

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.¹

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

**PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO.
11,697,028 UNDER 35 U.S.C. §§ 311–319 AND 37 C.F.R. § 42.100 *et seq.***

¹ Sun Pharmaceutical Industries, Inc. asserts it is the “sole owner” of U.S. Patent No. 11,697,028 and the surviving corporation after a merger with DUSA Pharmaceutical, Inc. on March 31, 2024. Ex. 1018 at 1 and 11, FN2.

TABLE OF CONTENTS

I.	INTRODUCTION	5
II.	MANDATORY NOTICES	5
A.	Real Party-In-Interest (37 C.F.R. § 42.8(b)(1))	5
B.	Related Matters (37 C.F.R. § 42.8(b)(2)).....	6
C.	Lead and Backup Counsel (37 C.F.R. § 42.8(b)(3))	7
D.	Service Information (37 C.F.R. § 42.8(b)(4))	7
E.	Payment of Fees (37 C.F.R. §§ 42.15(a) and 42.103(a))	8
F.	Certification of Word Count Under 37 C.F.R. § 42.24(d).....	8
III.	GROUND FOR STANDING UNDER 37 C.F.R. § 42.104(a).....	8
IV.	IDENTIFICATION OF GROUNDS FOR WHICH REVIEW IS REQUESTED UNDER 37 C.F.R. § 42.104(b)(1)	9
V.	THE CONTESTED PATENT	9
A.	Effective Filing Date of the ‘028 Patent	9
B.	Overview of the ‘028 Patent.....	9
C.	Prosecution History	11
D.	Claim Construction.....	12
VI.	State of Technology AT THE TIME OF THE INVENTION.....	13
A.	Actinic Keratosis	13
B.	Photodynamic therapy	14
C.	Photodynamic Therapy in the modern LED era (post-2000).....	15
VII.	SUMMARY OF PRIOR ART.....	17
A.	Lundahl (Ex.1014).....	17
B.	Larsen (Ex.1004)	21
C.	Bansal (Ex.1005).....	22
VIII.	Level of SKill in the Art	23
IX.	Proposed Grounds of Rejection.....	25

A.	Lundahl in view of Larsen Renders Obvious Claims 1, 2, 4-6, 16, 17, 19, 20, and 21	25
1.	Motivation to Combine	25
a.	Increasing flexibility of device for use with all head sizes and shapes, as well as varying anatomies	27
b.	Increasing light output consistency by changing the light source from fluorescent tubes to LEDs.....	31
c.	Increasing light absorption at deeper skin depths by emitting red light.....	32
2.	Claim 1	35
3.	Claim 2	49
4.	Claim 4.....	52
5.	Claim 5.....	52
6.	Claim 6.....	56
7.	Claim 16.....	58
8.	Claim 17	68
9.	Claim 19	68
10.	Claim 20	68
11.	Claim 21	71
B.	Lundahl in view of Larsen, and further in view of Bansal Render Obvious Claims 1, 2, 4-6, 16, 17, 19, 20, and 21	73
1.	Motivation to Combine	73
2.	Bansal further teaches “uniformly illuminate a treatment surface of a patient” recited in limitations 1(c), 5(d), 16(h), 20(c), and 21(c)	74
3.	Bansal further teaches “a higher intensity of light is emitted proximate the second edges” recited in limitations 1(g), 5(h), 16(k), 20(g), and 21(h)	75
4.	Remaining limitations and dependent claims	77
X.	The Board Should Not Exercise its Discretion to Deny Institution	78
A.	35 U.S.C. § 325(d).....	78
B.	<i>Fintiv</i>	80
XI.	CONCLUSION.....	80

PETITIONER’S EXHIBITS²

Exhibit No.	Description
1001	U.S. Patent No. 11,697,028 by Thomas Boyajian et al. entitled “Adjustable Illuminator for Photodynamic Therapy and Diagnosis” (“’028 Patent”)
1002	File History for U.S. Patent No. 11,697,028 provided in Application No. 17/942,353
1003	Reserved
1004	U.S. Patent Publication No. 2005/0075703 by Eric Larsen entitled “Photodynamic Stimulation Device and Methods” (“Larsen”)
1005	U.S. Patent Publication No. 2004/0068305 by Vineet Bansal et al. entitled “Phototherapy System and Device” (“Bansal”)
1006	Reserved
1007	Reserved
1008	U.S. Patent No. 7,033,381 (“Larsen ’381”)
1009	Office Action dated March 23, 2021, from file history of Application No. 17/009,871
1010	Office Action dated October 25, 2021, from file history of Application No. 16/791,004
1011	WO 99/56827 by Scott Lundhal et al. entitled “Illuminator for Photodynamic Therapy”
1012	Reserved
1013	U.S. Patent No. 11,179,574 by Thomas Boyajian et al. entitled “Method of administering 5-aminolevulinic acid (ALA) to a patient”
1014	U.S. Patent No. 6,223,071 (“Lundahl”)
1015	Declaration of Dr. Robert Grove
1016	Declaration of Dr. Michael Ehrenreich
1017	U.S. Pat. No. 5,079,262 (“Kennedy”)
1018	Complaint filed in <i>Sun Pharmaceutical Industries, Inc. v. Biofrontera Bioscience GmbH, Biofrontera Pharma GmbH</i> ,

² For consistency, Petitioner has used the same exhibit numbers as in IPR2024-00874 for identical documents. Exhibit number marked as “reserved” are exhibits submitted in IPR2024-00874 that are not relied on in the instant petition.

Petition for Inter Partes Review of
U.S. Patent No. 11,697,028

Exhibit No.	Description
	<i>Biofrontera AG, and Biofrontera Inc.</i> , Civil Action No. 1:24-cv-11637 (D. Mass) (filed on June 25, 2024)
1019	Plaintiff’s Infringement Contentions submitted as Exhibit 4 attached to complaint filed in <i>Sun Pharmaceutical Industries, Inc. v. Biofrontera Bioscience GmbH, Biofrontera Pharma GmbH, Biofrontera AG, and Biofrontera Inc.</i> , Civil Action No. 1:24-cv-11637 (D. Mass) (filed on June 25, 2024)
1020	<i>In Re Certain Photodynamic Therapy Systems, Components Thereof, And Pharmaceutical Products Used In Combination With The Same</i> , Investigation No. 337-TA-1411 (complaint filed on June 25, 2024)
1021	Agostinis et. al., <i>Photodynamic Therapy of Cancer: An Update</i> , <i>CA Cancer J Clin.</i> Author manuscript; available in PMC 2012 July 1 (also published in final edited form at <i>CA Cancer J Clin.</i> 2011 ; 61(4): 250–281)
1022	Levulan® Kerastick® (aminolevulinic acid HCl) for Topical Solution, 20% Initial U.S. Approval: 1999, Revised 3/2010
1023	Michael H, Gold, MD, <i>Therapeutic and Aesthetic Uses of Photodynamic Therapy Part two of a five-part series: Lasers and Light Treatments for Acne Vulgaris Promising Therapies</i> , <i>The Journal of Clinical and Aesthetic Dermatology</i> , Vol. 1 No. 3 (2008).

I. INTRODUCTION

Biofrontera Inc., Biofrontera Bioscience GmbH, Biofrontera Pharma GmbH, and Biofrontera AG (collectively, “Petitioner”) hereby respectfully request *inter partes* review of claims 1, 2, 4-6, 16, 17, and 19-21 (“Challenged Claims”) of U.S. Patent No. 11,697,028 (“the ‘028 Patent”) pursuant to 35 U.S.C. §§ 311-319. There exists a reasonable likelihood that Petitioner will prevail with respect to at least one of the Challenged Claims, which are unpatentable over the prior art identified herein.

Petitioner previously filed an IPR petition challenging the ‘028 Patent on April 30, 2024. *See* IPR2024-00874. Along with the instant IPR petition, Petitioner is concurrently submitting a separate notice addressing the parallel nature of these two IPR petitions and why the Board should institute the instant IPR petition. *See* Patent Trial and Appeal Board Consolidated Trial Practice Guide, November 2019 at 59-61.

II. MANDATORY NOTICES

Pursuant to 37 C.F.R. § 42.8, Petitioner provides the following disclosures:

A. Real Party-In-Interest (37 C.F.R. § 42.8(b)(1))

The real parties-in-interest for Petitioner are Biofrontera AG, Biofrontera Bioscience GmbH, Biofrontera Pharma GmbH, and Biofrontera Inc. Additionally, Petitioner further identifies Biofrontera Neuroscience GmbH and Biofrontera Development GmbH as real parties-in-interest for the IPR requested by this Petition,

solely to the extent that Patent Owner contends that these separate legal entities should be named real parties-in-interest in the requested IPR, and Petitioner does so to avoid the potential expenditure of resources to resolve such a challenge. No unnamed entity is funding, controlling, or otherwise has an opportunity to control or direct this Petition or Petitioner's participation in any resulting IPR.

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.

DISTRICT COURT LITIGATION

Sun Pharmaceutical Industries, Inc. v. Biofrontera Bioscience GmbH, Biofrontera Pharma GmbH, Biofrontera AG, and Biofrontera Inc., Civil Action No.

1:24-cv-11637 (D. Mass) (complaint filed on June 25, 2024). See Ex.1018 and Ex.1019.

C. Lead and Backup Counsel (37 C.F.R. § 42.8(b)(3))

Lead Counsel	Backup Counsel
James P. Murphy Reg. No. 55,474 Polsinelli PC 1000 Louisiana Street Suite 6400 Houston, Texas 77002 Tel: (713) 374-1631 jpmurphy@polsinelli.com	Corey Casey Reg. No. 66,950 Polsinelli PC 900 West 48 th Place Suite 900 Kansas City, Missouri 64112 Tel: (816) 572-4439 ccasey@polsinelli.com Megan Hart Reg. No. 79,202 Polsinelli PC 7676 Forsyth Blvd. Suite 800 St. Louis, Missouri 63105 Tel: (314) 622-6107 mkhart@polsinelli.com

Pursuant to 37 C.F.R. § 42.10(b), Powers of Attorney have been filed with this Petition.

D. Service Information (37 C.F.R. § 42.8(b)(4))

Petitioner consents to service by e-mail at the above e-mail addresses provided above for lead and backup counsel. Physical mailing service information is as follows:

James Murphy
Polsinelli PC
1000 Louisiana Street
Suite 6400
Houston, Texas 77002

E. Payment of Fees (37 C.F.R. §§ 42.15(a) and 42.103(a))

All required fees have been paid with the filing of this Petition. Petitioner further authorizes the U.S. Patent & Trademark Office to charge Deposit Account No. 50-1662 for any fees, including the fee set forth in 37 C.F.R. § 42.15(a) for this Petition.

F. Certification of Word Count Under 37 C.F.R. § 42.24(d)

Petitioner certifies that the word count in this Petition, including all footnotes, is 13,991 words as counted by the word-processing program (Microsoft Word for Office 365) used to generate this Petition, where such word count excludes the table of contents, mandatory notices, certificate of service, list of exhibits, and this certificate of word count. This Petition is in compliance with the 14,000 word limit set forth in 37 C.F.R. § 42.24(a)(1)(i).

III. GROUNDS FOR STANDING UNDER 37 C.F.R. § 42.104(A)

Petitioner certifies that the '028 patent is available for *inter partes* review. Petitioner is not barred or estopped from requesting an *inter partes* review of the '028 patent claims on the grounds identified in this Petition. 37 C.F.R. § 42.104(a).

IV. IDENTIFICATION OF GROUNDS FOR WHICH REVIEW IS REQUESTED UNDER 37 C.F.R. § 42.104(B)(1)

Petitioner asserts that claims 1, 2, 4-6, 16, 17, and 19-21 of the '028 patent are unpatentable based on the following ground:

Ground 1: Claims 1, 2, 4-6, 16, 17, and 19-21 are obvious over Lundahl in view of Larsen.

Ground 2: Claims 1, 2, 4-6, 16, 17, and 19-21 are obvious over Lundahl in view of Larsen and further in view of Bansal.

V. THE CONTESTED PATENT

A. Effective Filing Date of the '028 Patent

The '028 Patent claims priority to Provisional Application No. 62/241,902, filed on October 15, 2015. All of the prior art references were published more than one year before October 15, 2015.³

B. Overview of the '028 Patent

The '028 Patent describes illuminators providing “a uniform distribution of visible light in a number of configurations and is suitable for use in photodynamic therapy and diagnosis.” Ex.1001, 1:19-22. The illuminators are used in photodynamic therapy (“PDT”) or photodynamic diagnosis (“PD”). In PDT or PD,

³ Petitioner does not concede that the Challenged Claims are entitled to this effective filing date. Ex.1015, ¶51.

a patient is administered a photoactivatable agent or precursor of a photoactivatable agent. *Id.*, 1:36-39. The area in which the photoactivatable agent is administered is then exposed to visible light, which causes a chemical and/or biological change in the photoactivatable agent, which in turn results in the destruction or alteration of the target area. *Id.*, 1:29-44; Ex.1015, [0055].

As shown below, the illuminator uses multiple panels that are rotatably connected by hinges. Ex.1001, 4:25-50.

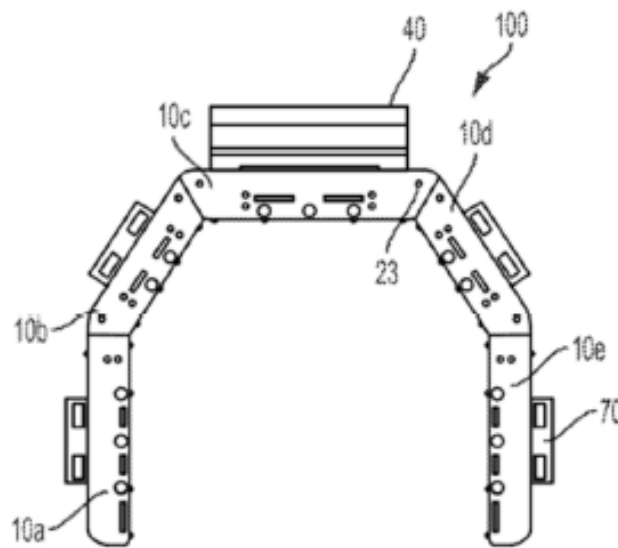


FIG. 1A

Each panel includes LED arrays that provide uniform light exposure to a patient using addressable strings of lights, as shown below. *Id.*, 6:11-27.

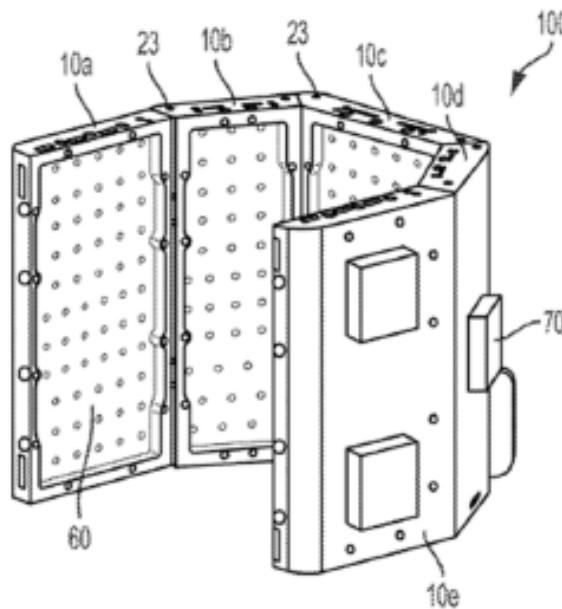


FIG. 2A

The '028 Patent admits that using illuminators that provide a uniform output of light on the patient's skin for PD or PDT was known in the art. Ex.1001, 1:36-62. Rather, in the embodiments in the '028 Patent, a higher intensity of light is emitted overall from the edges of the panels. *Id.*, 6:24-50. Yet numerous prior art references disclose or teach the claimed panels with varying intensities of light emitted from different regions of each panel to address this very same problem identified by the '028 Patent. See Ex.1015, ¶¶75-117.

C. Prosecution History

The '028 Patent was filed on September 12, 2022, as application number 17/942,353. Petitioner summarizes here the actions most relevant to its grounds of unpatentability. On November 18, 2022, the Examiner rejected filed claims 18 and

20-22 as being obvious over several references, including U.S. Patent No. 7,033,381. Ex.1002, 324-334. The Examiner also indicated that certain claims included allowable subject matter. *Id.*, 333. On February 16, 2023, Patent Owner amended the claims to incorporate the allowable subject matter. *Id.*, 199-208.

On March 1, 2023, the Examiner issued a Notice of Allowance (“NOA”) stating that the prior art of record did not anticipate or render obvious “wherein each of the five panels has two first edges and two second edges shorter than the two first edges, and the light sources are arranged such that a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges.” Ex.1002, 114-121.

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.

VI. STATE OF TECHNOLOGY AT THE TIME OF THE INVENTION

Phototherapy is the use of light - either ultraviolet, visible or infrared – for the treatment of disease. Ex.1015, ¶41. Photodynamic Therapy (PDT) is a subgroup of phototherapy that utilizes light to activate a chemical on or within the body to achieve a therapeutic effect, particularly in lesions like actinic keratosis (AK). Ex.1015, ¶41-49; Ex.1016, ¶46.

A. Actinic Keratosis

Actinic Keratosis (AK) is a tumor of the epidermis comprised of a proliferation of atypical keratinocytes confined to the lower levels of the epidermis. AK lesions may be subclinical and not readily apparent to visual inspection. AK presents in sun-exposed areas and is more common in people with fair skin and/or chronic exposure to sunlight. Ex.1016, ¶¶28-29. Sun damage produces genomic mutations in epidermal keratinocytes. *Id.*, ¶30. Left untreated, AK can develop into tumors, specifically squamous cell carcinoma. *Id.* AK is prevalent and a common reason for visiting the dermatologist. *Id.*, ¶31. It is estimated that 60% of predisposed persons aged 40 years and older have at least one AK lesion. *Id.* There are several ways to treat AK lesions, including pharmaceutical preparations and compounds

(e.g., imiquimod, diclofenac sodium, etc.). *Id.*, ¶32. Surgical methods, such as cryosurgery, curettage, excision, and laser surgery are also used. *Id.*

B. Photodynamic therapy

One common method of treating AK lesions is through photodynamic therapy (PDT), using a combination of a photosensitive compound, such as topical 5-aminolevulinic acid (ALA) and a photodynamic therapy light. Ex.1015, ¶46. The compound converts to an endogenous photosensitizer that absorbs light, initiating an activation process that leads to the destruction of the undesired cells. Ex.1016, ¶¶33-35. The photo-cytotoxic reactions therefore occur only within the pathological; thereby selectively killing the pre-cancerous or cancerous tissue. Ex.1016, ¶¶33-35; *see also* Ex. 1015, ¶¶42-44 (PDT allows for “selectively destroying the pre-cancerous or cancerous tissue”) (citing Ex.1021).

As far back as 1989, in a patent assigned to DUSA, the Patent Owner’s assignor in this case, Kennedy described PDT using ALA using a variety of wavelengths. Ex.1016, ¶¶47-50. Kennedy teaches that ALA can be administered topically, Ex.1016, ¶50, and then subjected to photoactivating light in the range of 350-640 nm, and, “more preferably,” a red light of about 610-630 nm. Ex.1016, ¶51. At the time, in 1989, it was known that red light (600 – 700 nm) could pass through a slab of human tissue 1 cm thick, with 1 to 10% of incident red light being transmitted. Ex.1016, ¶53. Using ALA in combination with a 500-watt tungsten

lamp filtered to remove both infrared (heat filter) and wavelengths below 600 nm, DUSA varied the fluence and successfully treated a variety of AK lesions on patients. Ex.1016, ¶¶44-45, 55-56.

PDT with ALA can be a useful treatment option for AKs and other skin conditions. Ideally, PDT can be completed in a single treatment session, and can destroy either a single AK or numerous AK lesions within a field with limited impact on any surrounding skin that is not actinically damaged. Ex.1016, ¶37. Because the treatment is completed in an office, it is not dependent on a patient's at-home compliance with, for instance, regular application of a topical cream, such as 5-FU or imiquimod.

C. Photodynamic Therapy in the modern LED era (post-2000)

Since at least 1989, ALA and other photosensitizers have been utilized successfully for both the effective treatment of actinic keratosis (AKs) and off-label treatment of other conduction, like squamous cell and basal cell carcinoma. Ex.1016, ¶¶33-37, 42. The response of the AK or acne lesion depends both on the uptake of the photosensitizer and the irradiance (in W/cm^2 or mW/cm^2 , the rate at which energy is delivered per unit area of skin). Ex. 1015, ¶46. Assuming that the drug uptake by individual lesions is similar, uniform efficacy then depends on the uniformity of the irradiance on the skin surface. *Id.*

The design of the light source plays an important role in achieving an irradiance that is as uniform as possible. Ex. 1015, ¶47. To visualize this, imagine a square-shaped lamp pointed directly at a white wall, at a close distance; and that further, the output surface of the lamp emits light with the same color and intensity across the entire surface of the lamp. *Id.* Despite this consistent light output, the wall surface directly in front of the lamp (corresponding with the middle of the square) will naturally be “brighter” than the rest of the wall (corresponding with the edges of the square); that is, it will receive a greater irradiance. *Id.* To at least partially compensate for this non-uniform illumination, the lamp can be designed to be “brighter” (i.e., to emit light at a greater intensity) near its four edges than from its central region. In this case the region of the wall with more uniform illumination would be significantly increased. *Id.*

If the lamp is made up of, for example, horizontal fluorescent tubes, the spacing between tubes could be reduced near the top and bottom of the lamp. Lundahl teaches this. If the lamp consists of a rectangular panel or panels of many LEDs, the number or density of LEDs could be increased near the upper and lower edges of the panel(s). Ex. 1015, ¶48.

For illumination of the face as an example, a U-shaped collection of fluorescent tubes (as in Lundahl and the Sun / DUSA Blu-U) or an array of hinged, rectangular panels with numerous LEDs (described, e.g., by Larsen [Ex.1004]) can

be utilized. Ex. 1015, ¶49. Each approach requires appropriate placement of the individual light sources, either tubes or LEDs, to minimize the variation in irradiance on the face. *Id.* For the Blu-U, this is accomplished by adding additional U-shaped fluorescent tubes near the upper and lower edges of the apparatus, since the light source length in this dimension is substantially less than the light source length completely around the U-shaped apparatus. *Id.* Uniformity is more easily achieved for an apparatus consisting of LED-populated panels, by simply placing more LEDs along the upper and lower edges of a horizontal array of panels, achieving adequate uniformity. *Id.*

VII. SUMMARY OF PRIOR ART

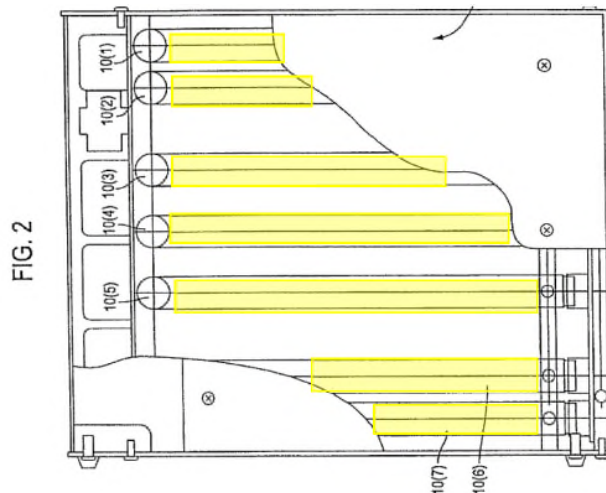
The prior art discloses and teaches the claimed subject matter of the ‘028 Patent as explained below. All the references are prior art under 35 U.S.C. § 102(a)(1). These references are directed to the same field as the ‘028 Patent and/or the same problems. Ex.1015, ¶¶113, 122, 137-138,144-146, 149. Petitioner is not aware of any secondary considerations that support a finding of non-obviousness. *Id.*, ¶128. Furthermore, none of the factors under 35 U.S.C. § 325(d) weigh in favor of the Board exercising its discretion to deny institution.

A. Lundahl (Ex.1014)

U.S. Patent No. 6,223,071 (hereinafter referred to as “Lundahl”) was filed on May 1, 1998 and issued on April 24, 2001 qualifying Lundahl as prior art under 35

U.S.C §§102 and 103. Ex.1016, ¶57. Lundahl contains substantively similar disclosure to WO 99/56827 that was submitted with the 874 IPR petition. See Ex. 1011.

Lundahl teaches an apparatus and method for photodynamic therapy or photodynamic diagnosis using an illuminator comprising a plurality of light sources. Ex.1014, Abstract. To achieve this uniformity, Lundahl utilizes the light distribution pattern illustrated in Figure 2 (which has been rotated 90° to better illustrate).

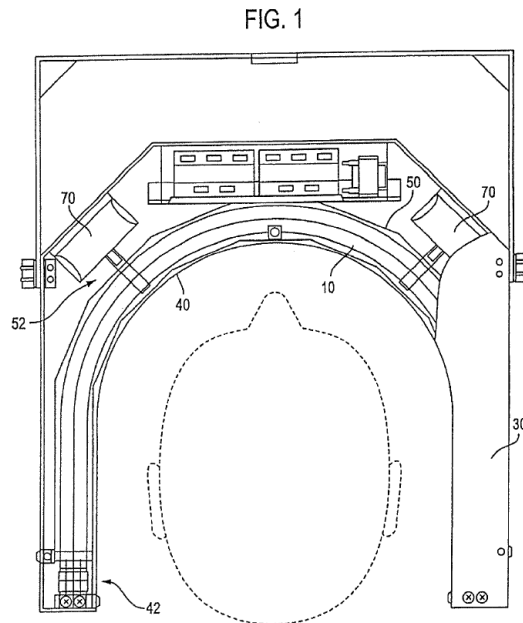


Lundahl explains that “[t]o avoid uniformity problems, one embodiment, of the present invention utilizes a plurality of U-shaped tubes 10(1)-10(7)...[An] advantage of the arrangement is that uniformity can also be adjusted by varying the

lateral spacing of the tubes (relative [vertical] spacing as shown in Figure 2).⁴ 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. Ex.1014, 6:16-30. Lundahl states that the spacing of lights and greater density of lighting near the top and bottom of the panel provide for uniform illumination. Ex.1014, 6:43-57 (“[t]he number of tubes used and the spacing between them were chosen to achieve desired uniformity and power output specifications.”).

Lundahl further states “the present invention uses a U-shaped emitting surface that more closely follows the contours of the human face and scalp, and minimizes lamp to target distance variations which in turn minimizes irradiance variations at the target.” Ex.1014, 4:33-38. Lundahl illustrates this positioning on the PDT device in Figure 1, showing the positioning of the patient’s head and nose within the device:

⁴ Although Ex.1014, 6:16-30 recites “relative horizontal spacing as shown in FIG. 2)”, this has been clarified as “vertical” to conform with the 90° rotated FIG. 2 above.



Ex.1014, Fig. 1.

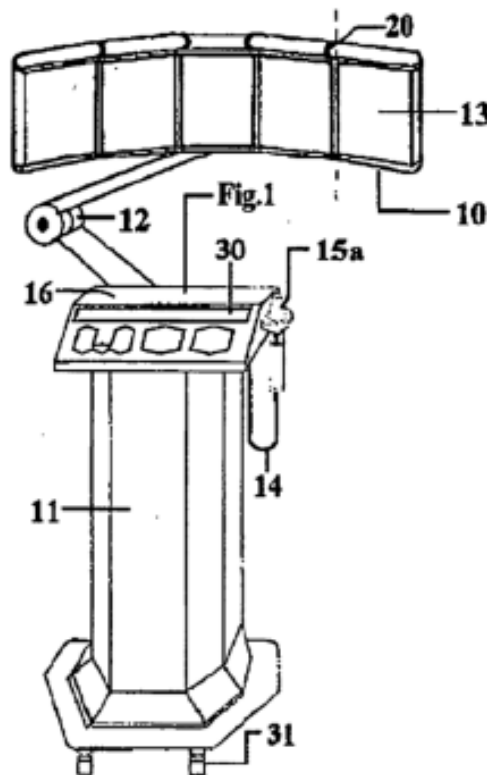
Additionally, in its discussion of the background on PDT treatment, Lundahl states “[g]eneral background information on PDT using 5-aminolevulinic acid (“ALA”) as the precursor of a photoactivatable agent can be found in U.S. Pat. No. 5,079,262, entitled “Method of Detection and Treatment of Malignant and Non-Malignant Lesions Utilizing 5-Aminolevulinic Acid,” issued to James C. Kennedy et al. on Jan. 7, 1992, and U.S. Pat. No. 5,211,938, entitled “Method of Detection of Malignant and Non-Malignant Lesions by Photochemotherapy of Protoporphyrin IX Precursors,” issued to James C. Kennedy et al. on May 18, 1993. The contents of these patents are incorporated herein by reference.” Ex.1014, 1:38-48. Thus, Lundahl expressly incorporates all teachings of U.S. Patent No. 5,079,262 to Kennedy et al. (“Kennedy”). See Ex.1017; Ex.1016, ¶58.

Thus, Lundahl is analogous art to the '028 Patent. Ex.1015, ¶90.

B. Larsen (Ex.1004)

U.S. Patent No. 7,311,722 (hereinafter referred to as “Larsen”) was filed on January 22, 2002 and issued on Dec. 25, 2007, qualifying Larsen as prior art under 35 U.S.C §§102 and 103.

Like the '028 Patent, Larsen describes devices for providing PDT to treat various skin conditions, such as cancers and pre-cancerous skin tissues. Ex.1004, [0011]-[0013]. Larsen’s mobile treatment device is shown below.



Id., Fig. 1. The treatment device includes a mobile stand (11) mounted on wheels (31), a controller (16), a joint arm (12), and multiple applicators (13) connected by

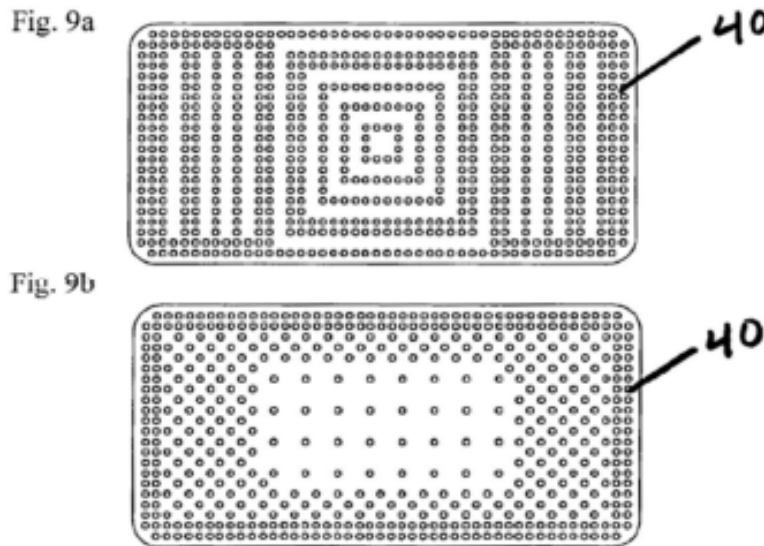
hinges. *Id.*, [0069]-[0070]. Each applicator includes printed circuit boards with multiple light sources for irradiating the treatment surface of a patient's skin using light at various wavelengths. *Id.*, [0070]-[0072], Figs. 2a-2c.

Larsen is from the same field of endeavor as the '028 Patent, which also describes illuminators for PDT. Ex.1001, 1:26-2:6. Larsen is also directed to the same problem as the '028 Patent, namely, an illuminator that can provide an "even and gap-free radiation of the surface with the multiple wavelengths of light." Ex.1004, [0028]. Thus, Larsen is analogous art to the '028 Patent. Ex.1015, ¶102.

C. Bansal (Ex.1005)

U.S. Publication No. 2004/0068305 (hereinafter referred to as "Bansal") was filed on October 7, 2002 and published on April 8, 2004, qualifying Bansal as prior art under 35 U.S.C §§102 and 103.

Bansal describes a phototherapy device with an array of light sources "so as to achieve substantially uniform distribution of light on a subject." Ex.1005, Abstract. Bansal's device is for "phototherapeutic treatment of illness and diseases," including skin cancer. *Id.*, [0002], [0004]. As shown below, Bansal's array of light sources (40) "can take a number of different non-uniform forms to achieve the goal of even exposure on the subject's skin." *Id.*, [0025], Figs. 9a-9b.



Bansal's arrays provide more uniform exposure compared to "a simple rectangular array," where "[t]he intensity will be significantly higher underneath the center of the array than around the periphery." *Id.*, [0008].

Bansal is from the same field of endeavor as the '028 Patent, which also describes illuminators for treatment purposes. Ex.1001, 1:26-2:6. Bansal is also directed to the same problem as the '028 Patent, namely, an illuminator that can "achieve substantially uniform distribution of light on a subject." Ex.1005, Abstract. Thus, Bansal is analogous art to the '028 Patent. Ex.1015, ¶114.

VIII. LEVEL OF SKILL IN THE ART

A person of ordinary skill in the art ("POSITA") at the time of the earliest effective filing date of the '028 Patent would have been an individual or member of a multi-disciplinary team with education of (1) at least a Bachelor of Science degree in one or more fields of electrical engineering, physics, biomedical engineering,

computer engineering, chemical engineering or material science, in fields relating to optics, optoelectronics, radiometry, photometry, photodynamic diagnosis (PD), photodynamic therapy (PDT), phototherapy (PT), and related technologies; and (2) a medical degree in fields relating to the diagnosis and treatment of skin conditions and related disease states. Alternatively, a POSITA individually or members of the multi-disciplinary team would have had at least four years of experience in one or more fields of optics, optoelectronics, radiometry, photometry, photodynamic diagnosis (PD), photodynamic therapy (PDT), or phototherapy (PT), and at least four years of experience in one or more fields of medical treatment of skin conditions and related disease states.

This petition is supported by the declarations of Dr. Grove and Dr. Ehrenreich. Dr. Grove's declaration provides testimony from the perspective of a POSITA regarding the teachings of the prior art and obviousness of the Challenged Claims which is based in part upon Dr. Grove's reading of Dr. Ehrenreich's declaration. Ex.1015, ¶118. Dr. Ehrenreich's declaration provides testimony about the background knowledge of a POSITA for medical treatments involving PDT and explains the teachings of medical treatments in the cited prior art. Ex.1016, ¶¶28-37.

IX. PROPOSED GROUNDS OF REJECTION

A. Lundahl in view of Larsen Renders Obvious Claims 1, 2, 4-6, 16, 17, 19, 20, and 21

1. Motivation to Combine

A POSITA would be motivated to combine the teachings of Lundahl and Larsen to incorporate the hinged panel LED displays of Larsen into the PDT device of Lundahl. Ex.1015, ¶118. As noted in the level of skill, a POSITA would represent a team of individuals, some with engineering expertise (like Dr. Grove), and some with expertise in the medical treatment of patients (like Dr. Ehrenreich). The combined opinions based on the education and experiences of both Drs. Grove and Dr. Ehrenreich are the appropriate POSITA combination from which the motivation to combine and modify the prior art should be judged. Ex.1015, ¶119-122

Dr. Ehrenreich sees patients diagnosed with AK every day, and routinely treats these patients with PDT. Ex.1016, ¶¶38-43. Dr. Ehrenreich notes that the BLU-U lamp device he uses often in his practice, including the years preceding 2015, resembles the lamp device described in Lundahl. Ex.1016, ¶41. Comparing the BLU-U lamp with Lundahl, Dr. Grove agrees that the Lundahl patent appears to disclose the BLU-U device, particularly given the fact that Lundahl is assigned on its face to DUSA Pharmaceuticals, Inc., the manufacturer of BLU-U. Ex. 1016, ¶¶40-41, 59; Ex.1015, ¶119. Consequently, Dr. Ehrenreich's comments regarding

his experience with BLU-U are equally applicable to the device described in Lundahl, as the two appear to be the same. Ex. 1016, ¶59.

Moreover, Dr. Ehrenreich explains that there were known issues and flaws when using the BLU-U/Lundahl design to treat patients for AK. *See* Ex.1016, ¶¶60-74. Dr. Ehrenreich points out that Lundahl discloses a fixed U-shape, that this fixed U-shape was developed based on “the average dimensions of the human head,” and, because of this, the Lundahl design may not be ideal given the variety of sizes and shapes of patients’ heads. Ex.1016, ¶67. Dr. Ehrenreich also states that the fixed U-shape design of Lundahl did not provide the flexibility needed to treat other parts of the patients’ bodies that would typically have AK lesions, including the arms, back, chest, and hands, particularly in view of the need to maintain a distance of 2-4” from the treatment surface (skin) to the lighting surface. Ex.1016, ¶¶42-43, 70.

In addition, Dr. Ehrenreich testifies as to known problems with the fluorescent tubes utilized in the Lundahl design. Ex.1016, ¶¶41-43, 72-74. For instance, Dr. Ehrenreich, citing Lundahl itself, notes that the uniformity of light from fluorescent tubes varies across the length of the tube, and the uniformity of lighting can also be affected by heat and the ability to cool the Lundahl device. Ex.1016, ¶¶68-69.

Consequently, as discussed in his expert declaration, Dr. Ehrenreich identifies certain problems associated with the Lundahl device design, which Dr. Ehrenreich has experienced these problems first-hand in his use of the BLU-U device. The

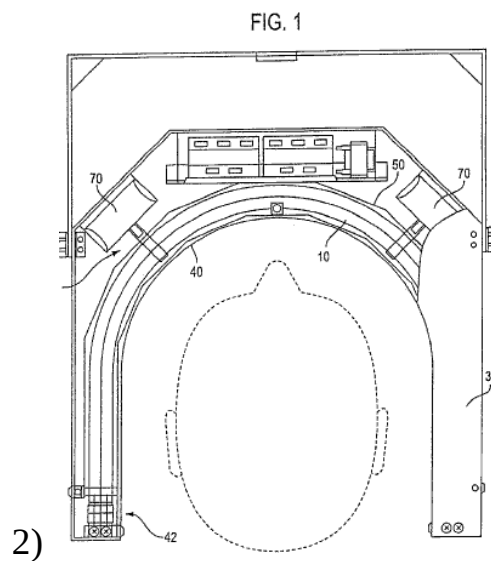
known problems outlined in Dr. Ehrenreich's declaration include: (1) the inflexibility of the fixed U-shape of Lundahl not only created issues ensuring the proper 2-4" treatment distance for the wide variety of patient head sizes and shapes, but also would not allow for proper treatment of other parts of the anatomy requiring AK treatment, including the arms, back, chest, and hands; and, (2) the fluorescent tubes utilized in Lundahl had inherent shortcomings due to the lack of uniform light output across the length of the tube and sensitivity to temperature. Ex.1016, ¶¶41-44, 68-73. These treatment issues (and others) represent known problems for which the POSITA team member with a background in engineering (such as Dr. Grove) would have been motivated to improve upon. See Ex.1016, ¶¶73-74.

a. Increasing flexibility of device for use with all head sizes and shapes, as well as varying anatomies

As discussed in the declaration of Dr. Ehrenreich, the PDT device and design of Lundahl appears to be the same design utilized for BLU-U, a device publicly known and used in the treatment of AK lesions from 1999-2015. Ex.1015, ¶123; Ex.1016, ¶41. Lundahl teaches that **“[t]he U-shape minimizes the variations in distance between the emitter and the target, providing a uniform visible light distribution to the face or scalp of the patient; the tube dimensions were chosen based on the average dimensions of the adult human head.** The mounting of the tubes minimizes the impact of the non-emitting area at their ends. This allows the

present invention to be more compact and permits easier centering of the patient's head within the visible light sources. Moreover, the “U” shape provides the desired irradiance and irradiance uniformity for scalp and facial irradiation, and thus ensures that the proper visible light dosage is applied to all target areas during PDT.”

Ex.1014, 6:31-42.⁵ Lundahl illustrates the “U” shape design in Figure 1:



Ex. 1014, Fig. 1. As can be seen from Figure 1, the various points of the treatment surface (i.e., the various points on the patient's skin) will have varying distances from the light surface (e.g., the nose will be closer to the light surface than the point where the nose meets the cheek). As noted in the declaration of Dr. Ehrenreich, the FDA approved indication for the treatment of AK using LEVULAN and BLU-U

⁵ Unless otherwise indicated, all emphasis added.

requires that the light surface be 2-4” from all points on the treatment surface (i.e., all points on the patient’s nose, cheeks, chin, ears, etc.). Ex.1016, ¶¶40-42, 43; Ex. 1022. While it is possible that a patient having head dimensions similar to “the average dimensions of the adult human head” would allow for positioning within the Lundahl device similar to Figure 1, a POSITA would also envision many scenarios where the shape and dimensions of the patient would not allow for the required 2-4” distance required by the FDA approved indication. Ex.1015, ¶124; Ex. 1016, ¶¶42-44.

POSITA considering Lundahl would have been motivated to increase the flexibility of the device to ensure the light panels could be maintained at a distance of 2-4” of the entire treatment surface of the patient (i.e., face, nose, forehead, ears, sides of head, etc.), particularly given the wide variety of head shapes and sizes. Additionally, POSITA would have understood that there are other bodily anatomies that could use treatment for AK lesions, such as the arms, back, and other body parts. Ex.1016, ¶¶42-43. In fact, Lundahl expressly contemplates the treatment of other parts of the body, stating that “[t]he present invention is directed to photodynamic therapy using an illuminator that provides a uniform distribution of visible light. In particular, the present invention is directed to an apparatus and method for photodynamic treatment (PDT) or diagnosis (PD) of actinic keratosis of the scalp or facial areas of a patient. Ex.1015, ¶125. The present invention is also directed to an

apparatus and method for PDT and PD of other indications (e.g., acne) **and other areas of the patient (e.g., arms, legs, etc.).**” Ex. 1014, 1:9-17.

Consequently, POSITA would have been motivated to change the design of the system of Lundahl to allow for adjustment of the light panels to ensure a 2-4” distance from the face and from other varying anatomies. *See* Ex.1016, ¶¶70-74, 87. POSITA would have understood that the easiest way to modify the fixed, curved U-shape of Lundahl would be to incorporate hinged panels that could be individually adjusted to account for variations in head shape/size or other anatomy selected for treatment. Ex.1015, ¶126.

Larsen teaches that “[f]or 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.” Ex.1004, [0072]. These teachings would have motivated POSITA to incorporate Larsen’s solution of connecting light applicators by hinges, to allow for adjustability of Lundahl’s device to provide the desired irradiance and irradiance uniformity to all target areas during PDT. Ex.1015, ¶127.

POSITA would have had a reasonable expectation of success in combining Lundahl with Larsen, because both references describe similar illuminators for using light to treat conditions on a patient's skin. Ex.1015, ¶128.

b. Increasing light output consistency by changing the light source from fluorescent tubes to LEDs

POSITA was also motivated to modify Lundahl to incorporate LEDs as taught by Larsen, rather than the fluorescent tubes. Lundahl discloses horizontally oriented fluorescent tube 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" (Ex. 1014, 6:31-42) and that "tube output may vary over its length" (Ex. 1014, 4:41-42). Third, by moving to adjustable panels connected by hinges to increase flexibility, the use of LEDs would be more practical to reduce spacing between light sources and the edges of the panels, as opposed to the bulky metal couplings at the end of fluorescent tubes, to reduce optical dead space across the light surface. Ex.1015, ¶129.

Larsen teaches that light sources are disposed on the surfaces of five applicators, the light sources being "semiconductor diodes (LED) and/or laser

diodes.” Ex.1004, [0070]. The state of illumination technology as described in the previous paragraph along with this teaching of Larsen would have motivated POSITA to incorporate Larsen’s solution of disposing light sources, specifically LEDs, on the surface of the light applicators to Lundahl’s device. Ex.1015, ¶130.

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. Ex.1015, ¶131.

c. Increasing light absorption at deeper skin depths by emitting red light

Moreover, POSITA was motivated to utilize red light wavelengths in the PDT device rendered obvious by Lundahl and Larsen. As previously discussed, Lundahl expressly incorporates all teachings of Kennedy. Ex. 1014, 1:38-48 (incorporating by reference the contents of Ex.1017); Ex.1015, ¶132.

Kennedy teaches that red light was preferred for PDT, as it penetrates deeper into the skin, as compared to blue light, and PpIX (the compound produced by topical application of ALA) strongly absorbs red light. Kennedy discloses “[a] method of detecting and treating malignant and non-malignant tissue abnormalities and lesions of the skin” in which “5-aminolevulinic acid is administered to the patient.” Ex.1017, Abstract; Ex.1016, ¶52. Kennedy states that “[i]n preferred

aspects of this invention the preferred precursor of protoporphyrin IX is 5-amino-4-oxo-pentanoic acid, otherwise known as 5-aminolevulinic acid, and a preferred wavelength of the photoactivating light is in the range 350-640 nm, more preferably a red light of about 610-630 nm.” Ex.1017, 4:3-8. Kennedy also states that “[t]he wavelength of the photoactivating light is of some importance, as it has been shown that between 1 and 10 percent of incident red light (600-700 nm) can pass through a slab of human tissue 1 cm thick, whereas only 0.001 percent or less of blue light (about 400 nm) can pass through the same thickness of human tissue. The photosensitizer will, therefore, be more successful if it strongly absorbs red light. PpIX does strongly absorb red light.” Ex.1017, 4:60-69. Based on the teachings of Kennedy, POSITA would have expected red light (preferably at wavelengths of about 610-630) to more effectively penetrate skin tissue, and for PpIX to more effectively absorb the red light, resulting in greater activation of the photosensitizer. These enhancements in the penetration of light and absorption by the photosensitizer would have led POSITA to reasonably expect enhanced efficacy of the PDT device. Ex.1015, ¶133.

Additionally, Larsen teaches that its applicators are configured to output red light: “devices are available for the photodynamic stimulation of human cell energy in the form of red and infrared radiation . . .” Ex.1004, [0024]. Larsen also teaches

using light radiation within the wavelength of 300 – 2000 nm, which includes red light. *Id.*, [0025], [0071]-[0076], [0083]. Ex.1015, ¶134.

Based on the expectation of enhanced light penetration and absorption by the photosensitizer, POSITA was motivated to combine the teachings of Lundahl, incorporating Kennedy, and Larsen to use red light for PDT. Ex.1015, ¶135.

Additionally, Kennedy reports in Examples 1-4 that patients were administered PDT with a light source that was “filtered to remove both infrared (heat filter) and wavelengths below 600 nm,” meaning red light, likely with wavelengths of 600-700 nm was utilized. Ex.1017, 5:47 to 6:47. Kennedy reports that PDT with this red light demonstrated clearance of treated lesions. *Id.*; Ex.1016, ¶54, 56. In view of this, POSITA had at least a reasonable expectation that red light could be utilized in the device rendered obvious by Lundahl (incorporating Kennedy) and Larsen. Ex.1015, ¶136.

For these reasons, claim 1, 5, 16, 20, and 21, and each of the claims that depend from them, are obvious over Lundahl in view of Larsen. Ex.1015, ¶¶137, 180, 204, 240, 253, 263.

2. Claim 1

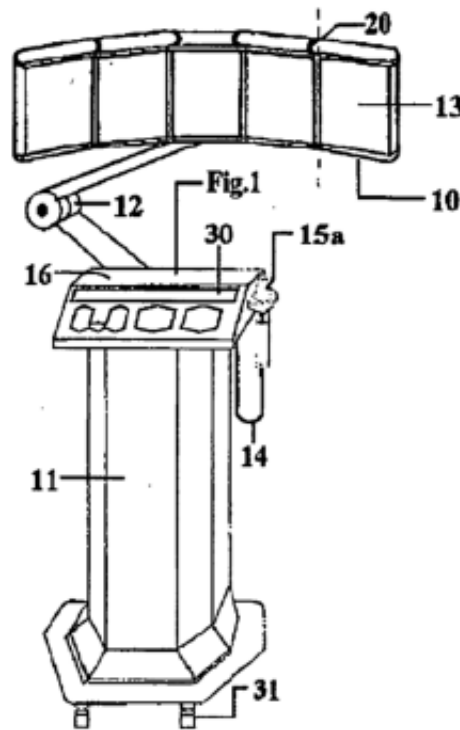
Claim 1[preamble]: “A system for photodynamically diagnosing or treating a patient, comprising:”

Lundahl discloses an “invention...directed to photodynamic therapy using an illuminator that provides a uniform distribution of visible light. In particular, the present invention is directed to an apparatus and method for photodynamic treatment (PDT) or diagnosis (PD) of actinic keratosis of the scalp or facial areas of a patient.” Ex.1014, 1:9-14. Larsen similarly discloses an “invention relat[ing] in general to electrotherapy devices and more particularly to devices and methods for photodynamic and electromagnetic stimulation of living tissue, directly and also indirectly, by stimulation of photosensitive substances introduced into or onto living tissue.” Ex.1004, [0001]. Larsen further states its device “provides multiple wavelength stimulation that is also effective in conjunction with photodynamic therapy (PDT) chemicals.” Ex.1004, [0037].

Thus, Lundahl and Larsen teaches the preamble of claim 1. Ex.1015, ¶¶148-150.

Claim 1(a): “an illuminator comprising five panels connected by hinged structures on inner side surfaces of adjacent panels; and”

Larsen’s illuminator has five hinged panels (13):



Ex.1004, Fig. 1; Ex.1015, ¶152.

Larsen teaches that “[f]or 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.”

Ex.1004, [0072]; Ex.1015, ¶153.

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

panels (13) are nearly flush with each other. Ex.1004, Fig. 1. The Office has already confirmed that the same disclosure in the Larsen ‘381 Patent taught “at least five panels [] connected by hinged structures [].” Ex.1002, 328 (citing Ex.1008, Fig. 1, 5:44-47). Similarly, during the prosecution of Application No. 17/009,871,⁶ the Examiner reviewed Larsen and determined that it taught “five panels connected by a plurality of hinges 20 . . . ***on inner side surfaces of adjacent panels that connect panels together*** . . .” Ex.1009, ¶4 (citing Ex.1004, Figs. 1-3, [0069], [0072], lines 1-4); Ex.1015, ¶154.

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

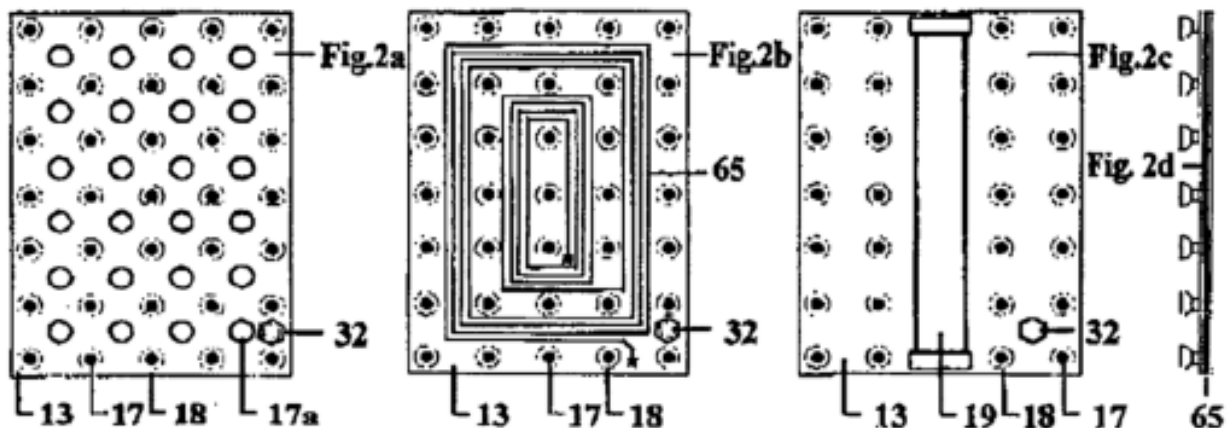
⁶ This application is a continuation of patent application no. 16/791,004 (the direct parent of the ‘028 Patent) and includes substantially the same specification as the ‘028 Patent. *Compare* Ex.1001 with Ex.1013.

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.

Claim 1(b): "light sources disposed on surfaces of the five panels,"

Larsen discloses that light sources are disposed on the surfaces of five applicators. Figs. 2a-2c of Larsen show "plain surfaced printed circuit boards with light sources mounted in the applicators 13." Ex.1004, [0070]; Ex.1015, ¶157.



Ex.1004, Figs. 2a-2c. The applicators are mounted in a shifting order “with semiconductor diodes (LED) and/or laser diodes 17 and 17a (in the following called light sources), whereby shifting the order of the light sources 17 means, that the respective light source 17a of one row is placed at the point of intersection of the two diagonals through the two respective light sources 17, which are placed adjoining on both sides.” *Id.*, [0070]. The light sources can be placed in regular row arrangements. *Id.*, [0071]⁷; Ex.1015, ¶157.

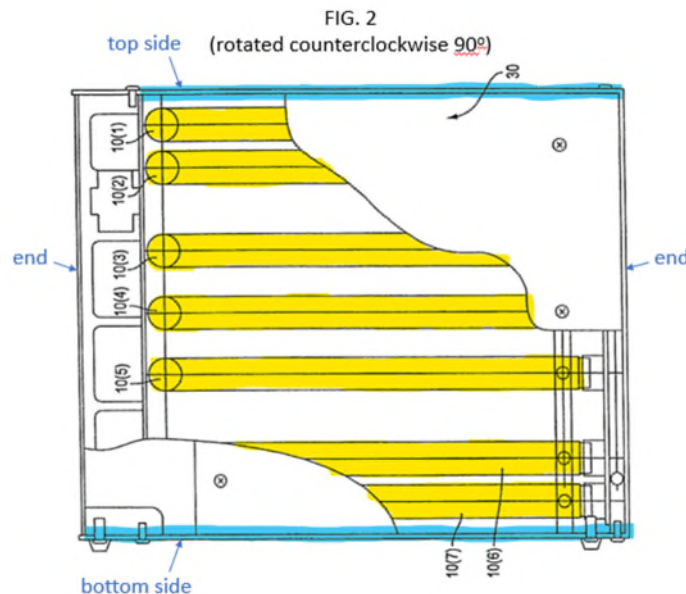
Thus, Larsen teaches the limitations of claim 1(b). Ex.1015, ¶158.

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

⁷ One embodiment of Larsen shows that the lights are inside of flattened oval tubes. Ex.1004, [0102], Fig. 17b. This is just one of many embodiments, and the light sources themselves are still individually controllable just like other light sources. Ex.1004, [0106].

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 unradiated 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.

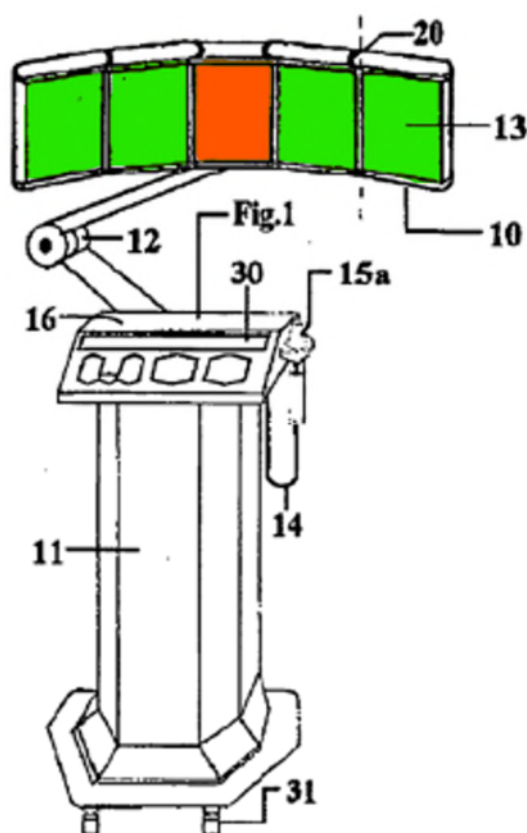
Larsen also teaches that its applicators “*permit[] an even and gap-free radiation* of the surface with multiple wavelengths of light.” Ex.1004, [0028]. An “even and gap-free radiation of the surface” would uniformly illuminate the

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.

Claim 1(d): “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,”

As shown in Figure 1 of Larsen, one of the five panels is positioned as the center panel, with two or more of the remaining panels configured to be angled relative to the center panel.



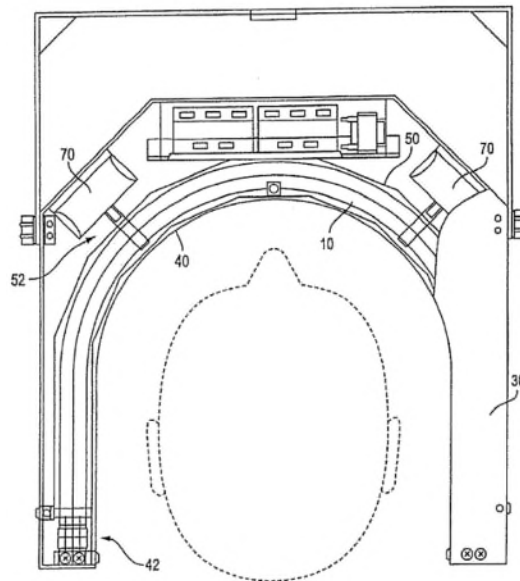
Ex.1004, Fig. 1; Ex.1015, ¶166. Larsen teaches that “the applicators are suitable for the treatment of, for example, the backs of humans and so become adjustable for an equidistant positioning of the applicators 13 above the skin.” *Id.*, [0072]. As shown above, the center panel (annotated in red) is positioned to illuminate the center of the patient’s back, with each adjacent side panel (annotated in green) angled relative to the center panel to accomplish the equidistant positioning described in Larsen. *Id.*, Fig. 1, [0072]; *see also* Ex.1002, 330 (finding this limitation disclosed by Figure 1 in the Larsen ‘381 Patent). Ex.1015, ¶167.

Thus, Larsen teaches the limitations of claim 1(d). Ex.1015, ¶168.

Claim 1(e): “wherein the five panels are positioned to allow treatment within approximately four inches of the treatment surface, and”

Lundahl teaches the position of the PDT device to allow treatment within approximately four inches of the treatment surface. Lundahl states “the present invention uses a U-shaped emitting surface that more closely follows the contours of the human face and scalp, and minimizes lamp to target distance variations which in turn minimizes irradiance variations at the target.” Ex.1014, 4:34-38. Lundahl illustrates this positioning on the PDT device in Figure 1, showing the positioning of the patient’s head and nose within the device:

FIG. 1



Ex.1014, Fig. 1; Ex.1015, ¶169.

Lundahl explains that the U-shape of the PDT device helps to maintain the proper distance between the light-emitting panel and the patient head, stating “[t]he

U-shape minimizes the variations in distance between the emitter and the target, providing a uniform visible light distribution to the face or scalp of the patient; the tube dimensions were chosen based on the average dimensions of the adult human head.” Ex.1014, 6:31-35; Ex.1015, ¶170.

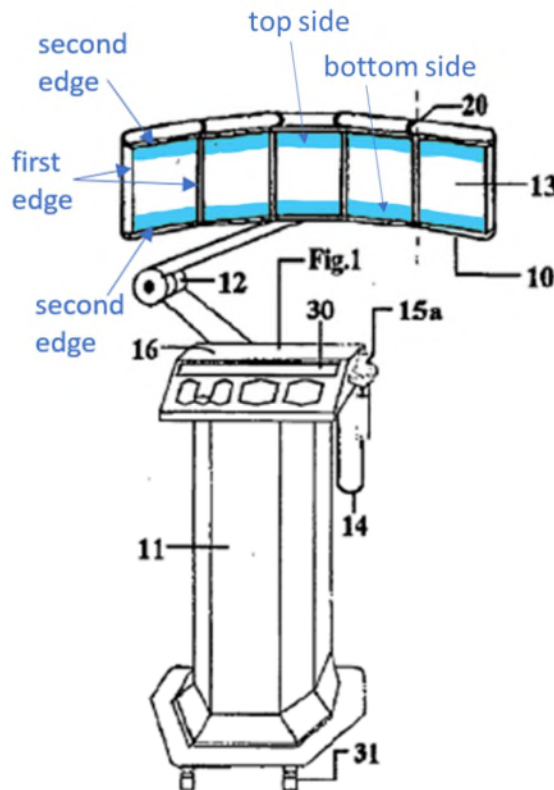
Lundahl further teaches that the light-emitting surface of the PDT device is positioned at distances of 2” and 4” from the treatment surface (i.e., the skin on the patient’s head), stating that “according to a preferred embodiment of the present invention, the measured output over the active emitting area is within 70% of the measured maximum when measured with a cosine response detector at distances of 4” and 2”.” Ex.1014, 15:22-27; Ex.1015, ¶171.

The disclosed distances of 2 inches and 4 inches of Lundahl are within approximately four inches of the treatment surface. Ex.1014, 15:22-27.

Thus, Lundahl and Larsen teach the limitations of claim 1(e). Ex.1015, ¶172.

Claim 1(f): “*wherein each of the five panels has two first edges and two second edges shorter than the two first edges, and*”

As shown in the annotated Figure 1 of Larsen below, each of the five panels (13) has two first edges (vertical edges) and two second edges (horizontal edges on the top and bottom of each panels that extend along the top and bottom sides of the panel arrangement). The two second edges are shorter than the two first edges. Ex.1004, Fig. 1; Ex.1015, ¶173.



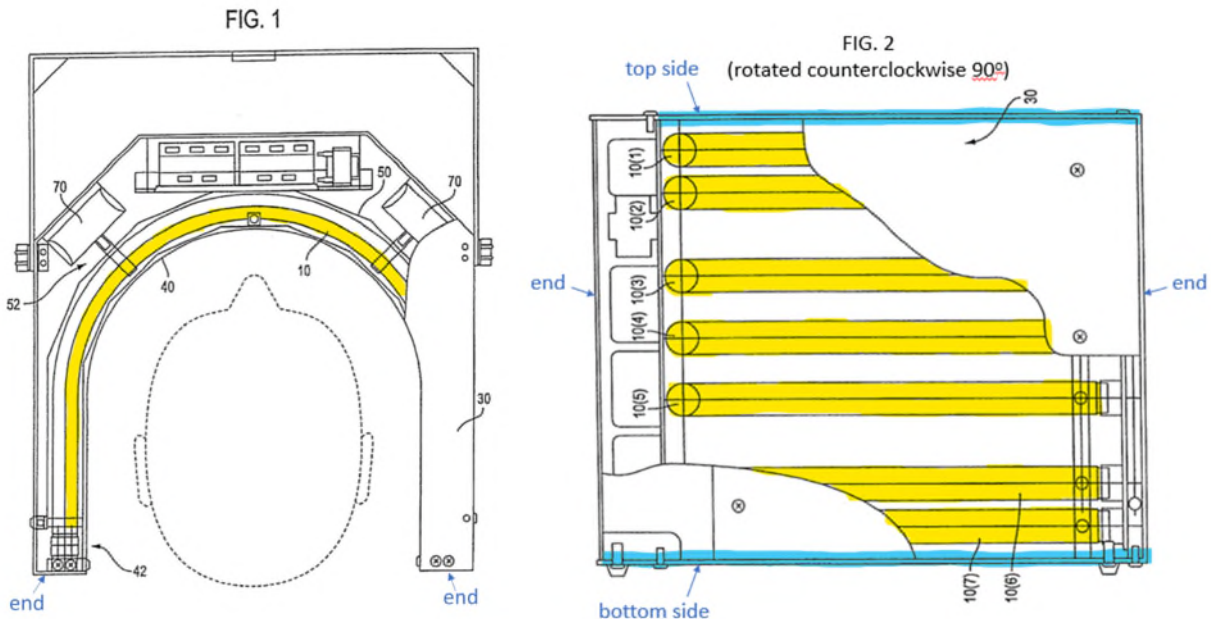
Thus, Larsen teaches the limitations of claim 1(f). Ex.1015, ¶174.

Claim 1(g): “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.”

Lundahl teaches that “[t]he number of tubes used and the spacing between them were chosen to achieve desired uniformity and power output specifications.” Ex.1014, 6:43-45. As shown in the annotated Figures 1 and 2 of Lundahl below (with the light tubes highlighted yellow, the top and bottom sides highlighted blue, and Figure 2 rotated to show the apparatus as oriented during operation), “[o]ptimum output distribution has been found to occur when seven tubes 10(1)-10(7) are placed

in the chassis in a symmetric pattern with respect to opposite edges of the unit”.

Ex.1014, 6:45-48.



Ex.1014, Figs, 1, 2; Ex.1015, ¶175.

Lundahl includes the “following approximate lateral spacing: 7 cm between the center tube 10(4) and each of the two tubes 10(3),10(5) adjacent to the center tube 10(4); 5 cm between the tubes 10(3),10(2) and 10(5),10(6), i.e., the next pairs of tubes out from the center; and 3.5 cm between tubes 10(2),10(1) and 10(6),10(7), i.e., the outermost pairs of tubes at the sides of the unit.” Ex.1014, 6:48-54. Lundahl also states that “[t]he outermost tubes 10(1),10(7) are approximately 2.5 cm from the edges of the housing” and “[t]he present invention provides a highly uniform output irradiance without the use of an additional diffusing element.” Ex.1014, 6:54-57. POSITA would have understood that the tubes of Lundahl are spaced to emit a

higher intensity of light proximate the top and bottom sides compared to the intensity of light emitted not proximate the top and bottom sides. Ex.1015, ¶176.

A POSITA would know from the Lundahl disclosure (including the combined disclosure of Figs. 1 and 2 shown above), that these curved tubes extend from one side of the “U” shape to the other. Ex.1015, ¶177. The picture below illustrates this understanding, and how a POSITA would expect to view the Lundahl device if viewed from the front, instead of the top (as in Fig. 1 of Lundahl):



Ex.1015, ¶177 (citing Ex.1023, 29). The tubes in the illustration above are situated in the same distribution pattern illustrated in Fig. 2 of Lundahl, but with a perspective that allows one to visualize the three-dimensional shape of the fixed “U” shape of Lundahl. *Id.*

As shown in the annotated figures of Larsen and Lundahl above with respect to claim 1(f) and claim 1(g), 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, for all the reasons described above at Section XI(A)(1). Ex.1015, ¶¶178-180.

Thus, Lundahl in view of Larsen renders obvious the limitations of claim 1(g). Ex.1015, ¶180.

For these reasons, Lundahl and Larsen teach claim 1. Ex.1015, ¶181.

3. Claim 2

Claim 2: “The system of claim 1, wherein the illuminator is configured to output red light at a dose of 30 J/cm^2 to 150 J/cm^2 .”

The combination of Lundahl in view of Larsen renders obvious the system of claim 1, for all the reasons given above. Lundahl also teaches and renders obvious the use of red light *at a dose of 30 J/cm^2 to 150 J/cm^2* . Ex.1015, ¶182.

Lundahl teaches that “[s]ince total light Dose (J/cm^2)=Irradiance (W/cm^2)
×Time (sec), the only additional parameter that needs to be controlled for delivery of the correct treatment light dose is exposure time”, which is “accomplished in a

preferred embodiment of the present invention by the timer which controls electrical power to the ballasts and which can be set by the physician.” Ex.1014, 15:55-61; Ex.1015, ¶183. As previously discussed, Lundahl expressly incorporates all teachings of Kennedy. Ex. 1014, 1:38-48 (incorporating by reference the contents of Ex.1017).; Ex.1015, ¶184.

Kennedy teaches that red light was preferred for PDT, as it penetrates deeper into the skin, as compared to blue light, and PpIX (the compound produced by topical application of ALA) strongly absorbs red light. Kennedy states “[a] method of detecting and treating malignant and non-malignant tissue abnormalities and lesions of the skin” in which “5-aminolevulinic acid is administered to the patient.” Ex.1017, Abstract. Kennedy states that “[i]n preferred aspects of this invention the preferred precursor of protoporphyrin IX is 5-amino-4-oxo-pentanoic acid, otherwise known as 5-aminolevulinic acid, and a preferred wavelength of the photoactivating light is in the range 350-640 nm, more preferably a red light of about 610-630 nm.” Ex.1017, 4:3-8. Kennedy also states that “[t]he wavelength of the photoactivating light is of some importance, as it has been shown that between 1 and 10 percent of incident red light (600-700 nm) can pass through a slab of human tissue 1 cm thick, whereas only 0.001 percent or less of blue light (about 400 nm) can pass through the same thickness of human tissue. The photosensitizer will, therefore, be

more successful if it strongly absorbs red light. PpIX does strongly absorb red light.” Ex. 1015, ¶185; Ex.1017, 4:60-69.

Further, Kennedy teaches and renders obvious a red light dose of 30 J/cm² to 150 J/cm². Ex.1015, ¶185. Examples 1-4 of Kennedy provide PDT treatment of patients with various skin conditions and disease states, including light doses ranging from 17 mWhr/cm² to 52.5 mWhr/cm². Ex.1017, 5:46-6:47. As 1 mWhr/cm² = 3.6 J/cm², examples 1-4 of Kennedy provide PDT treatment with light doses ranging from approximately 61 J/cm² to 189 J/cm², a range that overlaps with the claimed range of 30 J/cm² to 150 J/cm² in the ‘028 Patent.⁸ Ex. 1015, ¶186.

Larsen teaches that its applicators are configured to output red light: “devices are available for the photodynamic stimulation of human cell energy in the form of red and infrared radiation . . .” Ex.1004, [0024]. Larsen also teaches using light radiation within the wavelength of 300 – 2000 nm, which includes red light. *Id.*, [0025], [0071]-[0076], [0083]. Ex.1015, ¶187.

Thus, Lundahl and Larsen teach the limitations of claim 2. Ex.1015, ¶188.

⁸ When a prior art reference recites a range overlapping or touching the claimed range, the claim is anticipated if the range of the prior art reference discloses the claimed range with “sufficient specificity.” *Atofina v. Great Lakes Chem. Corp.*, 441 F.3d 991, 999 (Fed. Cir. 2006)

4. Claim 4

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

The combination of Lundahl in view of Larsen renders obvious the system of claim 1, for all the reasons given above. Lundahl teaches that “[a]ccording to one preferred embodiment of the present invention, blue light having wavelengths exceeding 400 nm (nanometers) is particularly advantageous for certain diagnostic purposes and treatments, especially when ALA is the photoactivatable agent used for PD and PDT of actinic keratosis” and that “visible light in other ranges of the spectrum, particularly in the green and red ranges between 400 and 700 nm, may also be used.” Ex.1014, 2:18-26; Ex. 1015, ¶189.

Thus, Lundahl and Larsen teach the limitations of claim 4. Ex.1015, ¶190.

5. Claim 5

Claim 5[preamble]: *“A method of photodynamically diagnosing or treating a patient, comprising.”*

Lundahl discloses a “method for photodynamic treatment (PDT) or diagnosis (PD) of actinic keratosis of the scalp or facial areas of a patient” and “PDT and PD of other indications (e.g., acne) and other areas of the patient (e.g., arms, legs, etc.).” Ex.1014, 1:9-17. Larsen similarly discloses a method for photodynamically diagnosing or treating a patient: “[t]he present invention relates in general to electrotherapy devices and more particularly to devices and methods for

photodynamic and electromagnetic stimulation of living tissue, directly and also indirectly, by stimulation of photosensitive substances introduced into or onto living tissue.” Ex.1004, [0001]; Ex. 1015, ¶191

Thus, Lundahl and Larsen teach the preamble of claim 5. Ex.1015, ¶192; Ex.1016, ¶¶75-76.

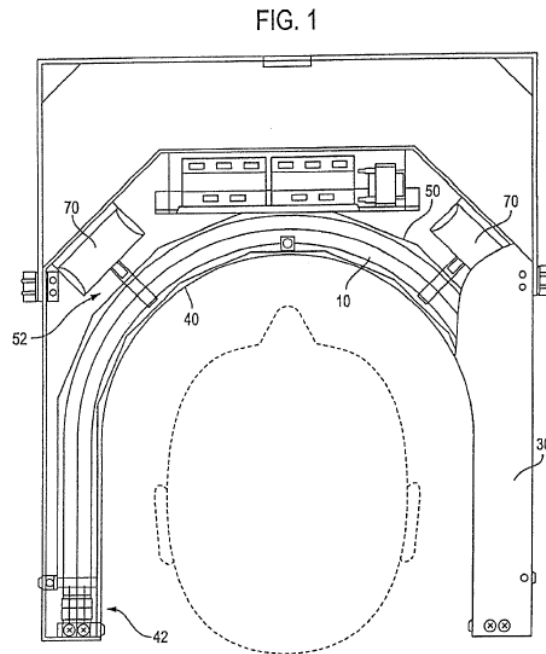
Claim 5(a): “*administering 5-aminolevulinic acid (ALA) to the patient;*”

Lundahl teaches that “[a]ccording to one preferred embodiment of the present invention, blue light having wavelengths exceeding 400 nm (nanometers) is particularly advantageous for certain diagnostic purposes and treatments, especially when ALA is the photoactivatable agent used for PD and PDT of actinic keratosis” and that “visible light in other ranges of the spectrum, particularly in the green and red ranges between 400 and 700 nm, may also be used.” Ex.1014, 2:18-26. Lundahl describes applying ALA to a patient for the treatment of actinic keratosis, stating “One example of a treatment method for precancerous lesions, such as actinic keratosis, by PDT utilizing an illuminator described above in conjunction with 5-aminolevulinic acid (ALA) will now be described. Essentially anhydrous ALA is admixed with a liquid diluent just prior to its use. The ALA admixture is topically applied to the lesions using a point applicator to control dispersion of the ALA admixture.” *Id.*, 15:29-37; Ex. 1015, ¶193.

Thus, Lundahl teaches the limitations of claim 5(a). Ex.1015, ¶194, Ex.1016, ¶¶77-78.

Claim 5(b): “positioning an illuminator proximate to the patient,”

Lundahl teaches positioning the PDT device proximate to the patient’s head for treatment. Lundahl states “the present invention uses a U-shaped emitting surface that more closely follows the contours of the human face and scalp, and minimizes lamp to target distance variations which in turn minimizes irradiance variations at the target.” Ex.1014, 4:33-38. Additionally, Lundahl illustrates the positioning of the PDT device proximate to the patient’s head in Figure 1:



Ex.1014, Fig. 1; Ex. 1015, ¶195-196.

Thus, Lundahl teaches claim 5(b). Ex.1015, ¶197, Ex.1016, ¶¶79-81.

Claim 5(c): “the illuminator comprising five panels connected by hinged structures on inner side surfaces of adjacent panels; and”

Larsen teaches that the applicators may be positioned over a patient’s back. Ex.1004, [0070]-[0072]. Larsen teaches (or renders obvious) that the five panels are connected by hinged structures on inner side surfaces of adjacent panels, for the same reasons given for claim 1(a) above. Ex.1015, ¶198; Ex.1016, ¶82.

Thus, Larsen teaches the limitations of claim 5(b). Ex.1015, ¶199.

Claim 5(d): “uniformly illuminating a treatment surface of the patient”

Lundahl and Larsen teach claim 5(d) for the same reasons given for claim 1(c) above. Ex.1015, ¶200; Ex.1016, ¶82.

Claim 5(e): “with light sources disposed on the five panels of the illuminator,”

Lundahl and Larsen teach claim 5(e) for the same reasons given for claim 1(b) above. Ex.1015, ¶201; Ex.1016, ¶82.

Claim 5(f): “the five panels being positioned to allow treatment within approximately four inches of the treatment surface,”

Lundahl and Larsen teach claim 5(f) for the same reasons given for claim 1(e) above. Ex.1015, ¶202.

Claim 5(g): “wherein each of the five panels has two first edges and two second edges shorter than the two first edges, and”

Lundahl and Larsen teach claim 5(g) for the same reasons given for claim 1(f) above. Ex.1015, ¶203.

Claim 5(h): “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.”

Lundahl and Larsen teach claim 5(f) for the same reasons given for claim 1(g) above. Ex.1015, ¶204.

6. Claim 6

Claim 6: “The method of claim 5, wherein the illuminating comprises outputting red light during at least part of the time when the treatment surface is illuminated.”

The combination of Lundahl in view of Larsen renders obvious the method of claim 5, for all the reasons given above. Ex.1015, ¶206.

Lundahl teaches that “[s]ince total light Dose (J/cm^2)= Irradiance (W/cm^2) $\times$ Time (sec), the only additional parameter that needs to be controlled for delivery of the correct treatment light dose is exposure time”, which is “accomplished in a preferred embodiment of the present invention by the timer which controls electrical power to the ballasts and which can be set by the physician.” Ex.1014, 15:55-61; Ex.1015, ¶207; Ex.1016, ¶83. As previously discussed, Lundahl expressly incorporates all teachings of Kennedy. Ex. 1014, 1:38-48 (incorporating by reference the contents of Ex.1017). Ex.1015, ¶207.

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

of detecting and treating malignant and non-malignant tissue abnormalities and lesions of the skin” in which “5-aminolevulinic acid is administered to the patient.” Ex.1017, Abstract. Kennedy states that “[i]n preferred aspects of this invention the preferred precursor of protoporphyrin IX is 5-amino-4-oxo-pentanoic acid, otherwise known as 5-aminolevulinic acid, and a preferred wavelength of the photoactivating light is in the range 350-640 nm, more preferably a red light of about 610-630 nm.” Ex.1017, 4:3-8. Kennedy also states that “[t]he wavelength of the photoactivating light is of some importance, as it has been shown that between 1 and 10 percent of incident red light (600-700 nm) can pass through a slab of human tissue 1 cm thick, whereas only 0.001 percent or less of blue light (about 400 nm) can pass through the same thickness of human tissue. The photosensitizer will, therefore, be more successful if it strongly absorbs red light. PpIX does strongly absorb red light.” Ex.1015, ¶209; Ex.1016, ¶84; Ex.1017, 4:60-69.

Larsen teaches that its applicators are configured to output red light: “devices are available for the photodynamic stimulation of human cell energy in the form of red and infrared radiation . . .”. Ex.1004, [0024]. Larsen also teaches using light radiation within the wavelength of 300 – 2000 nm, which includes red light. *Id.*, [0025], [0071]-[0076], [0083]; Ex.1015, ¶210; Ex.1016, ¶85-86.

Thus, Lundahl and Larsen teach the limitations of claim 6. Ex.1015, ¶211.

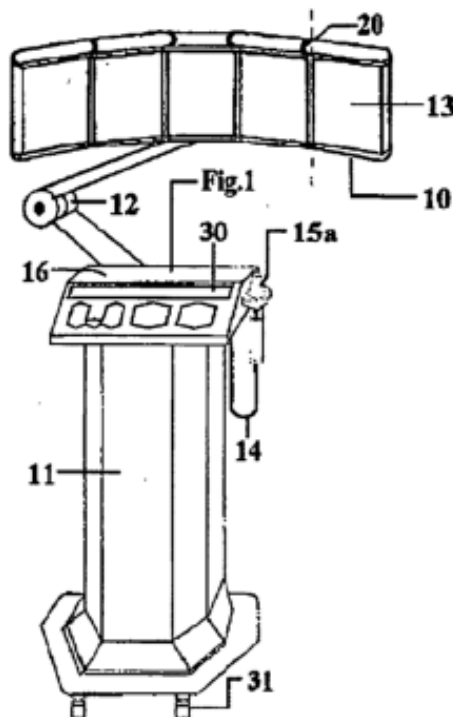
7. Claim 16

Claim 16[preamble]: “A system for photodynamically diagnosing or treating a patient, comprising:”

Lundahl and Larsen teach the preamble of claim 16 for the same reasons given for the preamble of claim 1 above. Ex.1015, ¶212.

Claim 16(a): “a mobile base supported by at least four wheels;”

As shown in Figure 1, Larsen discloses a mobile base supported by at least four wheels:



Ex.1004, Fig. 1; Ex.1015, ¶213.

Larsen teaches that the device is “freely moveable on wheels.” Ex.1004, [0027], [0069]. Larsen necessarily discloses that the base has at least four wheels in order to provide stability. Ex.1015, ¶214. The Examiner agreed. See Ex.1002, 328

(finding that in Figure 1 of Larsen ‘381, “it is inherent that there are at least two more wheels, for a total of 4, in order for the device to be stable”).

To the extent the Board determines that Larsen does not expressly or inherently disclose “at least four wheels,” it would have been obvious to POSITA to use at least four wheels to support the stand/pillar of Larsen, since it was well known that a four-wheeled stand is much more stable than a stand with only three wheels. Ex.1015, ¶215. Using at least four wheels to support the stand was one of a finite number of known solutions to support a mobile stand, and would have been obvious to try with predictable results (more stability compared to only three wheels). POSITA would have been motivated with a reasonable expectation of success to use four wheels, since the stability provided by four wheels was a well-known outcome. *Id.*

Thus, Larsen teaches the limitations of claim 16(a). Ex.1015, ¶216.

Claim 16(b): “a pillar perpendicular to the base;”

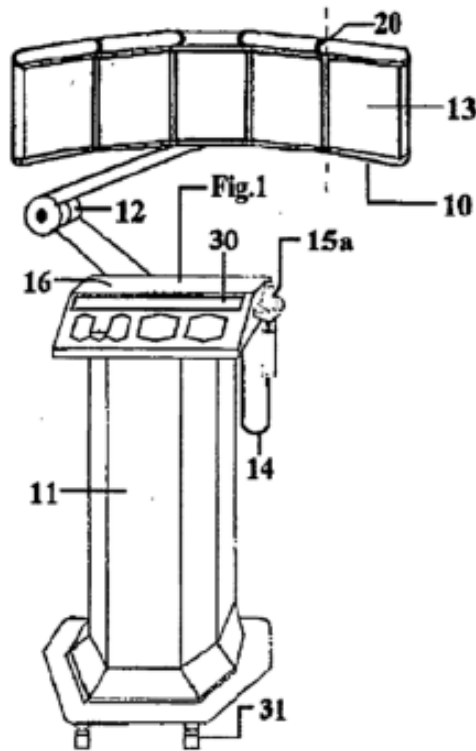
Larsen’s “stand 11” is perpendicular to the base, as shown in Figure 1. Ex.1004, Fig. 1, [0069]; *see also* Ex.1002, 328 (finding claim 16(b) disclosed by “a pillar 11” in Larsen ‘381); Ex.1015, ¶217.

Thus, Larsenes teach the limitations of claim 16(b). Ex.1015, ¶218.

Claim 16(c): “a controller disposed to be supported by the pillar;”

Lundahl teaches that “[a]ccording to a preferred embodiment of the present invention, an electronic control system 110 consists of six functional blocks. A microcontroller 200 is the central processing unit; it contains firmware which reads the system sensors, determines the system status, controls the ballast voltage (and tube output), and provides user information by way of a system status LED 112 (the firmware is described in detail below). To achieve output irradiance in the specified range, the microcontroller 200 monitors the tube output via a visible light sensor 120 which is located behind the tube reflector 50.” Ex.1014, 11:19-29; Ex.1015, ¶219.

Larsen discloses a controller (16) that is directly supported by the stand (11), as shown by Figure 1:

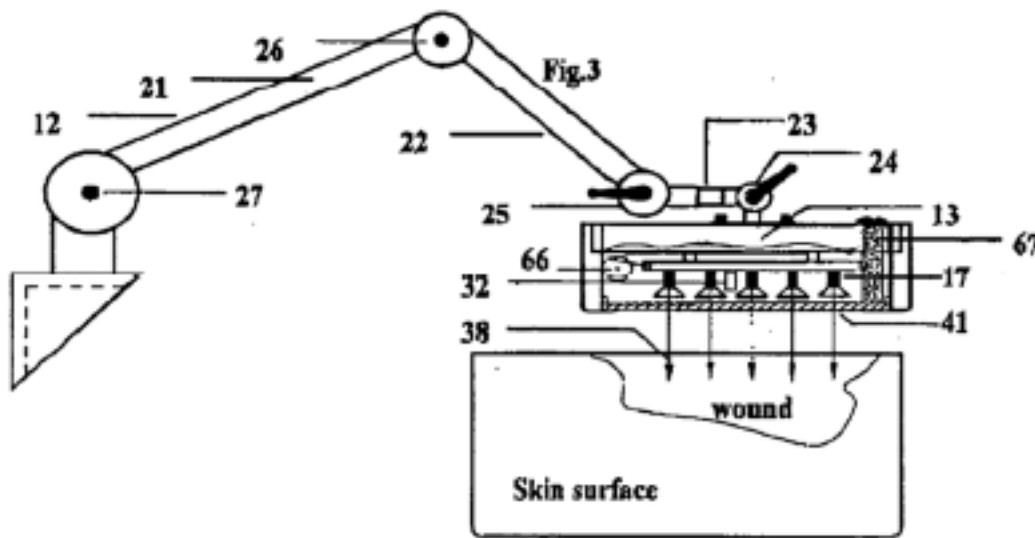


Ex.1004, Fig. 1, [0074]; *see also* Ex.1002, 328 (finding claim 16(c) disclosed by “a controller 16” in Larsen ’381); Ex.1015, ¶220.

Thus, Lundahl and Larsen teach the limitations of claim 16(c). Ex.1015, ¶221.

Claim 16(d): “an arm mounted to a top portion of the pillar; and”

Larsen discloses a joint arm (12) mounted to a top portion of the stand:



Ex.1004, Fig. 3; Ex.1015, ¶222.

The joint arm (12) is mounted to the top of the stand/pillar (11): “The joint carrier 21 is connected with the stand 11 through a joint 27 and one or more joints can also be produced as friction-adjustable ball-joints, which gives almost unlimited adjustment possibilities and user comfort.” *Id.*, [0073], Fig. 3; *see also* Ex.1002, 328 (finding claim 16(d) disclosed by “an arm 12” in Larsen ‘381); Ex.1015, ¶223.

Thus, Lundahl and Larsen teach the limitations of claim 16(d). Ex.1015, ¶224.

Claim 16(e): “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:”

Larsen’s applicator (13) is connected to the end of the joint arm (12), with hinges that allow adjustment of its position. Ex.1004, Fig. 3. Furthermore, “[t]he jointed arm 12 has three joint carriers. 21, 22, 23, where the joint carrier 21, together with the stand 11 and the joint carrier 23 are moveable at a free end through a fixing

joint 24 connected with one or more applicators 13.” *Id.*, [0073]. Another fixing joint 25 “connects the joint carrier 23 with 21, while the joint carrier 22 is connected with the joint carrier 21 **with a hinge 26.**” *Id.* In Larsen’s device, “[t]he joint carrier 21 is connected with the stand 11 through a joint 27 and one or more joints can also be produced as friction-adjustable ball-joints, which gives almost unlimited adjustment possibilities and user comfort.” *Id.*; Ex.1015, ¶225.

By this arrangement, “[t]he jointed arm 12 thereby allows the positioning of the applicators 13 in front of, or above, a tissue area while maintaining a correct positioning distance.” Ex.1004, [0073]; *see also* Ex.1002, 328 (finding claim 16(e) disclosed by “the hinged arm and joints/hinges 25/26/27” in Larsen ‘381); Ex.1015, ¶226.

Thus, Lundahl and Larsen teach the limitations of claim 16(e). Ex.1015, ¶227.

Claim 16(f): “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,”

Larsen discloses 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. Larsen’s five panels are connected by hinged structures, for all the reasons given at claim 1(a) above. Larsen also provides continuous illumination across the five panels

to treat large surfaces such as a patient's back. Ex.1004, [0027], [0072]; Ex.1015, ¶228.

Larsen also teaches that each of the applicators is individually configurable to control illumination from each of the five applicators. Ex.1015, ¶229. In Larsen, each of the applicators (13) “can be used in the working model according to Fig. 2a to 2c **individually**, side by side (in large numbers) or in combination with an applicator.” Ex.1004, [0070].⁹ Each of the applicators is connected to a control mechanism 16. Ex.1004, Figs. 1. Using the control mechanism, “the invented device is adjustable within a relatively large range with reference to duration, amplitude and frequency of surge of current, so that the semiconductor diodes 17, 17a and 18, as well as laser 17 diodes with the same realisation as semiconductor diode 17, can be used as light sources.” Ex.1004, [0074]. The control mechanism includes “a switch select system for operating different types of semiconductor diodes 17 and/or with laser diodes. Both semiconductor diodes and/or laser diodes with tuneable wavelengths can be operated, which is a great advantage, and therefore the printed circuit boards can be equipped with a more intensive radiation effect.” *Id.*

⁹ The Examiner cited this same disclosure from Larsen '381 in finding that it disclosed this limitation. Ex.1002, 328.

Furthermore, each applicator includes sensors 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], Figs. 2a-2c. 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.” *Id.*, [0080]. Thus, each applicator is individually configurable, since each one can be adjusted by the controller based on feedback from its own sensors. Ex.1015, ¶230.

Thus, Lundahl and Larsen teach the limitations of claim 16(f). Ex.1015, ¶231.

Claim 16(g): “*light sources disposed on surfaces of the five panels,*”

Larsen discloses “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,” for all the reasons given with respect to claim 1(b) above. Ex.1015, ¶232.

Thus, Larsen teaches the limitations of claim 16(g). Ex.1015, ¶233.

Claim 16(h): “*the illuminator being configured to uniformly illuminate a treatment surface of the patient via the light sources,*”

Lundahl and Larsen teach claim 16(h) for the same reasons given for claim 1(c) above. Ex.1015, ¶234.

Claim 16(i): “the light sources being configured to output light uniformly during at least part of a time when the treatment surface is illuminated,”

Larsen discloses that the light sources are configured to output light uniformly during at least part of a time when the treatment surface is illuminated. Larsen teaches that “[t]he semiconductor diodes and/or laser diodes useable in this invention emit a light radiation with either SPE (single photon emission), TPE (Two photon emission) and/or MTE (multiple photon emission) within the wavelength area of 300-2000 nanometers in order to correspond with available light sensitive substances (PDT).” Ex.1004, [0076]; *see also* Ex.1004, [0071] (showing applicators can radiate light at different discrete wavelengths). Furthermore, “[i]n each applicator the printed circuit board carrying the light sources is connected to a small electrical scan engine 66, which can move the light sources with linear movements, whereby a correctly adjusted scan length and frequency gives the radiated surface a total radiation at the necessary wavelengths without leaving any unradiated gaps.” Ex.1004, [0072]; Ex.1015, ¶235.

Thus, Larsen teaches claim 16(h). Ex.1015, ¶236.

Claim 16(j): “each of the five panels having two first edges and two second edges shorter than the two first edges,

Lundahl and Larsen teaches claim 16(j) for all the reasons given with respect to claim 1(f) above. Ex.1015, ¶237.

Claim 16(k): “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”

Lundahl and Larsen teach claim 16(k) for the same reasons given for claim 1(g) above. Ex.1015, ¶238.

Claim 16(l): “one or more fans mounted to at least one of the five panels.”

Lundahl teaches a cooling system incorporating fans. Lundahl states “a cooling system is provided to ensure proper bulb operation. According to an embodiment of the present invention, the cooling system comprises vents in the polycarbonate shield 40, the reflector 50 and the housing 30, as well as fans 70 to displace cooling air.” Ex.1014, at 9:14-18; Ex.1015, ¶239.

While Larsen does not disclose one or more fans mounted to at least one of the five panels, Larsen states that “[a] disadvantage of the known device is that the semiconductor diodes tend to overheat during use, which causes a decrease in the effectiveness of the device.” Ex.1004, [0006]. Thus, POSITA would have found it obvious to add one or more fans mounted to at least one of the five panels to cool the device in Larsen. Ex.1015, ¶240.

Thus, Lundahl and Larsen teach claim 16(l). Ex.1015, ¶241.

For these reasons, claim 16 is obvious over the combination of Lundahl in view of Larsen. Ex.1015, ¶242.

8. Claim 17

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

The combination of Lundahl in view of Larsen renders obvious the system of claim 16, for all the reasons given above. Lundahl and Larsen teach claim 17 for all the reasons given above with respect to claim 1(d). Ex.1015, ¶243.

9. Claim 19

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

The combination of Lundahl in view of Larsen renders obvious the system of claim 16, for all the reasons given above. Lundahl and Larsen teach claim 19 for all the reasons given above with respect to claim 6. Ex.1015, ¶244.

10. Claim 20

Claim 20[preamble]: *“A system for photodynamically diagnosing or treating a patient, comprising:”*

Lundahl and Larsen teach the preamble of claim 20, for all the reasons given above with respect to the preamble of claim 1. Ex.1015, ¶245.

Claim 20(a): “an illuminator comprising five panels connected by hinged structures on inner side surfaces of adjacent panels, wherein the illuminator is configured to output light at a variable irradiance density during treatment; and”

Larsen discloses (or renders obvious) an illuminator comprising five panels connected by hinged structures on inner side surfaces of adjacent panels, for all the reasons given with respect to claim 1(a) above. Ex.1015, ¶246.

Larsen also discloses that its illuminator (applicators) are configured to output light at a variable irradiance density during treatment. In Larsen, the applicators can produce “an intensive light radiation with selective multiple wavelengths” in order to provide intensive photodynamic therapy to a patient. Ex.1004, [0025]. Larsen further teaches that the energy output from its applicators is adjustable “within a relatively large range with reference to duration, amplitude and frequency of surge of current, so that semiconductor diodes 17, 17a and 18 . . . can be used as light sources.” *Id.*, [0074]. Larsen’s applicators are connected to sensors measuring the amount of energy radiated away from the skin surface and the temperature of the skin surface. Ex.1004, [0079]-[0080], Figs. 2a-2c. In response to readings from the sensors, “[a]n increase of the registered amount of energy can be achieved by the invented device by increasing the operating potential (and thereby the pulse amplitude) or the pulse frequency and/or prolonging the duration of the treatment

time through an adjustment of the control mechanism 16.” Ex.1004, [0079]; Ex.1015, ¶247.

Thus, Lundahl and Larsen teach the limitations of claim 20(a). Ex.1015, ¶248.

Claim 20(b): “*light sources disposed on surfaces of the five panels,*”

Lundahl and Larsen teach claim 20(b) for all the reasons given above with respect to claim 1(b). Ex.1015, ¶249.

Claim 20(c): “*the illuminator being configured to uniformly illuminate a treatment surface of the patient via the light sources.*”

Lundahl and Larsen teach claim 20(c) for all the reasons given above with respect to claim 1(c). Ex.1015, ¶250.

Claim 20(d): “*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,*”

Lundahl and Larsen teach claim 20(d) for all the reasons given above with respect to claim 1(d). Ex.1015, ¶251.

Claim 20(e): “*wherein the five panels are positioned to allow treatment within approximately four inches of the treatment surface, and*”

Lundahl and Larsen teach claim 20(e) for all the reasons given above with respect to claim 1(e). Ex.1015, ¶252.

Claim 20(f): “wherein each of the five panels has two first edges and two second edges shorter than the two first edges, and”

Lundahl and Larsen teach claim 20(f) for all the reasons given above with respect to claim 1(f). Ex.1015, ¶253.

Claim 20(g): “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.”

Lundahl and Larsen teach claim 20(g) for all the reasons given above with respect to claim 1(g). Ex.1015, ¶254.

For these reasons, claim 20 is obvious over the combination of Lundahl in view of Larsen. Ex.1015, ¶255.

11. Claim 21

Claim 21[preamble]: “A system for photodynamically diagnosing or treating a patient, comprising:”

Lundahl and Larsen teach the preamble of claim 21 for all the reasons given above with respect to the preamble of claim 1. Ex.1015, ¶256.

Claim 21(a): “an illuminator comprising five panels connected by hinged structures on inner side surfaces of adjacent panels; and”

Lundahl and Larsen teach claim 21(a) for all the reasons given above with respect to claim 1(a). Ex.1015, ¶257.

Claim 21(b): “light sources disposed on surfaces of the five panels,”

Lundahl and Larsen teach claim 21(b) for all the reasons given above with respect to claim 1(b). Ex.1015, ¶258.

Claim 21(c): “the illuminator being configured to uniformly illuminate a treatment surface of the patient via the light sources,”

Lundahl and Larsen teach claim 21(c) for all the reasons given above with respect to claim 1(c). Ex.1015, ¶259.

Claim 21(d): “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,”

Lundahl and Larsen teach claim 21(d) for all the reasons given above with respect to claim 1(d). Ex.1015, ¶260.

Claim 21(e): “wherein the five panels are positioned to allow treatment within approximately four inches of the treatment surface,”

Lundahl and Larsen teach claim 21(e) for all the reasons given above with respect to claim 1(e). Ex.1015, ¶261.

Claim 21(f): “wherein the five panels are individually configurable to control illumination from each of the five panels, and”

Lundahl and Larsen teach claim 21(f) for all the reasons given above with respect to claim 16(f). Ex.1015, ¶262.

Claim 21(g): “wherein each of the five panels has two first edges and two second edges shorter than the two first edges, and”

Lundahl and Larsen teach claim 21(g) for all the reasons given above with respect to claim 1(f). Ex.1015, ¶263.

Claim 21(h): “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.”

Lundahl and Larsen teach claim 21(h) for all the reasons given above with respect to claim 1(g). Ex.1015, ¶264.

For these reasons, claim 21 is obvious over the combination of Lundahl in view of Larsen. Ex.1015, ¶265.

B. Lundahl in view of Larsen, and further in view of Bansal Render Obvious Claims 1, 2, 4-6, 16, 17, 19, 20, and 21

As set forth in Ground 1, Lundahl and Larsen disclose each and every limitation of claims 1, 2, 4-6, 16, 17, 19, 20, and 21. However, Bansal provides additional support for the motivation to combine and teachings on claim limitations reciting “uniformly illuminate a treatment surface” recited in limitations 1(c), 5(d), 16(h), 20(c), and 21(c) and “a higher intensity of light is emitted proximate the second edges” recited in limitations 1(g), 5(h), 16(k), 20(g), and 21(h). Ex.1015, ¶266.

1. Motivation to Combine

POSITA would have been motivated with a reasonable expectation of success to incorporate the non-uniform light arrangement of Bansal into the combination of Lundahl and Larsen. As explained with respect to the combination of Lundahl and Larsen, a POSITA would have been motivated to uniformly illuminate a treatment surface of the patient. *Supra* Section IX(A)(1) (part of motivation is to “provide the

desired irradiance and irradiance uniformity to all target areas during PDT”). Bansal further supports this motivation in light of its teachings to “allow[] for a more uniform and precise phototherapeutic light exposure” and “to achieve the goal of even exposure to the subject’s skin.” Ex.1005, [0010], [0025]; Ex.1015, ¶266-268.

POSITA would have had a reasonable expectation of success in combining Bansal with Lundahl with Larsen, because all three references describe similar illuminators for using light to treat conditions on a patient’s skin. In addition, both Lundahl and Bansal teach one way to increase uniformity is to increase the intensity of light at the top and bottom edges while Larsen and Bansal teach using LEDs to perform PDT treatments. Thus, this combination is merely a combination of known components performing their expected functions. Ex.1015, ¶¶139-143 and 269-270;.

2. Bansal further teaches “uniformly illuminate a treatment surface of a patient” recited in limitations 1(c), 5(d), 16(h), 20(c), and 21(c)

Limitations 1(c), 5(d), 16(h), 20(c), and 21(c) recite the light sources of the illuminator are configured to “uniformly illuminate a treatment surface of a patient” Ex.1001, 10:29-31 (claim 1), 10:60-62 (claim 5), 11:59-62 (claim 16), 12:26-28 (claim 20) and 12:47-49 (claim 21). For these limitations Bansal’s teachings are in addition to what Lundahl and Larsen teach, as discussed in Ground 1. Ex.1015, ¶266.

Bansal describes a phototherapy system “including a non-uniform array of light sources, a clear light diffusing panel placed between the light sources and the

subject, and a target mechanism to assist in positioning the subject underneath the center of the array.” Ex.1005, [0010]. According to Bansal, these improvements **“allow[] for a more uniform and precise phototherapeutic light exposure.”** *Id.* Bansal describes a variety of light arrays “to achieve the goal of even exposure to the subject’s skin.” Ex.1005, [0025]. Bansal further describes known methods for measuring the uniformity of phototherapeutic light on the patient’s skin. Ex.1005, [0009]. Accordingly, Bansal discloses an illuminator configured to uniformly illuminate the treatment surface of the patient via the light sources. Ex.1015, ¶267-270.

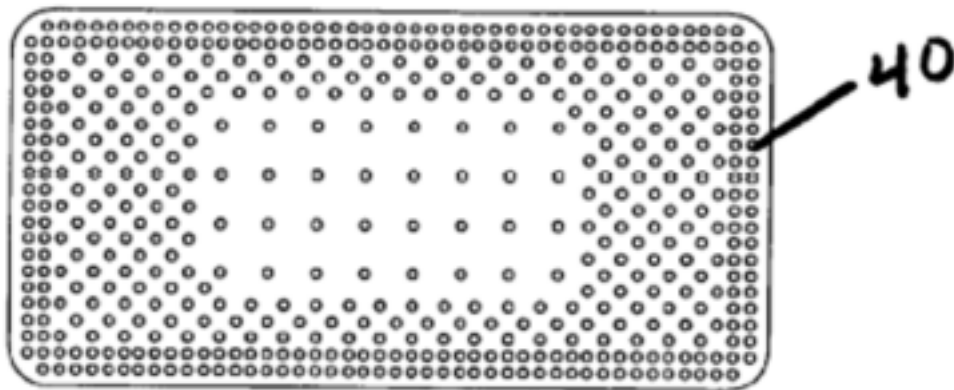
3. Bansal further teaches “a higher intensity of light is emitted proximate the second edges” recited in limitations 1(g), 5(h), 16(k), 20(g), and 21(h)

Limitations 1(g), 5(h), 16(k), 20(g), and 21(h) recite 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, 10:40-44 (claim 1), 10:66-11:3 (claim 5), 12:1-5 (claim 16), 12:37-40 (claim 20) and 12:59-63 (claim 21). For these limitations Bansal’s teachings are in addition to what Lundahl and Larsen teach, as discussed in Ground 1. Ex.1015, ¶271

For these limitations Bansal teaches the panel has an array of light sources (40) that may be “semiconductor light sources, LEDs 42, halogen lights, incandescent lights, low-intensity lasers, etc.” Ex.1005, [0025]. The array “can take

a number of different non-uniform forms to achieve the goal of even exposure on the subject's skin.” *Id.* One of Bansal's embodiments achieves this by varying “the density of light source distribution . . . throughout the array, ***such as with higher density in the periphery and a lower density in the center.***” *Id.*; see also claim 10 (“wherein said array has a peripheral area with a first density of light sources, and a central area with a second density of light sources, and wherein the light sources are distributed so that said first density is higher than said second density”). Figure 9b of Bansal shows one embodiment where more light sources are placed near the edges of the panel compared to the light sources in the center.

Fig. 9b



Id., Fig. 9b; see also Figs. 9a & 9c-9d. As seen above, due to the higher density of light sources at the shorter second edges of Bansal's panels, a higher intensity of light would be emitted from the areas proximate to those shorter second edges

compared to the intensity of light emitted from the center of the panel with fewer light sources (and thus lower intensity). *Id.*; Ex.1015, ¶272.

Bansal also teaches “low intensity light sources could be used in one portion of the array, and higher intensity light sources could be used in another section. This can be achieved by either using different intensity light sources ***or driving the light sources with a lower power in the center and a higher power on the outer edges.***” Ex.1005, [0025]. Bansal also describes a switch 44 “to control the light sources,” and “to provide a more precise control or larger range on the intensity of phototherapy provided.” Ex.1005, [0026]; Ex.1015, ¶273.

Accordingly, Bansal discloses an illuminator configured to uniformly illuminate the treatment surface of the patient via the light sources. Ex.1015, ¶274.

4. Remaining limitations and dependent claims

The remaining limitations of independent claims 1, 5, 16, 20 and 21 are taught for the same reasons provided in Ground 1. *See supra* Section XI(A)(2), (5), (7), (10), and (11), respectively. Ex.1015, ¶275.

Likewise the dependent claims 2, 4, 6, 17 and 19 are taught for the same reasons provided for Ground 1. *See supra* Section XI(A)(3), (4), (6), (8), and (9), respectively. Ex.1015, ¶276.

As such, the combination of Lundahl, Larsen and Bansal renders obvious claims 1, 2, 4, 5, 16, 17, and 19-21. Ex.1015, ¶¶277-278.

X. THE BOARD SHOULD NOT EXERCISE ITS DISCRETION TO DENY INSTITUTION

A. 35 U.S.C. § 325(d)

When evaluating a petition under § 325(d), the Board must determine “(1) whether the same or substantially the same art previously was presented to the Office or whether the same or substantially the same arguments previously were presented to the Office; and (2) if either condition of first part of the framework is satisfied, whether the petitioner has demonstrated that the Office erred in a manner material to the patentability of challenged claims.” *Advanced Bionics, LLC v. MED-EL Elektromedizinische Geräte GmbH*, IPR2019-01469, Paper 6 at 8 (PTAB Feb. 13, 2020) (precedential).

First, Bansel was never cited during the prosecution of the ‘028 Patent and thus could not have been considered by the examiner. Ex.1001, Cover. While Lundahl was previously presented to the examiner, there is no indication the Examiner considered its teachings to arrange the light sources to have higher intensity of light at the top and bottom edges, which is highly relevant to the reason for allowance. Ex.1014, 6:16-57. Finally, as to Larsen, the Examiner discussed a related Larsen ‘381 Patent in an Office Action. Ex.1002, 328-331, 425. However, Petitioner relies on Lundahl or Bansal for the limitations the examiner found missing in the Larsen ‘381 Patent, which was never considered by the Examiner. In addition,

Petition provides the testimony of Drs. Grove and Ehrenreich to explain how a POSITA would view the teachings of these references. *See* Ex.1015 and Ex.1016. Therefore, part one of the *Advanced Bionics* test favors institution, as the Grounds set forth herein were not considered by the Examiner even if some individual references were. *See Thorne Res., Inc. v. Trs. of Dartmouth Coll., IPR2021-00491, Paper 18 at 8 (PTAB Aug. 12, 2021).*

Further, under part two of *Advanced Bionics*, assuming the examiner was aware of the relevant teachings in the cited prior art, then the examiner erred in a manner material to the patentability. For example, as discussed below, both Lundahl (which is part of Grounds 1 and 2) and Bansal (Ground 2) when viewed in combination with Larsen teach all the claim limitations, including “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.” *Supra* Sections XI(A)(2) and XI(B)(3). In the Notice of Allowance, the Examiner found that none of the prior art of record taught this limitation. *Supra* Section V(C). Thus, the arguments presented in this IPR demonstrate the Office materially erred in issuing the Challenged Claims.

B. *Fintiv*

As set forth in the related matters discussion, the ‘028 Patent is the subject of an ITC proceeding and a District Court proceeding. There is no trial date set for the District Court proceeding and Petitioner anticipates that the District Court proceeding will be stayed pending the outcome of the ITC matter per 35 U.S.C. §1659(a). As set forth in Director’s Interim Guidance Memorandum¹⁰, “The PTAB will not discretionarily deny petitions based on applying *Fintiv* to a parallel ITC proceeding.”

XI. CONCLUSION

Petitioner requests this petition for *inter partes* review be granted and that the Challenged Claims be cancelled as unpatentable under 35 U.S.C. § 318(b).

Dated: August 21, 2024

Respectfully submitted,
/James P. Murphy/

¹⁰ Available at:

https://www.uspto.gov/sites/default/files/documents/interim_proc_discretionary_denials_aia_parallel_district_court_litigation_memo_20220621.pdf.

Petition for Inter Partes Review of
U.S. Patent No. 11,697,028

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CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. §§ 42.6(e)(4)(i) *et seq.* and 42.105(b), the undersigned certifies that on August 21, 2024, complete copies of this Petition for *Inter Partes* Review including all supporting exhibits, Petitioner's Notice Regarding Parallel Petitions, and Petitioner's Power of Attorney are being served by Federal Express® on the following counsel of record for U.S. Patent 11,697,028:

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