

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

v.

SUN PHARMACEUTICAL INDUSTRIES, INC.
Patent Owner.

Case No. IPR2024-01312
Patent 11,697,028

PETITIONER'S DEMONSTRATIVES

BIOFRONTERA INC., BIOFRONTERA BIOSCIENCE GMBH,
BIOFRONTERA PHARMA GMBH, and BIOFRONTERA AG
Petitioner,
v.
SUN PHARMACEUTICAL INDUSTRIES, INC.
Patent Owner.

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

Petitioner's Oral Hearing Demonstratives
December 3, 2025

Topics Of Discussion

I. Combination of Lundahl & Larsen

II. Contested Issues By Limitation & ITC Initial Determination Issues As Appropriate

A. Uniform Illumination

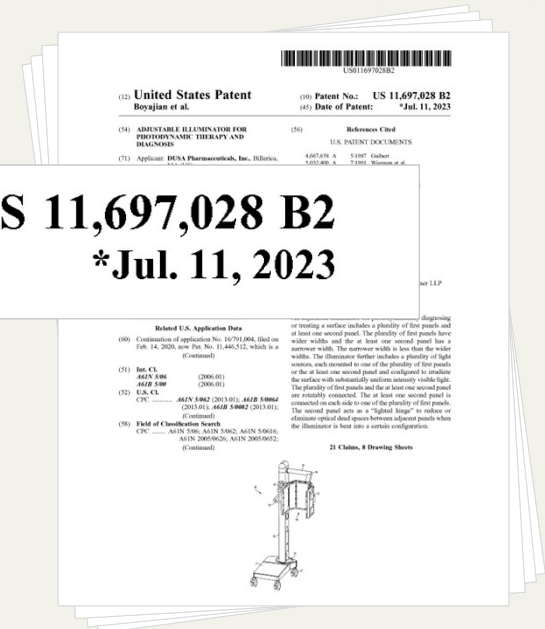
B. Higher Intensity Proximate Second Edges

C. Hinges

D. Individually Configurable

E. Continuous Illumination

Patent No.: **US 11,697,028 B2**
Date of Patent: ***Jul. 11, 2023**



U.S. Patent No. 11,697,028 (the '028 Patent)

FIELD

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.

Ex. 1001 ('028 Patent), 1:19-22

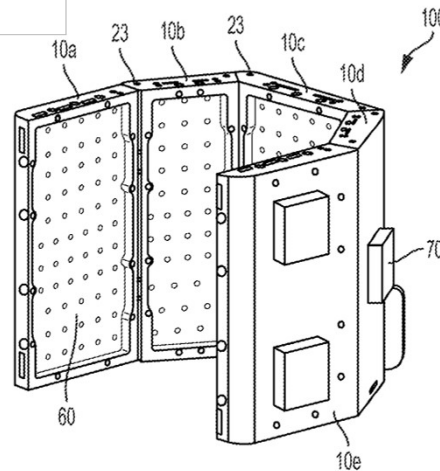


FIG. 2A

FIGS. 2A-2B show perspective views of the main body of the illuminator of FIGS. 1A-1B.

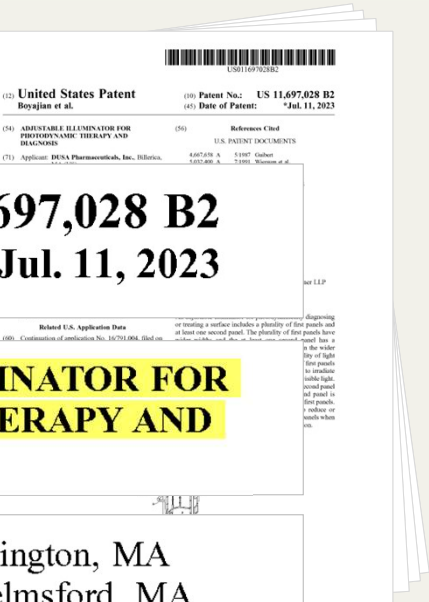
Ex. 1001 ('028 Patent), FIG. 2A, 3:29-30; Petition, 11

Patent No.: US 11,697,028 B2
Date of Patent: *Jul. 11, 2023

**ADJUSTABLE ILLUMINATOR FOR
 PHOTODYNAMIC THERAPY AND
 DIAGNOSIS**

**Thomas Boyajian, Wilmington, MA
 (US); Mark Carota, Chelmsford, MA
 (US); Brian Mazejka, Salem, NH (US)**

Claims priority to Prov. App. No.
 62/241,902 filed on October 15, 2015.



Ex. 1001 ('028 Patent)

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

Independent Claims of the '028 Patent

Claim 1

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

Claim 5

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.

Claim 16

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.

Claim 20

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.

Claim 21

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.

Ex. 1001 ('028 Patent), cls. 1, 16, 20, and 21

*This IPR was instituted for review of claims 1, 2, 4–6, 16, 17, 19–21 of the '028 Patent.

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

U.S. Patent No. 6,233,071 – Lundahl

(12) **United States Patent**
Lundahl et al.

(10) Patent No.: **US 6,233,071 B1**
(45) Date of Patent: **Apr. 24, 2001**

(54) **ILLUMINATOR FOR PHOTODYNAMIC THERAPY AND DIAGNOSIS WHICH PRODUCES SUBSTANTIALLY UNIFORM INTENSITY VISIBLE LIGHT**

(75) Inventors: **Scott Lundahl**, Lexington; **Rebecca Kozodoy**, Randolph; **Ronald Carroll**, Hingham, all of MA (US); **Elton Leppelmeier**, Highland Height, OH (US)

(73) Assignee: **DUSA Pharmaceuticals Inc.**, Toronto (CA)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **09/070,772**

(22) Filed: **May 1, 1998**

(51) Int. Cl.⁷ **A61B 5/00**

(52) U.S. Cl. **600/476**, 607/91

(58) Field of Search **607/88**, 90, 91; **600/476**

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(List continued on next page.)

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2007625	3/1979	(GB)
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93/21842	11/1993	(WO)

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Kennedy et al., "Photodynamic Therapy (PDT) and Photodiagnosis (PD) Using Endogenous Photosensitization Induced by 5-Aminolevulinic Acid (ALA): Mechanisms and Clinical Results," *Journal of Clinical Laser Medicine & Surgery*, vol. 14, No. 5, 1996, pp. 289-304.

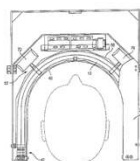
(List continued on next page.)

Primary Examiner—William E. Kamm
(74) **Attorney, Agent, or Firm**—Foley & Lander

ABSTRACT

(57) An apparatus and method for photodynamic therapy or photodynamic diagnosis using an illuminator comprising a plurality of light sources generally conforming to a contoured surface and irradiating the contoured surface with substantially uniform intensity visible light. The light sources may comprise generally U-shaped fluorescent tubes that are driven by electronic ballasts. Adjustment of the ballast voltage controls the output power of the tubes. The tubes are supported by a sheet-metal or plastic housing and are covered by a polycarbonate shield which directs cooling airflow within the unit and prevents glass-patient contact in the event of tube breakage. An aluminum reflector located behind the tubes increases both the output irradiance and the uniformity of the output distribution. The spacing of the U-shaped tubes is varied to increase the output at the edges of the illuminator to make the output more uniform. Also, different portions of the tubes are coiled at different amounts, to improve uniformity. A light sensor monitors output from the U-shaped tubes to provide a signal for adjusting the output from the tubes.

36 Claims, 15 Drawing Sheets



Ex. 1014 (Lundahl)

Patent No.: US 6,223,071 B1
Date of Patent: Apr. 24, 2001

(75) **Inventors:** **Scott Lundahl**, Lexington; **Rebecca Kozodoy**, Randolph; **Ronald Carroll**, Hingham, all of MA (US); **Elton Leppelmeier**, Highland Height, OH (US)

(73) **Assignee:** **DUSA Pharmaceuticals Inc.**, Toronto (CA)

Ex. 1014 (Lundahl); Reply, 17-21

Lundahl



There Was A Motivation To Modify Lundahl's Device To Provide Flexibility

Institution Decision

Based on our review of the Petition, Petitioner explains that a driving motivation for a POSITA to modify Lundahl to include Larsen's five panels is "to increase the flexibility of the device to ensure the light panels could be maintained at a distance of 2-4" from surface of the treatment area, whether the face, arm, or back, etc." Pet. 29 (emphasis added). As Lundahl's device is not flexible, and such flexibility would improve its ability to treat areas other than an average sized face, we determine, at this stage in the proceeding, that this motivation for the combination is sufficient.

Institution Decision, 20

Dr. Ehrenreich:

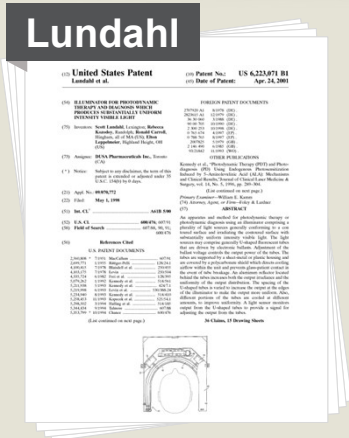
43. For arms, the back of hands, and the front of the neck and upper chest, my experience using the fixed BLU-U shape that I have in my office, and which is described in Lundahl, is that it makes it hard to treat hands, arms, and necks and upper chests. In my practice, we typically resort to using pillows, instrument stands, and other jury-rigged approaches to fit the arm or hand into the treatment area and make the patient comfortable. However, this is not ideal. It is sometimes awkward and uncomfortable for the patient and it can make setting and controlling the distance between the light and the treatment area difficult, especially on a convex surface such as a forearm. Hands and dorsal forearms are typically sun exposed and often have numerous AKs

Ex. 1016 (Ehrenreich Dec.), ¶ 43

The U-shape minimizes the variations in distance between the emitter and the target, providing a uniform visible light distribution to the face or scalp of the patient; the tube dimensions were chosen based on the average dimensions of the adult human head. The mounting of the tubes minimizes

Ex. 1014 (Lundahl), 6:31-35; Petition, 26

There Was A Motivation To Replace Lundahl's Fluorescents With LEDs



Ex. 1014 (Lundahl)

Institution Decision

As discussed above, based on our consideration of the current record, Petitioner has provided sufficient motivation for employing Larsen's flexible five panel configuration. These panels in Larsen already use LEDs as their light source. So, in our view, Petitioner's incorporation of the five panels includes the lighting source, i.e., LEDs, for those panels taught by Larsen. Further, we note that Petitioner has persuasively asserted that a skilled artisan would have been motivated to use Larsen's LEDs as they are more cost-efficient and last longer. See Pet. 31.

Institution Decision, 21

the adult human head. The mounting of the tubes minimizes the impact of the non-emitting area at their ends. This allows

Ex. 1014 (Lundahl), 6:35-36 ; Petition, 27-28

Since the output of tubular light sources may vary with temperature, temperature distribution also plays a key role in irradiance uniformity. Further, since the tube output may vary over its length, modulation of the temperature distribution may be used to control irradiance uniformity of the illuminator.

Ex. 1014 (Lundahl), 4:39-44 ; Petition, 31

Dr. Grove:

lights. However, by the late 2000's and early 2010's, POSITA would have been motivated to use solid-state light-emitting diodes (LEDs) as the illumination source for three reasons. First, LEDs have a lower cost and a longer lifetime than fluorescent tubes. Second, fluorescent tubes are known to have inconsistent light output within the tube itself, as acknowledged in Lundahl (the tubes have "non-emitting area at their ends" (6:31-42) and that "tube output may vary over its length"

Ex. 1015 (Grove Dec.), ¶ 129; Petition, 31

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

Larsen (US 2005/0075703)

Pub. No.: US 2005/0075703 A1
Pub. Date: Apr. 7, 2005

Inventor: Eric Larsen, Schaffhausen (CH)

SUMMARY OF THE INVENTION

[0026] The present invention provides a device with changeable applicators using a light and/or laser radiation of several wavelength ranges suited for the photodynamic stimulation of the cell energy in living cells, in particular human cells of both surface and underlying tissue. The light

Ex. 1004 (Larsen), [0026]; Petition, 21-22

Larsen

(19) **United States**
 (12) **Patent Application Publication** (10) **Pub. No.: US 2005/0075703 A1**
 Larsen (43) **Pub. Date: Apr. 7, 2005**

(54) **PHOTODYNAMIC STIMULATION DEVICE AND METHODS** (52) **U.S. CL.** 607/88; 607/100

(76) **Inventor:** Eric Larsen, Schaffhausen (CH) (57) **ABSTRACT**

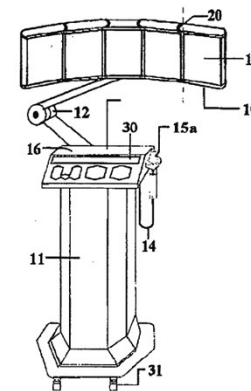
Correspondence Address:
 COHEN, PONTANI, LIEBERMAN & PAVANE
 551 FIFTH AVENUE
 SUITE 1210
 NEW YORK, NY 10176 (US)

(21) **Appl. No.:** 10/466,734
 (22) **PCT Filed:** Jan. 22, 2002
 (86) **PCT No.:** PCT/NO02/00033

(30) **Foreign Application Priority Data**
 Jan. 22, 2001 (NO) 2001 0373

Publication Classification
 (51) **Int. Cl.7** A61N 5/06; A61F 2/00

A treatment device which uses a light radiation of multiple wavelengths and pulse-shaped electromagnetic fields for the photodynamic stimulation of cells, especially cells of human tissue, and also for the activation and stimulation of light sensitive substances (PTD). The device produces energy radiation by the use of semiconductor and/or laser diodes, which emit light in several separate wavelengths due to a special operation mode and the use of tunable diodes. The equipment consists of a stand, with which machine applicators are connected via a jointed arm. The stand is freely movable on wheels and includes a control mechanism whereby the various parameters for therapy can be adjusted and switched on and off. The stand is also connected to a hand applicator for treatment of small tissue-areas, e.g., acupuncture points. Photodynamic substances are introduced into the tissue with a special hand applicator.



Ex. 1004 (Larsen)

Institution Decision Finds Prior Art Teaches Key Limitations

Claim Limitations	Institution Decision
Uniform Illumination	"... Petitioner has supported its motivation for applying Lundahl's teaching to space the light sources closer together at the top and bottom edges 'to increase the intensity of light emitted' from those edges to provide a more uniform exposure of light to the treatment surface." 21
Higher Intensity	"[B]ased on our review of the Petition, our understanding is that Petitioner's proposed modification applies Lundahl's disclosure of providing greater light intensity at the top and bottom sides to the top and bottom sides of Larsen, which are the shorter edges in Larsen." 19
Hinges	"Petitioner provides a reasonable argument that a skilled artisan considering Larsen's Figure 1 would have appreciated that, even if the hinges in Larsen were not located on the inner surface of the adjacent panels, placing the hinges in that location would have been a predictable means within the skill in the art for flexibly connecting the panels." 18-19

Institution Decision Finds Motivation and Reasonable Expectation of Success

	Institution Decision
Motivation - Flexibility	"As Lundahl's device is not flexible, and such flexibility would improve its ability to treat areas other than an average sized face, we determine, at this stage in the proceeding, that this motivation for the combination is sufficient." 20
Motivation – Light Source	"... These panels in Larsen already use LEDs as their light source. So, in our view, Petitioner's incorporation of the five panels includes the lighting source, i.e., LEDs, for those panels taught by Larsen. Further, we note that Petitioner has persuasively asserted that a skilled artisan would have been motivated to use Larsen's LEDs as they are more cost-efficient and last longer." 21
Reasonable Expectation of Success	"[W]e consider what the combined teachings of the references would have suggested to those of ordinary skill in the art. At this stage in the proceeding, we understand Petitioner's proposed incorporation of Larsen's five panels with LED lighting to include Larsen's control system and supply of light source voltage. Further, on this record, we find Petitioner has supported its motivation for applying Lundahl's teaching to space the light sources closer together at the top and bottom edges to increase the intensity of light emitted from those edges to provide a more uniform exposure of light to the treatment surface." 22 (cleaned up)

Contested Claim Limitations

Claim Limitations	Claim Language	Claims
Uniform Illumination	“the illuminator being configured to uniformly illuminate a treatment surface of the patient via the light sources” “uniformly illuminating a treatment surface of the patient with light sources disposed on the five panels of the illuminator”	1, 5, 16, 20, 21
Higher Intensity	“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”	1, 5, 16, 20, 21
Hinges	“an illuminator comprising five panels connected by hinged structures on inner side surfaces of adjacent panels”	1, 5, 20, and 21
	“five panels connected by hinged structures”	16
Individually Configurable	“wherein the five panels are individually configurable to control illumination from each of the five panels”	16
	“the five panels are individually configurable to control illumination from each of the five panels”	21
Continuous Illumination	“five panels connected by hinged structures to allow continuous illumination across the five panels”	16

The Board Is Not Bound By The ITC Initial Determination

Cuozzo Speed Techs. v. Com. for Intell. Prop., 579 U.S. 261, 282-83 (2016)

“A district court may find a patent claim to be valid, and the [Patent Trial and Appeal Board] may later cancel that claim in its own review. ... This possibility, however, has long been present in our patent system, which provides different tracks—one in the Patent Office and one in the courts—for the review and adjudication of patent claims. ...[T]he possibility of inconsistent results is inherent to Congress’ regulatory design.”

Novartis AG v. Noven Pharms. Inc., 853 F.3d 1289, 1294 (Fed. Cir. 2017)

“It is unsurprising that different records may lead to different findings and conclusions. Nevertheless, even if the record were the same, [patent owner's] argument would fail as a matter of law. ... [T]he PTAB properly may reach a different conclusion based on the same evidence.”

The Initial Determination is **not final** and Petitioner filed a Petition for Review of the ITC Initial Determination by the full International Trade Commission, on November 17, 2025.

Petitioner Has Petitioned The ITC For Review Of Errors In The Initial Determination

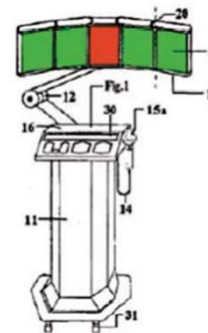
The ITC Initial Determination:

l's panels are angled relative to the center panel. Tr. (Jokerst) at 738:13-739:2. But Larsen does not disclose "a center panel configured to face the treatment surface," CX-0014C (Jokerst RWS) at Q/A 327-29, and Biofrontera makes no assertion to the contrary.

Biofrontera has not shown by clear and convincing evidence that Larsen discloses the center panel limitation.

Ex. 2090 (ITC Initial Determination), 116

The Evidence:



Q: These green panels in the figure of [Larsen] are drawn in at an angle to the orange panel in the center, correct?

A: They're at a slight arc, yes.

Q: They're at an angle, correct?

A: Yes.

Q: They're angled relative to the center panel, correct?

A: In this figure, yes.

Ex. 2015 (Grove Dec.), ¶ 166

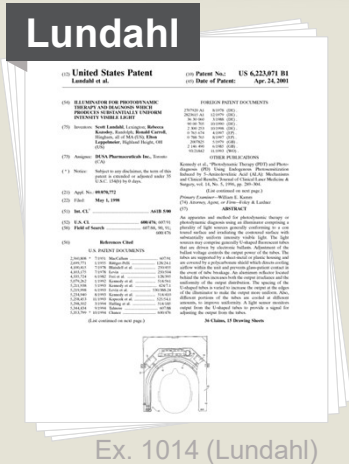
Ex. 1032 (Jokerst ITC Testimony), 738:13-739:2.

Uniform Illumination Limitation

(Claims 1, 5, 16, 20, and 21 of the '028 Patent)

Claim Limitations	Claim Language	Claims
Uniform Illumination	“the illuminator being configured to uniformly illuminate a treatment surface of the patient via the light sources” “uniformly illuminating a treatment surface of the patient with light sources disposed on the five panels of the illuminator”	1, 5, 16, 20, 21

Lundahl Teaches Lateral Spacing of Lights Provides Uniformity

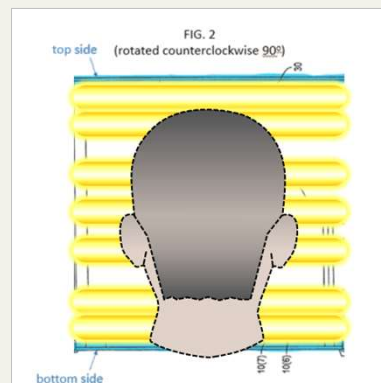


used for patient treatment. Another advantage of the arrangement is that uniformity can also be adjusted by varying the lateral spacing of the tubes (relative horizontal spacing as shown in FIG. 2). This is important since it is necessary to

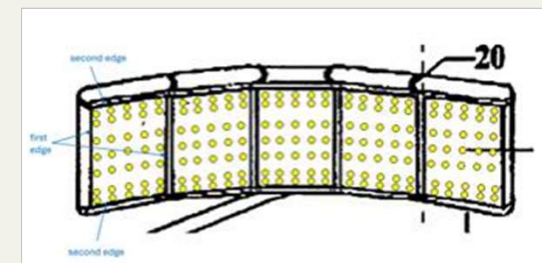
Ex. 1014 (Lundahl), 6:23-25; Petition, 18-19

The number of tubes used and the spacing between them were chosen to achieve desired uniformity and power output specifications. Optimum output distribution has been found

Ex. 1014 (Lundahl), 6:43-45; Petition, 41

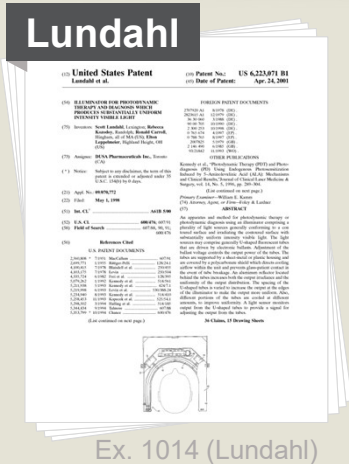


Ex. 1014 (Lundahl), FIG. 2 (modified); Reply, 19
DEMONSTRATIVE EXHIBIT – NOT EVIDENCE



Ex. 1015 (Grove Dec.), ¶ 178; Reply, 21

Lundahl Teaches *Why* Lateral Spacing of Lights Provides Uniformity

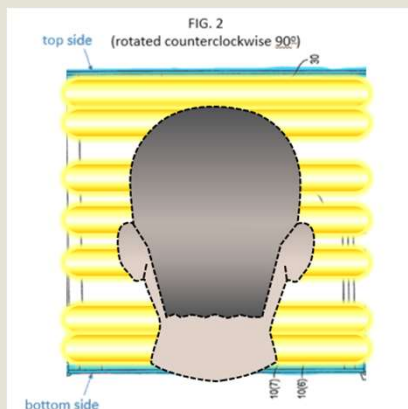


used for patient treatment. Another advantage of the arrangement is that uniformity can also be adjusted by varying the lateral spacing of the tubes (relative horizontal spacing as shown in FIG. 2). This is important since it is necessary to

Ex. 1014 (Lundahl), 6:23-25; Petition, 18-19

The number of tubes used and the spacing between them were chosen to achieve desired uniformity and power output specifications. Optimum output distribution has been found

Ex. 1014 (Lundahl), 6:43-45; Petition, 41

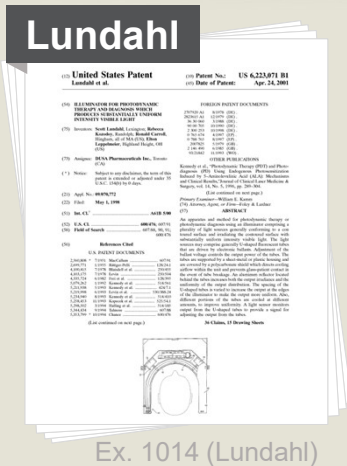


shown in FIG. 2). This is important since it is necessary to compensate for the fact that the output from a flat plane emitting light source drops near the edges. Varying the lateral spacing of the tubes creates the same effect as folding the edges of a larger illuminator in on itself, thus emulating an infinite plane emitter with a compact unit.

Ex. 1014 (Lundahl), 6:20-25; Petition, 18-19

18

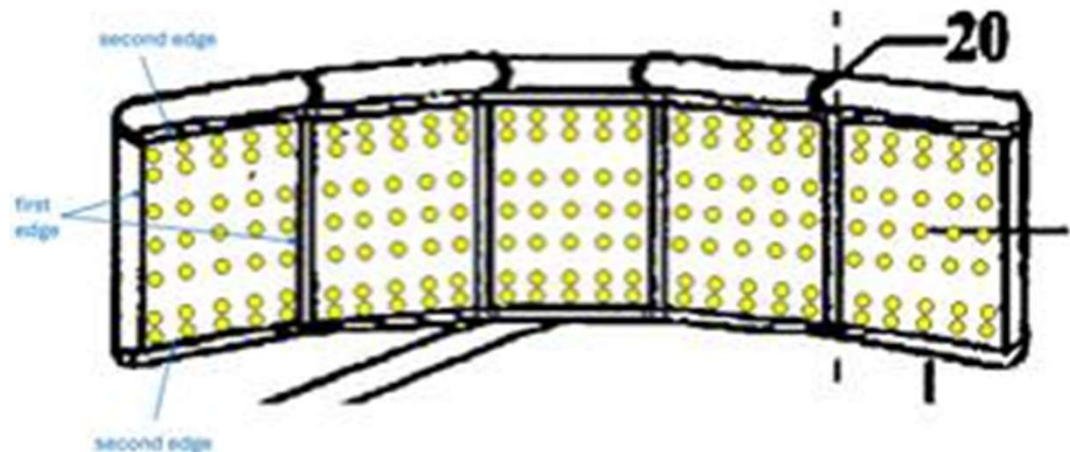
Lundahl Teaches Lateral Spacing of Lights Provides Uniformity



Ex. 1014 (Lundahl)

More specifically, achieving a desired uniformity of *illumination* with LEDs is based on (a) spacing between individual LEDs, (b) spacing between rows of individual LEDs, and (c) spacing between the LEDs and the treatment surface. EX1026, ¶14. Lundahl provides guidance as to (b), teaching that distance between light source rows can be manipulated to increase uniformity (EX1014, 6:43-57), and as to (c), teaching illumination of a treatment surface 2-4" away (EX1014, 15:22-28).

Reply, 10



Ex. 1014 (Lundahl), 6:25-20; Reply, 21

Lundahl Teaches Uniformity Within 60% Of Maximum

Lundahl Prior Art Reference:

The present invention is directed to photodynamic therapy using an illuminator that provides a uniform distribution of visible light. In particular, the present invention is directed

Ex. 1014 (Lundahl), 1:9-111; Petition, 9

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

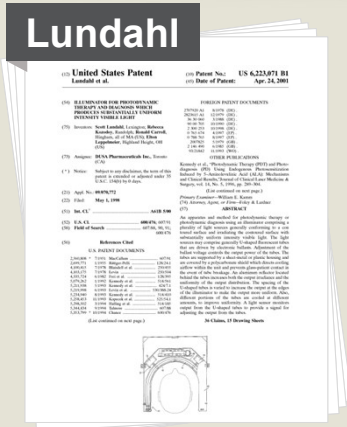
Ex. 1014 (Lundahl), 15:22-27; Petition, 45; Reply, 6

ITC Claim Construction:

“uniformly illuminate a treatment surface”:
“irradiating light over the active emitting area such that the irradiance at a treatment surface of the patient is at least within 60% of the measured maximum”

Ex. 2033 (ITC Markman Order), 13; Reply, 6

Fluorescent Light Output Is Inconsistent



Ex. 1014 (Lundahl)

the adult human head. The mounting of the tubes minimizes the impact of the **non-emitting area at their ends**. This allows

Ex. 1014 (Lundahl), 6:35-36; Petition, 27-28

Since the output of tubular light sources may vary with temperature, temperature distribution also plays a key role in irradiance uniformity. Further, since the tube output may vary over its length, modulation of the temperature distribution may be used to control irradiance uniformity of the illuminator.

Ex. 1014 (Lundahl), 4:39-44; Petition, 31

Dr. Grove:

have a lower cost and a longer lifetime than fluorescent tubes. Second, fluorescent tubes are known to have inconsistent light output within the tube itself, as acknowledged in Lundahl (the tubes have “non-emitting area at their ends” (6:31-42) and that “tube output may vary over its length” (4:41-42)). Third, by moving to adjustable panels connected by hinges to increase flexibility, the

Ex. 1015 (Grove Dec.), ¶ 129; Petition, 31

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

Summary of Patent Owner Arguments Against Uniform Illumination

- **Patent Owner Asserts:**

(1) Replacing continuous fluorescent tubes with discrete LEDs creates gaps (POR, 24-26)

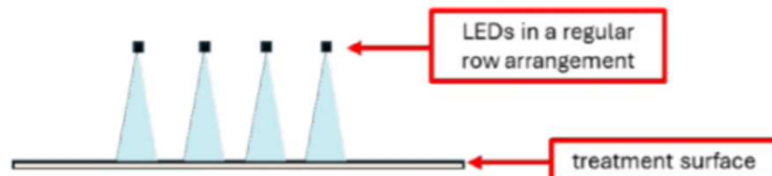
- **But this overlooks common knowledge regarding divergence angles (Reply, 6-11)**
- **The '028 Patent states that uniform illumination was achieved, but provides no discussion of spacing or gaps between LEDs (Reply, 11-13)**

(2) Petitioner fails to account for additional features in Lundahl that contributed to uniformity (POR, 26-29)

- **U-shape can be replicated with the flexible panels of Larsen combined with the device of Lundahl (Reply, 4-6)**
- **Reflectors, cooling system, and electrical system all specific to fluorescents and rendered superfluous by the transition to LEDs (Reply, 2-6)**

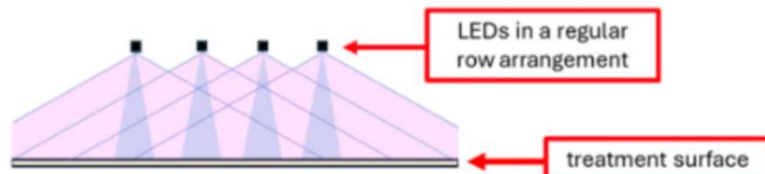
A POSITA Would Have Known to Account for Divergence Angles When Spacing LEDs within a Row to Ensure No Gaps

Dr. Jokerst's Illustration:



Ex. 2050 (Jokerst Dec.), ¶ 46; Reply, 9

Dr. Grove's Correct Illustration:



Ex. 1026 (Grove Supp. Dec.), ¶ 12; Reply, 10

46. LEDs, unlike fluorescent tubes, are discrete, point source, directional illuminators with a Lambertian output characteristic. LEDs were available in a

Ex. 2050 (Jokerst Dec.), ¶ 46; Reply, 8

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

Lambertian distribution
(as illustrated in Ndjiongue article
relied upon by Dr. Jokerst):

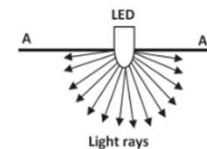
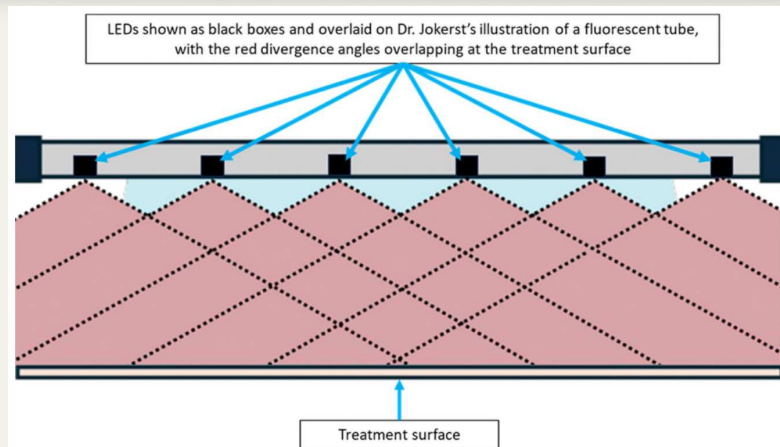


Figure 6: Scattering of the light from LEDs (Lambertian distribution); (A – A') represents the Lambertian surface in the profile view

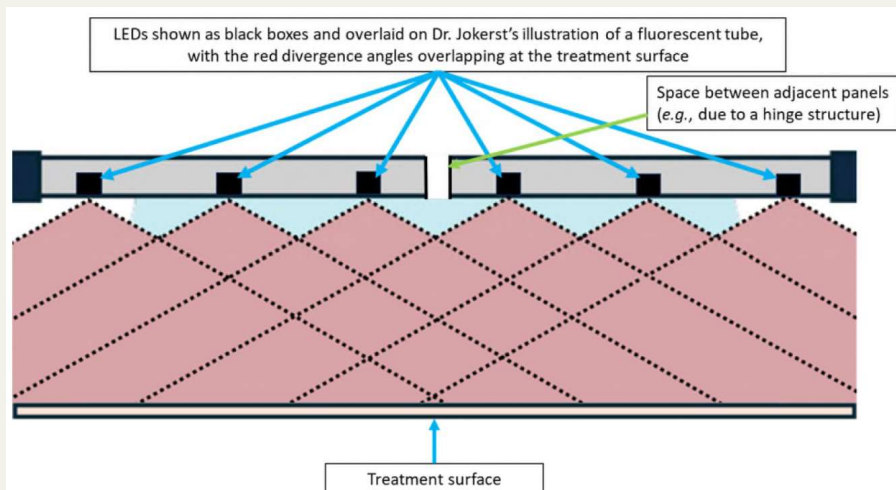
Ex. 2013 (Ndjiongue Article), 7
(cited in Ex. 2050 (Jokerst Dec.), ¶ 44); Reply, 8-9

A POSITA Would Have Known to Account for Divergence Angles When Spacing LEDs within a Row to Ensure No Gaps



Reply, 11

Straightforward task for a POSITA to space adjacent LEDs in a manner that allows the divergence angles to overlap to prevent gaps in illumination. Reply, 9-10; EX1026, ¶ 14-15.



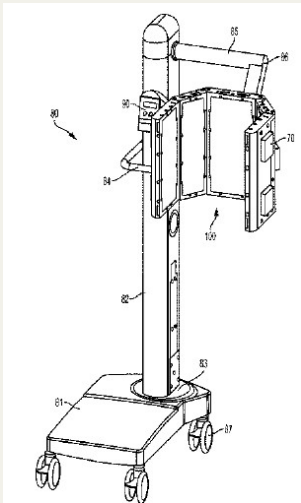
Reply, 15

Similarly, gaps between adjacent panels are easily addressed by accounting for the overlap of divergence angles. Reply, 14-15; EX1026, ¶ 17.

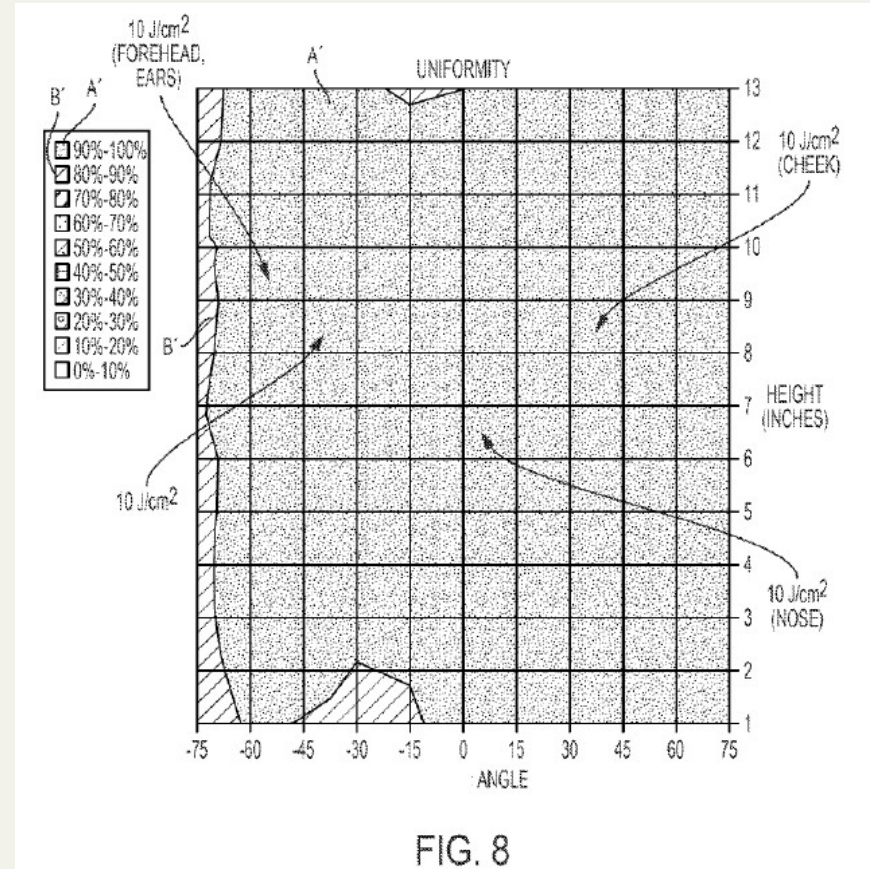
DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

The '028 Patent States That Uniform Illumination Was Achieved, But Provides No Discussion of LED Spacing or Potential Gaps

The '028 Patent reports uniformity of 90-100% was achieved – uniformity values significantly higher than the 60% standard claimed – but includes **NO** discussion of the specific spacing between the LEDs of the illuminator. Reply, 11-12; EX1026, ¶ 18-19.



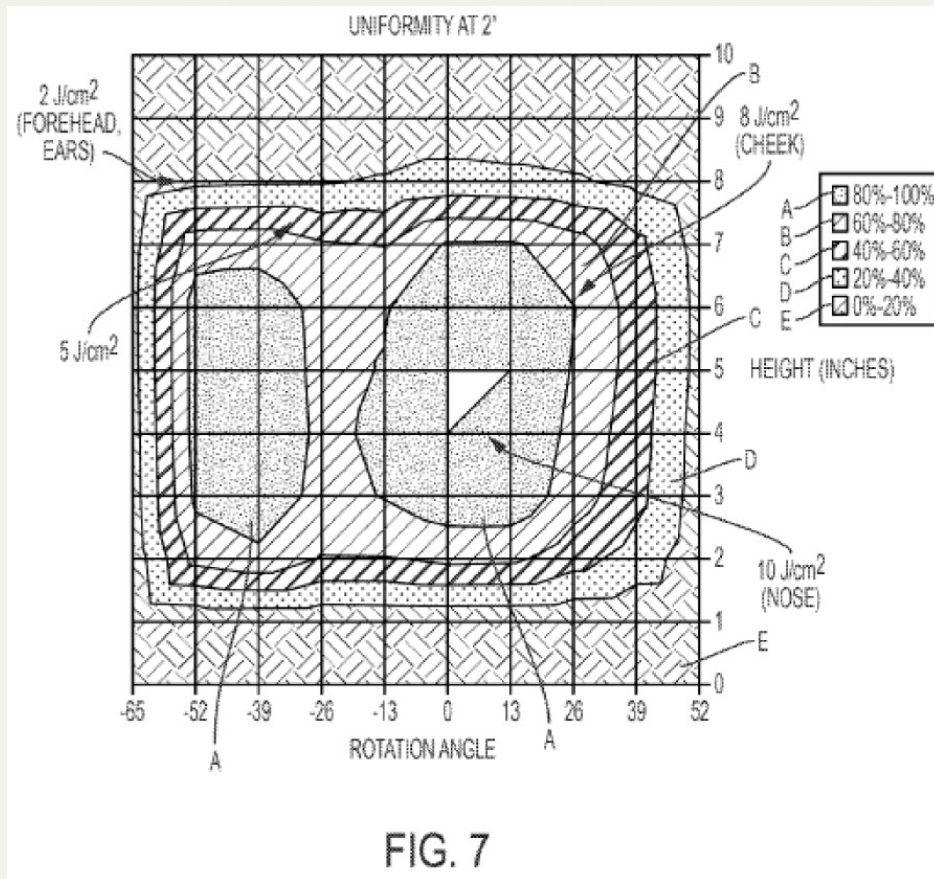
'028 Patent 5-panel LED Illuminator



Reply, 12

25

The '028 Patent States That Uniform Illumination Was Achieved, But Provides No Discussion of LED Spacing or Potential Gaps



Patent Owner argues that "conventional illuminators" achieved gap-free illumination (i.e., no unlit spaces) but failed to achieve uniform illumination such that intensities were at least within "60% of the measured maximum." PO Sur-Reply, 11.

Summary of Patent Owner Arguments Against Uniform Illumination

Patent Owner Asserts:

(1) Replacing continuous fluorescent tubes with discrete LEDs creates gaps (POR, 24-26)

- But this overlooks common knowledge regarding divergence angles (Reply, 6-11)
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- **Reflectors, cooling system, and electrical system all specific to fluorescents and rendered superfluous by the transition to LEDs (Reply, 2-6)**

Lundahl's Reflectors Re-Direct Light Emitted from the Back of Fluorescent Tubes and Are Not Required with Directional LEDs

Dr. Grove:

Do you recall being asked about reflectors?

A. Yes, I do.

Q. Okay. Are reflectors like those taught in Lundahl needed for LEDs?

A. No. The LEDs put out light in basically one direction, whereas fluorescent tubes put out light 360 degrees around the circumference of the tube.

Q. And would a POSA have understood that prior to 2015?

A. Oh, absolutely. The light sources that are producing light in all directions, if you're trying to illuminate a surface, you don't want to waste the light going away from your subject. And so light sources have had reflectors for, probably, as many years as there are light sources. But if you have a light source that's directional, as LEDs are, then there's no need for a reflector.

Ex. 1031 (Grove ITC Testimony), 593:7-22; Reply, 4

Lundahl:

In order to utilize the visible light emitted from the back of the tubes, and to increase the uniformity of the output distribution, a reflector 50 is positioned approximately 10 mm from the rear surface of the tubes. The reflector 50 is made of polished aluminum sheet which is bent to approximately conform to the configuration of the tubes.

Ex. 1014 (Lundahl), 8:61-67; Reply, 4

Dr. Jokerst:

46. LEDs, unlike fluorescent tubes, are discrete, point source, directional illuminators with a Lambertian output characteristic. LEDs were available in a variety of sizes and packages in 2015. LEDs emit light in a specific direction in a “noncoherent, narrow band.” Ex. 2011 (Bourget), 1944. As illustrated below, LEDs

Ex. 2050 (Jokerst Dec.), ¶ 46; Reply, 8

Lundahl's Fluorescent Electrical System Not Needed For Uniformity With LEDs

Lundahl:

Achieving satisfactory performance from a fluorescent tube requires the application of a voltage to the tube cathodes to initiate tube conduction and subsequently control the tube current. Fluorescent tubes, being gas discharge devices, are particularly sensitive to the electrical voltages and currents used to drive them. Higher tube currents will increase the electron yield causing the output irradiance to increase. But higher currents result in higher cathode temperatures, potentially increasing the erosion of the cathode emitting material and contamination of the tube atmosphere by material removed from the cathodes; this ultimately results in decreased tube life. Tube currents that are too low can result in low tube wall temperatures that may cause condensation of the mercury vapor, adversely affecting the uniformity of the lamp output. Furthermore, for most tube designs it is necessary to heat the cathodes to achieve proper tube starting. Control of the voltage and/or tube current characteristics, as well as heating of the cathodes is accomplished with external electronic circuitry which is usually engineered and packaged into a single device commonly referred to as a "ballast". There are many such ballast

Ex. 1014 (Lundahl), 7:11-31; Reply, 5

Dr. Jokerst:

Q. LEDs don't require the use of the same type of ballast or -- as fluorescent tubes, right?

A. Yes, LEDs do not require the same electrical ballasts as fluorescent tubes.

Q. Because LEDs don't face the electrical challenge of heating cathodes and controlling the voltage and/or tube current, right?

A. While LEDs do not face those challenges electrically, LEDs face other challenges electrically. So that is correct, they do not face the same challenges as fluorescent tubes.

Ex. 1027 (Jokerst Deposition), 38:7-18;
Reply, 5

Dr. Jokerst:

A. So by "those electrical systems," are you referring to the electrical systems to run LEDs?

Q. (BY MR. LANDMON) An electrical system that would provide no voltage spike or current spike to damage an LED was well-known prior to 2015, right?

MS. HIGGINS: Objection, form, vague.

A. So a person of skill in the art would know how to construct in 2015 an electrical system that would avoid producing or applying a voltage spike or a current spike to an LED.

Ex. 1027 (Jokerst Deposition), 41:14-42:3;
Reply, 5

Lundahl's Fluorescent Cooling System Not Needed For Uniformity With LEDs



Ex. 1014

Cooling Features

Since cathode and tube wall temperatures strongly affect the output distribution, a cooling system is provided to ensure proper bulb operation. According to an embodiment

* * *

The straight section of the tube between the cathode area and curved section of the "U" tubes produces slightly more output than the center portion of the curved section. This has been attributed to differences in the phosphor coating thickness caused by the bending process. To further increase irradiance uniformity, the reflector vents 52 are located in the reflector 50 so that cooling air flows primarily over the straight section and the end portions of the curved section. Less cooling air flows over the middle of the tubes between the sets of reflector vents 52, causing the tube wall temperature to be higher in this region. Since the output irradiance for this tube increases (to a point) with tube wall temperature, the hotter central region of the tube produces higher output irradiances than the rest of the tube and compensates for the lower emission efficiency of the central region.

Ex. 1014 (Lundahl), 9:12-15, 9:39-54; Reply, 5

Dr. Jokerst:

Ex. 1027 (Jokerst Deposition), 47:15-16; Reply, 5

A. So since LEDs do not have tubes, they are not subject to the alternating tube current;

A POSITA Is Not An Automaton

***KSR Intern. Co. v. Teleflex Inc.*, 550 U.S. 398, 420-21 (2007)**

“[I]n many cases a person of ordinary skill will be able to fit the teachings of multiple patents together like pieces of a puzzle....”

***PGS Geophysical AS v. Iancu*, 891 F.3d 1354, 1366 (Fed. Cir. 2018)**

“[Plaintiff’s] argument relies on the presumption that one of ordinary skill would blindly incorporate [secondary reference’s] exact methodology into [primary reference]. But the Board properly did not view [defendant’s] proposed combination to be so limited.”

The ITC Initial Determination Erred By Requiring Actual Testing to Support the Reasonable Expectation of Success

The ITC Initial Determination:

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

Ex. 2090 (ITC Initial Determination), 104

Petitioner's Reply:

for his combination (POR, 20-21), there is no "law-required minimum for what can support a 'reasonable' expectation of success," and the Federal Circuit has stated that testing is not required. *Acorda Therapeutics, Inc. v. Roxane Labs, Inc.*, 903 F.3d 1310, 1333 (Fed. Cir. 2018). That is particularly true here, where the combination of Lundahl and Larsen substitutes the more predictable light output from LEDs for "output from a fluorescent tube [which is] not inherently uniform." EX1014, 6:9-11.

Reply, 7

Acorda Therapeutics, Inc. v. Roxane Labs, Inc.,
903 F.3d 1310, 1333 (Fed. Cir. 2018)

"[A] person of ordinary skill . . . can draw reasonable inferences about the likelihood of success even without a perfectly designed clinical trial . . ."

PLACEHOLDER

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

Dr. Grove Testified That It Would Require Undue Experimentation to Achieve Uniform Illumination for the *Torso* and *Extremities*

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.**

Ex. 2034 (Grove ITC Exp. Rep.), ¶ 186

At paragraph 186, do you recall being asked -- there we go.

A. Yes.

Q. And do you recall giving a response which -- I don't want to put words in your mouth, but I think you said it dealt with undue experimentation in a different context. Do you recall that?

A. I did say that, yes.

Ex. 1031 (Grove ITC Testimony), 587:19-588:1

Q. And I'm trying to understand, is the context you were addressing them relating to uniform illumination relating to the **extremities and torso**?

A. **That's exactly correct.**

Ex. 1031 (Grove ITC Testimony), 588:15-21

Higher Intensity Proximate Second Edges Limitation

(Claims 1, 5, 16, 20, and 21 of the '028 Patent)

Claim Limitations	Claim Language	Claims
Uniform Illumination	“the illuminator being configured to uniformly illuminate a treatment surface of the patient via the light sources”	1, 5, 16, 20, 21
Higher Intensity	“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”	1, 5, 16, 20, 21

Lundahl Teaches Varying the Lateral Spacing of Tubes Near Forehead and Chin to Achieve Uniformity

Lundahl

(12) United States Patent
Lundahl et al.

(19) Patent No.:
US 6,223,071 B1

(11) Date of Patent:
Apr. 24, 2001

(54) ILLUMINATOR FOR PHOTODYNAMIC THERAPY AND DIAGNOSIS WHICH PRODUCES SUBSTANTIALLY UNIFORM INTENSITY VISIBLE LIGHT

(75) Inventors: Scott Lundahl, Lexington, Rebecca Kennedy, Randolph, Ronald Carroll, Highland, all of MA (US), Ellen Lippman, Highland Heights, OH (US)

(73) Assignee: DUSA Pharmaceuticals Inc., Toronto (CA)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: 09/078,772

(22) Filed: May 1, 1998

(51) Int. Cl.⁷: A61B 5/00

(52) U.S. Cl.: 606/476, 607/01

(56) Field of Search: 607/88, 96, 97; 606/476

(56) References Cited

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Kennedy et al., "Photodynamic Therapy (PDT) and Photodiagnosis (PDI) Using Endogenous Porphyrinization Induced by 5-Aminolevulinic Acid (ALA) Mechanisms and Clinical Results," *Journal of Clinical Laser Medicine & Surgery*, vol. 14, No. 5, 1996, pp. 289-304.

(11) (continued on next page)

Primary Examiner—William E. Kamm

(71) Attorney, Agent, or Firm—Foley & Lander

(57) ABSTRACT

An apparatus and method for photodynamic therapy or photodynamic diagnosis using an illuminator comprising a plurality of light sources generally conforming to a conical surface and emitting the conical surface with substantially uniform intensity visible light. The light sources may comprise generally U-shaped fluorescent tubes that are driven by electronic ballasts. Adjustment of the ballast voltage controls the output power of the tubes. The tubes are supported by a sheet-metal or plastic housing and are covered by a polycarbonate shield which directs cooling airflow within the unit and prevents glass-to-skin contact in the event of tube breakage. An aluminum reflector located behind the tubes increases both the output and the uniformity of the output distribution. The spacing of the U-shaped tubes is varied to increase the output at the edges of the illuminator to make the output more uniform. Also, different portions of the tubes are coated at different amounts, to improve uniformity. A light sensor monitors output from the U-shaped tubes to provide a signal for adjusting the output from the tubes.

(11) (continued on next page)

Ex. 1014 (Lundahl)

FIG. 1 is a top-down view of a circular illuminator assembly. It features a central circular opening (10) surrounded by a ring of U-shaped fluorescent tubes (40). The tubes are supported by a housing (70) and are connected to a power source (50) at the top. The assembly is mounted on a base (30). FIG. 2 is a side view of the illuminator, rotated counterclockwise 90 degrees. It shows the top side (28) and bottom side (107, 108) of the device. The tubes are arranged in a row, and the assembly is shown in a perspective view.

used for patient treatment. Another 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

Ex. 1014 (Lundahl), FIGs. 1-2 (Modified and Annotated), 6:22-30; Reply, 19

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

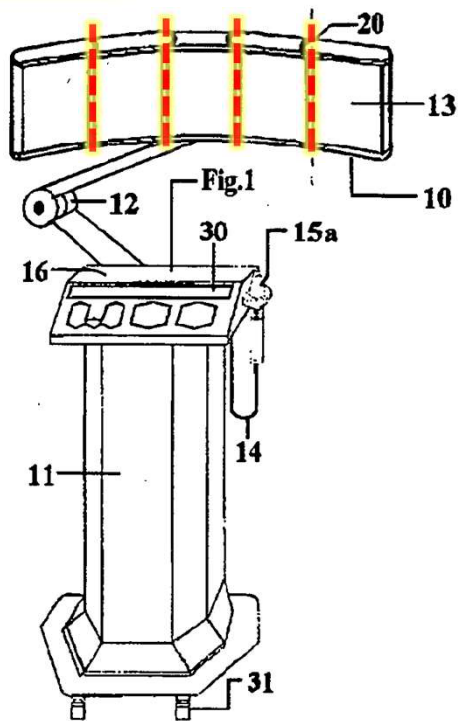
Biofrontera

37

Lundahl Teaches Higher Light Source Density at the Forehead and Chin

Larsen

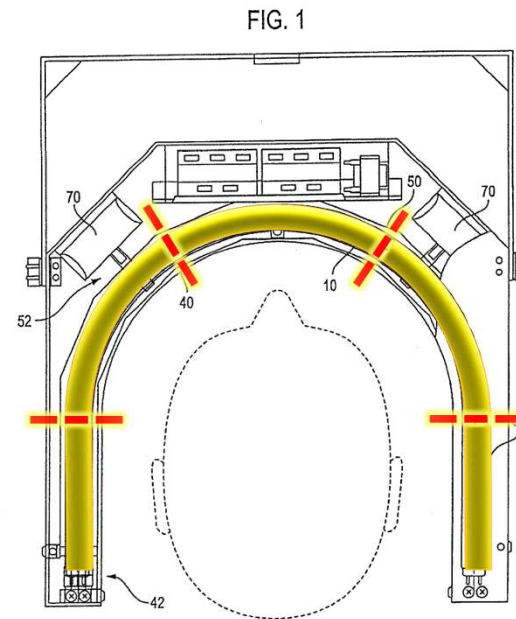
(Published 2005)



Ex. 1004 (Larsen), FIG. 1; Reply, 20

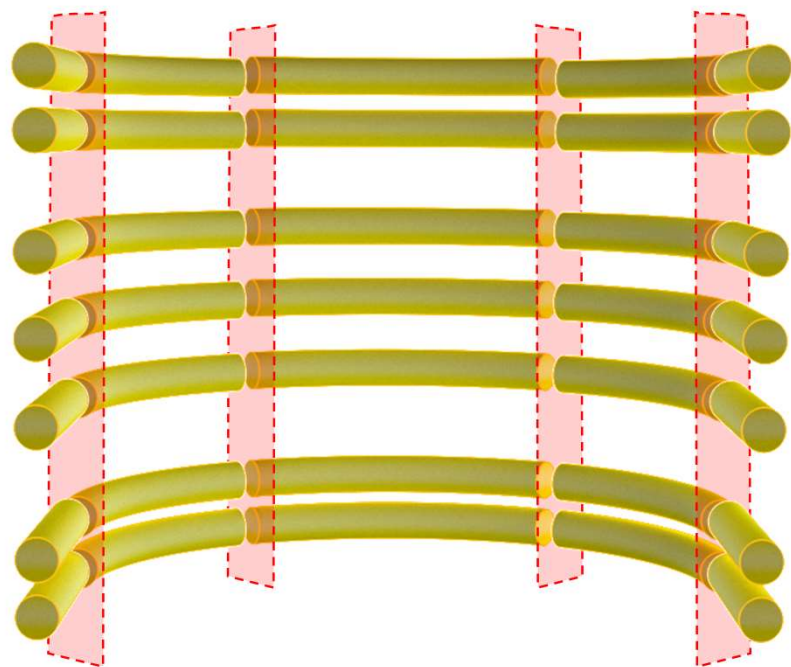
Lundahl

(Filed 1998)



Ex. 1014 (Lundahl), Fig. 1; Reply, 20

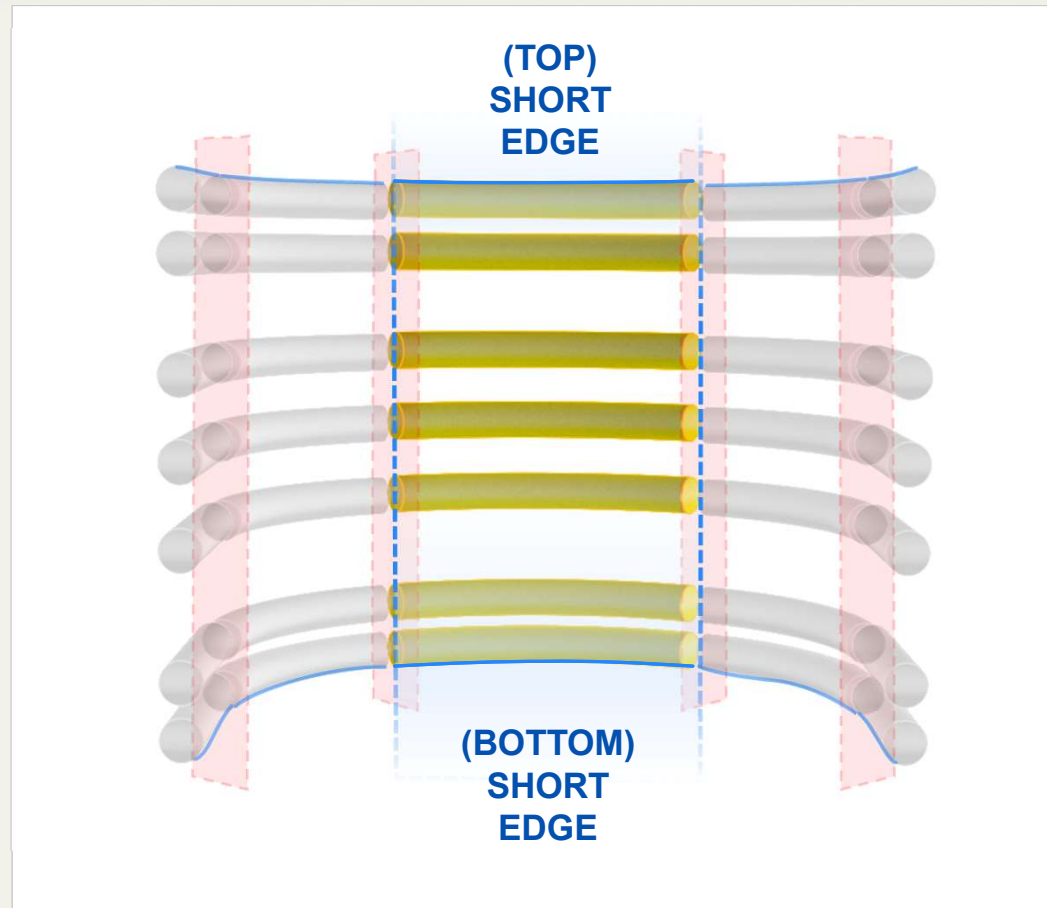
Lundahl Teaches Higher Light Source Density at the Forehead and Chin



Reply, 20

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

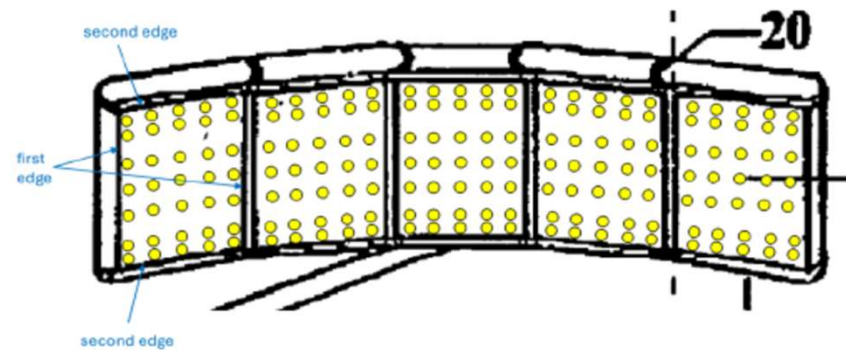
Lundahl's Light Source Distribution Would Result In Higher Intensity At The Shorter Edges Of Panels



Reply, 21

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

Lundahl's Light Source Distribution Would Result In Higher Intensity At The Shorter Edges Of Larsen's Panels



Ex. 1015 (Grove Dec.), ¶¶ 178; Reply, 21

required by the claims.” *Id.* at 61. However, based on our review of the Petition, our understanding is that Petitioner’s proposed modification applies Lundahl’s disclosure of providing greater light intensity at the top and bottom sides to the top and bottom sides of Larsen, which are the shorter edges in Larsen. *See, e.g.*, Pet. 45–48.

Institution Decision, 19

Dr. Jokerst: Lundahl Has Higher Intensity Near Forehead and Chin

So Figure 1 of Lundahl shows a U-shaped PDT device positioned around a patient's head, right?

A. Yes.

Q. And when the Lundahl device is used as shown in Figure 1, the device has a higher intensity of light emitted at the regions near the patient's forehead and chin, correct?

A. Yes, in the curved region, which would be near the forehead and the chin, yes.

Q. At the top and bottom?

A. Forehead and chin, yes.

Ex. 1032 (Jokerst ITC Testimony), 740:22-741:7; Reply, 19

Dr. Jokerst: Lundahl Divided into Five Panels Results in Shorter Edges on Top and Bottom Near Forehead and Chin

Q. Okay. So let's assume that a POSA were to divide up Lundahl's U shape and do a five-panel device. You would agree that the short edges of the five panels would roughly conform to the shape of the long edges of the fluorescent tubes when treating a patient, right?

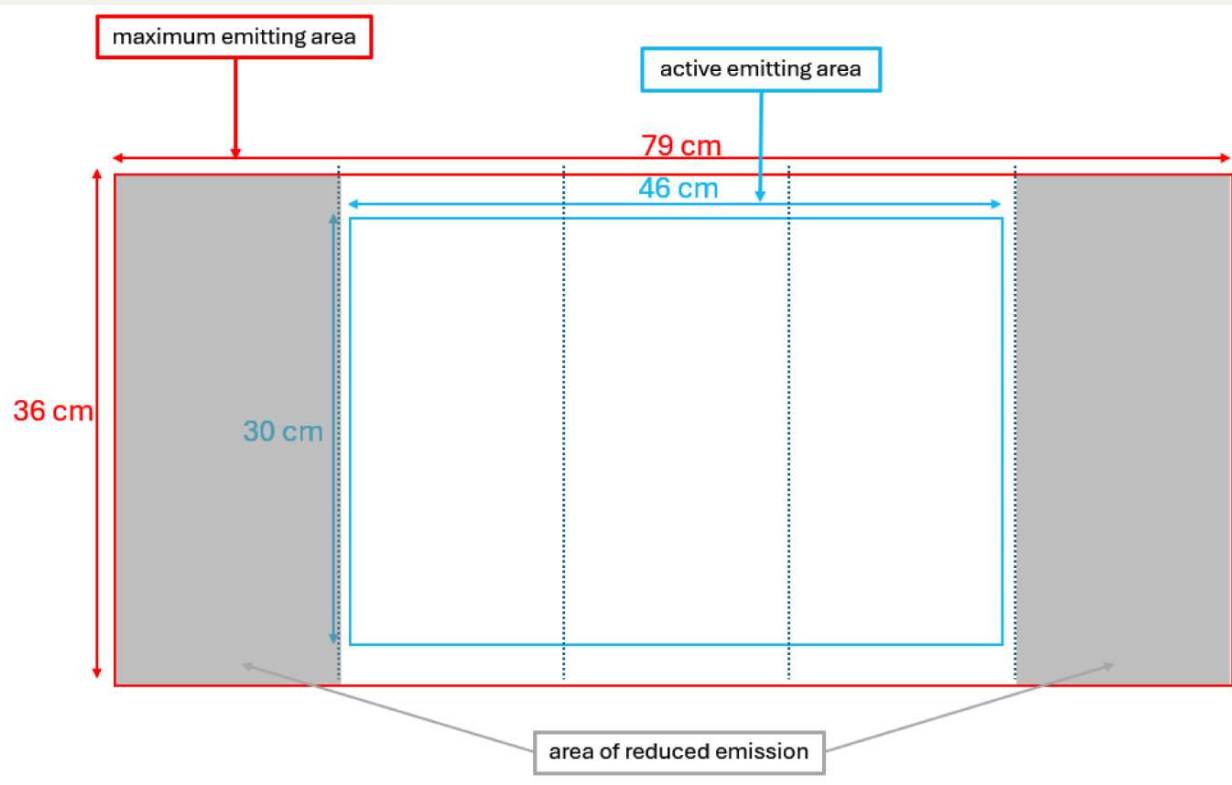
A. Yes.

Q. And if a POSA were to divide up that single U shape of Lundahl in the five-hinge panels, the panels would have a shorter edge on the top and bottom where the forehead and chin of a patient would be, right?

A. Yes.

Ex. 1032 (Jokerst ITC Testimony), 748:22-749:7; Reply, 19-20

Faraday Dark Spaces Don't Apply To A Combination Using LEDs



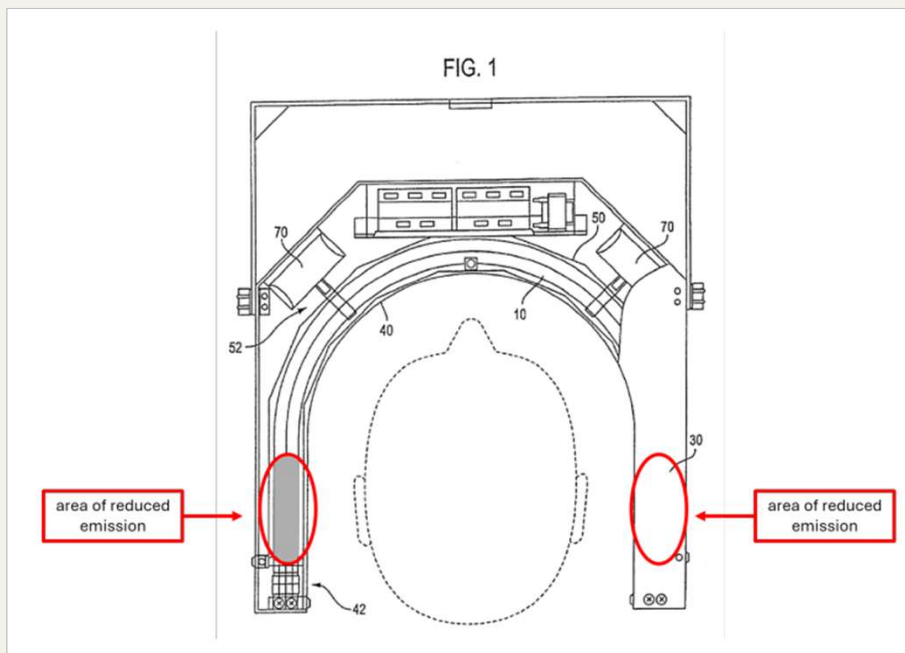
Reply, 17-18

Patent's Owner's argument is based on the Faraday Dark spaces consuming two of the panels, so that the first and fifth panels supposedly don't have higher intensity along the shorter edges.

POR, 35-38

Faraday Dark Spaces Don't Negate Lundahl's Teaching Of Higher Intensity

Patent's Owners representation of Lundahl's Faraday dark spaces



Ex. 2050 (Jokerst Dec.), ¶ 145; Reply, 15-18

Lundahl's Disclosure

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).

Ex. 1014 (Lundahl), 6:16-20

Patent Owner Response, 12

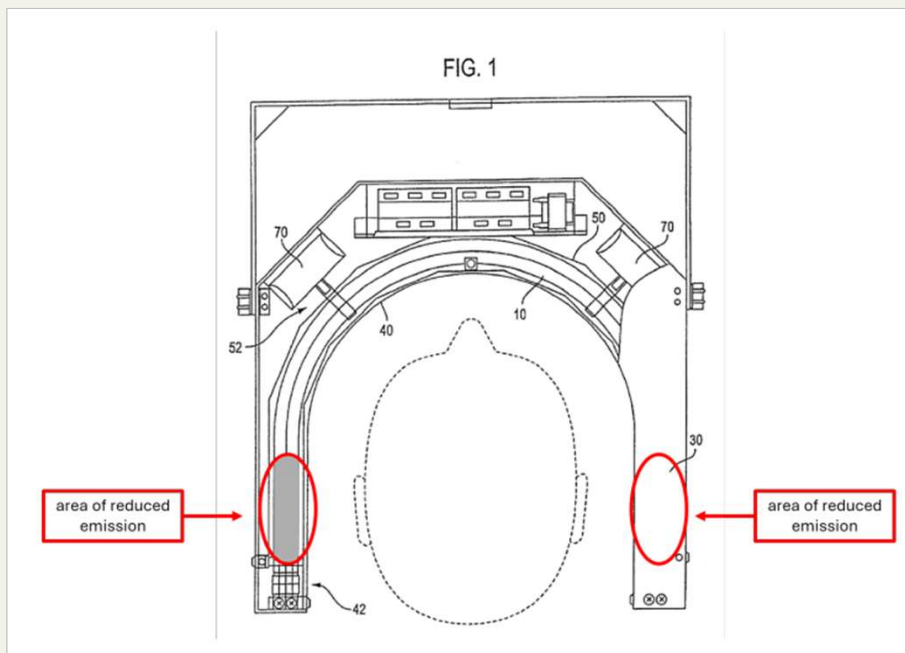
5:43-46, 9:43-54. Lundahl discloses the tubes have “*area[s] of reduced emission*” and “[t]he output measured in the immediate vicinity of the cathode is typically much lower than the output over the rest of the tube.” EX1014, 6:10-16.

Reply, 16

45

Patent Owner Exaggerates Faraday Dark Spaces

Patent's Owners representation of Lundahl's Faraday dark spaces



Ex. 2050 (Jokerst Dec.), ¶ 145; Reply, 15-18

≠

Dr. Roberts:

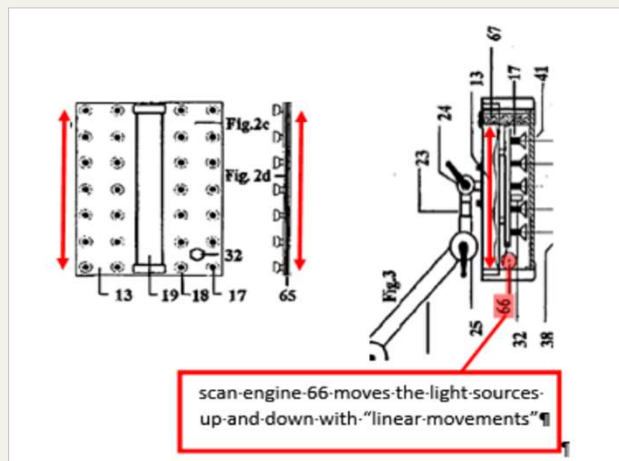
36. When treating patients' faces or necks, I have positioned them in the "U" of the device as shown above. When treating patients' arms or hands, I position the device over their extremities. When treating patients' chests or backs, I have had the patient turn to the right so the "U" of the device wraps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

Ex. 2015 (Roberts Dec.), ¶ 36; Reply, 18

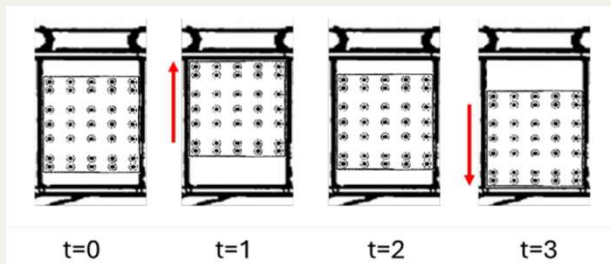
DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

No Basis For Patent Owner's Theory That Larsen's Scan Engine Would Interfere With Higher Intensity Proximate the Second Edges

Patent Owner's misrepresentation of Larsen's scan engine



Ex. 2050 (Jokerst Dec.), ¶ 151



Ex. 2050 (Jokerst Dec.), ¶ 152; Reply, 22

Dr. Jokerst's admission of the misrepresentation

19 Q. And these figures don't exist, as you show them
20 here, in Larsen, correct?

21 A. That is correct.

22 Q. And you've illustrated in this demonstrative your
23 opinion that, when included in a combination with aspects of
24 Lundahl, Larsen's scan engine would move the light sources
25 with linear movements up and down along the longer axis of
1 the applicators, correct?

2 A. Yes.

3 Q. Larsen doesn't disclose whether the scan engine
4 causes movements up or down or side to side, correct?

5 A. That's correct.

6 Q. Larsen doesn't disclose a pattern of movement for
7 the scan engine, right?

8 A. He says it's a linear motion.

9 Q. But other than saying it's a linear motion, he
10 doesn't disclose any pattern of movement, correct?

11 A. That's correct.

Ex. 1032, 741:19-742:11; Reply, 22

47

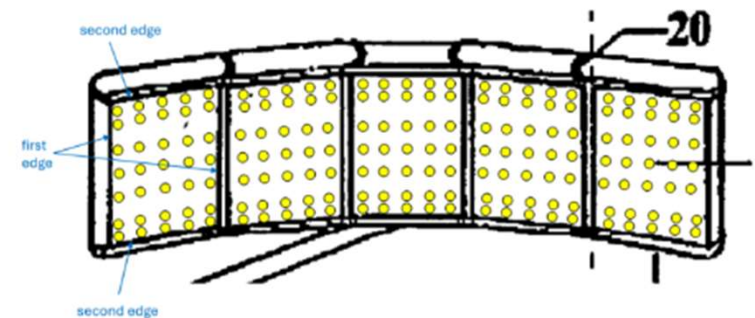
The ITC Initial Determination Overlooked Evidence

The ITC Initial Determination:

invention is further evidence of impermissible hindsight. Biofrontera never explains how combining Lundahl's disclosures with Larsen would satisfy the full limitation. Additionally,

Ex. 2090 (ITC Initial Determination), 114

Dr. Grove's IPR Declaration:



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.

Ex. 2015 (Grove Dec.), ¶¶ 178-179; Reply, 21

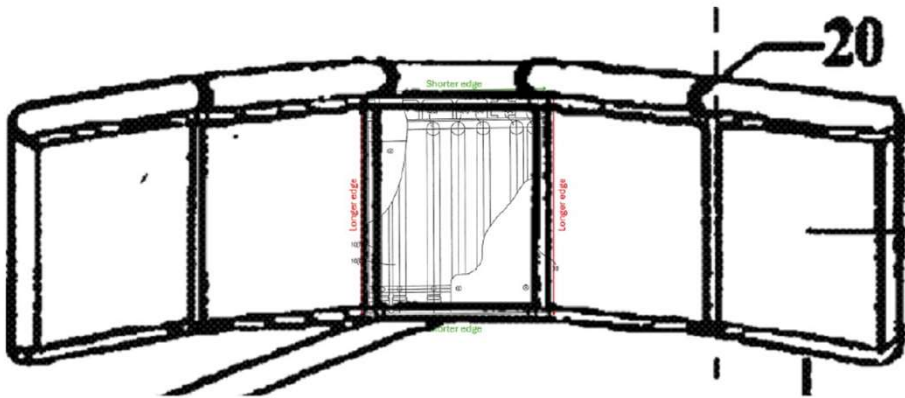
DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

The ITC Initial Determination Erred By Treating A POSITA Like An Automaton

The ITC Initial Determination:

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.

Ex. 2090 (ITC Initial Determination), 109



Ex. 2090 (ITC Initial Determination), 109

KSR Intern. Co. v. Teleflex Inc., 550 U.S. 398, 420-21 (2007)

“[I]n many cases a person of ordinary skill will be able to fit the teachings of multiple patents together like pieces of a puzzle...A person of ordinary skill is also a person of ordinary creativity, not an automaton.”

PGS Geophysical AS v. Iancu, 891 F.3d 1354, 1366 (Fed. Cir. 2018)

“[Plaintiff's] argument relies on the presumption that one of ordinary skill would blindly incorporate [secondary reference's] exact methodology into [primary reference]. But the Board properly did not view [defendant's] proposed combination to be so limited....”

The ITC Initial Determination Erred By Requiring Physical Incorporation Of Prior Art Structures

The ITC Initial Determination:

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

Ex. 2090 (ITC Initial Determination), 112

The ITC Initial Determination Mis-Applied Law To Find That Higher Intensity Near The Shorter Edges Was Not Obvious

The ITC Initial Determination:

Biofrontera further argues that insisting on a precise disclosure for this limitation “ignores a POSA’s capacity for basic creativity and common sense.” RIB at 59. But the Federal Circuit warned that “‘common sense’...cannot be used as a wholesale substitute for reasoned analysis and evidentiary support especially **when dealing with a limitation missing from the prior art references specified.**” *Arendi S.A.R.L. v. Apple Inc.*, 832 F.3d 1355, 1362 (Fed. Cir. 2016) (endorsing

Ex. 2090 (ITC Initial Determination), 110

So Figure 1 of Lundahl shows a U-shaped PDT device positioned around a patient's head, right?

A. Yes.

Q. And when the Lundahl device is used as shown in Figure 1, the device has a higher intensity of light emitted at the regions near the patient's forehead and chin, correct?

A. Yes, in the curved region, which would be near the forehead and the chin, yes.

Q. At the top and bottom?

A. Forehead and chin, yes.

Ex. 1032 (Jokerst ITC Testimony), 740:22-741:7; Reply, 19

Q. Okay. So let's assume that a POSA were to divide up Lundahl's U shape and do a five-panel device. You would agree that the short edges of the five panels would roughly conform to the shape of the long edges of the fluorescent tubes when treating a patient, right?

A. Yes.

Q. And if a POSA were to divide up that single U shape of Lundahl in the five-hinge panels, the panels would have a shorter edge on the top and bottom where the forehead and chin of a patient would be, right?

A. Yes.

Ex. 1032 (Jokerst ITC Testimony), 748:22-749:7; Reply, 20

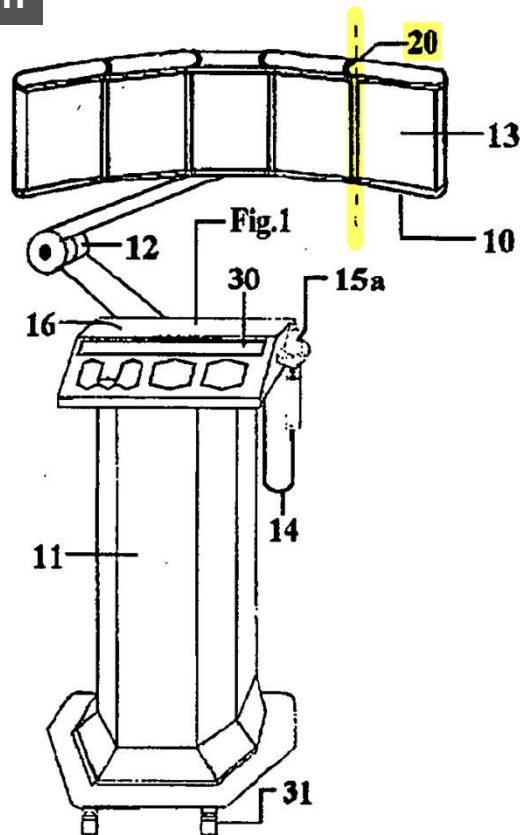
Hinges Limitation

(Claims 1, 5, 16, 20, and 21 of the '028 Patent)

Claim Limitations	Claim Language	Claims
Uniform Illumination	“the illuminator being configured to uniformly illuminate a treatment surface of the patient via the light sources”	1, 16, 20, 21
Higher Intensity	“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”	1, 16, 20, 21
Hinges	“an illuminator comprising five panels connected by hinged structures on inner side surfaces of adjacent panels”	1, 5, 20, and 21
	“five panels connected by hinged structures”	16

Larsen Teaches Hinges Between Panels

Larsen



Ex. 1004 (Larsen), FIG. 1; Reply, 23

[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

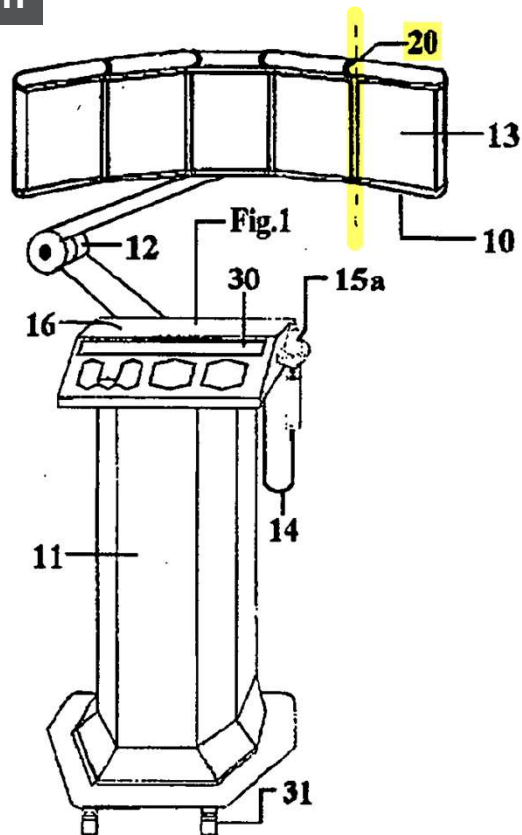
Ex. 1004 (Larsen), [0072]; Reply, 23-24

[0069] As shown in FIG. 1, the invented device 10 for the stimulation of cells with the aid of (PDT) photodynamic light and electromagnetic fields combined with light sensitive substances consists of a stand 11, with which machine applicators 13 (in the following just called applicators 13) are connected through a jointed arm 12. The stand 11 is also

Ex. 1004 (Larsen), [0069]; Reply, 23

Examiner Recognized that Larsen Teaches Hinges On Inner Side Surfaces Between Panels

Larsen



Examiner of the '028 Patent:

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

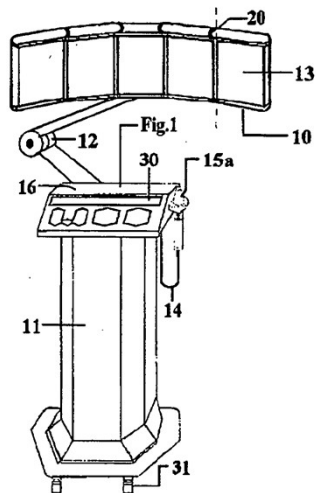
Ex. 1009 (file history of Application No. 17/009,871), 3; Reply, 24

Ex. 1004 (Larsen), FIG. 1; Reply, 23

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

Dr. Grove: Finite Number of Locations for Hinges and Most Common is On Inner Side Surfaces Between Panels

Larsen



Ex. 1004 (Larsen), FIG. 1

Dr. Grove:

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,

Ex. 1015 (Grove Dec.), ¶ 155; Petition, 38

Dr. Grove:

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.

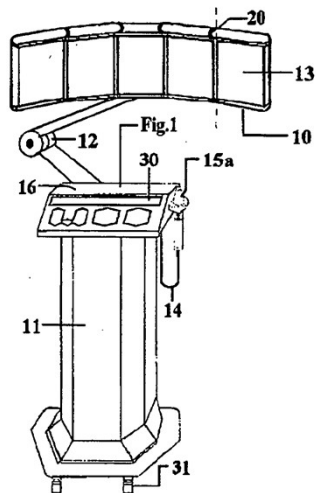
Q. Would a POSA have known that prior to 2015?

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

Ex. 1031 (Grove ITC Testimony), 592:2-8; Reply, 2

Larsen Reasonably Suggests Hinges On Inner Side Surfaces Between Panels

Larsen



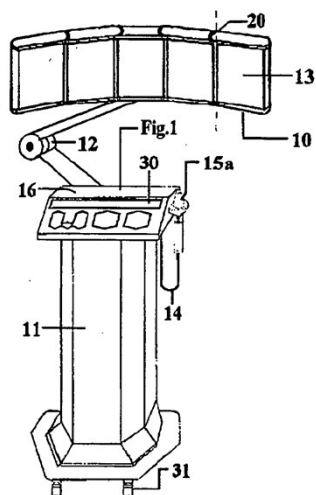
Ex. 1004 (Larsen), FIG. 1

Institution Decision, 18

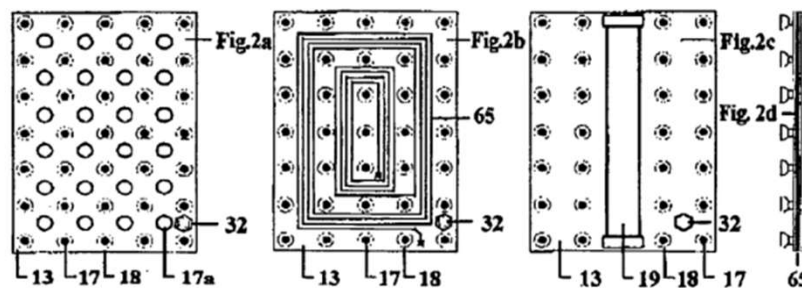
10); Ex. 1004 ¶ 72). However, Petitioner provides a reasonable argument that a skilled artisan considering Larsen's Figure 1 would have appreciated that, even if the hinges in Larsen were not located on the inner surface of the adjacent panels, placing the hinges in that location would have been a predictable means within the skill in the art for flexibly connecting the panels. See Pet. 37–38 (citing Ex. 1015 ¶¶ 154–156).

Dr. Jokerst: Element 20 is Not Listed in Figs. 2a-d

Larsen



Ex. 1004 (Larsen), FIG. 1



Ex. 1004 (Larsen), FIGS. 2a-d

Dr. Jokerst:

Q. Okay. And if we could bring up Figures 2A through D, they're all in a row.

You don't see any element 20 listed there, right?

A. In Figure 2, no.

Q. And -- yeah, just so we're clear, in Figures 2A, 2B, 2C, or 2D, you don't see anything relating to element 20, right?

A. There's not a number 20 pointing to any of those, but those are the regular row arrangements of LEDs and lasers.

Q. No, I understand that, but there is no element 20 listed there, right?

A. There's no number 20 pointing to any of those, yes.

Ex. 1032 (Jokerst ITC Testimony), 746:6-19

The ITC Initial Determination Erred By Treating Claim Scope Differently For Infringement Vs. Validity

The ITC Initial Determination:

In Finding Infringement:

“*The claims* require only that the ‘panels’ be ‘connected by’ hinges; they *do not specify where or how the hinges are connected to the panels.*” ID at 19 (emphasis added).

In Finding Validity:

The “cited art lacks a depiction of hinges, a description of their physical structure, and ‘does not disclose hinges in any detail.’” ID at 101; *see also id.* at n.8.

Larsen:

[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

Ex. 1004 (Larsen), [0072]; Petition, 30

Individually Configurable

(Claims 16 and 21 of the '028 Patent)

Claim Limitations	Claim Language	Claims
Uniform Illumination	“the illuminator being configured to uniformly illuminate a treatment surface of the patient via the light sources”	1, 16, 20, 21
Higher Intensity	“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”	1, 16, 20, 21
Hinges	“an illuminator comprising five panels connected by hinged structures on inner side surfaces of adjacent panels”	1, 5, 20, and 21
	“five panels connected by hinged structures”	16
Individually Configurable	“wherein the five panels are individually configurable to control illumination from each of the five panels”	16
	“the five panels are individually configurable to control illumination from each of the five panels”	21

Larsen Teaches Panels Connected to Control Mechanism for Adjustability of Light Output

Larsen

(19) United States
(12) Patent Application Publication (16) Pub. No.: US 2005/0075703 A1
Larsen (43) Pub. Date: Apr. 7, 2005

(54) PHOTODYNAMIC STIMULATION DEVICE AND METHODS (52) U.S. CL. 607/506, 607/100

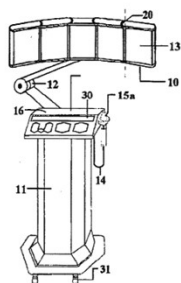
(70) Inventor: Erik Larsen, Schaffhausen (CH) (57) ABSTRACT

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(21) Appl. No.: 10466734
(22) PCT Filed: Jan. 22, 2002
(86) PCT No.: PCT/NO02/00033
(90) Foreign Application Priority Data
Jan. 22, 2001 (NO) 2001/0073

Publication Classification
(51) Int. Cl.⁷ A61N 5/06, A61F 2/00

A treatment device which uses a light radiation of multiple wavelengths and pulse-shaped electromagnetic fields for the photodynamic stimulation of cells, especially cells of human tissue, and also for the activation and stimulation of light sensitive substances (PTDs). The device produces energy radiation by the use of semiconductor and/or laser diodes, which emit light in several separate wavelengths due to a special operation mode and the use of tunable diodes. The equipment consists of a stand, with which machine applicators are connected via a jointed arm. The stand is flexibly movable on wheels and includes a control mechanism whereby the various parameters for therapy can be adjusted and switched on and off. The stand is also connected to a hand applicator for treatment of small tissue areas, e.g., suspicious spots. Photodynamic substances are introduced into the tissue with a special hand applicator.



Ex. 1004 (Larsen)

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

Ex. 1004 (Larsen), [0074]; Petition, 64

LED Controls Known to Adjust Brightness

An Introduction to Light-emitting Diodes

C. Michael Bourget

LED control systems allow the user to set various parameters of system operation, including brightness, time on or off (photo-periods), light quality, and color mixing (if multiple LED colors are used). Controls are usually interfaced to the driver circuitry to allow the brightness of the individual LEDs to be set. The control system can be as simple or complex as the application demands. Controls can be anything from manual adjustments to fully automated computer systems.

Ex. 2011 (Bourget Article), 2; Reply, 27

61

Larsen Discloses Individually Turning Light Sources On or Off

Larsen

(19) United States
(12) Patent Application Publication (10) Pub. No.: US 2005/0075703 A1
Larsen (43) Pub. Date: Apr. 7, 2005

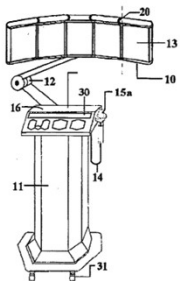
(54) PHOTODYNAMIC STIMULATION DEVICE AND METHODS (52) U.S. CL. 607/508, 607/100

(59) Inventor: Erik Larsen, Schiffman (30) (57) ABSTRACT

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(21) Appl. No.: 10/466,734
(22) PCT Filed: Jan. 22, 2002
(86) PCT No.: PCT/US02/00033
(80) Foreign Application Priority Data
Jan. 22, 2001 (US) 2001 00733

Publication Classification
(51) Int. Cl. A61N 5/06, A61F 2/00



Ex. 1004 (Larsen)

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,

the wavelength of the light source is adjustable to correspond with the light sensitive substance and the indication type,

the supply of the light sources are adjustable and selectable in modes like a continuous and a pulsed mode, wherein the frequency, pulse-length and amplitude of the current pulses are selected to correspond with the type of indication and/or light sensitive substance,

the frequency, pulse-shape and amplitude of the electromagnetic field pulses are adjustable to correspond with the type of indication and the light sensitive substance, wherein the light sensitive substances is are introduced to the tissue to be treated by help of a hand applicator of the inventive device using a method of air-pressure and/or iontophoresis and/or photophoresis.

Ex. 1004 (Larsen), cl. 1

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

Ex. 1004 (Larsen), cl. 5; Reply, 26-27

Larsen's Feedback Control Demonstrates Individual Configurability

Larsen

(19) United States
(12) Patent Application Publication (16) Pub. No.: US 2005/0075703 A1
Larsen (43) Pub. Date: Apr. 7, 2005

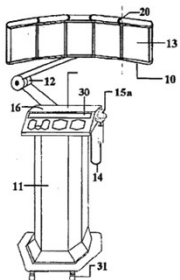
(54) PHOTODYNAMIC STIMULATION DEVICE AND METHODS (52) U.S. CL. 607/506, 607/100

(73) Inventor: Erik Larsen, Schaffhausen (CH) (57) ABSTRACT

Correspondence Address:
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(21) Appl. No.: 18046674
(22) PCT Filed: Jan. 22, 2002
(86) PCT No.: PCT/NO2002/00033
(80) Foreign Application Priority Data
Jan. 22, 2001 (NO) 2001/0073

Publication Classification
(51) Int. Cl. A61N 5/06; A61F 2/00



Ex. 1004 (Larsen)

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

Ex. 1004 (Larsen), [0079]; Petition, 42

[0080] A sensor 32a is also contained in at least one of the machine applicators, measuring the temperature change of the radiated tissue, whereby the control unit can react with a feedback regulation of the radiation parameters depending on the therapy indication, location and (PDT) light sensitive substance used.

Ex. 1004 (Larsen), [0080]; Petition, 65

The ITC Initial Determination Misinterpreted Claim 1

Larsen

(19) United States
(12) Patent Application Publication (10) Pub. No.: US 2005/0075703 A1
Larsen (43) Pub. Date: Apr. 7, 2005

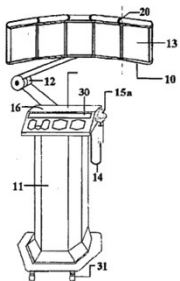
(54) PHOTODYNAMIC STIMULATION DEVICE AND METHODS (52) U.S. CL. 607/506, 607/100

(50) Inventor: Erik Larsen, Schiffman (30) (57) ABSTRACT

Correspondence Address:
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SUITE 1210
NEW YORK, NY 10076 (US)

(21) Appl. No.: 18046734
(22) PCT Filed: Jan. 22, 2002
(86) PCT No.: PCT/NO2002/00033
(80) Foreign Application Priority Data
Jan. 22, 2001 (NO) 2001/0373

Publication Classification
(51) Int. Cl.⁷ A61N 5/06, A61F 2/00



Ex. 1004 (Larsen)

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,

the wavelength of the light source is adjustable to correspond with the light sensitive substance and the indication type,

the supply of the light sources are adjustable and selectable in modes like a continuous and a pulsed mode, wherein the frequency, pulse-length and amplitude of the current pulses are selected to correspond with the type of indication and/or light sensitive substance,

the frequency, pulse-shape and amplitude of the electromagnetic field pulses are adjustable to correspond with the type of indication and the light sensitive substance, wherein the light sensitive substances is are introduced to the tissue to be treated by help of a hand applicator of the inventive device using a method of air-pressure and/or iontophoresis and/or photophoresis.

Ex. 1004 (Larsen), cl. 1

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

Ex. 1004 (Larsen), cl. 5; Reply, 26

Continuous Illumination

(Claim 16 of the '028 Patent)

Claim Limitations	Claim Language	Claims
Uniform Illumination	“the illuminator being configured to uniformly illuminate a treatment surface of the patient via the light sources”	1, 16, 20, 21
Higher Intensity	“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”	1, 16, 20, 21
Hinges	“an illuminator comprising five panels connected by hinged structures on inner side surfaces of adjacent panels”	1, 5, 20, and 21
	“five panels connected by hinged structures”	16
Individually Configurable	“wherein the five panels are individually configurable to control illumination from each of the five panels”	16
	“the five panels are individually configurable to control illumination from each of the five panels”	21
Continuous Illumination	“five panels connected by hinged structures to allow continuous illumination across the five panels,”	16

Larsen Teaches Treating Large Areas with Gap-Free Radiation

Larsen

(19) United States
(12) Patent Application Publication (10) Pub. No.: US 2005/0075703 A1
Larsen (43) Pub. Date: Apr. 7, 2005

(54) PHOTODYNAMIC STIMULATION DEVICE AND METHODS (52) U.S. CL. 607/506, 607/100

(59) Inventor: Erik Larsen, Schiffman (30) (57) ABSTRACT

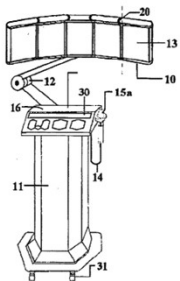
Correspondence Address:
COHEN, PONTANI, LIEBERMAN & PASANE
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(21) Appl. No.: 10/466,734
(22) PCT Filed: Jan. 22, 2002
(86) PCT No.: PCT/NO2002/00033

(90) Foreign Application Priority Data
Jan. 22, 2001 (NO) 2001/0073

Publication Classification
(51) Int. Cl.⁷ A61N 5/06, A61F 2/00

A treatment device which uses a light radiation of multiple wavelengths and pulse-shaped electromagnetic fields for the photodynamic stimulation of cells, especially cells of human tissue, and also for the activation and stimulation of light sensitive substances (PTDs). The device produces energy radiation by the use of semiconductor and/or laser diodes, which emit light in several separate wavelengths due to a special operation mode and the use of tunable diodes. The equipment consists of a stand, with which machine applicators are connected via a jointed arm. The stand is flexibly movable on wheels and includes a control mechanism whereby the various parameters for therapy can be adjusted and switched on and off. The stand is also connected to a hand applicator for treatment of small tissue areas, e.g., suspicious growth. Photodynamic substances are introduced into the tissue with a special hand applicator.



Ex. 1004

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.

Ex. 1004, [0027]

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

Ex. 1004, [0028]; Petition, 22

Patent Owner Misrepresents Bretschneider Declaration

Patent Owner's misrepresentation
of Dr. Bretschneider's declaration

Dr. Bretschneider's declaration

Indeed, Petitioner's own expert, Dr. Bretschneider, admitted in the first IPR that Larsen does not provide continuous illumination across the five panels—he stated there are “lower irradiance regions at the junction of two of Larsen's panels.” EX2082, ¶151. A POSITA would understand that with “lower irradiance regions

POR, 64

151. A person of ordinary skill in the art would understand that the gaps between adjacent panels could lead to regions of low irradiance on the patient's skin. Larsen's applicators are designed to provide an “even and gap-free radiation of the surface with multiple wavelengths of light.” [Larsen, ¶0028]. Larsen also recognizes that using multiple light panels allows for better treatment of different surface areas of a patient, such as the back, to allow for “equidistant positioning of the applicators 13 above the skin.” [Larsen, ¶0072]. A POSITA would have been motivated to use Bansal's non-uniform LED arrays which include a higher density of LEDs at the periphery of panels to ameliorate lower irradiance regions at the junction of two of Larsen's panels. Bansal's Figures 9a-9d provide examples of this.

Ex. 2082, ¶151 (quoting Ex. 1004 (Larsen), [0028])

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

Appendix

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

Patent Owner's Motion to Exclude Under FRE 403

Patent Owner:

Pursuant to 37 C.F.R. § 42.64(c), Patent Owner Sun Pharmaceutical Industries, Inc. ("Patent Owner" or "Sun Pharma") moves to exclude ¶¶12-17 and 19 (the "New Opinion Paragraphs") of EX1026 (Supplemental Declaration of Dr. Grove) and 591:5-7 and 592:2-8 (the "ITC Testimony") of EX1031 (ITC Trial Transcript Day 3) under Federal Rule of Evidence (FRE) 403 because they introduce new theories and opinions that were not included in the Petition.

Paper 40 at 1

In short, ¶¶12-17 and 19 of EX1026 introduce new obviousness theories that could have been included in the Petition, but were not. Petitioner's reliance on the New Opinion Paragraphs in its Reply is unduly prejudicial to Patent Owner, and these paragraphs should be excluded.

Paper 40 at 10

***Apple. v. Parus*, IPR2020-00686, Paper No. 37 at 41-42 (PTAB Sept. 9, 2021)**

"a motion to exclude is not a vehicle to 'address arguments or evidence that a party believes exceeds the proper scope of reply or sur-reply.'"

Paper 41 at 10-11

***Neste Oil Oyj v. Reg Synthetic Fuels, LLC*, IPR2013-00578, Paper No. 53 at 10 (PTAB Mar. 12, 2015)**

"Proceedings before the Board are not jury trials; in the absence of a jury, the risk of unfair prejudice against which Rule 403 guards is diminished, if not eliminated entirely."

Paper 41 at 9

Petitioner Opposition to Motion to Exclude Under FRE 403

FRE 403:

headings, but never once addresses FRE 403 in any of its arguments. FRE 403 states that “[t]he court may exclude relevant evidence if its probative value is substantially outweighed by a danger of one or more of the following: unfair prejudice,...” FRE

Paper 41 at 8

Probative Value of Evidence is Considerable:

Here, the probative value of the evidence is considerable, as it presents Dr. Groves’s testimony regarding how a POSITA would interpret the combined teachings of Lundahl and Larsen to render obvious uniform illumination of a treatment surface, relying in part on the well-established knowledge of a POSITA related to light distribution properties of LEDs. *See* Ex 1026 at ¶¶12-17; Ex. 1032

Paper 41 at 8

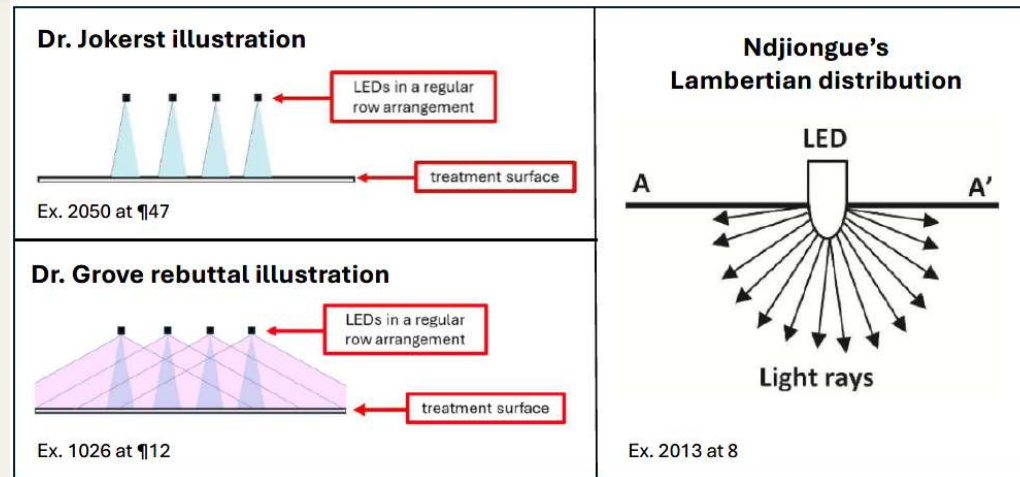
Captioncall LLC v. Ultratec, Inc., IPR2014-00780, Paper No. 35 at 8 (PTAB Dec. 1, 2015)

“Patent Owner fails to address the ‘substantially outweighed’ aspect of the Rule [FRE 403].”

Paper 41 at 8

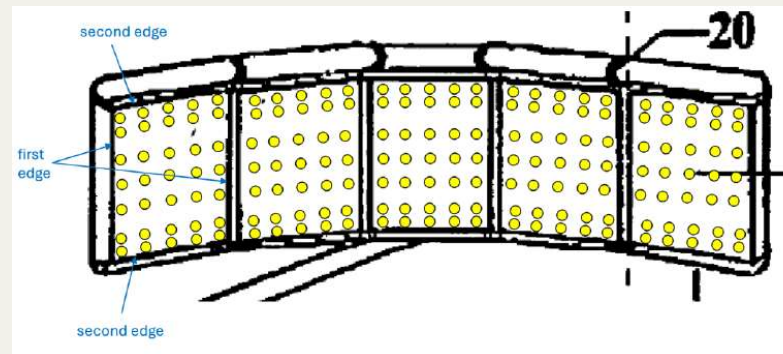
Petitioner Opposition to Motion to Exclude Under FRE 403

Ex 1026 is Rebuttal Evidence:



Paper 41 at 4

Ex 1026 Maintains Same Argument in Petition:



Paper 41 at 13

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

Petitioner Opposition to Motion to Exclude Under FRE 403

Ex 1031 is Rebuttal Evidence:

Larsen's panels. Starting with the first excerpt at 591:5-7, Dr. Grove testified that there are "three locations" to place a hinge on Larsen's panels. Ex. 1031 at 590:25-591:7; *see also id.* at 591:18-20 (ITC judge overruling Patent Owner's objection to this testimony). This testimony directly rebuts Dr. Jokerst's testimony that the "hinges could be placed in numerous locations." *See* Ex. 2050 at ¶174.

Ex 1031 Maintains Same Argument:

Patent Owner acknowledges that Dr. Grove's original declaration asserts that hinges on an inside panel "involved nothing more than the use of a known prior art element according to known methods to yield predictable results," but inexplicably argues to exclude Dr. Grove's ITC testimony providing an example of a known prior art hinge being a "butt hinge," which is the "most common option for connecting

Next, the second excerpt at 592:2-8, provides Dr. Grove's testimony that the most common option known to a POSITA for connecting panels with hinges "is to put what are called butt hinges between the two panels," which had been used for generations. Ex. 1031 at 592:2-8. Again, this is direct rebuttal to at least Dr. Jokerst's testimony that "a POSITA reading Larsen's disclosure would have attached hinges to the bottom of the panels." Ex. 2050 at ¶174 (emphasis omitted).

Paper 41 at 7

Similarly, Patent Owner acknowledges that Dr. Grove's original declaration opined that there are a "finite number" of ways to connect hinges to Larsen's panels but now asks the Board to exclude Dr. Grove's ITC testimony that there are "three locations" to connect hinges to Larsen's panel. PO Mot. to Exclude at 11-12; Ex. 1031 at 592:2-5. Yet, Dr. Grove is still relying on a theory of a "finite number" but has simply elaborated that the finite number of locations is three.

Paper 41 at 15 72

CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of the Petitioner's Demonstratives was previously served on November 25, 2025, via email directed to the following counsel of record for the Patent Owner:

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