

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.

DUSA PHARMACEUTICALS, INC.
Patent Owner

Inter Partes Review Case No. 2024-00874

**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.***

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PETITIONER’S EXHIBITS

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
1003	Declaration of Eric Bretschneider, Ph.D.
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	U.S. Patent Publication No. 2014/0067024 by Ross Peter Jones et al. entitled “Dual Panel Photodynamic Therapy Lamp” (“Jones”)
1007	WO 02/13788 by Richard Anderson entitled “Topical Aminolevulinic Acid-Photodynamic Therapy for Acne Vulgaris” (“Anderson”)
1008	U.S. Patent No. 7,033,381 (“Larsen ’381 Patent”)
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” (“Lundhal”)
1012	WO 2005/030328 by Nicholas Mackinnon et al. entitled “Apparatus and Methods for Performing Phototherapy, Photodynamic Therapy and Diagnosis” (“Mackinnon”)
1013	U.S. Patent No. 11,179,574 by Thomas Boyajian et al. entitled “Method of administering 5-aminolevulinic acid (ALA) to a patient” (“’574 Patent”)

Pursuant to 35 U.S.C. §§ 311-319, Biofrontera Inc., Biofrontera Bioscience GmbH, Biofrontera Pharma GmbH, and Biofrontera AG (collectively, “Petitioner”) hereby respectfully request *inter partes* review of claims 1-8, 10, 11, 13, 14, and 16-21 (“Challenged Claims”) of U.S. Patent No. 11,697,028 (“the ’028 Patent”). 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.

I. 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))

There are no related matters.

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

<u>Lead Counsel:</u> George B. Davis (Reg. No. 68,205) Email: gdavis@mcguirewoods.com <u>Postal/Hand Delivery Address:</u> MCGUIREWOODS LLP Gateway Plaza 800 East Canal Street Richmond, VA 23219 Tel.: (804) 775-1129 Fax.: (804) 775-2016	<u>Backup Counsel:</u> Tyler T. VanHoutan (Reg. No. 54,506) Email: tvanhoutan@mcguirewoods.com <u>Postal/Hand Delivery Address:</u> MCGUIREWOODS LLP 845 Texas Ave., Suite 2400 Houston, TX 77002 Tel.: (713) 571-9191 Fax.: (713) 571-9652
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D. Service Information (37 C.F.R. § 42.8(b)(4))

Service on Petitioner may be made by email, mail, or hand delivery at the addresses shown above. A power of attorney is submitted with this Petition.

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

The Office is authorized to charge the fees specified by 37 C.F.R. §§ 42.103(a) and 42.15(a) to Deposit Account No. 23-1951 as well as any additional fees that might be due in connection with this Petition.

F. Grounds for Standing (37 C.F.R. § 42.104(a))

Petitioner certifies that the '028 Patent is eligible for *inter partes* review and that Petitioner is not barred or estopped from requesting the *inter partes* review sought herein.

II. OVERVIEW OF CHALLENGE AND RELIEF REQUESTED

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

Pursuant to 37 C.F.R. § 42.104(b), Petitioner requests *inter partes* review of the Challenged Claims and requests that the Challenged Claims be cancelled based on the grounds of unpatentability set forth in Section II.B below. Additional support for each ground is set forth in the Declaration of Eric Bretschneider, Ph.D., Ex.1003.

A. Publications Relied Upon

Exhibit	Reference	Publication Date	Availability as Prior Art
1004	U.S. Patent Publication No. 2005/0075703 (“Larsen”)	4/7/2005	§ 102(a)(1)
1005	U.S. Patent Publication No. 2004/0068305 (“Bansal”)	4/8/2004	§ 102(a)(1)
1006	U.S. Patent Publication No. 2014/0067024 (“Jones”)	3/6/2014	§ 102(a)(1)
1007	WO 02/13788 (“Anderson”)	2/21/2002	§ 102(a)(1)
1012	WO 05/030328 (“Mackinnon”)	4/7/2005	§ 102(a)(1)

B. Grounds For Challenge

Petitioner requests cancellation of the Challenged Claims as being obvious under 35 U.S.C. § 103.

Ground	Claims	Basis
I	1, 2, 4-8, 16-21	Obvious over Larsen in view of Bansal, further in view of Jones
II	2-4	Obvious over Ground 1 references, further in view of Anderson
III	10-11 and 13-14	Obvious over Ground 1 references, further in view of Mackinnon

III. 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, 2015.¹

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, 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.1003, ¶¶81-83.

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

¹ Petitioner does not concede that the Challenged Claims are entitled to this effective filing date. Ex.1003, ¶90.

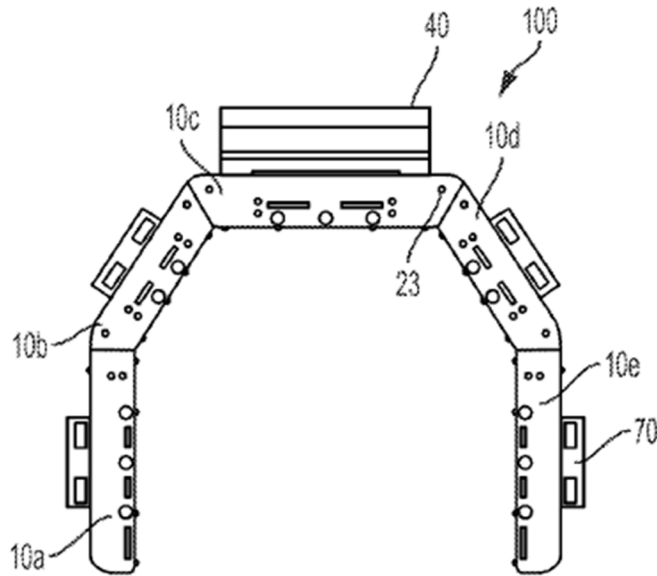


FIG. 1A

Each panel includes LED arrays that provide uniform light exposure to a patient using addressable strings of lights, as shown below. *Id.*, 6:11-24.

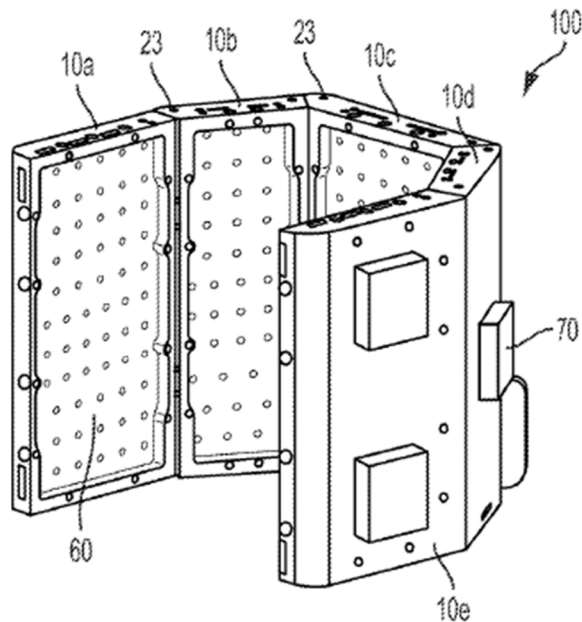


FIG. 2A

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. *Id.*, 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. For example, as shown below, a higher current may be supplied to areas 3 and 4 of panels 10a and 10b, respectively, compared to the current supplied to areas 5 and 6 of the same panels. *Id.*, 6:37-40, Fig. 5.

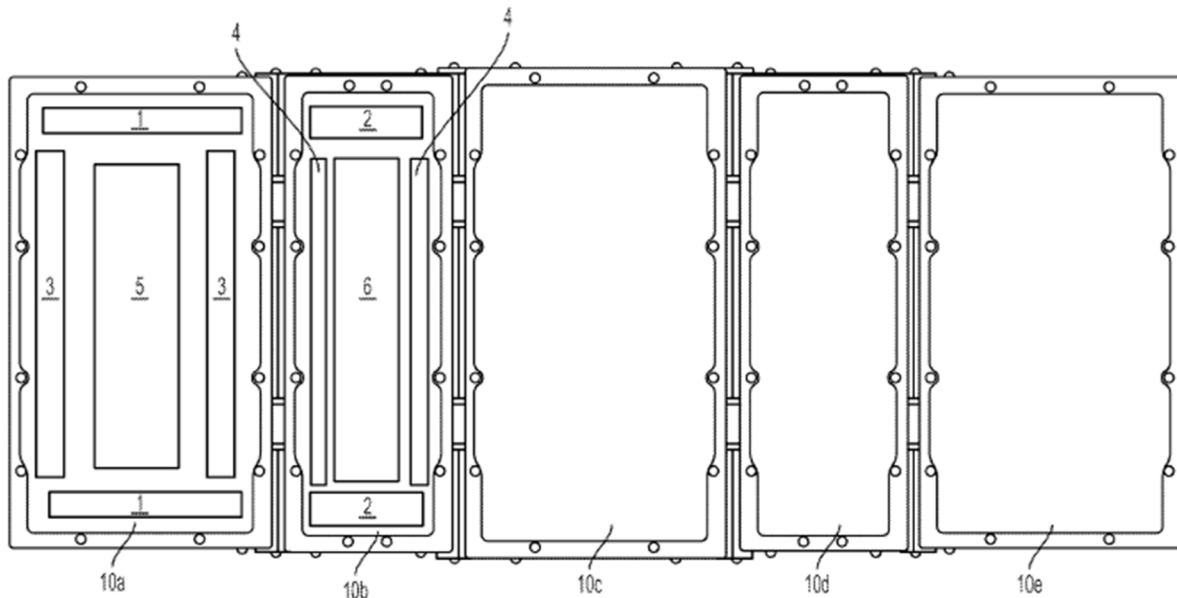


FIG. 5

In other embodiments, the number of diodes in different regions of a panel may be varied to change the power output and/or intensity of the light emitted from different regions of the panel. *Id.*, 6:51-7:6. By increasing the intensity of light and/or concentration of light sources around the periphery of a panel, the '028 Patent

purports to reduce or eliminate the “optical dead spaces” or “fall off” that may otherwise occur at the edges of the panels. *Id.*, 5:8-12, 6:4-10. Yet as explained in detail below, 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. Ex.1003, ¶¶52-78.

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 (“Larsen ’381 Patent”). 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.*, 199-205.

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.” *Id.*, 120.

D. Claim Construction

1. Level of Ordinary 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 had at least a Bachelor of Science in electrical engineering, physics, biomedical engineering, computer engineering, chemical engineering, material science, or a related scientific or engineering field, and at least one year of work or research experience in optics, optoelectronics, radiometry, photometry, photodynamic diagnosis (PD), photodynamic therapy (PDT), phototherapy (PT), or a related field. Alternatively, POSITA in the relevant time frame would have had at least four years of industry or academic experience in optics, optoelectronics, radiometry, photometry, PD, PDT, PT, or a related field. Ex.1003, ¶37.

2. Petitioner’s Proposed Constructions

A claim in an *inter partes* review is given its ordinary and customary meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005) (en banc). Petitioner proposes, for purposes of this IPR only, that all claim terms of the ’028 Patent are presumed to take on their ordinary and customary meaning that the terms would have to POSITA at the time of the invention, and there is no need to resolve any controversy with respect to these terms. Ex.1003, ¶100.

See 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 citations omitted).

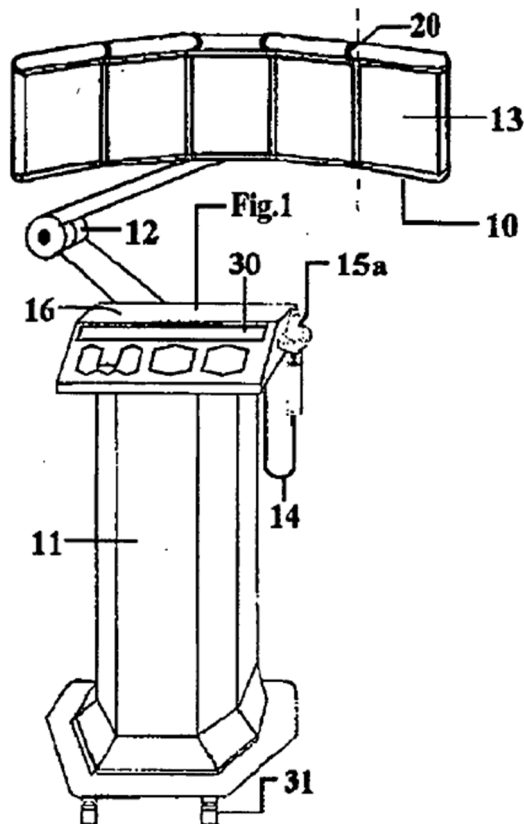
IV. SUMMARY OF PRIOR ART AND ANALYSIS UNDER § 325(D)

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.1003, ¶¶113, 122, 137-138,144-146, 149. Petitioner is not aware of any secondary considerations that support a finding of non-obviousness. *Id.*, ¶187. 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. Brief Summary of the Prior Art

1. Larsen (Ex.1004)

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.

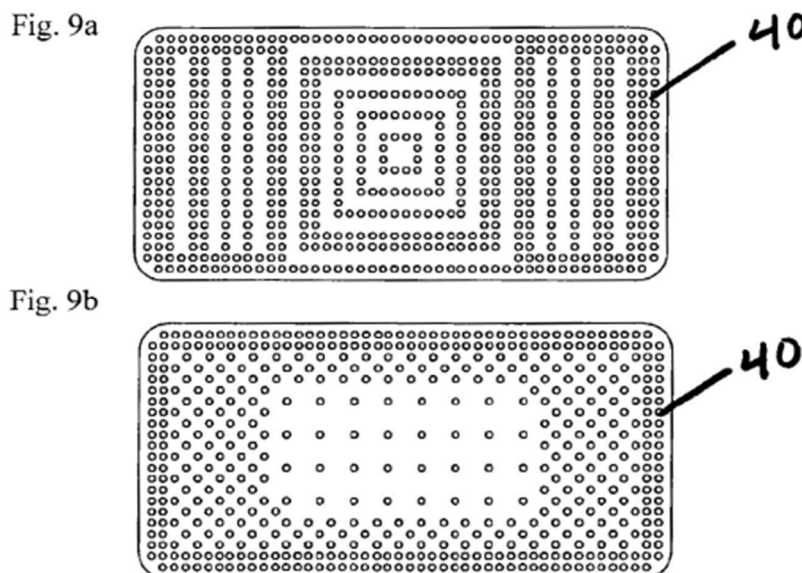


Id., Fig. 1. The treatment device includes a mobile stand (11) mounted on wheels (31), a controller (16), a joint arm (12), and multiple applicators (13) connected by hinges. *Id.*, [0069]-[0070]. Each applicator includes printed circuit boards with multiple light sources for irradiating the treatment 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.1003, ¶113.

2. Bansal (Ex.1005)

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].

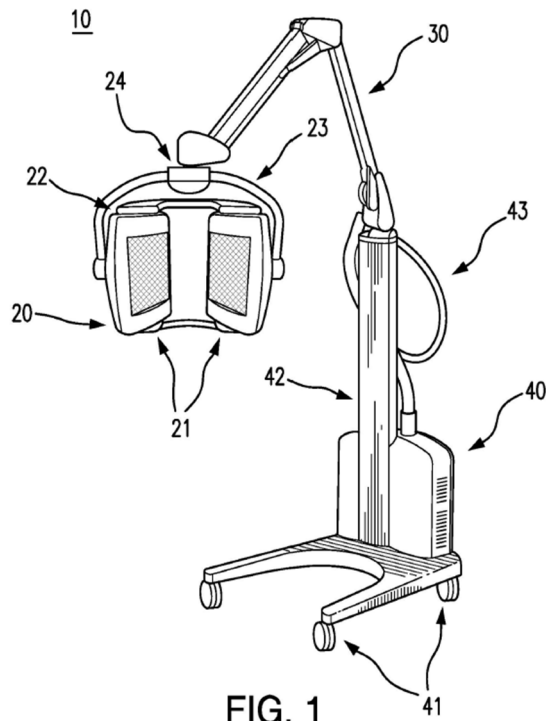
Bansal is from the same field of endeavor as the ’028 Patent, which also describes illuminators for treatment purposes. Ex.1001, 1:26-2:6. Bansal is also directed to the same problem as the ’028 Patent, namely, an illuminator that can

“achieve substantially uniform distribution of light on a subject.” Ex.1005, Abstract.

Thus, Bansal is analogous art to the '028 Patent. Ex.1003, ¶122.

3. Jones (Ex.1006)

Jones’ “photodynamic therapy lamp includes two lamp modules comprising an array of LEDs.” Ex.1006, Abstract. An embodiment of Jones’ PDT lamp is shown below in Figure 1.



Jones’ lamp modules comprise an array of LEDs, connected by a hinge (22) that allows them to be individually moved relative to each other. *Id.*, [0074], Fig. 1. Each lamp module is contained in a housing, which can include fans for cooling of the LEDs to prevent overheating. *Id.*, [0083]-[0084], Fig. 4D.

Jones is from the same field of endeavor as the '028 Patent, which also describes PDT illuminators. Ex.1001, 1:26-2:6. Jones is also directed to the same problem as the '028 Patent, namely, an illuminator with multiple lamp modules that can be positioned so that “the selected treatment area (e.g. larger relatively flat surfaces and contoured surface of a patient) are homogeneously illuminated.” Ex.1006, [0068]. Thus, Jones is analogous art to the '028 Patent. Ex.1003, ¶¶137-138.

4. Anderson (Ex.1007)

Anderson describes methods for treating skin disorders using a combination of 5-ALA and an energy source for PDT. Ex.1007, 2:12-15, 3:1-4. Anderson describes using a variety of light sources, including LEDs. *Id.*, 8:8-11. The total energy applied can vary depending on the treatment needs. *Id.*, 8:12-15.

Anderson is from the same field of endeavor as the '028 Patent, which also describes PDT illuminators for light therapy in conjunction with 5-ALA. Ex.1001, 1:26-2:6. Thus, Anderson is analogous art to the '028 Patent. Ex.1003, ¶¶144-146.

5. Mackinnon (Ex.1012)

Mackinnon describes a device for use in PDT. Ex.1012, 1:21-22, 3:13-16, 14:14-22. The light sources can include “red, green and blue LEDs or other desired lamps and photo generators.” *Id.*, 4:5-6. Mackinnon’s system selects desired wavelength, intensity, and duration suitable for activating different drugs for PDT.

Id., 11:15-20. Mackinnon’s system includes a projection system which “may match the shape and size of the illumination area to correspond to the shape and size of a target region discerned by an imaging system, for example an imaging sensor and image processing system of an endoscope or surgical microscope, such as those discussed herein.” *Id.*, 21:23-27.

Mackinnon is from the same field of endeavor as the ’028 Patent, which also describes PDT illuminators for light therapy. Ex.1001, 1:26-2:6. Thus, Mackinnon is analogous art to the ’028 Patent. Ex.1003, ¶149.

B. The Board Should Not Exercise its Discretion to Deny Institution Under 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). Here, the prior art and arguments presented by Petitioner are not the same or substantially the same as those presented during prosecution of the ’028 Patent.

First, Bansal and Mackinnon were never cited or discussed during the prosecution of the '028 Patent. Ex.1001, Cover. Second, these references are materially different from the prior art of record during prosecution. For example, as discussed below, Bansal (which is part of Grounds 1-3) discloses “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.” *Infra* § V.A.3 (claim 1(f)). In the Notice of Allowance, the Examiner found that none of the prior art of record included this limitation. *Supra* § III.C. Thus, Bansal is not cumulative of the art evaluated during prosecution, and Petitioner’s arguments are different from those presented during prosecution, since there was no reference the Examiner relied on that taught this limitation of claim 1.

Mackinnon is also materially different from the prior art of record. Mackinnon discloses sensors that are used to measure the size and shape of the treatment surface, which is found in dependent claims 10 and 13. *Infra* § V.C.2. During prosecution, no prior art or arguments were presented with respect to these limitations. Ex.1002, 326-333. Thus, Mackinnon is not cumulative of the art evaluated during prosecution, and Petitioner’s arguments are different from those

presented during prosecution, since there was no reference the Examiner relied on that taught the limitations of claims 10, 11, 13, and 14.

As to Larsen, Jones, and Anderson, Patent Owner cited these references in an IDS during prosecution, and the Examiner discussed the Larsen '381 Patent in an Office Action. Ex.1002, 329-331, 425. Larsen and the Larsen '381 Patent share the same inventor and much of the same disclosure. Ex.1003, ¶99. During prosecution, the Examiner determined the Larsen '381 Patent failed to disclose “one or more fans mounted to at least one of the panels.” Ex.1002, 329. However, Petitioner relies on Jones for this limitation. The Examiner and Patent Owner never discussed Jones or Anderson during prosecution.

This Petition therefore does not raise the same or substantially the same prior art or arguments previously considered by the Examiner. *See Unified Patents, Inc. v. Berman*, IPR2016-01571, Paper 10 at 13 (Dec. 14, 2016) (rejecting patent owner’s 325(d) argument because the secondary reference in a two-reference combination had not been vetted during prosecution); *Oticon Medical AB v. Cochlear Ltd.*, IPR2019-00975, Paper 15 at 15, 20 (PTAB Oct. 16, 2019) (refusing to deny institution based on § 325(d) where one of the references before the Board was not in front of the Examiner during prosecution and was not cumulative of the prior art of record). Thus, the Board should not deny institution under 35 U.S.C. § 325(d).

**V. A REASONABLE LIKELIHOOD EXISTS THAT THE
CHALLENGED CLAIMS ARE UNPATENTABLE**

**A. Ground 1: Claims 1, 2, 4-8, and 16-21 of the '028 Patent are obvious
over Larsen, in view of Bansal, further in view of Jones**

1. Reasons to Combine Bansal with Larsen

**a. Eliminating Gaps in Treatment of the Surface of the
Patient's Skin**

Larsen uses semiconductor diodes (such as LEDs) on printed circuit boards to illuminate a patient's skin. Ex.1004, [0070], [0072]. Larsen's applicators are designed to provide an "even and gap-free radiation of the surface with the multiple wavelengths of light." *Id.*, [0028]. Larsen's multiple light panels also allow for "equidistant positioning of the applicators 13 above the skin" on different regions of the patient (such as the back). *Id.*, [0072]. One of Larsen's stated goals is to "give[] the radiated surface a total radiation at the necessary wavelengths without leaving any unirradiated gaps." *Id.*; Ex.1003, ¶151.

POSITA considering Larsen would have been motivated to further reduce unirradiated gaps on the skin and make illumination more uniform. Ex.1003, ¶¶151-152. Bansal describes the problem caused by simple rectangular arrays (such as Larsen's), where the light "intensity will be significantly higher underneath the center of the array than around the periphery." Ex.1005, [0008]. Bansal provides several solutions to this problem, including (1) providing higher intensity lights at the edges of the panel compared to areas not proximate to the edges, and/or (2)

providing a higher density of light sources at the edges of the panel compared to areas not proximate to the edges. Ex.1005, [0025]; Figs. 9a-9d; Ex.1003, ¶¶119-121, 151-152. These teachings would have motivated POSITA to incorporate Bansal's solution of increasing the intensity of the lights at the edges of Larsen's applicators (including the shorter edges) in order to achieve a more uniform distribution of light on the surface of the patient's skin and reduce the unradiated gaps, to accomplish Larsen's stated goals. Ex.1003, ¶152.

While Larsen's applicators include "a small electrical scan engine 66, which can move the light sources with linear movements," (Ex.1004, [0072]), this would not have dissuaded POSITA from modifying Larsen in view of Bansal, since the scan engine is a less effective way to achieve more uniform illumination compared to Bansal's solution. Ex.1003, ¶154. First, the scan engine can only move lights in one direction at a time, which would only decrease unradiated gaps on certain portions of the treatment surface (as opposed to Bansal, which would eliminate unradiated gaps across the entire treatment surface). *Id.* Second, Larsen's scan engine is configured to only move the lights along a single axis, while Bansal's solution provides higher intensity (or density) of lights around all edges of the panel. And POSITA would have understood how to incorporate Bansal's solution with Larsen's scan engine, since it could still work with more lights (or higher intensity lights) placed at the edges of Larsen's panels. *Id.*

POSITA would have had a reasonable expectation of success in combining Larsen with Bansal, because both references describe similar illuminators for using light to treat conditions on a patient's skin. Ex.1004, Fig. 1; Ex.1005, Fig. 1; Ex.1003, ¶153.² Furthermore, Larsen states that each of the light sources (17) "are adjustable," which POSITA could use to increase the current to certain light sources at the edge of the applicator using Larsen's controller. Ex.1004, [0071], [0074], [0077]-[0079]. Bansal similarly describes a switch (44) that "can provide for operation in either a high or low intensity mode or a potentiometer could be added to provide a more precise control or larger range on the intensity of phototherapy provided." Ex.1005, [0026]. POSITA would have found it obvious to incorporate Bansal's switch 44 into Larsen's controller to provide more precise control of the intensity of light from LEDs at the edges of the applicator, as taught by Bansal. Ex.1003, ¶153.

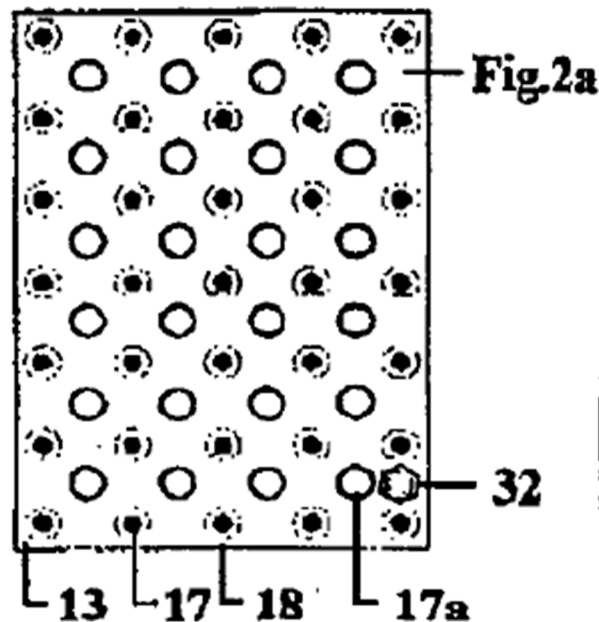
Additionally, the combination of Larsen with Bansal would simply have been a combination of prior art elements (increasing the intensity of light sources at the edges of Larsen's applicators, as taught by Bansal) according to known methods (adding LEDs near the edge of the applicator and/or increasing the light intensity of

² While Bansal does not specifically mention PDT, the operating principle for its illuminators are the same as those used for PDT. Ex.1003, ¶21.

the LEDs near the edge of the applicator) to yield predictable results (more uniform distribution of light on the surface of the patient's skin). Ex.1003, ¶155.

b. Improving the Response to Larsen's Sensors

In Larsen, “[t]he Figs. 2a, 2b and 2c show plain surfaced printed circuit boards with light sources mounted in the applicators 13.” Ex.1004, [0070]. These circuit boards can be used “individually, side by side (in large numbers) or in combination with an applicator.” *Id.* Furthermore, “[t]he applicators 13, according to the Figs. 2a., 2b and 2c are equipped with sensors 32 arranged between the semiconductor and/or laser diodes 17.” Ex.1004, [0079]. An example is shown below in Figure 2a.



Id., Fig. 2a.

The sensors 32 “measure the amount of energy radiated away from the skin surface, which is indicative of the total energy penetrating into the tissue.” *Id.*, [0079]. According to Larsen, “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.*; claim 13 (“the at least one applicator contains sensors connected to the control mechanism for measurement of reflected light for feedback control and automatic adjustment”).

Larsen teaches that each applicator can have “large numbers” of circuit boards, and thus a large number of energy sensors located at different points on each applicator. Ex.1004, [0070]. These teachings would have motivated POSITA to selectively increase the intensity of certain LED lights on the perimeter of Larsen’s applicators (as described in Bansal) in response to sensors at the edge of Larsen’s applicator detecting less energy radiated away from the skin surface closer to the edges of the applicator compared to sensors detecting more energy being radiated away from the skin surface in the center of the treatment area. Ex.1003, ¶¶156-160. POSITA would have had a reasonable expectation of success, since the outputs from Larsen’s sensors already feed into the control panel for the applicators. Ex.1004, Fig. 4, [0030], [0079]-[0080]; Ex.1003, ¶¶161-162. POSITA would have expected that light intensity at the edges of Larsen’s applicators could be increased in response to measurements received from Larsen’s sensors, particularly because both Larsen

and Bansal describe selectively controlling the light sources. Ex.1004, [0071], [0074], [0077]-[0079]; Ex.1005, [0026]; Ex.1003, ¶162. Additionally, this combination of Larsen and Bansal would simply have been a combination of prior art elements (increasing intensity of light sources at the edges of Larsen’s applicators, as taught by Bansal) according to known methods (using feedback from Larsen’s sensors) to yield predictable results (better treatment of the surface of a patient’s skin in response to temperature feedback). Ex.1003, ¶163.

2. Reasons to Combine Jones with Larsen and Bansal

a. Preventing Overheating of the Applicators

Larsen describes a known disadvantage of PDT illuminators is that “semiconductor diodes tend to overheat during use, which causes a decrease in the effectiveness of the device.” Ex.1004, [0006]. POSITA would have understood the same to be true of Bansal’s illuminator, particularly at the edges of the panel where higher intensity of light is generated. Ex.1003, ¶165. POSITA would also know that temperature changes affect the wavelengths of the light sources, which must be carefully controlled for specific absorption bands used for PDT. *Id.* POSITA reading Larsen and Bansal would have been motivated to look to Jones in order to mitigate the known disadvantages of overheating and temperature changes. *Id.* Jones describes a PDT lamp with a “cooling unit [which] includes at least one fan,

preferably a fan configured to provide forced-air cooling of the array of LEDs.”

Ex.1006, [0028]. This is shown in Figure 4D of Jones.

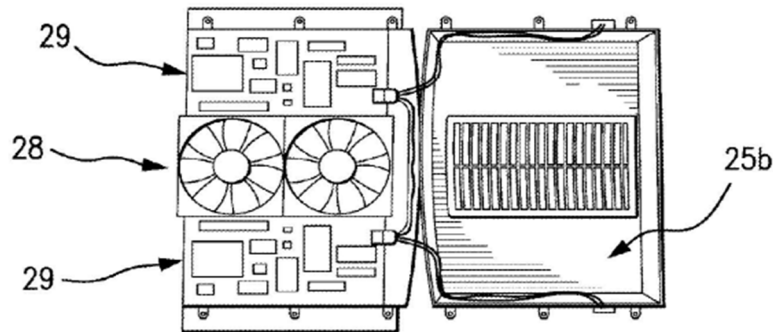


FIG. 4D

Id., Fig. 4D. As shown above, “each lamp module 21 may be mounted to one or more cooling fans 28 and associated ducts for cooling.” *Id.*, [0084]; *see also id.*, [0083].

POSITA would have known that Jones’ fan would keep the Larsen/Bansal combination from overheating, and POSITA would have been motivated to incorporate Jones’ fans into Larsen’s PDT device (as modified by Bansal) to increase its effectiveness. Ex.1003, ¶¶165-166. This would be of particular importance where Larsen’s applicator is already modified to increase the intensity of illumination from the edges of the applicator (per Bansal). *Id.* This combination of Larsen/Bansal with Jones would simply have been a combination of prior art elements (adding Jones’ cooling fan to Larsen’s applicators) according to known methods to yield predictable results (more effective applicators). POSITA would

have also had a reasonable expectation of success, since Larsen and Jones both describe illuminators with multiple panels for use in PDT. Ex.1004, [0072], [0076], [0079], Fig. 1; Ex.1006, Abstract, Fig. 1; Ex.1003, ¶166. POSITA would have expected that installing one or more fans on the applicators would successfully cool them down to prevent overheating. Ex.1003, ¶166.

Additionally, there were finite number of known, predictable solutions for cooling the LED circuits in Larsen's applicators (as modified by Bansal), such as a fan or a heat sink (both described in Jones). Ex.1006, [0083]-[0084]. POSITA would have found it obvious to try incorporating one or more fans into Larsen to cool the light sources of Larsen's applicators. Ex.1003, ¶167. The resulting increased effectiveness of Larsen's applicators would have been predictable to POSITA. *Id.*

b. Placing Illuminators at an Optimal Distance from the Treatment Surface

Larsen's PDT device includes a jointed arm that "allows the positioning of the applicators 13 in front of, or above, a tissue area while maintaining a correct positioning distance." Ex.1004, [0073]. Larsen also describes the importance of an even and gap-free radiation of the treatment surface. *Id.*, [0028], [0072]. Bansal also describes the importance of even exposure of light to the patient's skin, and the ability to modify the distance between the lamp and the treatment surface. Ex.1005, [0022], [0025]. POSITA reading Larsen and Bansal would have been motivated to

determine an optimal distance between Larsen's applicators (as modified by Bansal) and the treatment surface to provide the best therapeutic treatment for the patient. Ex.1003, ¶169.

Jones describes aligning the treatment lamps for optimal treatment, and more specifically describes a preferable treatment distance "from about 5 cm to about 8 cm." Ex.1006, [0041], [0024], [0092], [0094], Fig. 8A. POSITA would have known that the distance between the illuminator and the treatment surface is a result-effective variable, since it directly impacts the radiation received at the treatment surface. Ex.1003, ¶169. Determining an optimum distance would have required nothing more than routine experimentation, which would have permitted POSITA using Larsen's applicators to arrive at the optimal distances described in Jones. *Id.* This modification would have involved nothing more than using known techniques (using Jones' optimized distance between the lamp and treatment surface) to improve similar devices (Larsen's PDT applicators) in the same way. And POSITA would have had a reasonable expectation of success, given Jones and Larsen's similar design and purpose. *Id.* Furthermore, POSITA would have expected to successfully use Larsen's mobile base and jointed arm to position the applicators at

an optimized distance from the treatment surface, as described by Jones. Ex.1004, [0073]; Ex.1003, ¶¶170-172.

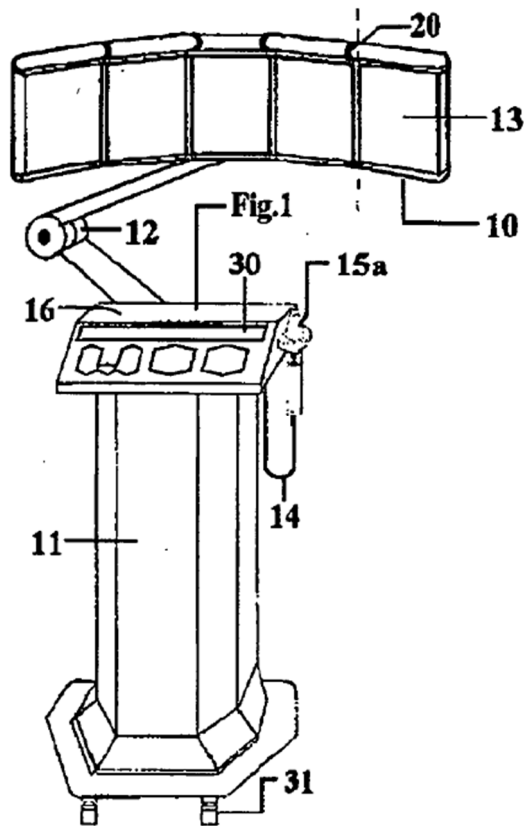
3. Claim 1

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

Larsen discloses a device 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]. Larsen further states its device “provides multiple wavelength stimulation that is also effective in conjunction with photodynamic therapy (PDT) chemicals.” *Id.*, [0037]. Thus, Larsen discloses the preamble of claim 1. Ex.1003, ¶188.

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.

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.”³

Ex.1004, [0072]; *see also id.*, [0027].

³ Unless otherwise indicated, all emphasis added.

Larsen discloses that the hinges (indicated as element 10 in the specification, but shown as element 20 in Figure 1) are on the inner side surfaces of the adjacent panels, because they “connect[] one edge with the other.” *Id.*, [0072]. As shown in Figure 1, the panels (13) are flush with each other. Thus, the hinges must necessarily be on the inner side surfaces of the panels. Ex.1003, ¶¶191, 195. 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, Figure 1, 5:44-47). Similarly, during the prosecution of Application No. 17/009,871,⁴ 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, Figures 1-3, [0069], [0072], lines 1-4).

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.

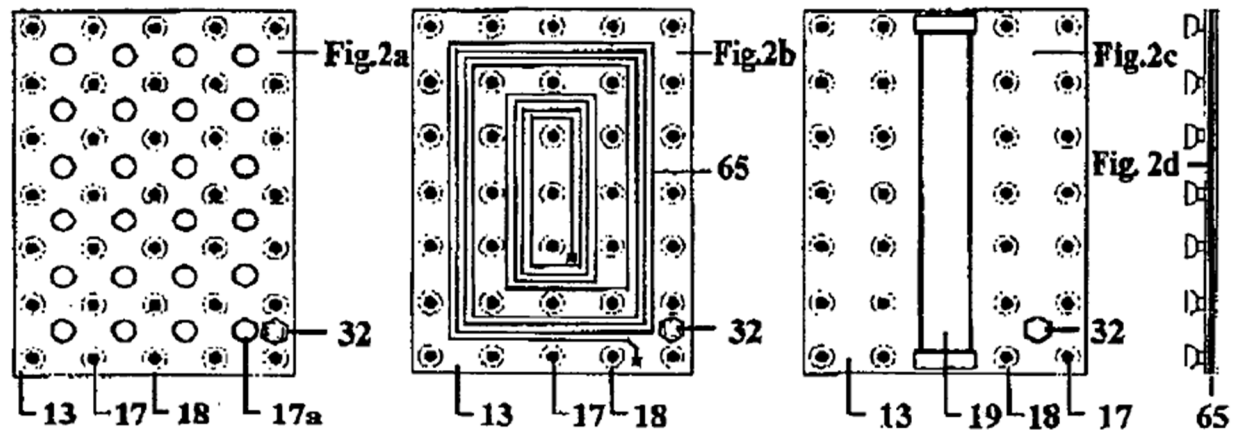
⁴ This application is a continuation of patent application no. 16/791,004 (the direct parent of the ’028 Patent) and includes identical disclosure to the ’028 Patent. *See* Ex.1001, Cover; Ex.1013, Cover.

Ex.1003, ¶193. First, Figure 1 of Larsen shows that the inner edges of each of the panels (13) are 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 flush arrangement. *Id.*, ¶¶194-196. Such a modification would have involved nothing more than the use of a known prior art element according to known methods to yield predictable results. *Id.* Second, there were finite number of known, predictable solutions for Larsen's panels to be "flexibly connected to each other through hinges," and POSITA would have found it obvious to try placing the hinges on the inner side surfaces of the panels. *Id.*, ¶197. 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 flush arrangement as shown in Figure 1. *Id.*

Thus, Larsen discloses (or renders obvious) claim 1(a). *Id.*, ¶198.

Claim 1(b): *"light sources disposed on surfaces of the five panels, the illuminator being configured to uniformly illuminate a treatment surface of the patient via the light sources,"*

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



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.* The light sources can be placed in regular row arrangements. *Id.*, [0071].⁵

Larsen also 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

⁵ 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. *Id.*, [0106].

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]).

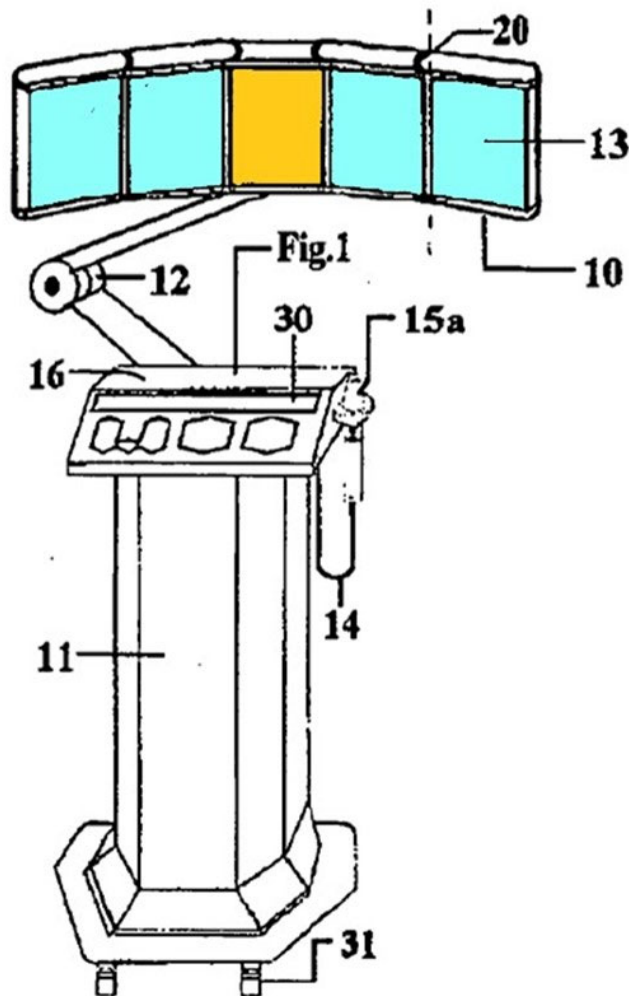
Larsen further teaches that its applicators “*permit[] an even and gap-free radiation* of the surface with multiple wavelengths of light.” Ex.1004, [0028]. An “even and gap-free radiation of the surface” would uniformly illuminate the treatment surface. Ex.1003, ¶202. Larsen also describes measurements 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. Thus, Larsen discloses claim 1(b). Ex.1003, ¶¶199-203.

To the extent the Board determines that Larsen does not expressly or inherently disclose “the illuminator being configured to uniformly illuminate a treatment surface of the patient via the light sources,” this is disclosed in Bansal. 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.” *Id.*, [0025]. Bansal further describes known methods for measuring the uniformity of phototherapeutic light on the patient’s skin. *Id.*, [0009]. Accordingly, Bansal discloses an illuminator configured to uniformly illuminate the treatment surface of the patient via the light sources. Ex.1003, ¶¶204-205.

POSITA would have found it obvious and would have been motivated with a reasonable expectation of success to incorporate the non-uniform light arrangement of Bansal into Larsen in order to uniformly illuminate a treatment surface of the patient, for all the reasons described above at § V.A.1.a-b. Thus, Larsen discloses (or in view of Bansal renders obvious) claim 1(b). Ex.1003, ¶¶206-207.

Claim 1(c): “one of the five panels being positioned as a center panel configured to face the treatment surface, and two or more of the five panels being configured to be angled relative to the center panel,”

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. 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 orange) is positioned to illuminate the center of the

patient's back, with each adjacent side panel (annotated in blue) angled relative to the center panel to accomplish the equidistant positioning described in Larsen. *Id.*, [0072]; *see also* Ex.1002, 329 (finding this limitation disclosed by Figure 1 in the Larsen '381 Patent).

Thus, Larsen discloses claim 1(c). Ex.1003, ¶¶208-211.

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

Larsen teaches that its jointed arm (12) “allows the positioning of the applicators 13 in front of, or above, a tissue area while maintaining *a correct positioning distance.*” Ex.1004, [0073]. While Larsen does not expressly teach that the five panels are positioned to allow treatment within approximately four inches of the treatment surface, this is disclosed by Jones. Jones describes “an exemplary variant of the present invention, when the photodynamic therapy lamp is in use, a distance between the lamp modules and a treatment surface of a patient is between about 5 cm to about 8 cm.” Ex.1006, [0024]. Jones also describes finding the optimal distance between the lamp and the treatment surface. *Id.*, [0093]. POSITA would have understood that to be “within approximately four inches” means to be equal to or less than approximately four inches. Ex.1003, ¶212. Jones disclosed distance of 5-8 cm is equal to or less than approximately four inches. *Id.*

In the alternative, to the extent “within approximately four inches” is construed to mean “approximately four inches,”⁶ POSITA would have also been motivated to slightly increase Jones’ treatment distance by less than one inch (to approximately 4 inches), since POSITA would know that the degree of overlap of light emitted by adjacent panels increases as the treatment distance increases, which improves uniformity. *Id.*, ¶213. POSITA would also know that shadows could result from the lamp panels being positioned too close to the patient and that moving them further away from the patient (i.e., to 4 inches) would reduce or eliminate shadows. *Id.*, ¶214; Ex.1006, [0095].

POSITA would have found it obvious and would have been motivated with a reasonable expectation of success to incorporate the treatment distance described in Jones into Larsen, for all the reasons described above at § V.A.2.b. Thus, Larsen in view of Jones renders obvious claim 1(d). Ex.1003, ¶¶215-216.

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

⁶ This construction would improperly read out the term “within.” *See Wasica Fin. GmbH v. Cont'l Auto. Sys., Inc.*, 853 F.3d 1272, 1288 n.10 (Fed. Cir. 2017) (“It is highly disfavored to construe terms in a way that renders them void, meaningless, or superfluous.”)

As shown in Figure 1 of Larsen, each of the five panels (13) has two first edges (vertical sides) and two second edges (horizontal edges on the top and bottom of the panels) shorter than the two first edges. Ex.1004, Fig. 1. Thus, Larsen discloses claim 1(e). Ex.1003, ¶¶217-218.

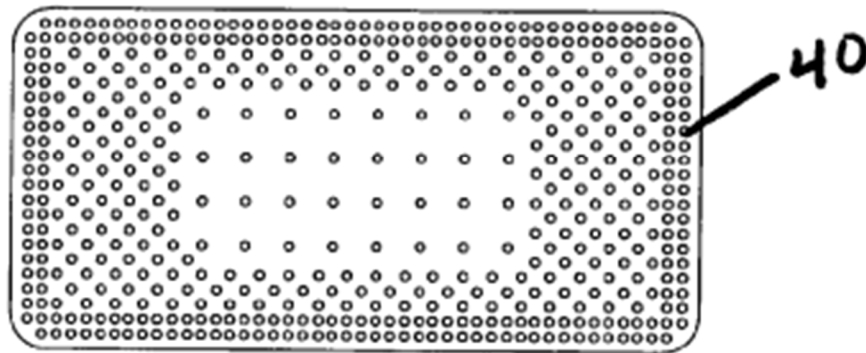
Claim 1(f): “*the light sources are arranged such that a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges.*”

While Larsen does not expressly teach that the light sources on its applicators 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, this feature is disclosed by Bansal.

In Bansal, 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). Ex.1003, ¶219.

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." *Id.*, [0026].

POSITA would have found it obvious and would have been motivated with a reasonable expectation of success to incorporate the non-uniform light arrangement of Bansal into Larsen to increase the intensity of light emitted from the second edges of the panels compared to regions not proximate to the edges, for all the reasons described above at § V.A.1.a-b. Thus, Larsen in view of Bansal renders obvious claim 1(f). Ex.1003, ¶¶220-221.

For these reasons, claim 1 is obvious over Larsen, in view of Bansal, further in view of Jones. *Id.*, ¶222.

4. Claim 2

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

The combination of Larsen in view of Bansal, further in view of Jones renders obvious the system of claim 1, for all the reasons given above. 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]. While Larsen does not expressly disclose the amount of energy output by the applicators, Jones teaches “the light dose may be varied between 1 and 99 J/cm².” Ex.1006, [0082], [0034]. Furthermore, POSITA would have found it obvious and would have been motivated with a reasonable expectation of success to increase the

light dose of Larsen's applicators to output red light at a dose from 30 to 150 J/cm².
Ex.1003, ¶¶224-227.

First, Larsen teaches the importance of PDT that can stimulate "human cells of both surface *and underlying tissue*." Ex.1004, [0026]. Jones teaches "red light penetrates deeper into the skin than for instance blue light, thus being able to reach and treat deeper layers and structures in the skin," and that higher doses of red light are used to treat acne. Ex.1006, [0080], [0082]. POSITA would have been motivated by this disclosure of Jones and Larsen to configure the applicators to increase the irradiance and/or treatment time of the red light from 30 to 150 J/cm², to more effectively treat deeper layers and structures of the skin, particularly since it was known that doses of 150 J/cm² would provide a permanent improvement in sebaceous gland disorders such as acne. Ex.1003, ¶225. POSITA would have had a reasonable expectation of success, since the unique benefits of red light for treatment purposes were well known. Ex.1004, [0083]; Ex.1003, ¶225.

Second, Larsen also teaches that "high-intensity treatments (higher doses of PDT substances and strong irradiation) are used where it is desired to destroy tissue, as in destroying tumor tissue to cure cancer, or in hair-removal where it is desired to destroy the hair follicle." Ex.1004, [0112]. POSITA would have known that the total light dose (J/cm²) is equal to irradiance (W/cm²) multiplied by time (in seconds). Ex.1011, 30:7-10; Ex.1003, ¶227. Larsen teaches that "[a]n increase of

the registered amount of energy [in J/cm²] 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]. POSITA would have found it obvious and would have been motivated with a reasonable expectation of success to adjust the controllable timer (29) on Larsen’s applicator to increase the treatment time, and therefore increase the total light dose in a range of 30-150 J/cm², to destroy cancerous tissue. Ex.1003, ¶226; Ex.1004, [0074]. This would have involved nothing more than applying a known technique (increased irradiance over a longer period) to a known device (Larsen’s applicators) ready for improvement to yield predictable results (destroying cancerous tumors). Ex.1003, ¶226. POSITA would have had a reasonable expectation of success, since Larsen and Jones both describe PDT illuminators for treating skin conditions, and Larsen teaches that its light sources are adjustable “within a relatively large range with reference to duration, amplitude and frequency of surge of current,” which allows “the printed circuit boards can be equipped with a more intensive radiation effect.” Ex.1004, [0074]; Ex.1003, ¶226. Indeed, if Larsen’s timer (29) is set for a long enough duration, any dose of red light can be easily achieved. Ex.1003, ¶226.

Finally, POSITA would have known that the amount of energy used to radiate light is a result-effective variable, since it directly impacts the radiation received at

the surface of the patient's skin (as well as below the surface). Ex.1006, [0080]-[0082]. Configuring Larsen's applicators to output red light at a dose of 30 J/cm² to 150 J/cm² would have required nothing more than routine experimentation by POSITA. Ex.1003, ¶230. This operation would have involved nothing more than combining prior art elements according to known methods to yield predictable results. And POSITA would have had a reasonable expectation of success, given Jones and Larsen's similar design and purpose.⁷ *Id.* The '028 Patent does not identify any unexpected results associated with the claimed range compared to the prior art.

Accordingly, Larsen in view of Bansal and Jones renders claim 2 obvious. *Id.*, ¶231.

5. 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 Larsen in view of Bansal, further in view of Jones renders obvious the system of claim 1, for all the reasons given above. Furthermore, Larsen's light sources emit light “within the wavelength area of 300-2000

⁷Notably, during prosecution of the '004 Application, the Examiner found that this same limitation would have been obvious over prior art that described an illuminator configured to output red light at an intensity of only 20 J/cm². Ex.1010, ¶33.

nanometers in order to correspond to available light sensitive substances (PDT).” Ex.1004, [0076]; *see also id.*, [0025], [0071], [0083]; Ex.1003, ¶¶232-233. And during prosecution of the ’004 Application, the Examiner found that “Larsen discloses that a plurality of the light sources are configured to emit light having a wavelength in a range of 400 nm to 700 nm”. Ex.1010, ¶25 (citing paragraph [0071] of Ex.1004).

To the extent the Board finds that Larsen does not expressly or inherently disclose a range of 400 nm to 700 nm, this limitation would have been obvious to POSITA. Ex.1003, ¶234. Larsen teaches applicators that emit light across a broad spectrum of wavelengths (between 300 and 2000 nm). Ex.1004, [0076]. And Larsen describes adjustable light sources that can be “selected” for radiating blue, fluorescent, or red light in different wavelengths. *Id.*, [0071]. Configuring Larsen’s panels to emit light at wavelengths in a range of 400 nm to 700 nm would have involved nothing more than routine experimentation by POSITA. Ex.1003, ¶234. And POSITA would have been motivated to do so since the benefits of red and blue light (which span 400-700 nm) for PDT were well known. *Id.* The ’028 Patent does not identify any unexpected results associated with the claimed range compared to the prior art.

Accordingly, Larsen in view of Bansal and Jones renders claim 4 obvious. *Id.*, ¶235.

6. Claim 5

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

Larsen 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]. Thus, Larsen discloses the preamble of claim 5. Ex.1003, ¶236.

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

Larsen teaches that “ALA (5-Aminolavulinacid) is externally applied as a 10 to 20 percent mixture in an oil in water emulsion or in a cream. 4 to 6 hours is allowed for absorption, during which time the patient should remain in dim light.” Ex.1004, [0116], *see also* [0120].

Thus, Larsen discloses claim 5(a). Ex.1003, ¶¶237-238.

Claim 5(b): *“positioning an illuminator proximate to the patient, 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.1003, ¶¶239-240.

Thus, Larsen discloses, or renders obvious, claim 5(b).

Claim 5(c): *“uniformly illuminating a treatment surface of the patient with light sources disposed on the five panels of the illuminator, the five panels being positioned to allow treatment within approximately four inches of the treatment surface,”*

Larsen in view of Bansal, further in view of Jones renders obvious claim 5(c) for the same reasons given for claims 1(b)-(d) above. Ex.1003, ¶¶241-243.

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

Larsen discloses claim 5(d) for the same reasons given for claim 1(e) above. Ex.1003, ¶¶244-245.

Claim 5(e): *“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.”*

Larsen in view of Bansal renders claim 5(e) obvious for the same reasons given for claim 1(f) above. Ex.1003, ¶¶246-247.

Accordingly, claim 5 is obvious over Larsen, in view of Bansal, further in view of Jones. Ex.1003, ¶248.

7. 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 Larsen in view of Bansal, further in view of Jones renders obvious the method of claim 5, for all the reasons given above. Larsen discloses outputting red light during at least part of the time when the treatment surface is

illuminated: “devices are available for the photodynamic stimulation of human cell energy in the form of red and infrared radiation emitted by laser diodes and semiconductor diodes.” Ex.1004, [0024]. Larsen also teaches using light radiation within the wavelength of 300–2000 nm, which includes red light. *Id.*, [0025], [0071], [0076]. Thus, Larsen, in view of Jones and Bansal renders claim 6 obvious. Ex.1003, ¶¶249-251.

8. Claim 7

Claim 7: “*The method of claim 5, wherein the illuminating comprises outputting blue light during at least part of the time when the treatment surface is illuminated.*”

The combination of Larsen in view of Bansal, further in view of Jones renders obvious the method of claim 5, for all the reasons given above. Larsen discloses outputting blue light during treatment: “the light sources 17a (Fig. 2a) radiate light with a wavelength of 350 – 500 nm, i.e., blue light.” Ex.1004, [0071]; *see also* Ex.1002, 330 (finding this limitation disclosed by identical text in the Larsen ’381 Patent). Thus, Larsen, in view of Jones and Bansal renders claim 7 obvious. Ex.1003, ¶¶252-255.

9. Claim 8

Claim 8: “*The method of claim 5, further comprising changing intensities of the light sources of the illuminator with a controller in accordance with information received from at least one sensor relating to a curvature of the treatment surface.*”

The combination of Larsen in view of Bansal, further in view of Jones renders obvious the method of claim 5, for all the reasons given above. Larsen discloses changing intensities of the light sources of the illuminator with a controller in accordance with information received from at least one sensor relating to a curvature of the treatment surface: “[t]he applicators 13, according to the Fig. 2a, 2b and 2c are equipped with sensors 32 arranged between the semiconductor and/or laser diodes 17.” Ex.1004, [0079], Figs. 2a-2c. These “[s]ensors 32 measure the amount of energy radiated away from the skin surface, which is indicative of the total energy penetrating into the tissue.” *Id.* According to Larsen, “[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.* Larsen’s applicators also include “[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].

POSITA reading Larsen would understand that the sensors (32 and/or 32a) measure radiated energy and temperature change information relating to the curvature of the treatment surface. Ex.1003, ¶258. If a treatment surface curves away from the light source, then the portion of the surface further from the light

source will radiate less energy and/or have a lower temperature, which would be detected by the sensors on Larsen's applicators. *Id.* This is confirmed by the prosecution of the '004 Application, where the Examiner found that the limitation "changing intensities of light sources of the illuminator with a controller in accordance with information received from at least one sensor relating to a curvature of the treatment surface," was taught by Larsen. Ex.1010, ¶28 (citing paragraphs [0030] and [0079] of Larsen).⁸ Thus, Larsen discloses claim 8.

To the extent the Board determines that Larsen does not expressly or inherently teach claim 8, POSITA would have found it obvious and would have been motivated with a reasonable expectation of success to modify Larsen to change intensities of the light sources of the illuminator with a controller in accordance with information received from at least one sensor relating to a curvature of the treatment surface. Ex.1003, ¶259. Larsen expressly discloses a controller that receives readings from sensors 32 and 32a. Ex.1004, [0079]-[0080], Figs. 2a-2c. The controller uses these readings to adjust the radiation parameters of the applicators.

⁸ The Examiner mistakenly cited "Tobin," but the context makes clear that the Examiner meant to cite Larsen, since the citation is part of a 102(a)(1) rejection of the claims over Larsen, and the specific paragraphs cited by the Examiner ([0030] and [0079]) disclose the sensor cited by Petitioner above.

Id. This would have motivated POSITA to add sensors to measure the curvature of the treatment surface in order to more finely tune the radiation parameters of the applicators, and thus provide a more “even and gap-free radiation,” as taught by Larsen. *Id.*, [0028]; Ex.1003, ¶259. This would have involved nothing more than applying a known technique (sensor that measured the curvature of the treatment surface) to a known device (Larsen’s applicators) ready for improvement to yield predictable results (more even and gap-free radiation). POSITA would have had a reasonable expectation of success, since Larsen’s controller was already configured to adjust the radiation parameters based on sensor data. Ex.1003, ¶259.

Thus, Larsen, in view of Bansal and Jones renders obvious claim 8. Ex.1003, ¶260.

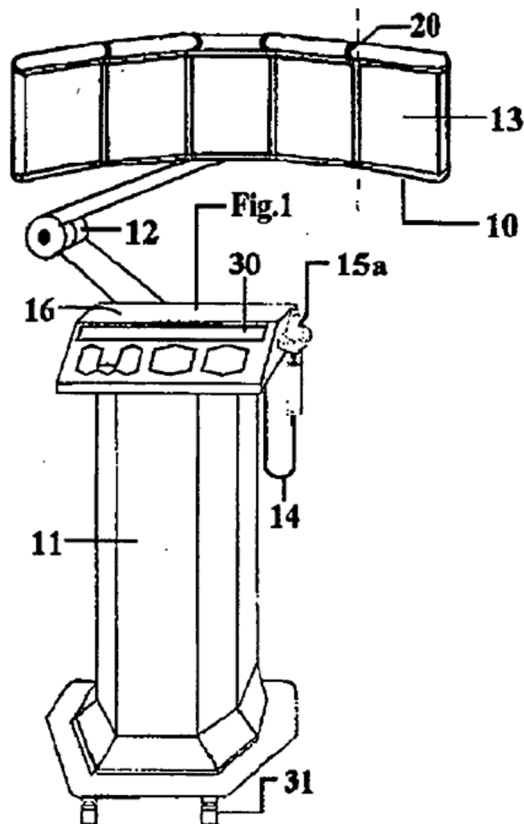
10. Claim 16

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

Larsen discloses the preamble of claim 16 for the same reasons given for the preamble of claim 1 above. Ex.1003, ¶261.

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.

Larsen teaches that the device is “freely moveable on wheels.” *Id.*, [0027], [0069]. Larsen necessarily discloses that the base has at least four wheels in order to provide stability. Ex.1003, ¶265. The Examiner agreed. *See* Ex.1002, 328 (finding that in Figure 1 of Larsen ’381 Patent, “it is inherent that there are 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.1003, ¶¶265-266. 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.*, ¶266.

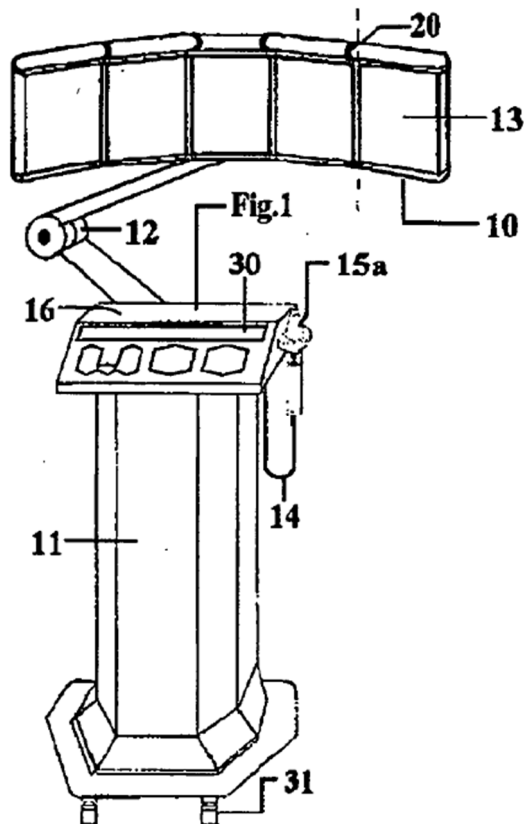
Thus, Larsen discloses (or renders obvious) claim 16(a). *Id.*, ¶267.

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 the Larsen ’381 Patent). Thus, Larsen discloses claim 16(b). Ex.1003, ¶¶268-270.

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

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

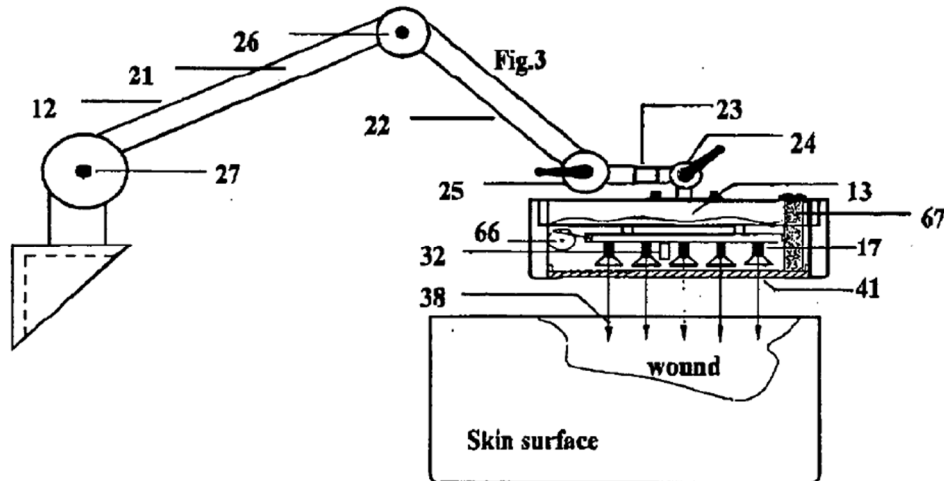


Ex.1004, Fig. 1, [0074], Fig. 4; *see also* Ex.1002, 328 (finding claim 16(c) disclosed by “a controller 16” in the Larsen ’381 Patent).

Thus, Larsen discloses claim 16(c). Ex.1003, ¶¶271-274.

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.

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. 1; *see also* Ex.1002, 328 (finding claim 16(d) disclosed by “an arm 12” in the Larsen ’381 Patent).

Thus, Larsen discloses claim 16(d). Ex.1003, ¶¶275-279.

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.*

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.” *Id.*; *see also* Ex.1002, 328 (finding claim 16(e) disclosed by “the hinged arm and joints/hinges 25/26/27” in the Larsen ’381 Patent).

Thus, Larsen discloses claim 16(e). Ex.1003, ¶¶280-284.

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.1003, ¶285.

Larsen also teaches that each of the applicators are individually configurable to control illumination from each of the five applicators. Ex.1003, ¶286. 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. *Id.*, Figs. 1 and 4. 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.” *Id.*, [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.*

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.” *Id.*, [0079], Figs. 2a-2c. A “sensor 32 a is also contained

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

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.1003, ¶¶286-287. Thus, Larsen discloses claim 16(f). *Id.*, ¶288.

Claim 16(g): “light sources disposed on surfaces of the five panels, the illuminator being configured to uniformly illuminate a treatment surface of the patient via the light sources, the light sources being configured to output light uniformly during at least part of a time when the treatment surface is illuminated,”

Larsen, or Larsen in view of Bansal, disclose or render obvious “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. Furthermore, Larsen discloses 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 id.*, [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.” *Id.*, [0072].

Thus, Larsen, or Larsen in view of Bansal, disclose or render obvious claim 16(g). Ex.1003, ¶¶289-291.

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

Larsen teaches claim 16(h) for all the reasons given with respect to claim 1(e) above. Ex.1003, ¶¶292-294.

Claim 16(i): “*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*”

Larsen in view of Bansal render obvious claim 16(i), for all the reasons given with respect to claims 1(f) above. Ex.1003, ¶295.

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

While Larsen does not disclose one or more fans mounted to at least one of the five panels, Jones teaches this feature. Jones describes a photodynamic therapy lamp with two lamp modules, “each lamp module comprising a two-dimensional array of LEDs.” Ex.1006, [0014], Figs. 2A-2C. Each module includes a housing with “a cooling unit configured to cool the array of LEDs and at least one driver

module.” *Id.*, [0027]. As shown below in Figure 4D, “the cooling unit includes at least one fan, preferably a fan configured to provide forced-air cooling of the array of LEDs.” *Id.*, [0028].

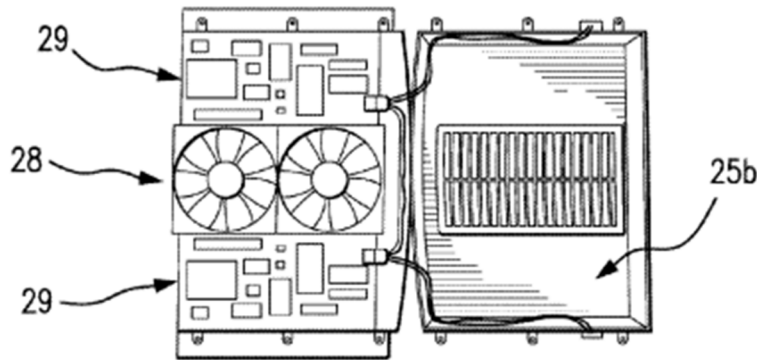


FIG. 4D

Id., Fig. 4D.

In Jones, “the support and/or heat sink of each lamp module 21 may be mounted to one or more cooling fans 28 and associated ducts for cooling, and one or more driver modules 29 for control of the lamp module 21 as illustrated in FIG. 4D.” *Id.*, [0084].

POSITA would have found it obvious and would have been motivated with a reasonable expectation of success to combine the cooling fans on Jones’ lamp modules with the device in Larsen, for all the reasons give above. *Supra* § V.A.2.a. Accordingly, Larsen in view of Jones renders obvious claim 16(j). Ex.1003, ¶¶296-299.

For these reasons, claim 16 is obvious over the combination of Larsen, in view of Bansal, further in view of Jones. Ex.1003, ¶300.

11. 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 Larsen in view of Bansal, further in view of Jones renders obvious the system of claim 16, for all the reasons given above. And Larsen in view of Bansal, further in view of Jones renders obvious claim 17, for all the reasons given above with respect to claim 1(c). Ex.1003, ¶¶301-302.

12. Claim 18

Claim 18: “*The system of claim 16, wherein the light sources are configured to output blue light during at least part of the time when the treatment surface is illuminated.*”

The combination of Larsen in view of Bansal, further in view of Jones renders obvious the system of claim 16, for all the reasons given above. And Larsen in view of Bansal, further in view of Jones renders obvious claim 18, for all the reasons given above with respect to claim 7. Ex.1003, ¶¶303-304.

13. 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 Larsen in view of Bansal, further in view of Jones renders obvious the system of claim 16, for all the reasons given above. And Larsen in view

of Bansal, further in view of Jones renders obvious claim 19, for all the reasons given above with respect to claim 6. Ex.1003, ¶¶305-306.

14. Claim 20

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

Larsen discloses the preamble of claim 20, for all the reasons given above with respect to the preamble of claim 1. Ex.1003, ¶307.

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. 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]-[0026]. 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.” *Id.*, [0079]; Ex.1003, ¶308.

Thus, Larsen discloses claim 20(a). Ex.1003, ¶309.

Claim 20(b): *“light sources disposed on surfaces of the five panels, the illuminator being configured to uniformly illuminate a treatment surface of the patient via the light sources.”*

Larsen discloses claim 20(b), for all the reasons given above with respect to claim 1(b). Ex.1003, ¶310.

Claim 20(c): *“one of the five panels being positioned as a center panel configured to face the treatment surface, and two or more of the five panels being configured to be angled relative to the center panel,”*

Larsen discloses claim 20(c), for all the reasons given above with respect to claim 1(c). Ex.1003, ¶311.

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

Larsen in view of Jones renders obvious claim 20(d), for all the reasons given above with respect to claim 1(d). Ex.1003, ¶312.

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

Larsen discloses claim 20(e), for all the reasons given above with respect to claim 1(e). Ex.1003, ¶313.

Claim 20(f): *“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.”*

Larsen in view of Bansal renders obvious claim 20(e), for all the reasons given above with respect to claim 1(f). Ex.1003, ¶314.

For these reasons, claim 20 is obvious over the combination of Larsen, in view of Bansal, further in view of Jones. Ex.1003, ¶314.

15. Claim 21

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

Larsen discloses the preamble of claim 21, for all the reasons given above with respect to claim 1. Ex.1003, ¶315.

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

Larsen discloses (or renders obvious) claim 21(a), for all the reasons given above with respect to claim 1(a). Ex.1003, ¶316.

Claim 21(b): *“light sources disposed on surfaces of the five panels, the illuminator being configured to uniformly illuminate a treatment surface of the patient via the light sources,”*

Larsen in view of Bansal renders obvious claim 21(b), for all the reasons given above with respect to claim 1(b). Ex.1003, ¶317.

Claim 21(c): *“one of the five panels being positioned as a center panel configured to face the treatment surface, and two or more of the five panels being configured to be angled relative to the center panel,”*

Larsen discloses claim 21(c), for all the reasons given above with respect to claim 1(c). Ex.1003, ¶318.

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

Larsen in view of Jones renders obvious claim 21(d), for all the reasons given above with respect to claim 1(d). Ex.1003, ¶319.

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

Larsen discloses claim 21(e), for all the reasons given above with respect to claim 16(f). Ex.1003, ¶¶320-321.

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

Larsen discloses claim 21(f), for all the reasons given above with respect to claim 1(e). Ex.1003, ¶324.

Claim 21(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.”*

Larsen in view of Bansal renders obvious claim 21(g), for all the reasons given above with respect to claim 1(f). Ex.1003, ¶325.

For these reasons, claim 21 is obvious over the combination of Larsen, in view of Bansal, further in view of Jones. Ex.1003, ¶326.

B. Ground 2: Claims 2-4 of the '028 Patent are obvious over Larsen in view of Bansal, further in view of Jones, further in view of Anderson

1. Reasons to Combine Anderson with Larsen, Bansal, and Jones

a. Providing “Optimized Conditions” for PDT

Larsen’s device is designed to deliver “an intensive light radiation with selective multiple wavelengths” in order to provide intensive photodynamic therapy to a patient. Ex.1004, [0025]-[0026]. The device uses PDT to activate chemical reactions in photosensitive chemicals introduced into or onto the tissue. *Id.*, [0107]-[0111]. 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.” *Id.*, [0074].

POSITA considering Larsen would have been motivated to seek other references describing varying irradiance densities, wavelengths, and total energy for PDT treatment. Ex.1003, ¶¶173-174. Anderson teaches that “[f]or photodynamic effects, lower average irradiance exposures given over longer exposure time would be appropriate for example approximately 10-100 mW/cm² delivered for about 100-2000 seconds (total fluence, 1-200 J/cm²).” Ex.1007, 20:23-25. And Anderson teaches that “light with a wavelength range of between about 320 and 700 nm, is delivered to the ALA-treated skin, PpIX is excited into a triplet state, which reacts with oxygen to produce singlet oxygen, causing membrane damage and cell

destruction,” which provides “optimized conditions for treatment of skin.” *Id.*, 2:19-26. POSITA would have been motivated to incorporate Anderson’s varying irradiance densities and wavelengths over varying time periods to achieve better photodynamic effects in the combination of Larsen’s applicators with Jones and Bansal. Ex.1003, ¶175.

The combination of Larsen, Bansal, and Jones with Anderson would simply have been a combination of prior art elements (varying the irradiance density, wavelengths, and/or total fluence from Larsen’s light sources, as taught by Anderson) according to known methods to yield predictable results (more effective photodynamic effects). Ex.1003, ¶¶176-177. POSITA would have had a reasonable expectation of success, since Larsen’s controller and applicators support a large range with respect to duration, wavelengths, amplitude and frequency of surge current for the light sources on the applicators. Ex.1004, [0074], [0076]; Ex.1003, ¶177.

b. Irradiance Density, Wavelengths, and Total Energy are Result-Effective Variables

POSITA would have known that the irradiance density, wavelengths of light, and total fluence are result-effective variables, since they directly impact the effectiveness of various PDT treatments. Ex.1003, ¶178. Configuring Larsen’s applicators to output red light at an irradiance density of 10 mW/cm² to 30 mW/cm², to output total energy between 30-150 J/cm², or to output light at wavelengths of

400-700 nm would have required nothing more than routine experimentation. This operation would have involved nothing more than combining prior art elements according to known methods to yield predictable results. *Id.* The '028 Patent does not identify any unexpected results associated with the claimed ranges compared to the prior art. And POSITA would have had a reasonable expectation of success, given the capability of Larsen's controller discussed above. Ex.1003, ¶¶178-179.

2. Claim 2

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

Larsen in view of Bansal and Jones render obvious the system of claim 1, for all the reasons given in Ground 1. Further, Anderson's “energy source emits visible light, especially red visible light,” and “the range of energy applied to the skin surface ranges from 1 J/cm² to about 200 J/cm², *preferably from about 25 J/cm² to about 200 J/cm²*, and most preferably about 100 J/cm².” Ex.1007, 8:12-15; Ex.1003, ¶328.

POSITA would have found it obvious and would have been motivated with a reasonable expectation of success to incorporate the red light doses of Anderson into the combination of Larsen, Bansal, and Jones, for all the reasons given above at Section V.B.1.a-b. Thus, Larsen, in view of Bansal, further in view of Jones, further in view of Anderson renders obvious claim 2. Ex.1003, ¶¶327-330.

3. Claim 3

Claim 3: *“The system of claim 1, wherein the illuminator is configured to output light at an irradiance density of 10 mW/cm² to 30 mW/cm².”*

Larsen in view of Bansal and Jones render obvious the system of claim 1, for all the reasons given in Ground 1. Furthermore, Anderson describes PDT illuminators that provide “lower average irradiance exposures given over longer exposure time would be appropriate for example approximately **10-100 mW/cm²** delivered for about 100-2000 seconds (total fluence, 1-200 J/ cm²).” Ex.1007, 20:23-25. Thus, Anderson discloses the features of claim 3. Ex.1003, ¶332.

POSITA would have found it obvious and would have been motivated with a reasonable expectation of success to incorporate the irradiance densities of Anderson into the combination of Larsen, Bansal, and Jones, for all the reasons given above at Section V.B.1.a-b. Thus, Larsen, in view of Bansal, further in view of Jones, further in view of Anderson renders obvious claim 3. Ex.1003, ¶¶333-334.

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.”*

Larsen in view of Bansal and Jones render obvious the system of claim 1, for all the reasons given in Ground 1. Further, Anderson describes “[i]n general, the wavelength range for therapeutic treatment is from about 320 nm to about 700 nm .

. .” Ex.1007, 8:16-18. Thus, Anderson discloses the features of claim 4. Ex.1003, ¶335.

POSITA would have found it obvious and would have been motivated with a reasonable expectation of success to incorporate the wavelengths of light from Anderson into the combination of Larsen, Bansal, and Jones, for all the reasons given above at Section V.B.1.a-b. Thus, Larsen, in view of Bansal, further in view of Jones, further in view of Anderson renders obvious claim 4. Ex.1003, ¶¶336-337.

C. Ground 3: Claims 10, 11, 13, and 14 of the '028 Patent are obvious over Larsen in view of Bansal, further in view of Jones, further in view of Mackinnon

1. Reasons to Combine Mackinnon with Larsen, Bansal, and Jones

a. Improving the Capabilities of Larsen’s Applicators

Larsen’s applicators include a controller that can adjust the light dosage based on feedback received from sensors. Ex.1004, [0079]-[0080], Figs. 2a-2c, Fig. 4. Larsen’s panels are also individually configurable and controllable, and can treat various surfaces. *Id.*, [0070]-[0072], [0074]. In order to improve the effectiveness of Larsen’s applicators to treat different sizes and shapes on the surface of the patient’s skin, POSITA would have been motivated to look to Mackinnon, which provides an imaging sensor and image processing system on a PDT light source which can determine the size and shape of the treatment surface (e.g., a cancerous skin lesion) and then modify the illumination accordingly based on the detected size

and shape. Ex.1012, 21:23-22:6; Ex.1003, ¶180. Indeed, Larsen's applicators are designed to treat skin lesions (such as melanoma and basal cell carcinoma). Ex.1004, [0107]. This combination of Larsen, Bansal and Jones with Mackinnon would simply have been a combination of prior art elements (adding the sensor and image processing system of Mackinnon to Larsen's applicators and controller) according to known methods to yield predictable results (better treatment of the surface of a patient's skin in response to size and shape feedback). Ex.1003, ¶180.

POSITA would have had a reasonable expectation of success, since the outputs from Larsen's other sensors already feed into the control panel for the applicators. Ex.1004, Fig. 4; [0030], [0079]-[0080]; Ex.1003, ¶181. POSITA would have expected that Mackinnon's image sensors and processing system could be readily incorporated into Larsen's controller, particularly because both Larsen and Mackinnon describe selectively controlling the light sources. Ex.1004, [0070], [0074], [0077]-[0079]; Ex.1012, 21:23-22:6, 34:18-25; Ex.1003, ¶181. And both Larsen and Mackinnon are designed for PDT applications using medical optical systems. Ex.1004, Abstract; Ex.1012, 8:20-23, 11:15-23.

b. Reducing Heat and Power Requirements of Larsen's Applicators

One of the benefits of Mackinnon's system is that it "is more power friendly, produces less heat, thereby possibly requiring fewer or less robust parts, and in addition should assist in increasing the longevity of various parts of the system due,

for example, to the reduced heat generated and the reduced electricity transmitted and the reduced light transmitted.” Ex.1012, 29:27-30:3. POSITA would have been motivated to add the imaging sensor and processing system of Mackinnon to the Larsen, Bansal, and Jones combination to reduce the heat and power of the applicators. Ex.1003, ¶182. Both Larsen and Jones recognize how excessive heat diminishes the effectiveness of the applicators. Ex.1004, [0006]; Ex.1006, [0082]. POSITA would have had a reasonable expectation that adding Mackinnon’s sensor and image processing capabilities to the Larsen, Bansal, Jones combination would lead to less heat and power consumption. Ex.1003, ¶182.

2. Claims 10 and 13

Claim 10: “*The method of claim 5, further comprising determining a size of the treatment surface of the patient using a sensor.*”

Claim 13: “*The method of claim 5, further comprising determining a shape of the treatment surface of the patient using a sensor.*”

Larsen in view of Bansal and Jones render obvious the method of claim 5, for all the reasons given in Ground 1. Furthermore, Mackinnon describes that its system “may match the shape and size of the illumination area to correspond to the shape and size of a target region discerned by an imaging system, for example an imaging sensor and image processing system of an endoscope or surgical microscope, such as those discussed herein.” Ex.1012, 21:23-27. Mackinnon provides an example where the imaging system can identify a skin lesion on the treatment surface, then

control the shape of the illumination light to match the shape of the lesion. *Id.*, 21:27-22:6; *see also id.*, 34:18-25. Thus, Mackinnon discloses determining the size and shape of the treatment surface using a sensor. Ex.1003, ¶¶338, 344.

POSITA would have found it obvious and would have been motivated with a reasonable expectation of success to incorporate the imaging sensor and system of Mackinnon into the combination of Larsen, Bansal, and Jones, for all the reasons given above at Section V.C.1.a-b. Thus, Larsen, in view of Bansal, further in view of Jones, further in view of Mackinnon renders obvious claims 10 and 13. Ex.1003, ¶¶339-340, 344-346.

3. Claims 11 and 14

Claim 11: “*The method of claim 10, further comprising adjusting an overall light dose with a controller based on the determined size of the treatment surface.*”

Claim 14: “*The method of claim 13, further comprising adjusting an overall light dose with a controller based on the determined shape of the treatment surface.*”

Mackinnon’s system “receives the data from the sensor and uses the data to coordinate the tunable light source and the processor such that the programming *varies the selected spectral output and wavelength dependent intensity distribution of the illumination light.*” Ex.1012, 34:29-35:4; *see also id.*, 21:23-22:6; Ex.1003, ¶¶341, 347.

POSITA would have found it obvious and would have been motivated with a reasonable expectation of success to configure the controller in the combination of

Larsen, Bansal, and Jones to adjust the light dose using data from the image sensor of Mackinnon related to the size and shape of the treatment surface, for all the reasons given above at Section V.C.1.a-b. Thus, Larsen, in view of Bansal, further in view of Jones, further in view of Mackinnon renders obvious claims 11 and 14. Ex.1003, ¶¶342-343, 348-349.

VI. CONCLUSION

Petitioner requests *inter partes* review of the '028 Patent be instituted and that the Challenged Claims be cancelled as unpatentable under 35 U.S.C. § 318(b).

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Respectfully submitted,

By: /s/ George B. Davis
George B. Davis
Reg. No. 68,205
MCGUIREWOODS LLP
Gateway Plaza
800 East Canal Street
Richmond, VA 23219
Telephone: (804) 775-1000
Facsimile: (804) 775-2016
Email:
gdavis@mcguirewoods.com

Attorney for Petitioner

Certification under 37 C.F.R. § 42.24(d)

I hereby certify that this petition, excluding its table of contents, table of authorities, mandatory notices, table of exhibits, certification under 37 C.F.R. § 42.24(d), and certificate of service has 13,997 words as counted by Microsoft Word for Microsoft 365, the word-processing system used to prepare this petition.

/George B. Davis/
George B. Davis
Reg. No. 68,205

Date: April 30, 2024

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 April 30, 2024, a complete and entire copy of this Petition for *Inter Partes* Review, and all supporting exhibits, was served on the following counsel of record for Patent Owner by Federal Express®:

Foley & Lardner LLP
3000 K. Street, N.W., Suite 600
Washington, DC 20007-5109

By: /George B. Davis/
George B. Davis
Reg. No. 68,205
gdavis@mcguirewoods.com
Attorney for Petitioner