73-75

Outline

A Industry Praise

B Commercial Success

The Patented Features Of The '028 Patent Have Received Industry Praise

“

The RhodoLED® XL should be the lamp of choice for PDT, as it will be a great improvement for patients, in my opinion. The RhodoLED® XL multi-panel lamp head fits nicely over a patient's face or scalp for the short treatment, while providing better coverage. Overall, it will offer a better experience for both the patient and the healthcare provider.

— Ted Lain, MD, MBA —

”



EX2042, 4; POR, 77; Sur-Reply, 27

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 satisfaction among both staff and patients with the outcomes of using Ameluz PDT in conjunction with the RhodoLED XL. “Additionally, the Biofrontera team made the purchase and transition to the XL an entirely seamless process for us,” he added.

EX2046, 1; POR, 73, 75-77; Sur-Reply, 27, 29

Outline

A Industry Praise

B Commercial Success

The RhodoLED® -XL Is Commercially Successful

Reported record total revenues of \$37.3 million for 2024, reflecting a 9.5% increase from \$34.1 million in 2023 with Q4 2024 growing 18.5% over Q4 2023. The growth was primarily driven by increases in Ameluz® sales volume and unit price, and the successful launch of our RhodoLED® XL Lamp.

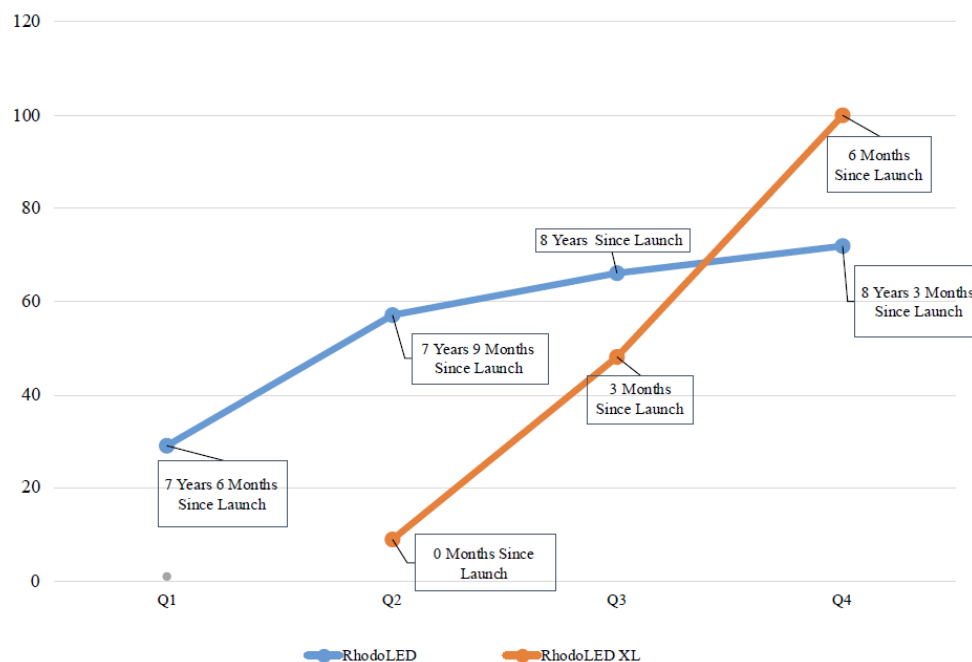
EX2047, 1; POR, 73, 76; Sur-Reply, 28

RhodoLED®



EX2056, 2; POR, 73

2024 Cumulative Sales Units of RhodoLED® and RhodoLED® XL



EX2048, ¶¶27-33; POR, 76

RhodoLED® -XL



EX2041, 5; POR, 74

EX2049, ¶¶10-12; EX2039, 56:19-57:4, 91:2-10, 114:20-22; EX2078, 1; EX2045, 1; EX2046, 1; EX2064, 1; EX2066, 3, 8; EX2067, 3; EX2068, 2; EX2069, 1-2; EX2070-EX2077; EX2048, ¶¶27-36; POR, 72-77; Sur-Reply, 28-29

The RhodoLED® -XL Is Commercially Successful



Hermann Luebbert
Petitioner's CEO

I am pleased with \$37.3 million in sales in 2024. This represents an annual sales growth of 18.5% for Q4 and almost 10% for the entire year and is a record for our company. We strongly believe our past investments, business plan, and execution will allow us to achieve another record year in 2025.

The year included some further milestones that we are very pleased with. First and foremost, we placed 52 RhodoLED XL lamps in the first quarter -- fourth quarter alone and 100 between the launch in June 2024 and the end of 2024. Providing a larger PDT lamp to our customers is an important milestone in our overall strategy to extend the use of Ameluz PDT for treating mild to moderate actinic keratosis on the face and scalp and potentially further indications in the future that are currently in development.

EX2057, 3; POR, 73, 75-76; Sur-Reply, 28

EX2049, ¶¶10-12; EX2039, 56:19-57:4, 91:2-10, 114:20-22; EX2078, 1; EX2045, 1; EX2046, 1; EX2064, 1; EX2066, 3, 8; EX2067, 3; EX2068, 2; EX2069, 1-2; EX2070-EX2077; EX2048, ¶¶27-36; POR, 72-77; Sur-Reply, 28-29

Outline

- A** Overview of the '028 Patent
- B** Overview of the Prior Art
- C** Disputed Issues
- D** Motion to Exclude Evidence

Legal Standard

- New opinion testimony absent from the Petition should be excluded



***Wasica Finance GmbH v. Continental Automotive Systems, Inc.*, 853 F.3d 1272, 1286–87 (Fed. Cir. 2017)**

“After Wasica pointed out the flaws of this position, Continental’s ensuing arguments to the Board and to us effectively abandoned its petition in favor of a new argument. ... Continental’s subsequent arguments amount to an ***entirely new theory*** of prima facie obviousness ***absent from the petition***. Shifting arguments in this fashion is foreclosed by statute, our precedent, and Board guidelines.”



***Interactive Communications International, Inc. v. Blackhawk Network Inc.*, IPR2023-01235, Paper 34 (PTAB 2025)**

Granting Patent Owner’s Motion to Exclude portions of Petitioner’s expert’s supplementary declaration submitted with Petitioner’s Reply because Petitioner’s expert presented ***new opinions*** regarding obviousness, ***the knowledge of a POSITA***, and reasonable expectation of success that ***were not presented in the original expert declaration*** or Petition.

Outline

A EX1026 (¶¶12-17 and 19)

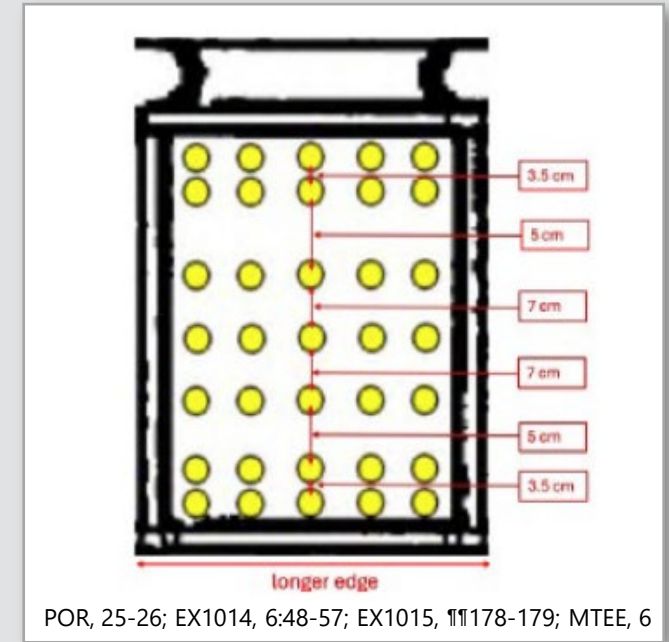
B EX1031 (591:5-7 and 592:2-8)

The New Opinion Paragraphs (Exhibit 1026) Should Be Excluded Under Federal Rule Of Evidence 403

- Petitioner initially relied on **Lundahl's "uneven spacing"** of light sources.

179. The annotated figure above demonstrates a rendering whereby the hinged panels and LEDs taught by Larsen are incorporated into the device of Lundahl, while maintaining the same light distribution pattern Lundahl utilized for the fluorescent bulbs, as shown in Fig. 2 above and the accompanying disclosure. A POSITA would have found it obvious and would have been motivated with a reasonable expectation of success to incorporate the uneven spacing of light sources of Lundahl to increase the intensity of light emitted from the second edges (e.g., extending along the top and bottom sides of the panel arrangement) of the panels of Larson compared to regions not proximate to the second edges.

EX1015, ¶179



Dr. Grove
Petitioner's Expert

Q: And you're saying that you are incorporating the uneven spacing of light sources of Lundahl, right? That's what you say you're doing?

A: Yes.

EX2084, 229:3-14; MTEE, 6-7

EX1015, ¶¶178-179; Pet., 46-49, MTEE, 3-10

Dr. Grove Introduces New Theories Because Patent Owner Highlighted The Flaws In His Obviousness Analysis

- Patent Owner pointed out that “applying Lundahl’s teaching of spacing would not result in the claimed **uniform illumination**.”

Dr. Grove also argues a POSITA would “*replace the fluorescent bulbs of Lundahl with LEDs*.” EX1015, ¶¶178, 129. But, replacing Lundahl’s diffuse fluorescent tube illuminators with discrete, point-source LEDs would also create gaps between the LEDs, impacting the uniformity. EX2050, ¶¶127, 38-48; EX2053, 100:22-101:15 (Mr. Boyajian explaining the difference between fluorescent tubes with “no gaps” and LEDs with “points of light” that “give an area that you can’t have light”). Dr. Grove states he “*incorporate[s] the uneven spacing of light sources of Lundahl*” in his alleged combination (EX1015, ¶¶178-179), but applying Lundahl’s teaching of spacing of the light sources to LEDs would not result in the claimed uniform illumination. EX2050, ¶127; Petition 47-48; EX1015, ¶¶176-177 (Dr. Grove relying on express teaching of Lundahl’s spacing); EX2036, 149:24-150:4 (Dr. Grove testifying he is relying on Lundahl’s spacing, not Larsen’s spacing).

POR, 24-25

POR, 24-25; MTEE, 3-10

The New Opinion Paragraphs (Exhibit 1026) Should Be Excluded Under Federal Rule Of Evidence 403

- Petitioner initially relied on **Lundahl's "uneven spacing"** of light sources.

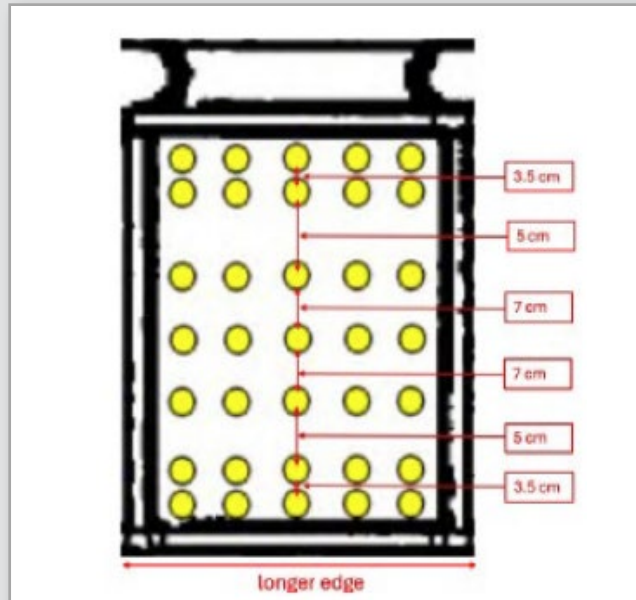
Q: And you're saying that you are incorporating the uneven spacing of light sources of Lundahl, right? That's what you say you're doing?

A: Yes.

EX2084, 229:3-14; MTEE, 6-7.



Dr. Grove
Petitioner's Expert



POR, 25-26; EX1014, 6:48-57; EX1015, ¶¶178-179; MTEE, 6.

- Dr. Grove added new opinion testimony (¶¶12-17 and 19 of EX1026) that a POSITA would have been able to modify the spacing of the LEDs in any manner to achieve the claimed **uniform illumination**:

15. In particular, as I discussed in my original declaration (EX1015), based on the teachings of Lundahl and Larsen, a POSA would be motivated to replace the fluorescent tubes of Lundahl with the LEDs taught by Larsen for a number of reasons. EX1015, ¶¶129-131. As described by Dr. Jokerst, fluorescent tubes are a continuous light source, as illustrated below:

EX2050, ¶45. Thus, knowing that this continuous light source was being replaced by discrete LEDs, a POSA would simply ensure that the divergence angles of the adjacent LEDs overlap at the desired treatment distance to ensure no "gaps" between the light emission of the individual LEDs. As I have illustrated below, it is a simple process of replacing the fluorescent tube with discrete LEDs, ensuring overlap of adjacent divergence angles at a distance from the treatment surface of a minimum of two inches¹:

EX1026, ¶15

EX1015, ¶¶178-179; EX1026, ¶¶12-17, 19; Reply, 10-15; MTEE, 3-10

The New Opinion Paragraphs (Exhibit 1026) Should Be Excluded Under Federal Rule Of Evidence 403

12. The description of Lambertian light output provided in Ndjongue is consistent with a POSA's understanding of LED light divergence (*i.e.*, spread). Consequently, the illustration of light output provided by Dr. Jokerst is inconsistent and contradictory to this well-known principle. Furthermore, Dr. Jokerst does not define the distance from the LEDs to the treatment surface, but it is my interpretation that this treatment surface is consistent with what is provided in the '028 Patent and Lundahl, meaning that the treatment surface is at a distance of approximately 2-4" from the light-emitting surface. Additionally, Dr. Jokerst fails to identify the lateral spacing between the LEDs provided in her illustration. However, because the lights are illustrated above a "treatment surface," ~~it is my assumption that the lights are intended to reflect the general spacing of lights that would be expected on an LED panel (e.g., the LED panels described in Larson), whereby the LEDs have a likely lateral spacing of several centimeters or less.~~ Applying the Lambertian light output profile described in Ndjongue to the illustration provided by Dr. Jokerst, and assuming a treatment surface distance of 2-4", ~~with lateral spacing of LEDs of several centimeters or less,~~ a POSA would expect the revised illustration below, which shows a more accurate and realistic emission angle for each LED, where the rays shown represent $I = I_0/2$, at an emission angle from each LED that is associated with a Lambertian distribution.

13. As can be seen from the modified illustration above, ~~a POSA would understand that, while LEDs placed in a regular row arrangement are discrete light sources, unlike a fluorescent tube, a row of individual LEDs would not be expected to have the gaps in illumination that are illustrated by Dr. Jokerst.~~

17. ~~Additionally, even the physical space between adjacent panels resulting from the attachment of adjacent panels via hinges (or other means) is easily addressed by accounting for the overlap of divergence angles at a distance from the treatment surface of a minimum of two inches², as I have illustrated below:~~

14. ~~Achieving a desired uniformity with LEDs is based on (a) the lateral spacing between individual LEDs in a given row, (b) the spacing between rows of individual LEDs, and (c) the spacing between the panels with the LED light emitting surface and the treatment surface.~~

In the case of the teachings of Lundahl and Larsen and the combined device developed in view of their respective teachings, Lundahl provides guidance on (b) the spacings between rows of individual LEDs (as evidenced by the more dense grouping of rows at the top and bottom of the device, corresponding with the general location of the patient's forehead and chin), as well as (c) the spacing between the panels with the LED light emitting surface and the treatment surface (Lundahl expressly teaches that the treatment surface is 2-4" from the light emitting surface). EX1014, 6:43-57, 15:22-28. ~~Consequently, the only factor that needs to be addressed is the spacing between LEDs within each row, but this is a very straightforward process, and is easily within the skill of a POSA.~~

15. In particular, as I discussed in my original declaration (EX1015), based on the teachings of Lundahl and Larsen, a POSA would be motivated to replace the fluorescent tubes of Lundahl with the LEDs taught by Larsen for a number of reasons. EX1015, ¶129-131. As described by Dr. Jokerst, fluorescent tubes are a continuous light source, as illustrated below: EX2050, ¶45. Thus, knowing that this continuous light source was being replaced by discrete LEDs, ~~a POSA would simply ensure that the divergence angles of the adjacent LEDs overlap at the desired treatment distance to ensure no "gaps" between the light emission of the individual LEDs. As I have illustrated below, it is a simple process of replacing the fluorescent tube with discrete LEDs, ensuring overlap of adjacent divergence angles at a distance from the treatment surface of a minimum of two inches¹.~~

16. ~~It is a very straightforward process for a POSA to space adjacent LEDs in a manner that allows the divergence angles of these LEDs to overlap and prevent any gaps in illumination between adjacent LEDs.~~ Indeed, the '028 patent seems to recognize this fact, as the first paragraph of the detailed description describes embodiments of a "configurable illuminator according to the present invention," and states that, in addition to LEDs, "other types of light sources may be used, such as fluorescent or halogen lamps." EX1001, 3:52-62. The '028 patent does not provide any discussion or disclosure suggesting that the transition from fluorescents to LEDs, or vice versa, would be challenging or require any specific design considerations or strategies, underscoring the understanding of a POSA that exchanging fluorescents for LEDs is a straightforward process for a POSA, contrary to Dr. Jokerst's assertions.

19. The uniformity of 90-100% provided in the '028 Patent is significantly higher than the 60% standard required by the claims. EX2033, 15. Notably, these uniformity values of 90-100% were achieved, yet the '028 Patent does not once describe the specific spacing of LEDs on the illuminator tested in Fig. 8. EX1001, 3:59-60. While the '028 Patent references "addressable strings" included in areas 1, 3, and 5, and 2, 4, and 6 (as illustrated in Fig. 5), the '028 Patent includes no disclosure as to the specific spacing of LEDs within each of these strings. See EX1001, 6:24-37. Additionally, the '028 Patent states that, "[e]ach panel contains an array of light emitting diodes (LED) 60, which may be configured in an evenly spaced pattern across the face of the panel[.] [t]he number of individual LEDs arranged in a given array is not particularly limited[.]" EX1001, 3:56-60, but once again provides no discussion of the specific spacing of the LEDs on the panel. ~~This is because a POSA would find the determination of the specific spacing between LEDs in a row to be a straightforward task given the understanding in the art, accounting for divergence angles and the Lambertian distribution.~~

EX1026, ¶¶12-17, 19; MTEE, 3-10; Reply to Opp. To MTEE, 1-2

Outline

A EX1026 (¶¶12-17 and 19)

B EX1031 (591:5-7 and 592:2-8)

The ITC Testimony (Exhibit 1031) Should Be Excluded Under Federal Rule Of Evidence 403

- Dr. Grove initially presented only conclusory statements:

155. Even if the Board determines that Larsen's hinges are not expressly (or inherently) disclosed on the inner side surfaces of the panels, POSITA would have found it obvious and would have been motivated with a reasonable expectation of success to locate Larsen's hinges on the inner side surfaces of adjacent panels. First, Figure 1 of Larsen shows that the inner edges of each of the panels (13) are nearly flush with each other. This disclosure would have motivated POSITA to place the hinges on the inner side surfaces of Larsen's panels in order to facilitate this nearly flush arrangement. Such a modification would have involved nothing more than the use of a known prior art element according to known methods to yield predictable results. *Id.* Second, there were finite number of known, predictable solutions for Larsen's panels to be "flexibly connected to each other through hinges," and POSITA would have found it obvious to try placing the hinges on the inner side surfaces of the panels. And POSITA would have had a reasonable expectation of success, since POSITA would have known that hinges located on the inside surfaces of the applicator would allow them to be positioned in a nearly flush arrangement as shown in Figure 1.

EX1015, ¶155

Dr. Grove Introduces New Theories Because Dr. Jokerst Highlighted The Flaws In His Obviousness Analysis

- Patent Owner pointed out that Petitioner did not provide any example of a [hinge on inner side surfaces](#) and that there were numerous locations and orientations to place hinges:

Second, Larsen does not render obvious “hinged structures on inner side surfaces of adjacent panels.” EX2050, ¶172. Petitioner provides only unsupported, conclusory argument that a POSITA “would have found it obvious to try placing the hinges on the inner side surfaces of the panels.” Petition, 37-38; EX1015, ¶155. *Petitioner does not identify a single prior art reference that discloses a “hinged structure on inner side surfaces of adjacent panels.” Nor does Petitioner provide any evidence that the claimed hinge was known at the time of the invention or that it would work for its intended purpose in an illuminator to output uniform light for PDT. Indeed, Petitioner cites only a single paragraph of Dr. Grove’s declaration that merely regurgitates verbatim its unsupported assertions. Petition, 37-38 (citing*

POR, 53-54

Petition, 38; EX1015, ¶155. But, contrary to Dr. Grove’s unsupported argument, a POSITA would have attached hinges on the *bottom* of the panels, as disclosed in Larsen, and would have understood *there were numerous other designs that could have attached the hinges, for example, on the bottom, top, or back of the panels.* EX2050, ¶174. For example, there are butt hinges that sit on top of the surfaces you are connecting; overlay hinges that are used on cabinet doors to help them sit flush; strap hinges that include a leaf and a strap; offset hinges that attach at an angle to increase the clearance; and knife hinges, also called pivot hinges, where the hinge rotates around a center point. *Id.* *A POSITA would have understood that these hinges could be placed in numerous locations in various orientations.* *Id.* Contrary

POR, 55

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EX1015, 1155

- Dr. Grove added new opinion testimony:



Dr. Grove
Petitioner's Expert

Q: Correct. With the figure disclosed in Larsen.

A: Yeah, in general, there are three locations to connect adjacent panels.

EX1031, 591:5-7; MTEE, 13

Q: ...what's the most common option for connecting panels with hinges?

A: The most common option is to put what are called butt hinges between the two panels.

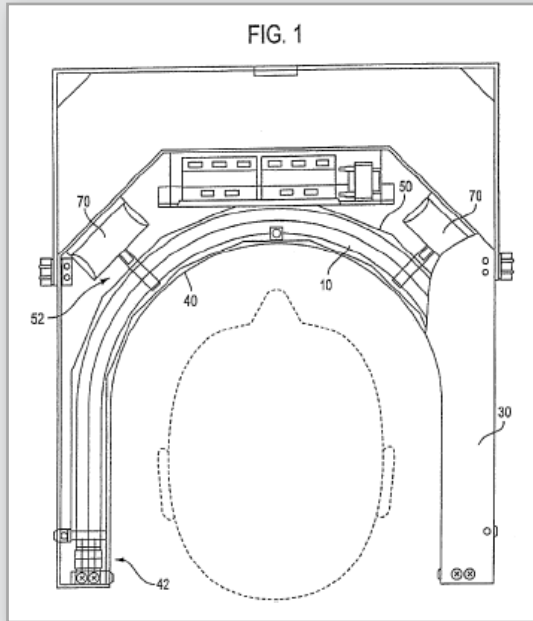
Q: Would a POSA have known that prior to 2015?

A: Absolutely. It's generations of hinges. Generations of people have used those hinges.

EX1031, 592:2-8; MTEE, 12

Reply, 2, 24-25; MTEE, 10-13

Lundahl Uses Fluorescent Tubes That Requires “Carefully Selected And Engineered Components” To Achieve Uniformity



The present invention differs from conventional light sources because of the biological requirements imposed on a PDT light source. A much higher degree of precision and integration is required for the components of the present invention. Output spectrum, irradiance, and irradiance uniformity all must be controlled to assure that the properties of the device are suitable to deliver light to the target lesions and drive the photodynamic reaction. To achieve this, each functional block within the present invention comprises carefully selected and engineered components.

- **U-shaped tubes:** to “ameliorate” the problem of “flat emitting surface[s that] would not deliver a uniform light dose” the “invention uses a U-shaped emitting surface,” which “*provides the desired...uniformity*” and “ensures that the proper visible light dosage is applied to all target areas during PDT.”
- **reflector:** “to *increase the uniformity* of the output distribution” the invention uses “reflector 50...which is bent to approximately conform to the configuration of the tubes.”
- **electrical system:** “[T]he U-shaped tubes” “are driven by electronic ballasts” and “[a]djustment of the ballast voltage controls the output power of the tubes.”

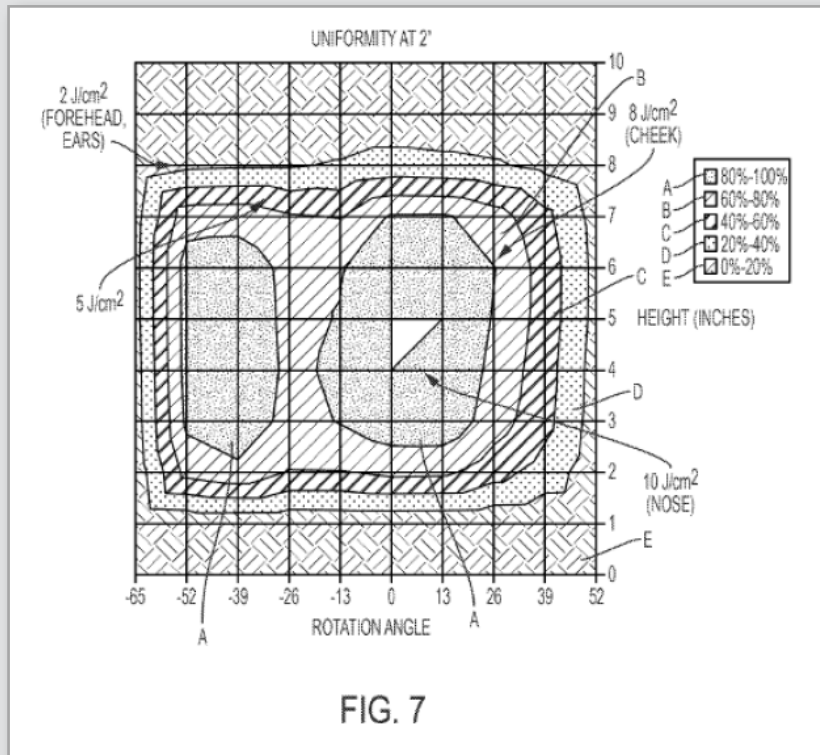
The ballasts “correct[] output of said light from said plurality of light sources so as to *maintain said substantially uniform intensity.*” *Id.*
- **cooling system:** “modulation of the temperature distribution may be used to *control irradiance uniformity.*”

EX1014, Abstract, 2:46-48, 2:62-67, 3:22-28, 3:62-67, 4:12-21, 4:27-44, 5:30-32, 6:31-42, 7:10-35, 8:10-59, 8:62-67, 9:13-53, claims 1, 26, FIGS. 1, 3, 4A, 5B, 7, 8, 9A; POR, 9-14

A POSITA Would Have Been Discouraged From Putting Hinges 10 On Inner Side Surfaces Of Adjacent Panels

- Conventional illuminators had optical dead spaces at or near the hinges that achieved gap-free illumination (*i.e.*, no unlit spaces) without achieving the required uniform illumination

Conventional Illuminator



EX1001, Fig. 7; Sur-Reply, 11-12

The optical dead space that can occur at or near the hinges of conventional adjustable illuminators reduces the uniformity of the light along the treatment area, thereby reducing the effectiveness of PDT for these specific treatments. More-

EX1001, 2:41-44; POR, 4



Dr. Bretschneider
Petitioner's Expert

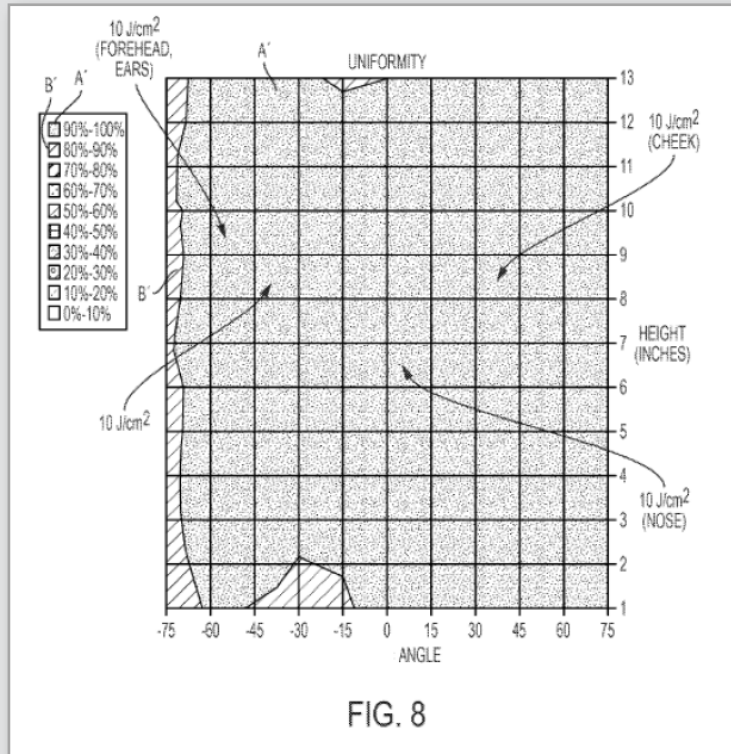
- There are "lower irradiance regions at the junction of two of Larsen's panels."

EX2082, ¶1151; Sur-Reply, 4

The '028 Patent Inventors Achieved The Required **Uniform Illumination** With **Hinges 10 On Inner Side Surfaces Of Adjacent Panels**

- '028 Patent solved this exact problem

'028 Patent



EX1001, Fig. 8; Sur-Reply, 11-12

FIG. 8, on the other hand, illustrates the light uniformity produced by an embodiment of the present invention. The targeted treatment area is the same as that measured in FIG. 7. However, compared to FIG. 7, the **light output uniformity produced by the illuminator is greatly enhanced across the patient's face** and exhibits little to no deviation from the light output measured in the center of the patient's face to the light output measured at the edges of the patient's face.

EX1001, 2:41-44; POR, 4



Mark Carota

Inventor of '028 Patent

- Explained the "difficulty" the inventors had in achieving uniform illumination "because of the **gap between the lights at the place where there was a hinge.**"

EX2052, 88:8-89:1; Sur-Reply, 4

A POSITA Would Have Been Discouraged From Putting Hinges 10 On Inner Side Surfaces Of Adjacent Panels



Mark Carota

Inventor of '028 Patent

- Explained the “difficulty” the inventors had in achieving uniform illumination “because of the **gap between the lights at the place where there was a hinge.**”

EX2052, 88:8-89:1; Sur-Reply, 4



Dr. Bretschneider

Petitioner's Expert

- There are “**lower irradiance regions at the junction** of two of Larsen's panels.”

EX2082, ¶1151; Sur-Reply, 4

EX1004, FIG. 1, [0072]; EX2052, 88:8-89:1, EX2082, ¶1151; POR, 53-56; Sur-Reply, 3-5

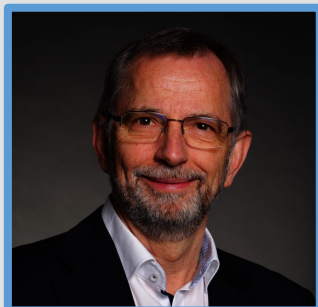
Petitioner Disputes Commercial Success Of The RhodoLED® -XL

Reply

Q: And I'm just looking at the language in the second paragraph of the section under your name, total revenues for the third quarter of 2024 were \$9 million compared with 8.9 million for the third quarter of 2023.

A: Well, that's why I was confused. In my head, I would, you know, call that flat.

EX1033, 410:3-8; Reply, 31



Hermann Luebbert
Petitioner's CEO

Sur-Reply

Q: ...And in this press release, Biofrontera announced that it placed a total of 100 RhodoLED XL in the U.S. market, right?

A: Right.

EX1033, 310:16-19; Sur-Reply, 28

I am pleased with \$37.3 million in sales in 2024. This represents an annual sales growth of 18.5% for Q4 and almost 10% for the entire year and is a record for our company. We strongly believe our past investments, business plan, and execution will allow us to achieve another record year in 2025.

The year included some further milestones that we are very pleased with. First and foremost, we placed 52 RhodoLED XL lamps in the first quarter -- fourth quarter alone and 100 between the launch in June 2024 and the end of 2024. Providing a larger PDT lamp to our customers is an important milestone in our overall strategy to extend the use of Ameluz PDT for treating mild to moderate actinic keratosis on the face and scalp and potentially further indications in the future that are currently in development.

EX2057, 4; Sur-Reply, 28

for the past five years. EX2048, ¶¶20–22. On an annualized basis, RhodoLED®-XL sold approximately 2.47x the number of nonpracticing RhodoLED® units, despite RhodoLED® being on sale for more than 7 years. EX2048, ¶¶30-32.

Sur-Reply, 29