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**UNITED STATES INTERNATIONAL TRADE COMMISSION
WASHINGTON, DC**

In the Matter of

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

Investigation No. 337-TA-1411

**RESPONDENTS BIOFRONTERA INC., BIOFRONTERA PHARMA GMBH,
BIOFRONTERA BIOSCIENCE GMBH, AND BIOFRONTERA AG'S
RESPONSE TO THE COMMISSION'S REQUEST FOR ADDITIONAL BRIEFING**

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TABLE OF ABBREVIATIONS

Abbreviation	Meaning
CX-	Complainant's Exhibit
CX-xxxxC	Confidential Complainant's Exhibit
RX-	Respondents' Exhibit
RX-xxxxC	Confidential Respondents' Exhibit
JX-	Joint Exhibit
JX-xxxxC	Confidential Joint Exhibit
'512 Patent	U.S. Patent No. 11,446,512
'028 Patent	U.S. Patent No. 11,697,028
4170D	BLU-U® 4170 or BLU-U® 4170D
4170E	BLU-U® 4170E
Asserted Patents	The '512 Patent and the '028 Patent
Complainant <i>or</i> Sun Pharma	Sun Pharmaceutical Industries, Inc.
Respondents <i>or</i> Biofrontera	Biofrontera Inc., Biofrontera Pharma GMBH, Biofrontera Bioscience GMBH, & Biofrontera AG
ITC	International Trade Commission
FID	Final Initial Determination
USPTAB or PTAB or the Board	United States Patent Trial and Appeal Board
USPTO <i>or</i> PTO	United States Patent and Trademark Office
IPR	<i>Inter Partes</i> Review
POSA or POSITA	Person of Ordinary Skill in the Art at the time of the invention
CMIB	Complainant's Initial Markman Brief
CMRB	Complainant's Reply Markman Brief
RMIB	Respondents' Initial Markman Brief
RMRB	Respondents' Reply Markman Brief
PD	Photodynamic diagnosis
PDT	Photodynamic therapy
ALA	5-aminolevulinic acid
CPHB	Complainant's Pre-Hearing Brief
RPHB	Respondent's Pre-Hearing Brief
CIB	Complainant's Initial Post-Hearing Brief

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RIB	Respondent's Initial Post-Hearing Brief
CRB	Complainant's Responsive Post-Hearing Brief
RRB	Respondent's Responsive Post-Hearing Brief
ITC Tr.	ITC Evidentiary Hearing Transcript
IPR Tr.	IPR2024-01312 Oral Hearing Transcript
FWD	IPR2024-01312 Final Written Decision
RPR	Respondent's Petition for Review
CCPR	Complainant's Contingent Petition for Review
CIUCL	Complainant's Identification of Undisputed Claim Limitations Pursuant to Ground Rule 14.1
Prior Art References	
Lundahl	U.S. Patent No. 6,223,071 to Lundahl, et al.
Larsen	U.S. Patent Publication No. 2005/0075703 to Larsen
Kennedy	U.S. Patent No. 5,079,262 to Kennedy, et al.
Hente	U.S. Patent Publication No. 2010/0118522 to Hente
Perutz	U.S. Patent No. 4,823,858 to Perutz
'902 prov.	U.S. Provisional Application No. 62/241,902

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I. INTRODUCTION

Respondents Biofrontera Inc., Biofrontera AG, Biofrontera Bioscience GmbH, and Biofrontera Pharma GmbH (“Biofrontera”) respectfully submit the following response to the Commission’s Notice Requesting Additional Briefing, issued March 5, 2026, EDIS Doc. ID 874461 (“Commission Notice”). Consistent with Biofrontera’s arguments, the Patent Trial and Appeal Board’s (the “PTAB”) Final Written Decision (“FWD”) in IPR2024-01312 confirms that the Asserted Claims¹ of U.S. Patent No. 11,697,028 (“’028 Patent”) are invalid as obvious. While the PTAB applied a preponderance of the evidence standard, the FWD and the record demonstrate that the PTAB was clearly convinced that the claims of the ’028 Patent are unpatentable as obvious. For instance, given *“the strong case of obviousness in view of Lundahl and Larsen,”* the PTAB determined that “any evidence of secondary considerations would need to be given substantial weight in order to determine that the claims have not been shown to be unpatentable by a preponderance of the evidence” FWD, 33-34 (emphasis added). Indeed, during the PTAB hearing, PTAB Judge Michael Weatherly remarked that he *“can’t think of something more obvious”* than the ’028 Patent. The full quote is worth the Commission’s attention:

Why isn't this case as simple as you all developed a system with Levulan as the drug and a light that depended on fluorescent tubes, and then when LEDs became available, you adapted the light source to just an LED panel, a set of LED panels? *I have to tell you that my first impression of this case is that I can't think of something more obvious.*

Ex. A (IPR2024-01312 Oral Hearing Transcript), 51:15-23 (Weatherly, ALJ) (emphasis added).

The Commission should accord substantial persuasive weight to the PTAB’s FWD finding the asserted claims unpatentable. Although the PTAB applied a preponderance standard, three

¹ Sun Pharma asserted claims 1-2, 4, 16-17, and 19-21 of the ’028 Patent. In addition to the ’028 Patent asserted claims found obvious in the FWD, Sun Pharma asserted Claims 1, 3, 5, 8, 17-18, and 20 of the ’512 Patent. As described herein, the FWD is persuasive as to the asserted claims from both patents.

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expert PTAB judges evaluated the evidence, including some expert evidence not in the record before the ALJ here, and concluded that there was a “strong case” for obviousness. As described below, in some instances, the PTAB acknowledges differences in the factual record before it. However, as discussed below, the conclusions of the three-judge panel were driven by the application of the correct legal analysis to the mixed questions of law and fact presented by the obviousness analysis. Rather than treating a POSA as an automaton, as the ALJ did here, the PTAB FWD applied the principle that a POSA possesses the capacity for reason and ordinary creativity. Rather than treating hinges as “mysterious,” as the ALJ did here, the PTAB FWD applied the analysis the Supreme Court prescribed in *KSR* – that selecting one of a “finite number of identified, predictable solutions...is likely the product not of innovation but of ordinary skill and common sense.” *See KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007). As similarly situated courts have recognized, PTAB findings can be persuasive notwithstanding differing burdens of proof and courts regularly arrange their schedules to be able rely on the PTAB’s expertise. *See, e.g., TAS Energy, Inc. v. San Diego Gas & Elec. Co.*, No. 12–cv–2777–GPC(BGS), 2014 WL 794215, at *4 (S.D. Cal. Feb. 26, 2014). Here, given the clear errors of law and fact in the Final Initial Determination (“FID”), the PTAB’s FWD, while not controlling on this Commission, lights the way towards correcting the legal and factual errors that resulted in the FID.

The PTAB’s FWD finds the ’028 Patent invalid but is also highly persuasive for the ’512 Patent. For the reasons explained in Biofrontera’s Petition for Review, the Commission should find that the term “nested hinge” used in all asserted claims of U.S. Patent No. 11,446,512 (“’512 Patent”) is indefinite. However, if the Commission confirms the construction of “nested hinge” adopted in the ALJ’s claim construction order, Order No. 18 (Mar. 4, 2025), then there are no meaningful differences between the asserted independent claims of the ’028 Patent and ’512 Patent

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for purposes of the obviousness analysis because Order No. 18's construction of the nested hinge limitation is virtually identical to the hinges limitation of the '028 Patent and because the other disputed claim limitations are virtually identical between the independent claims of the '028 and '512 Patents. Thus, if "nested hinge" is not indefinite, the Commission should determine the '512 Patent to be invalid as obvious. In either event, the Commission has the opportunity to correct the clear errors of law and fact at the heart of the FID. Biofrontera respectfully requests that the Commission reverse the FID and find no violation.

II. NOTWITHSTANDING THE DIFFERING EVIDENTIARY STANDARDS, THE PTAB FWD PROVIDES A COMPELLING INDICATION THAT THE ASSERTED CLAIMS ARE OBVIOUS.

The Commission requested additional briefing addressing "whether, and to what extent, the FWD should impact the Commission's determination regarding validity of the asserted claims of both the '028 patent and the '512 patent," with special attention to the following two issues:

1. For motivation to combine and for each claim limitation that the PTAB found satisfied under a preponderance of the evidence standard, explain whether the limitation or issue is satisfied under a clear and convincing evidence standard.
2. With reference to the existing record of this investigation, explain whether any differences in the arguments or evidence presented before the PTAB and the ALJ impacts the weight the Commission should give to the PTAB's findings, if any.

Commission Notice, 3. Biofrontera addresses both of these questions together, in sections below organized by claim limitation (and motivation to combine) addressed by the PTAB. Regarding the first question in particular, case law demonstrates that courts considering PTAB decisions do find the PTAB's conclusions persuasive, even when applying a different standard.

A. Courts Applying the Clear and Convincing Standard Nevertheless Frequently Find the PTAB's Conclusions Persuasive.

District courts and the Court of Federal Claims have regularly recognized the persuasive value of PTAB decisions, even though the PTAB applies the preponderance of evidence standard.

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Ultratec, Inc. v. Sorenson Commc'ns, Inc., No. 14-CV-66-JDP, 2015 WL 5330284, at *14 (W.D. Wis. Sept. 11, 2015) (“This court is not bound by the PTAB decision, but its reasoning is persuasive.”); *DSS Tech. Mgmt., Inc. v. Apple, Inc.*, No. 14-CV-05330-HSG, 2015 WL 1967878, at *4 (N.D. Cal. May 1, 2015) (“the PTAB’s claim construction and invalidity analyses would likely prove helpful to this Court, whether or not the standard applied is identical to the one this Court must apply in the litigation”) (internal quotations removed); *TAS Energy*, 2014 WL 794215, at *4 (explaining “the PTO’s decision ‘is strong evidence that the court must consider in assessing whether the party asserting invalidity has met its burden of clear and convincing evidence’”). The rationale for the PTAB’s persuasive power is common sense. In this IPR, Judge Weatherly commented that a three-judge panel also has the advantage to be able to “to talk about this case and figure out where we go in a consensus way.” Ex. A (IPR Tr.), 90:14-17.

While the preponderance and clear and convincing standards are different, one indication of the strength of an obviousness case is how the PTAB or tribunal considers secondary considerations of nonobviousness alongside the *prima facie* case of obviousness. It is a well-settled legal principle, acknowledged both by the ITC and the Federal Circuit, that secondary indicia of non-obviousness, even substantial evidence, cannot overcome a strong *prima facie* case of obviousness. *Certain Robotic Floor Cleaning Devices and Components Thereof*, 337-TA-1252 Comm’n Op. 33 (Apr. 13, 2023) (“On balance, the Commission finds that the secondary consideration factors do not outweigh a strong *prima facie* case of obviousness as established here”) (citing *Sundance, Inc. v. DeMonte Fabricating Ltd*, 550 F.3d 1356, 1368 (Fed. Cir. 2008); *Leapfrog Enters., Inc. v. Fisher-Price, Inc.*, 485 F.3d 1157, 1162 (Fed. Cir. 2007)); *Certain Filament Light-Emitting Diodes and Products Containing Same (II)*, Inv. No. 337-TA-1220 Comm’n Op. at 68 (Mar. 8, 2022); *Certain Strontium-Rubidium Radioisotope Infusion Systems*,

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and Components Thereof Including Generators, Inv. No. 337-TA-1110 Comm’n Op. at 39 (Dec. 11, 2019). In the present FWD, the PTAB “determine[d] that any evidence of secondary considerations *would need to be given substantial weight* in order to determine that the claims have not been shown to be unpatentable by a preponderance of the evidence.” FWD, 33. The Commission can thus draw the inference that, whatever evidentiary standard applies, the PTAB found the obviousness case presented in the IPR to be compelling. In fact, the PTAB said as much, commenting on “the strong case of obviousness in view of Lundahl and Larsen.” *Id.* at 34.

III. THE COMMISSION SHOULD FIND THE ASSERTED PATENTS INVALID USING THE SAME RATIONALE AS THE PTAB APPLIED IN ITS FWD.

A. Sun Pharma Did Not Contest Many of the Claim Limitations at the PTAB.

In the PTAB proceedings, Sun Pharma only contested a limited number of limitations. As indicated in the table, many of the contested limitations in the ’028 Patent have an identical or nearly identical corresponding limitation in the ’512 Patent:

<u>Limitation</u>	<u>’028 Patent Limitation</u>	<u>Corresponding ’512 Patent Limitation</u>
“an illuminator comprising five panels connected by hinged structures on inner side surfaces of adjacent panels”	<i>Independent Claims 1 and 20-21</i> <i>Contested by Patent Owner at PTAB (FWD, 22-24)</i>	See Section I.B regarding overlap with “nested hinges” limitation
“light sources disposed on surfaces of the [at least] five panels the illuminator being configured to uniformly illuminate a treatment surface of the patient via the light sources” / “uniformly illuminating a treatment surface of the patient”	<i>All Asserted Independent Claims</i> <i>Contested by Patent Owner at PTAB (FWD, 26-29)</i>	<i>All Asserted Independent Claims</i>
“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”	<i>All Asserted Independent Claims</i> <i>Contested by Patent Owner at PTAB (FWD, 26-29)</i>	<i>All Asserted Independent Claims</i>
“five panels connected by hinged structures to allow continuous illumination across the five panels, wherein the five	<i>Independent Claim 16</i>	N/A

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panels are individually configurable to control illumination from each of the five panels”	<i>Contested by Patent Owner at PTAB (FWD, 44-47)</i>	
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In contrast, Sun Pharma did not contest many of the limitations in the Asserted Claims in the PTAB proceedings, including the following:

<u>Limitation</u>	<u>'028 Patent</u>	<u>'512 Patent</u>
“A system for photodynamically diagnosing or treating a patient, comprising”	<i>All Asserted Claims</i> <i>Not contested by Patent Owner at PTAB or at the ITC (FWD, 21)</i>	<i>All Asserted Claims</i> <i>Not contested at the ITC</i>
“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”	<i>Independent Claims 1, 20-21 & Dependent Claim 17</i> <i>Not contested by Patent Owner at PTAB (FWD, 30)</i>	<i>Independent Claims 1, 20</i>
“wherein the five panels are positioned to allow treatment within approximately four inches of the treatment surface”	<i>Independent Claims 1, 5, 20, 21</i> <i>Not contested by Patent Owner at PTAB or at the ITC (FWD, 30)</i>	N/A
“administering 5-aminolevulinic acid (ALA) to the patient”	<i>Independent Claim 5</i> <i>Not contested by Patent Owner at PTAB, nor asserted at ITC (FWD, 48-49)</i>	<i>Independent Claim 8</i> <i>Not contested at the ITC</i>
“positioning an illuminator proximate to the patient”	<i>Independent Claim 5</i> <i>Not contested by Patent Owner at PTAB, nor asserted at ITC (FWD, 48-49)</i>	<i>Independent Claim 8</i>
“ <i>a mobile base supported by at least four wheels</i> ; a pillar perpendicular to the base; a controller disposed to be supported by the pillar; an arm mounted to a top portion of the pillar; and an illuminator connected at an end of the arm, the arm being hinged to allow adjustment of a position of the illuminator relative to the base”	<i>Independent Claim 16</i> <i>Not contested at the ITC, aside from the bolded portion (FWD, 47-48)</i>	N/A
“wherein the illuminator is configured to output red light at a dose of about 30 J/cm ² to about 150 J/cm ² .”	<i>Claim 2</i> <i>Not contested by Patent Owner at PTAB (FWD 48)</i>	<i>Claim 3</i>

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“wherein a plurality of the light sources are configured to emit light having a wavelength in a range of 400 nm to 700 nm.”	Claim 4 <i>Not contested by Patent Owner at PTAB</i> (FWD, 48)	Claim 5
“wherein the illuminating comprises outputting red light during at least part of the time when the treatment surface is illuminated.”	Claim 6 <i>Not contested by Patent Owner at PTAB, or asserted at the ITC</i> (FWD, 49)	N/A
“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.”	Claim 17 <i>Not contested by Patent Owner at PTAB</i> (FWD, 48)	N/A
“wherein the light sources are configured to output red light during at least part of the time when the treatment surface is illuminated.”	Claim 19 <i>Not contested by Patent Owner at PTAB</i> (FWD, 49)	N/A

Where Sun Pharma has not contested a limitation, one can draw a reasonable inference that it did not believe it could overcome the arguments as to obviousness presented in Biofrontera’s Petition. The limitations Sun Pharma did not contest at the PTAB included elements it hotly contested before the ALJ here, including “one of the five panels being positioned as a center panel configured to face the treatment surface,” and whether Larsen’s perspective view drawing of medical device with two wheels rendered obvious to POSA the existence of another two wheels. The FID adopts Complainant’s briefing on these limitations, determining that a hypothetical POSA, having obtained an MD and/or Ph.D., would simply be stumped by the concept of applying four wheels to the bottom of a medical device, identifying a center panel among a series of five, or knowing that the bright light part of the PDT device would be configured to face the treatment surface. *Compare* CRB, 29, 36; to FID, 116, respectively.²

² For the “four wheels” limitation, Sun Pharma argues, and the FID credulously accepts, that Biofrontera did not address this limitation. It did. *See* RIB, 65.

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B. If the Commission Affirms Order No. 18’s Construction of “Nested Hinges,” There Are No Meaningful Differences in the Obviousness Analysis for the ’512 and ’028 Patent Independent Claims.

The Asserted Claims of the ’512 and ’028 Patents are virtually identical and vary primarily in the differences in how the claims address the hinge limitations. The table below summarizes the differences between the hinge limitations for the ’028 and ’512 Patents.

	’028 Patent, claims 1-2, 4, 19-21	’512 Patent, 1, 3, 5, 8, 17-18, and 20
Claim language	“ <i>hinged structures</i> on inner side surfaces of adjacent panels.”	“ <i>nested hinges</i> on inner side surfaces of adjacent panels.”
Proposed constructions	Not contested	Complainant: Plain and ordinary meaning; “hinges that fit on inner side surfaces of adjacent panels” Respondent: Indefinite
Claim construction	“hinged structures on inner side surfaces of adjacent panels.”	“hinges that fit on inner side surfaces of adjacent panels”

Compared to the “hinged structures” language of the ’028 Patent, the corresponding “nested hinges” claim limitation of the ’512 Patent, as construed, is virtually identical. Specifically, Order No. 18’s construction of “nested hinges” (1) reads “nested” out of the claim, (2) replaces “hinged structures” with “hinges,” and (3) inserts “that fit on” between hinges and “inner side surfaces.” That these differences are immaterial is underscored by how the FID and Sun Pharma analyzed these elements. *See* FID, 19 (“Indeed, the construction of ‘nested hinges on inner side surfaces...’ requires only that the hinges fit on inner side surfaces. Order No. 18 at 35. The claims require only that the ‘panels’ be ‘connected by’ hinges; they do not specify where or how the hinges are connected to the panels.”); CRB, 2 (verbatim the same). Thus, to the extent that the Commission does not find “nested hinges” indefinite, obviousness of the hinge limitation for the

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'028 and '512 Patent³ should be analyzed the same. With that understanding, the '512 Patent's "nested hinges" limitation and '028 Patent's "hinged structures" limitation are hereinafter referred to as "the hinges limitation."

The remaining differences between the '512 and '028 Patents are slight. First, four of the five independent claims of the '028 Patent recite "wherein the five panels are positioned to allow treatment within approximately four inches of the treatment surface," a narrowing limitation not present in any of the '512 Patent asserted claims.⁴ JX-0002, cls. 1, 5, 20-21. The PTAB found that the combination of Lundahl and Larsen met this limitation and Sun Pharma did not contest this limitation in either forum. FWD, 30. The '028 Patent contains independent claim 16, which has no corollary in the '512 Patent. The '512 Patent contains two dependent claims—claims 17 and 18—that are not present in the '028 Patent and require, *inter alia*, "wherein at least one panel includes a recess configured to receive a flange of one of the nested hinges." JX-0001, cls. 17-18. Contested limitations common between the Asserted Patents are discussed below.

C. The PTAB's Conclusion That the "Hinges Limitation" Is Obvious Supports Obviousness Here

With respect to the hinges limitation, Larsen indisputably teaches panels "flexibly *connected to each other through hinges . . . connecting one edge with the other.*" RX-0099, [0072] (emphasis added). While there has been some debate between the parties in both IPR2024-01312 and the ITC as to whether Larsen explicitly points out hinges between inner edges of panels in its Figure 1 via element number 20 or instead identifies hinges via element number 10, the

³ Consistent with Biofrontera's indefiniteness theory, Sun Pharma's counsel told the Board, "Honestly, I don't actually know exactly what a nested hinge looks like...." Ex. A (IPR Tr.), 59:24-60:5.

⁴ Claim 8 of the '512 Patent recites "positioning an illuminator proximate to the patient," which is broader than the "the five panels being positioned to allow treatment within approximately four inches of the treatment surface."

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PTAB correctly found that, regardless of how that dispute is resolved, “[t]he choice of whether to place hinges between panels, on the top or bottom, or on the back is not an act of invention.” FWD, 26.

While the PTAB made this determination under the preponderance of the evidence standard, the obviousness of choosing a hinge location to connect two panels is not controversial. As the PTAB correctly noted, “common sense limits the number of possible locations to six sides (top, bottom, front, back, and two sides) on a three-dimensional rectangular panel, and six is a reasonable finite number.” FWD, 26; *see KSR.*, 550 U.S. at 421 (holding finite number of identified, predictable solutions leading to the recited result is common sense, not invention). Choosing one out of a maximum of six locations to place a hinge is comfortably within the ambit of a POSA having an “M.D. and/or a Ph.D. in an electrical engineering, optoelectronics, physics, optical sciences, optical engineering, or related scientific or engineering field, and at least one to two years of work or research experience.” Order No. 18, 13. As noted by one PTAB judge, “hinges aren’t mysterious....” Ex. A (IPR Tr.) 64:8 (Weatherly, ALJ). By the 2015 priority date, hinges were not an advanced or unpredictable technology. At oral argument, Sun Pharma’s counsel agreed with the PTAB’s observation that “hinges aren’t mysterious” and that those include known hinges that “allow you to mount things next to each other without gaps or with gaps or gaps that change as the two things move relative to each other, or gaps that don’t change as the two things move relative to each other.” Ex. A (IPR Tr.), 64:8-13. In fact, as Dr. Grove noted, people have been utilizing hinges placed between panels for generations prior to 2015. ITC Tr. (Grove), 592:2-8. This testimony was erroneously discounted by the FID, as explained on pages 34-35 in Biofrontera’s Petition for Review. When considered under the proper *KSR* standard, the available

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evidence shows clearly and convincingly that it is obvious for a POSA to place hinges between panels.

This is even more clear before this tribunal, where (unlike at the PTAB) there is also an infringement determination that rests on the premise that “[t]he *claims* require only that the ‘panels’ be ‘connected by’ hinges; they *do not specify where or how the hinges are connected to the panels.*” FID, 19 (emphasis added). The breadth of the claim articulated in the infringement determination (which is not under review) is also controlling for the invalidity analysis before the Commission. The FID’s broad claim interpretation for infringement should correspondingly set the bar for obviousness low, requiring only that “the ‘panels’ be ‘connected by’ hinges.” *Id.*; *TVIIM, LLC v. McAfee, Inc.*, 851 F.3d 1356, 1362 (Fed. Cir. 2017) (holding claim terms construed the same way for purposes of infringement and invalidity). In light of this further clarity provided by the parallel infringement analysis at issue here, the Commission should find that the hinges limitation is obvious under the clear and convincing standard.

D. The PTAB’s Conclusion That The “Uniformity” Limitation Is Obvious Supports Obviousness Here

Claims 1, 16, 20, and 21 of the ’028 Patent and claims 1, 8, and 20 of the ’512 Patent each recite the “uniform illumination limitation,” which was agreed to mean “irradiating light over the active emitting area such that the measured irradiance at a treatment surface of the patient is at least within 60% of the measured maximum.” Order No. 18, 13. The parties do not dispute that Lundahl discloses this limitation verbatim (RX-0065, 15:22-26; *see also* RX-0065, 1:9-11) but merely whether there is a reasonable expectation of success in maintaining the disclosed uniformity once the PDT device of Lundahl is combined with the LEDs and hinged panels of Larsen. The PTAB’s FWD found that “upgrading fluorescent systems in a PDT to an LED system while maintaining uniform illumination, particularly for a small and/or flat treatment area, is akin

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to routine optimization and well within the level of ordinary skill.” FWD, 28. This conclusion is the result of the FWD adhering to the correct legal framework for analysis, in a number of areas where the FID legally erred, and it supports a similar finding by the Commission under the clear and convincing standard.

As an initial matter, the PTAB correctly framed its analysis in light of the breadth of the claims, stating that “the recited ‘treatment area’ is unspecified, and therefore includes very small and/or flat areas of a patient’s body (for example, the forehead or back of the hand) selected by, *e.g.*, a dermatologist.” FWD, 27. Thus, while the PTAB considered certain inventor testimony that was also presented before the ALJ here – *e.g.*, that uniformity was “one of the more difficult challenges” and required “numerous tests” – it correctly recognized that the challenge being discussed by the inventors (*i.e.*, producing a device designed for regulatory compliance⁵) was not commensurate in scope with the breadth of the claims. FWD, 28. This is true under both the preponderance of the evidence and the clear and convincing standard and should inform the Commission’s analysis here. Further, this claims-driven analysis of reasonable expectation of success corrects legal error in the FID, which improperly elevated the standard of uniformity beyond what was required by the claims via reliance on inventor testimony and the prior art itself. RPR, 47-49.

The PTAB also provided a legally correct analysis by applying a consistent standard to both reasonable expectation of success in light of the prior art and enablement in view of the patent’s disclosure. The Federal Circuit held in *Alcon Research, Ltd. v. Apotex, Inc.*, 687 F.3d 1362, 1369 (Fed. Cir. 2012), that a disclosure (or lack thereof) sufficient to establish enablement

⁵ JX-0014C (Boyajian), 73:21-74:9, 75:11-22 (explaining that the inventors’ goal was to “produce something that was on label” and noting that “what got into the patent is disjoint [sic] from what I did”).

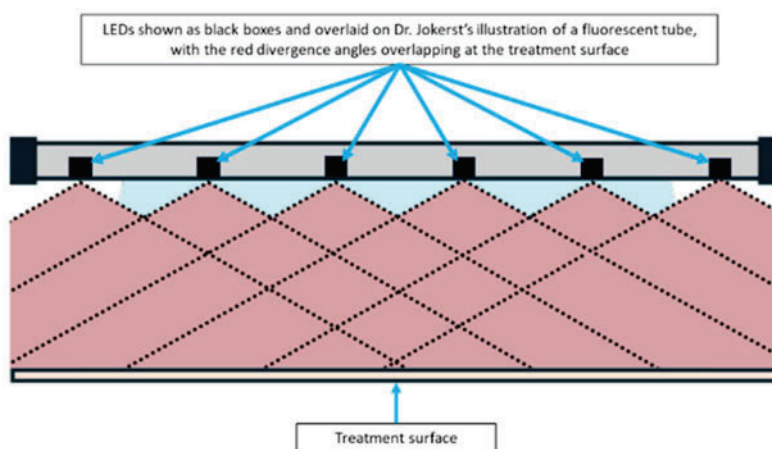
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when it appears in the specification is sufficient to establish reasonable expectation of success when it appears in the prior art. *Id.* Here, the Asserted Patents recite and disclose uniformity in a paneled illuminator in the same words as Lundahl but fail to disclose any particular detail as to the necessary light source spacing or as to the specific LED characteristics necessary for achieving it. *See* RPR, 50-51. The PTAB recognized the legal and logical problem that arises, noting that “the inventors talk about how hard it was but they don’t describe in the patent how they solved all these difficult problems or claim the things that they overcame, but instead they just say, put five panels together with hinges.” Ex. A (IPR Tr.), 55:8-13 (Weatherly, ALJ). Accordingly, the PTAB applied the consistent approach sanctioned by the Federal Circuit to find that, “as Patent Owner’s witness explains, light uniformity is affected by a variety of factors, including ‘density, power, angle, diffuser, the LED itself,’ ***none of which is laid out with specificity in the ’028 patent claims, suggesting that achieving uniformity was routine optimization within the level of ordinary skill.***” FWD, 28-29 (emphasis added).

Finally, while the FID incorrectly treated the POSA as an automaton for purposes of its obviousness analysis, the FWD recognized that such a rigid approach is incorrect under *KSR*. 550 U.S. at 406 (“A person of ordinary skill is also a person of ordinary creativity, not an automaton.”). FWD, 28. Although Sun Pharma argued in both forums that a POSA would need to incorporate multiple components from Lundahl’s fluorescent device – *e.g.*, U-shaped fluorescent tubes, a reflector, a fluorescent-specific electrical control system, and a fluorescent-specific cooling system – that argument was only accepted in the FID and was rejected by the PTAB. FID, 104. The FWD applied the correct legal standard, relying on a long line of cases that support two propositions. First, “[t]he test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference.” FWD, 29 (quoting *In re Keller*, 642 F.2d

413, 425 (CCPA 1981). Second, “the artisan is not compelled to blindly follow the teaching of one prior art reference over the other without the exercise of independent judgment.” FWD, 29 (citing *Lear Siegler, Inc. v. Aeroquip Corp.*, 733 F.2d 881, 889 (Fed. Cir. 1984)). Thus, the FWD found that a POSA would have a reasonable expectation of success in adapting Lundahl’s device to achieve the required uniformity with LEDs. FWD, 26-29. But the FID ignored this law and applied the wrong legal standard in coming to the opposite conclusion here.

It is the correct legal framework that drove the PTAB’s conclusions as to obviousness and reasonable expectation of success, and which should lead the Commission to the same conclusion here. In making this determination, the PTAB also cited declaration testimony from Dr. Grove, explaining that it would have been routine for a POSA in 2015 to have placed LEDs so that divergence angles of light emission from individual LEDs overlap so as to prevent gaps and improve uniformity.



Ex. B (Ex. 1026, Grove Supplemental Declaration) (cited by FWD, 29). Although this testimony was not before the ALJ here, this is not the only testimony cited by the FWD. The PTAB also cited testimony from the '028 Patent inventors (Ex. 2052 in IPR2024-01312 (JX-0015C in the present case), 74:2-14, 88:15-89:8) regarding parameters they adjusted to reach uniformity, which were

not discussed in any detail in the '028 Patent specification. This testimony is before the Commission and should lead to the same conclusion – that this discussion was left out of the '028 Patent disclosure because “achieving uniformity was routine optimization within the level of ordinary skill.” FWD, 28-29.

Regardless of these differences, application of the correct legal principles as set out in the FWD (and correction of the legal errors in the FID) should drive a finding of obviousness here.

E. The PTAB’s Conclusion That The “Higher Intensity Proximate Second Edges” Limitation Is Obvious Supports Obviousness Here

All of the asserted claims recite “a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges.” JX-0002, cls. 1, 16, 20, 21; JX-0001, cls. 1, 8, 20. The PTAB correctly found that it would be obvious to combine Lundahl’s light source distribution with Larsen’s panels to arrive at a “higher intensity proximate second [shorter] edges.” FWD, 31-32. Once again, the FWD rights the legal wrongs promulgated in the FID. The application of the correct legal and logical frameworks, as set out in the FWD, should lead to the same conclusion of obviousness here, despite some differences in the record.

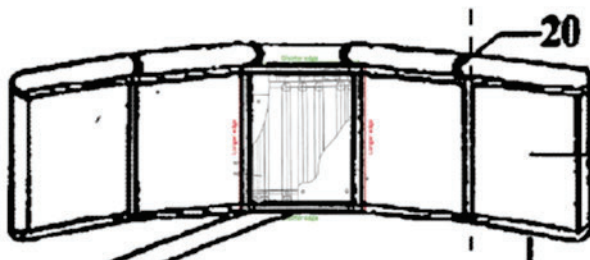
Initially, the PTAB once again avoided the erroneously rigid and inflexible treatment that the FID applied to a POSA and to the obviousness inquiry. RPR, 44-45. Instead, the PTAB gave due deference to the 50+ years of precedent stating that obviousness does not require that “features of a secondary reference may be bodily incorporated into the structure of the primary reference.”⁶ FWD, 29. Further, the FWD noted that “[n]onobviousness cannot be established by attacking the

⁶ *In re Keller*, 642 F.2d 413, 425 (CCPA1981) (internal citations omitted); *see also In re Sneed*, 710 F.2d 1544, 1550 (Fed. Cir. 1983) (“[I]t is not necessary that the inventions of the references be physically combinable to render obvious the invention under review.”); *In re Nievelt*, 482 F.2d 965, 968 (CCPA 1973) (“Combining the teachings of references does not involve an ability to combine their specific structures.”).

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references individually when the rejection is based upon a combination of prior art, and each reference ‘must be read, not in isolation, but for what it fairly teaches in combination with the prior art as a whole.’” FWD, 31-32 (*citing In re Merck & Co.*, 800 F.2d 1091, 1097 (Fed. Cir. 1986)).

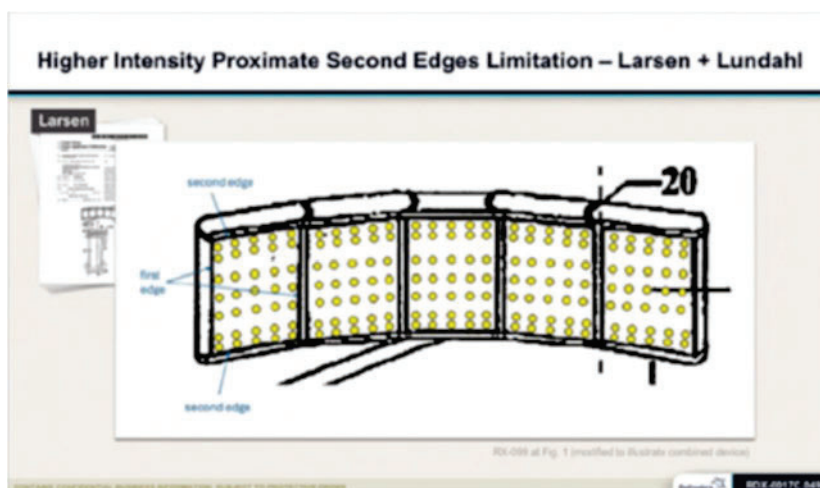
Applying the correct legal principles, the FWD rejected Sun Pharma’s contention that a POSA would robotically apply Lundahl’s teachings of light source distribution to arrive at a device having higher intensity at the longer edges of panels, as illustrated by Sun Pharma below and adopted by the FID:



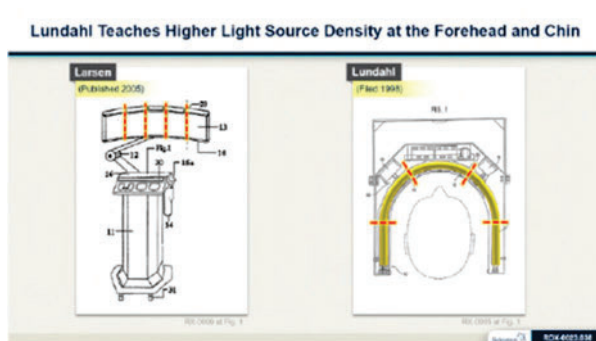
FID, 109 (citing CDX-0018C.77). Instead, the PTAB properly found that a POSA would understand that “the longer top and bottom edges of Lundahl’s fluorescent tubes (which indisputably teach emitting higher intensity light due to the uneven spacing), when modified in view of Larsen, correspond to the shorter top and bottom edges of panels.” FWD, 32. In coming to this conclusion, the FWD not only corrected legal errors made by the FID, but also remedied factual mistakes. The FWD specifically noted that “[w]e disagree with the ITC’s finding that ‘[a]pplying Lundahl’s light distribution to Larsen’s five panels yields a higher intensity of light on the longer edges of each panel,’ as seen in the annotated figure CDX-0018C.77. Ex. 2090, 109. *Petitioner provides several illustrations* clarifying that when combined as proposed, Lundahl and Larsen teach emitting light at a higher intensity close to shorter edges.” FWD, 32 n. 14 (emphasis added). While the FID stated that “Biofrontera never explains how combining Lundahl’s disclosures with Larsen would satisfy the full limitation,” (FID, 114) this is pure factual error.

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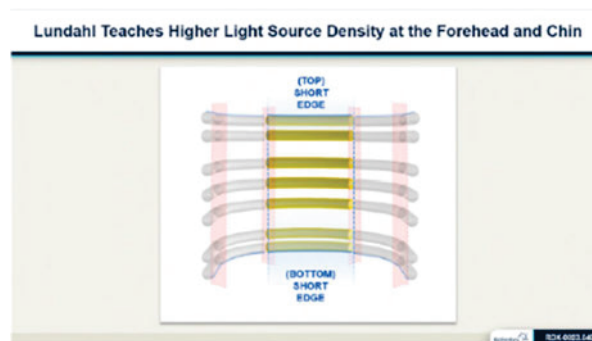
Biofrontera (and Dr. Grove in his testimony) explained extensively in both initial and responsive post-hearing briefs that, because Lundahl teaches the benefits of providing higher intensity near a patient's forehead and chin, as illustrated in its Fig. 1, it would be obvious to apply this principle in combination with Larsen's five panels. RIB, 32-34, 56-61; RRB, 21-25; RX-0006C, Q/A 94-95, 97, 209-220, 321; *see also* ITC Tr. (Jokerst), 740:25-741:5 (answering that Lundahl teaches a higher intensity, "near the forehead and chin...")⁷ As in the IPR, Biofrontera also provided numerous illustrations of the proposed combination:



RDX-0017C.049; RX-0006C, Q/A 97, 215.



RDX-0023.038.



RDX-0023.040.

⁷ Ex. C (Petitioner's Reply), 20-21.

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The FID committed clear factual error and created a de facto difference in the record by ignoring large swaths of evidence and argument provided by Biofrontera as to this claim element. The Commission can and should correct this error.

The PTAB also rejected Sun Pharma's argument that the "higher intensity near the second edges" limitation is not obvious due to the areas of reduced emission near the ends of Lundahl's fluorescent tubes, stating that "Patent Owner's argument, however, is illogical and ignores that the reduced emission areas are simply a consequence of using tubular fluorescent light sources....We agree with Petitioner that a POSITA would not incorporate Lundahl's shortcomings into a combination using LEDs...." FWD, 31. In rejecting this argument, the PTAB cited testimony from Dr. Grove (Ex. B (Ex. 1026, Grove Supplemental Declaration) ¶¶ 22-26), which was not presented in this case. However, at the evidentiary hearing here, Dr. Jokerst also admitted that a POSA would not typically incorporate the shortcomings of a prior device when developing a new device. ITC Tr. (Jokerst), 768:10-13. Thus, there is sufficient evidence on the record here to support the same conclusion. This conclusion also comports with the treatment of a POSA as an individual having the capacity for ordinary creativity and reason, as the law demands. *KSR*, 550 U.S. at 421. When the proper legal standard for a POSA is applied, it is inescapable that Sun Pharma's arguments on this point are "illogical" as noted in the FWD. FWD, 31.

Thus, when all available evidence is considered under the correct legal framework set forth in the FWD, the "higher intensity proximate second edges" limitation is obvious over the prior art, under the clear and convincing standard.

F. The PTAB's Conclusion That The "Continuous Illumination" Limitation Is Obvious Supports Obviousness Here

Claim 16 of the '028 Patent and claim 20 of the '512 Patent each recite that the hinged structures (or "nested hinges," in the case of the '512 Patent) be configured so as to "allow

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continuous illumination across” the at least five panels. JX-0002, cl. 16; JX-0001, cl. 20. Once again, the PTAB correctly let the breadth of the claims lead its obviousness analysis, recognizing that “continuous” is a lower standard than “uniform illumination” and that “[i]n our view, illumination is continuous regardless of whether the illumination is lower or higher.” FWD, 44.

In finding that this claim limitation was not disclosed or rendered obvious, the FID incorrectly stated that “Biofrontera’s expert confirmed Larsen cannot have ‘continuous illumination’ because it has ‘lower irradiance regions at the junction of two of Larsen’s panels.’” FID, 102-103. As an initial matter, the testimony the FID cited was truncated and taken out of context, as explained on page 39 of Biofrontera’s Petition for Review. However, even if the FID’s characterization of the testimony were accurate, the claim limitation would still be satisfied because, as the PTAB correctly reasoned, “lower irradiance regions still allow for some irradiance, therefore, continuous illumination of those regions.” FWD, 44.

The PTAB also rejected Sun Pharma’s argument that “continuous illumination” would not be obvious because Larsen fails to teach detailed structure for hinges on inner side surfaces of panels, correctly noting that “claim 16, however, does not require hinged structures on inner side surfaces.” FWD, 44. Applying this correct analysis to the record here, the claim limitation is obvious under the clear and convincing standard.

G. The PTAB’s Conclusion That The “Individually Configurable” Limitation Is Obvious Supports Obviousness Here

Claims 16 and 21 of the ’028 Patent recite “the five panels are individually configurable to control illumination from each of the five panels” (the “individually configurable” limitation), which was construed to mean “the power output and/or light intensity of each panel can be individually controlled.” Order No. 18, 40; JX-0002, cls. 16, 21. The PTAB found that Larsen

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taught and/or suggested control of light output from individual panels. FWD, 45-47. In doing so, the PTAB gave due consideration to evidence that the FID ignored and failed to address.

Specifically, the FWD rejected Sun Pharma's argument that Larsen could not teach or render obvious control of light output from individual panels because Larsen discloses "a controller" in the singular. FWD, 45. Initially, the PTAB noted that, on its face, this argument (which Sun Pharma also made before the ALJ) is not "commensurate with the scope of the claim because, here, there is no requirement for each panel to have a dedicated control unit." FWD, 45. Additionally, the PTAB noted that "we also agree with Petitioner that a POSITA would have understood that a single controller can control multiple applicators and/or LEDs" and expressed skepticism as to Sun Pharma's arguments otherwise. FWD, 45; *see also* IPR Tr. 71:17-72:3 ("Mr. Ha:that's talking about the control mechanism of the entire device, the invented device, not the different panels...So it's really talking about turning on and off one type of diodes across the entire device....Judge Weatherly: Seems like an awfully fancy on-off switch control mechanism."). In arriving at this conclusion, the PTAB cited Ex. 2011, which states that "*controls* are usually interfaced to the driver circuitry to *allow the brightness of the individual LEDs to be set.*" CX-1231.2. Ex. 2011 is a 2008 academic article discussing the state of the art as to LEDs, their advantages, and their rapid adoption at the time, as well as principles for designing LED lighting systems. CX-1231. This article is in evidence before the Commission and was in fact originally cited by Sun Pharma's expert Dr. Jokerst. CX-0014C.119 (citing CX-1231). Although Biofrontera directed the ALJ to the same discussion regarding the capabilities of controllers in its post-hearing briefing (RRB, 25), the FID ignored this evidence and completely failed to address it. By overlooking evidence that the PTAB properly considered, the FID created a de facto difference in the record.

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Additionally, the FWD took Larsen's disclosure at face value, paying specific attention to Larsen's claim 5, which recites "wherein the *light sources are individually selected*—switched *ON* or *OFF*." RX-0099, cl. 5 (emphasis added). The PTAB found that "[c]laim 5's teaching that laser diodes are individually switched supports Petitioner's position that Larsen's teachings go beyond simply adjustability/switching across all applicators." FWD, 46-47. The PTAB rejected Sun Pharma's argument (adopted by the FID) that claim 5 must be interpreted to mean something other than what it says on its face. FWD, 46-47; IPR Tr. 34:10-37:16. Accordingly, when the correct legal principles are applied and all available evidence is properly considered, this limitation is rendered obvious under the clear and convincing standard.

H. The PTAB's Conclusion That A POSA Would Have Been Motivated to Combine Larsen's LED Panels with Lundahl's PDT Device Supports Obviousness Here

Before the PTAB and at the ITC, Biofrontera argued that (A) a POSA would have been motivated to replace Lundahl's fluorescent tubes with Larsen's more modern LED light sources, and (B) a POSA would have been motivated to modify Lundahl's fixed-shape device with Larsen's hinged panels in order to increase flexibility of the device. RIB, 30-31, 74-79, 160-161. In the IPR, Sun Pharma did not even attempt to argue otherwise. As the FWD acknowledged, "Patent Owner does not meaningfully dispute the Petitioner's proposed reasons to combine Lundahl and Larsen." FWD, 21.

a. The PTAB's Conclusion That A POSA Would Have Been Motivated to Replace Lundahl's Fluorescent Tubes with Larsen's LEDs Supports Obviousness Here

With respect to (A), at the ITC, both Sun Pharma and the FID largely failed to address Biofrontera's argument that prevailed in the IPR. At the ITC, Biofrontera made two arguments as to why a motivation existed to replace the fluorescent tubes of Lundahl with the LEDs of Larsen: (i) fluorescent tubes had known *performance* issues that were solved by LEDs; and

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(ii) fluorescents were becoming *disfavored* in the industry and by the government. RPR, 52-58; RIB, 30-31, 77-79, 160-161. In the IPR, Biofrontera focused its arguments on (i). Ex. D (Petition), 25-32. Before the Commission, Sun Pharma did not comment on argument (i) in its post-hearing briefing, and the FID completely failed to address – and appears to have ignored – this argument (and the related evidence).⁸ RPR, 54-57. The FWD illustrates that, when this evidence and argument (which Sun Pharma fails to contest) is properly considered, “a POSITA would have been motivated to combine Lundahl and Larsen for the reasons advanced by Petitioner.” FWD, 21.

Although the FWD made this determination under the preponderance of the evidence standard, additional arguments and evidence were before the ITC on this issue. Specifically, in the ITC investigation, Biofrontera also argued and presented evidence showing a motivation to replace fluorescents with LEDs because (ii) fluorescents were becoming *disfavored* in the industry and by the government. RPR, 56-57; RIB, 30-31, 77-78. While the FID dismissed this argument in one sentence, stating that “fluorescent tubes did not ‘become obsolete by the 2015 priority date,’” (FID, 121) this was legal error because the standard for motivation does not require that the prior art become obsolete or unavailable. Instead, the desire to *improve* already functional technology can be sufficient. *DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co.*, 464 F.3d 1356, 1368 (Fed. Cir. 2006). When considered under the proper legal standard, this additional argument and evidence provide more than enough basis to show clearly and convincingly that a POSA would have been motivated to modify Lundahl’s device with Larsen’s LEDs.

⁸ Although the FID found that Biofrontera waived arguments related to the *safety* issues of fluorescents (FID, 121), this finding is both erroneous and, at best, ancillary to Biofrontera’s main arguments as to motivation, as explained on pages 54-56 of Biofrontera’s Petition for Review.

b. The PTAB's Conclusion That A POSA Would Have Been Motivated to Modify Lundahl's Fixed U-Shaped Device with Larsen's Hinged Panels to Increase Device Flexibility Supports Obviousness Here

In both forums, Biofrontera additionally argued that (B) a POSA would have been motivated to modify Lundahl's fixed-shape device with Larsen's hinged panels in order to increase flexibility of the device. RIB, 74-77; Ex. D (Petition), 25-32. In rejecting this argument, the FID continued with the same legal error to suggest that simply because the older fixed U-shape device of Lundahl *could* be used to provide PDT (no matter how inconvenient or difficult), there would be no motivation to increase flexibility. RPR, 60-61; FID, 118. However, the law does not require that the prior art be inoperable in order for there to be motivation to improve it. *DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co.*, 464 F.3d 1356, 1368 (Fed. Cir. 2006). The FID also erroneously concluded that, because the gaps introduced by including hinges between panels could affect uniformity, this would defeat any motivation to increase flexibility. RPR, 62-65; FID, 120. However, using the correct legal framework, the PTAB concluded that "the motivating benefit here—using adjustable LED panels instead of monolith fluorescent tubes—outweighs the alleged disadvantages for the many reasons given by Petitioner, including greater adjustability and improved LED performance. *See Medichem, S.A. v. Rolabo, S.L.*, 437 F.3d 1157, 1165 (Fed. Cir. 2006) ('[t]he fact that the motivating benefit comes at the expense of another benefit, however, should not nullify its use as a basis to modify.')." FWD, 21.

In sum, with respect to motivation, the PTAB reviewed evidence and argument that the FID overlooked and applied correct legal standards where the FID went astray. Its findings are instructive as to what should happen when the full record is considered under the correct legal framework. Further, there is additional evidence before the Commission here supporting motivation to modify fluorescents based on disfavor in the industry and the regulatory environment

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as of the priority date. Accordingly, the robust record here supports a finding of motivation under the clear and convincing standard.

IV. CONCLUSION

For the foregoing reasons, the Commission should grant the relief requested in Biofrontera's Petition for Review and find the Asserted Claims of the '512 and '028 Patents invalid.

Dated: March 12, 2026

Respectfully submitted,

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Exhibit A

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

v.

SUN PHARMACEUTICAL INDUSTRIES, INC.,
Patent Owner

IPR2024-01312
Patent 11,697,028 B2

Record of Oral Hearing
Held: December 3, 2025

Before MITCHELL G. WEATHERLY, ZHENYU YANG, and MARY C.
HOFFMAN, *Administrative Patent Judges*.

IPR2024-01312
Patent 11,697,028 B2

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The above-entitled matter came on for hearing on December 3, 2025, commencing at 1:32 p.m., via video teleconference.

P R O C E E D I N G S

- - - - -

JUDGE HOFFMAN: Good afternoon, all. This is the hearing in IPR2024-01312, involving U.S. Patent Number 11,697,028. I am Judge HOFFMAN, with Judges Yang and Weatherly. I'd like to welcome both the Petitioner and the Patent Owner. Starting with appearances for both parties, who is arguing on behalf of Petitioner today?

MR. LANDMON: Good afternoon, Your Honor. Chad Landmon from Polsinelli. And with me arguing as well will be Kendall Gurule.

JUDGE HOFFMAN: I'm sorry, I didn't catch your last name.

MR. LANDMON: Landmon.

JUDGE HOFFMAN: Landmon, okay. Thank you, Mr. Landmon.

MR. LANDMON: Thank you.

JUDGE HOFFMAN: And who do we have for Patent Owner?

MR. HA: Hello, Your Honors. This is Yung-Hoon Ha, LEAP counsel. And also arguing with me will be Bridget Belcher under the LEAP program.

JUDGE HOFFMAN: Thank you, Mr. Ha. Again, welcome to the USPTO's Alexandria headquarters. A few housekeeping items before we begin. Recording of this hearing is prohibited. The court reporter will provide a transcript of the hearing that will become part of the record in the proceeding at a later date. To ensure that the transcript of this hearing is clear, we ask you to speak directly into the microphone when talking and to identify specific slide numbers, numbering in the figures, and any other pertinent identifying information when referring to the demonstratives.

1 We have allotted 60 minutes per side in our oral argument. We've
2 received Petitioner's request for Ms. Gurule. Am I saying that correctly?

3 MS. GURULE: Close enough. It's a difficult name.

4 JUDGE HOFFMAN: Okay, I'll try. And also, Patent Owner's
5 request for Ms. Belcher to participate in the oral hearing under the Legal
6 Experience and Advancement Program, also known as LEAP. As such, both
7 Petitioner and Patent Owner will receive an additional 15 minutes of
8 argument time during this hearing, bringing the total argument time to 75
9 minutes per side. We remind the parties that the LEAP practitioners must
10 have a meaningful and substantive opportunity to argue during today's
11 hearing.

12 Petitioner will open the argument and may reserve rebuttal time.
13 Patent Owner will then respond to Petitioner's arguments and may reserve
14 surrebuttal time. When you are arguing, please speak slowly. And if you
15 hear another voice, particularly one of the judges, please stop speaking so
16 that we do not talk over each other.

17 I will maintain a clock. Our hearing room has a timer that I will
18 set up for each party. With the requested time allotment, the light on the
19 clock changes to yellow when you're nearing the end of your time. When
20 the light is red, you have run out of time. With that, I'll ask counsel for
21 Petitioner and Patent Owner whether there are any other preliminary matters
22 you'd like to discuss before we go into arguments.

23 MR. LANDMON: Nothing from Petitioner, Your Honor.

24 MR. HA: Nothing from us either.

25 JUDGE HOFFMAN: All right, thank you very much.

26 JUDGE WEATHERLY: For the record, does either party have

1 other counsel here attending? And if so, who are they?

2 MR. LANDMON: We do, Your Honor. So with me behind me is
3 Corey Casey, James Murphy, Brian Larivee, and then in-house counsel for
4 Petitioner, Dan Hakansson.

5 JUDGE WEATHERLY: Thank you.

6 MR. HA: And with me is Tuhin Ganguly, as well as our corporate
7 representative director IP, Jennifer Dereka.

8 JUDGE WEATHERLY: Thanks very much.

9 JUDGE HOFFMAN: Mr. Landmon, do you wish to reserve any
10 rebuttal time?

11 MR. LANDMON: Yes, Your Honor. 15 minutes.

12 JUDGE HOFFMAN: Okay, we got there. And with that,
13 Petitioner, when you're ready, let me know and I'll start the clock.

14 MR. LANDMON: Your Honors, we do have paper copies of the
15 slides. Does anyone need them?

16 JUDGE WEATHERLY: We've all got electronic versions.

17 MR. LANDMON: I figured. Thank you.

18 JUDGE WEATHERLY: It would be helpful, though, to keep the
19 record as clear as possible. Just let us know which slide you're on --

20 MR. LANDMON: Understood.

21 JUDGE WEATHERLY: -- during the discussion. That makes the
22 transcript more useful for us.

23 MR. LANDMON: Sure.

24 JUDGE WEATHERLY: Thanks.

25 MR. LANDMON: That makes a lot of sense. May I proceed?

26 JUDGE HOFFMAN: You may.

1 MR. LANDMON: Thank you, Your Honors. So if we could turn
2 to Slide 2, just to set the stage of what I plan to talk about this afternoon. I'm
3 going to start by talking about the combination of Lundahl and Larsen, and
4 explain just really briefly why a POSITA would have been both motivated
5 and had a reasonable expectation of success. The bulk of my time I plan to
6 spend -- we plan to spend on the contested issues, which we have before you
7 up on the slide, on Slide 2. I'll discuss the majority of them. Ms. Gurule
8 will discuss the individually configurable limitation, and she'll also address
9 secondary considerations.

10 So if we could turn to Slide 3. As Your Honors are aware, the '028
11 Patent is directed to a system and method for treating PDT.

12 JUDGE WEATHERLY: We're having a feedback issue. Can you
13 get this mic on --

14 MR. LANDMON: Feedback, thank you. I was trying to be
15 discreet. Keep my mic on.

16 JUDGE WEATHERLY: Discreet is not my specialty. You'll all
17 know that very well by the end of this hearing.

18 MR. LANDMON: Is that better? Okay, great. Thank you, Your
19 Honors. And if we can turn to Slide 4, the '028 has five independent claims.
20 The IPR was instituted with respect to Claims 1, 2, 4 through 6, 16, 17, 19 to
21 21 of the '028 Patent. If we could turn to Slide 5, the problem for the Patent
22 Owner here is that the '028 Patent is merely an obvious modification of its
23 earlier, already expired PDT Patent, the '071 Patent of Lundahl.

24 And if we turn to Slide 6, the Lundahl Patent discloses a fixed U-
25 shaped device that uses fluorescent bulbs, and it disclosed that it did two
26 important things. One, it provided uniformity of illumination on a treatment

1 surface by bunching the light sources near the top and bottom of the panel
2 near the patient's forehead and chin. And two, it provided for the ability to
3 treat AK lesions around a patient's face by virtue of the U-shape. But if we
4 go to Slide 8, as we can see, the Lundahl device was useful for treating AK
5 lesions generally, but by 2015, it became readily apparent to practitioners,
6 and Dr. Ehrenreich sets this forth in his declaration, that there were
7 drawbacks.

8 First, with respect to the fixed U-shaped design, there were
9 drawbacks in treating both different-sized heads for patients, but also more
10 importantly, as he explains, different parts of the body. So the fixed U-
11 shape had difficulty when treating chest, back, and other parts of the body,
12 because he needed to keep a 2- to 4-inch distance between the light and the
13 treatment surface. So as recognized in the institution decision, the
14 inflexibility of the U-shape presented a clear and readily apparent known
15 problem that POSITAs would be motivated to fix.

16 But if we go to Slide 9, there was a second problem with the
17 device, and that was its use of fluorescent bulbs. Those had issues relating
18 to uniformity. They had issues relating to temperature issues that would
19 interrupt the uniformity. They were sensitive, basically, to temperature, and
20 the industry was moving away from fluorescents and towards LEDs at that
21 time. So the two problems of Lundahl that would motivate a --

22 JUDGE WEATHERLY: What do you mean by the industry?

23 MR. LANDMON: Well, by the industry, both the PDT industry,
24 generally, was moving away from fluorescents, and frankly, the entire world
25 by that time was moving away from fluorescents due to a bunch of different
26 issues, environmental and cost issues as well. But certainly, as we have here

1 in the record, Dr. Grove and Ehrenreich, or Dr. Grove in particular, explains
2 how the industry was moving away from them due to their finicky nature,
3 essentially.

4 JUDGE WEATHERLY: And by the industry -- when he refers to
5 the industry, he's talking about the PDT industry?

6 MR. LANDMON: He is, yes.

7 JUDGE WEATHERLY: Okay.

8 MR. LANDMON: Thank you, Your Honor.

9 JUDGE WEATHERLY: Thank you.

10 MR. LANDMON: If we turn to Slide 10, so to address the
11 inflexibility of the U-shape, it would have been obvious to a POSITA to
12 look to the art and to look to Larsen in particular. As we see, Larsen has a
13 five-panel design, flexible with hinges between to flex the panels. That
14 achieves the flexibility that a POSITA would have looked to solve from
15 Lundahl. It also uses LEDs, again, to address the issues of the fluorescent
16 bulbs that I just mentioned. For these reasons, it would have been natural
17 and obvious to modify Lundahl's PDT device to incorporate Larsen's
18 flexibility in the LED technology. And throughout our petition, we lay out
19 how the prior art discloses and renders obvious the various claim limitations.

20 As I mentioned before, and if we turn to Slide 13, the parties are
21 essentially disputing five issues, and I'll walk through those in turn. But as
22 you're probably aware, if we go to Slide 11, starting there, in the institution
23 stage, the panel recognized that the Petitioner was reasonably likely to
24 prevail on each of those issues. And if we go to Slide 12, also reasonably
25 likely to prevail on motivation and reasonable expectation.

26 But before I get to those five different issues, I did want to address

1 one other issue, and that's the International Trade Commission's initial
2 determination by the ALJ there. As you are aware, the ALJ determined that
3 the '028 Patent was not invalid for obvious. But I wanted to address a
4 couple of issues, and let's turn to Slide 14.

5 As we explained in our papers on November 14th, the law is clear,
6 the Board is not required to follow the initial determination. In fact, the
7 Supreme Court and the Federal Circuit have both recognized that Congress
8 established this system, the IPR system, with the recognition that there could
9 be inconsistent results between decisions by the Board and decisions by
10 courts and other tribunals. But perhaps more importantly, the initial
11 determination is filled with fundamental errors of law and fact.

12 We filed a petition for review with the Commission. That petition
13 is pending, but we are confident the Commission will grant it. And the
14 Commission will then issue and render a final decision. It's currently
15 scheduled for February 2nd, although the government shutdown may have
16 delayed that yet. We don't know yet whether it will or not.

17 JUDGE WEATHERLY: What, if anything, does the PTO director
18 say about what we are supposed to do with the ITC decision?

19 MR. LANDMON: Yeah, so as Your Honor is probably referring
20 to, the more recent guidance trying to get consistency between decisions.
21 But I think there are two things to keep in mind. One, obviously, courts, the
22 Supreme Court and Federal Circuit, have recognized that you aren't bound to
23 follow that and you may have inconsistent decisions. Two, this is an initial
24 determination. We are fully confident the Commission will come out
25 differently. And I think you can only give so much credence and weight to
26 the initial determination by the administrative law judge.

1 JUDGE WEATHERLY: You said February is when -- what's
2 scheduled to happen in the ITC in February again?

3 MR. LANDMON: Yeah, so currently the Commission will need
4 to render a final determination.

5 JUDGE WEATHERLY: Right.

6 MR. LANDMON: It's currently scheduled for February 2nd, but
7 they were actually closed for the duration of the government shutdown.
8 They have not yet issued any order in our case to say that date might be
9 pushed, so we're not sure if it will or not.

10 JUDGE WEATHERLY: Okay.

11 JUDGE YANG: Is the record before the ITC the same as it is
12 here?

13 MR. LANDMON: So they're not, Your Honor. And I think that's
14 an important thing. And they're not in some fundamental ways. And I'll
15 address just a couple of them really quickly, especially when you look at the
16 uniform illumination, which is kind of one of the key terms, one of the first
17 terms that's in dispute here. There are a couple of critical ways where the
18 record is not clear.

19 First, Dr. Grove submitted, as you know, a second declaration
20 here, a supplemental declaration. In it, he was able to address and respond
21 to issues raised by Dr. Jokerst and the Patent Owner relating to divergence
22 of light from LEDs. None of that evidence was before the ITC for
23 procedural reasons. That evidence did not get before the ITC Administrative
24 Law Judge. Secondly, in another key area, Dr. Jokerst, before in this
25 proceeding, submitted a declaration talking about various aspects of Lundahl
26 that she says were required for uniform illumination, things like reflectors

1 and such that I might get into more detail in a little bit.

2 Before the ITC, we didn't have the opportunity to depose her on
3 those issues, because those issues weren't clearly presented at the time.
4 They were obviously in her declaration here. We did depose her here. And
5 as we set forth in our papers, she made some critical admissions with respect
6 to those. She admitted that LEDs just shine light forward. They don't shine
7 light backwards like fluorescents, so you don't need a reflector.

8 She admitted that LEDs have a different electrical system. They're
9 not as finicky as fluorescent bulbs, so you wouldn't need the same electrical
10 system. She admitted that fluorescents are very sensitive to temperature and
11 have a specific cooling system in Lundahl. Again, you don't need those for
12 LEDs. So, the record here is different as well as, obviously, the legal
13 standard.

14 And I did want to just point out really quickly, on Slide 15, one of
15 the fundamental errors that the initial determination made. Now, this issue
16 is not even disputed before you. Patent Owner apparently didn't feel it was a
17 strong enough argument to bring before you, but it was disputed before the
18 ITC. And this is whether Larsen discloses a center panel that's configured to
19 face the treatment surface and also with panels around it that are angled with
20 respect to it.

21 So I don't want to state the obvious here, but we can see on the
22 screen that Larsen has five panels. Five panels means there's a center panel.
23 The panels are used --

24 JUDGE WEATHERLY: So if this issue isn't before us, why are
25 you putting it in front of us?

26 MR. LANDMON: Because I think it's emblematic of the errors in

1 the ALJ's decision.

2 JUDGE WEATHERLY: I shouldn't believe Judge Moore?

3 MR. LANDMON: I'm sorry?

4 JUDGE WEATHERLY: That I shouldn't believe Judge Moore's --

5 MR. LANDMON: Well, I think it's that you should question the
6 findings in his opinion, as we believe the Commission will -- the ITC, the
7 full ITC will, as they review our petition.

8 JUDGE WEATHERLY: All right. He's a former colleague, by
9 the way.

10 MR. LANDMON: I do understand that. I do understand that. So
11 why don't I turn to the uniform illumination disputed term? That's on Slide
12 16. We've got the term on that slide. Patent Owner has thrown out multiple
13 arguments relating to uniform illumination. But I wanted to first start by just
14 walking through quickly why Lundahl and Larsen render that claim
15 limitation obvious.

16 And let's go back, actually, to Slide 7. I skipped over that a little
17 bit in my introduction. One thing to keep in mind here, uniformity of light
18 for treating PDT is not new. In fact, in 1998, Lundahl discussed that. He
19 discussed that he achieved both -- well, he discussed generally the
20 importance of uniform illumination, and that his device achieved uniform
21 illumination within 70 percent.

22 And what Dr. Grove says is, looking at the prior art, a POSITA
23 would have had a reasonable expectation of success in achieving Lundahl's
24 uniformity when moving the LEDs. And he says this for three reasons. The
25 first of which he says, Lundahl teaches the light source distribution pattern
26 that's necessary for uniformity. And a POSITA would know how to

1 incorporate LEDs to do that as well.

2 And if we go to Slide 17, it's important to note here, because it is
3 disputed, that Lundahl does in fact provide a disclosure that states that the
4 light source spacing is key to providing the desired uniformity. I got it up on
5 the screen here; it's really the center callout there. Larsen talks about the
6 number of tubes used and the spacing between them being chosen to achieve
7 the desired uniformity.

8 But perhaps more importantly than that, if we go to Slide 18,
9 Lundahl also explains why that spacing, why the spacing and greater
10 intensity of light at top and bottom is so important. If we look at the bottom
11 callout here, he says it's important because it's necessary to compensate for
12 the fact that the output from a flat plane emitting light source drops near the
13 edges. So Lundahl teaches a POSITA, one, how to achieve uniformity, and
14 two, why it's important and why one would want to achieve that.

15 So if we go to Slide 19, Dr. Grove explains that a POSITA then
16 would have applied the teachings of Lundahl, the teachings that you should
17 have a greater intensity of light at the top and bottom, and use that in
18 combination with Larsen's five-panel device to group the lighting to have a
19 greater intensity at the top and bottom, which is the very factor that Lundahl
20 discloses was used, the spacing of light to achieve uniformity. And Dr.
21 Grove, this is an illustration from his declaration that he actually put
22 forward.

23 Now, the second reason Dr. Grove says there would be a
24 reasonable expectation of success is that the conversion from fluorescents to
25 LEDs was common knowledge and routine practice by 2015. He explains
26 this in his declaration. Dr. Jokerst admitted during her deposition that a

1 POSITA would know how to set up LED electronics prior to 2015. She says
2 that on page 40, lines 12 to 42 and 3.

3 And if we go to Slide 25, the '028 Patent itself confirms that this is
4 the case. And why do I say that? So the '028 Patent has disclosures about it
5 achieving uniformity. You're going to see Patent Owner put a Figure 8,
6 which is, it's actually tasked to demonstrate that it achieves uniformity that
7 we have here. But here's the key thing about it. What the '028 Patent
8 doesn't do, it doesn't provide any details on the dimensions for arranging
9 LEDs, how close or far apart they should be to achieve the claimed
10 uniformity. The only thing it actually does, it incorporates by reference the
11 Lundahl reference.

12 JUDGE WEATHERLY: And why? What's the significance of
13 that?

14 MR. LANDMON: Yeah, thank you. So we need to assume that
15 the claims of the '028 Patent are enabled to treat uniformity. They don't
16 disclose -- the '028 Patent doesn't disclose on its face the distances between
17 LEDs or even the arrangement of LEDs.

18 JUDGE WEATHERLY: And so, I'm guessing your argument is
19 that it is enabled, even though it doesn't say anything, because everybody
20 knows about that issue.

21 MR. LANDMON: Precisely, Your Honor.

22 JUDGE WEATHERLY: Okay.

23 MR. LANDMON: And they cite Lundahl. They actually
24 incorporate Lundahl by reference. And Lundahl, we know, has the teaching.

25 JUDGE WEATHERLY: In connection with fluorescent tubes.

26 MR. LANDMON: Correct. But it has the teaching about the

1 spacing of a light.

2 JUDGE WEATHERLY: Yeah.

3 MR. LANDMON: The other last interesting thing about the '028
4 Patent, while it claims uniformity without talking about spacing between
5 LEDs, it also says that you can achieve this uniformity using fluorescence.
6 But again, it doesn't provide any details about the spacing between LEDs or
7 the fluorescence. So again, the '028 Patent is assuming and enabled.

8 JUDGE WEATHERLY: Which claims, if any, require LEDs as
9 the light source? Are there any dependent claims that do that? My
10 understanding is none of the independent claims require LEDs, correct?

11 MR. LANDMON: Yeah. No, that's correct, Your Honor.

12 JUDGE WEATHERLY: So do any of the dependent claims? I
13 apologize for not knowing this answer off the top of my head.

14 MR. LANDMON: I mean, not the ones we're challenging.

15 JUDGE WEATHERLY: Okay. Are there -- I'm curious. Well, I
16 can figure out whether there are any unchallenged claims that do.

17 MR. LANDMON: And one of the terms -- if we can turn to Slide
18 21, there's a third reason Dr. Grove puts forth for a reasonable expectation of
19 success in achieving uniform illumination. And that's that a POSITA would
20 reasonably expect that uniformity would only be improved by switching
21 from fluorescence to LEDs. And we know this because Lundahl discloses
22 the problems with uniformity in fluorescence. And we've got it on the
23 screen here, Lundahl talking about the problems with fluorescence in
24 achieving uniformity. So if you remove these inconsistency issues with
25 fluorescence, Dr. Grove explains it would have been reasonable to expect a
26 greater uniformity with LEDs.

1 Now, I do want to address on uniformity just a couple of Sun's
2 arguments. If we turn to Slide 22. So, Sun has two primary arguments
3 against uniformity. First, it says that using LEDs would create gaps in
4 illumination, and then second, that Lundahl required a variety of these
5 different things in the device to lead to uniformity. But let's focus on the
6 first one, the LEDs and the gaps.

7 So if you turn to Slide 23, one thing to keep in mind here first,
8 when Patent Owner talks about gaps, and it talks about gaps between LEDs,
9 it talks about gaps between panels, Patent Owner is focused on the surface of
10 the light device. They are focused on the emitter, but the claims are focused
11 on the treatment surface, so uniformity along the treatment surface. But
12 Patent Owner goes further, and we see this on the top left here. Dr. Jokerst
13 makes an argument that LEDs basically have narrow divergence angles, and
14 we see she draws here the LEDs narrowly shining down light on a treatment
15 surface, and then she obviously, she's showing gaps.

16 But here's the problem with it, that's contrary to the evidence. If
17 you look to the right, there's an article, it's Exhibit 2013.

18 JUDGE WEATHERLY: So I have a problem with actually both
19 the experts' characterization of these LEDs. I mean, none of them -- both of
20 them seem simplistic in the sense, unless it's sort of a stylized kind of
21 representation that includes some sort of threshold for intensity. I mean, my
22 understanding of LEDs is that they do emit more light perpendicular to their
23 surface, more energy perpendicular to their surface than they do to an
24 extremely oblique angle, but they illuminate a 180-degree field.

25 So does the declaration testimony or any of the cross-examination
26 testimony -- in other words, I understand LED light emission to be more like

1 what's shown on the right-hand side of your slide here --

2 MR. LANDMON: Correct.

3 JUDGE WEATHERLY: -- where it's a kind of a smooth function
4 of intensity with a hotspot in the center. Does that matter? And are both
5 experts wrong in this sort of simplistic kind of cartoonish depiction, or is
6 that even important?

7 MR. LANDMON: So I guess I'd say I think it's important.

8 JUDGE WEATHERLY: And thank you for not objecting to my
9 compound question.

10 MR. LANDMON: Yeah, no, I think it's important. I think
11 obviously they're just representations. I think you were totally correct that
12 the Lambertian distribution shown on the right in Exhibit 2013 is what
13 happens with LEDs.

14 JUDGE WEATHERLY: But even that's a characterization, a kind
15 of a schematic characterization, right?

16 MR. LANDMON: Yeah. So what Dr. Grove testified to when
17 asked about this in deposition, he did testify to the fact that, as you stated,
18 there would be stronger energy emitted directly below the LED if it's shining
19 down or directly out, as you described. But that a POSITA would be able to
20 calculate all this, that a POSITA would know exactly -- I mean, two things.
21 A POSITA would know that his drawing is at least more accurate in
22 showing that there is a distribution of light and then its overlap between the
23 LEDs. But then a POSITA would be able to calculate to find, calculate to --

24 JUDGE WEATHERLY: Kind of a map of intensity, essentially.

25 MR. LANDMON: Yeah, and put the LEDs in the right space to
26 make sure that there was uniformity. You know, what he says is there's a

1 key. You need to know the distance to the treatment surface, and we know
2 from one to all that's 2 to 4 inches. And once you know that, you then need
3 to look at, you know, the LEDs. And he says, it'd be within the person of
4 ordinary skill in the art to adjust the spacing between the individual rows and
5 within the rows to provide that uniformity.

6 JUDGE WEATHERLY: Don't the prior art and the patent at issue
7 both -- they virtually overlap in the way that they discuss this issue of
8 uniformity, don't they? I mean, there at least is some overlap.

9 MR. LANDMON: In terms of the percentage --

10 JUDGE WEATHERLY: Right.

11 MR. LANDMON: Yeah, so Lundahl discloses that the goal was
12 60 percent. Lundahl discloses that due to his spacing, he achieved 70
13 percent in the patent here.

14 JUDGE WEATHERLY: And the patent at issue also says that 60
15 percent is the goal and that more is better.

16 MR. LANDMON: Correct, yes.

17 JUDGE WEATHERLY: Okay.

18 MR. LANDMON: Yeah. And the prior art, certainly in Lundahl,
19 would have motivated and directed a POSITA to achieve uniformity.

20 JUDGE WEATHERLY: Of at least 60 percent.

21 MR. LANDMON: Yes. So I briefly already mentioned the
22 fluorescent component argument that Patent Owner is making here. I don't
23 need to really belabor that. I do want to just quickly address. So they've got
24 four factors, they say, that Lundahl is using. They started with the U-shaped
25 fluorescent bulbs, as they say, being critical to achieve uniformity.

26 Obviously, and we can see on Slide 27, it's obvious to everyone, I think, that

1 the Larsen device can be shaped into a U. Certainly Dr. Jokerst doesn't
2 dispute that.

3 JUDGE WEATHERLY: What's the best text in Larsen to support
4 that contention?

5 MR. LANDMON: So as far as a line and column I can point you
6 to, Larsen does talk about how it is adjustable. And no one frankly is --

7 JUDGE WEATHERLY: Well, except that I think the language
8 that you focus on for adjustability seems to be talking about a different kind
9 of adjustability, like an adjustability in the driver circuit to control the light
10 output of the LEDs, not an adjustability like a physical configuration sort of
11 adjustability. Am I misunderstanding?

12 MR. LANDMON: Yeah. So there's two issues. One is there's an
13 issue on individually configurable that Ms. Gurule actually will be
14 addressing on the adjustability of, like you said, the configurability.

15 JUDGE WEATHERLY: How hard am I driving the LED.

16 MR. LANDMON: Correct.

17 JUDGE WEATHERLY: But then there's also this adjustability or
18 configurability about how do I physically position the panels.

19 MR. LANDMON: Yes.

20 JUDGE WEATHERLY: And I didn't see anything in Larsen that
21 talked about that specifically.

22 MR. LANDMON: Larsen does talk about the adjustability of its
23 panels. And I don't think anybody --

24 JUDGE WEATHERLY: Physically, the physical adjustability.

25 MR. LANDMON: Yeah, because it talks about being able to use it
26 for both small and large surfaces.

1 JUDGE WEATHERLY: Physical is the wrong word. The
2 positional adjustability is what I really mean to be saying.

3 MR. LANDMON: Yeah. And --

4 JUDGE WEATHERLY: The spatial arrangement of the panels.

5 MR. LANDMON: Right.

6 JUDGE WEATHERLY: Okay.

7 MR. LANDMON: And it talks about the hinges connecting the
8 panels. The hinges would allow the movement --

9 JUDGE WEATHERLY: Not very much.

10 MR. LANDMON: -- to run. And I'll get to that in a bit, but it does
11 talk about the hinges connecting the panels and the movability of the panels.
12 So why don't I turn to the higher intensity limitation? We want to turn over
13 to Slide 36. This has the limitation that a higher intensity of light is emitted
14 proximate the second edges compared to the intensity not proximate the
15 second edges.

16 We've already covered some of this ground. But if we go to Slide
17 37, Lundahl teaches that uniformity is important for PDT. And that varying
18 the lateral spacing, as I mentioned before, can improve that uniformity. And
19 I just wanted to walk through in the next few slides.

20 JUDGE WEATHERLY: When you say lateral spacing, do you
21 mean the spacing up and down as your altered Figure 2 shows?

22 MR. LANDMON: The spacing -- exactly, the spacing between the
23 light tubes --

24 JUDGE WEATHERLY: Okay. I know that Figure 2, as it appears
25 in the prior art, it would be correct to talk about that spacing as lateral in
26 terms of side to side. But that figure, as I understand it, is a rotated

1 representation of the light panel, correct?

2 MR. LANDMON: So, it's --

3 JUDGE WEATHERLY: That's why you make that adjustment in
4 your modified version on this slide.

5 MR. LANDMON: So it's rotated to show you what it would look
6 like when a patient is --

7 JUDGE WEATHERLY: Is sitting in front of it, yeah.

8 MR. LANDMON: Correct.

9 JUDGE WEATHERLY: So lateral doesn't seem to apply
10 anymore. I'm a big stickler for frames of reference, because oftentimes
11 parties talk past each other because they're talking from a different frame of
12 reference.

13 MR. LANDMON: Yeah. So I don't think we're talking past each
14 other. I might be using the wrong word. I think what the key is here is that
15 Lundahl discloses that there should be a higher intensity of light near the top
16 and bottom, near a patient's forehead and chin than there is in other places --

17 JUDGE WEATHERLY: Yeah.

18 MR. LANDMON: -- and that that's how he achieves -- well, that's
19 how he achieves uniformity. But this is talking about the approximate light
20 limitation, and that's how Lundahl discloses it. And if we actually go to the
21 next slide, we have a couple of slides to kind of walk through how this
22 would physically happen. Larsen on the left, Lundahl on the right.
23 Obviously, we've annotated these to show how a POSITA would go from
24 the Lundahl fixed U-shape into five panels. If we go to the next slide. So
25 this is now, as you mentioned, kind of rotating it. This is from the patient's
26 view when the patient's head is being treated.

1 At the top, we see the -- top and bottom, we see the lights, we see
2 the higher intensity of lights. And if we go to the next slide.

3 JUDGE WEATHERLY: I don't know if any of you have had the
4 pleasure of having one of these treatments, but it's quite an experience, I'll
5 tell you.

6 MR. LANDMON: Thankfully, I have not.

7 JUDGE WEATHERLY: Yes, you are thankful.

8 MR. LANDMON: Yes.

9 JUDGE WEATHERLY: Yes.

10 MR. LANDMON: And here, we're showing how there's a higher
11 intensity of light along the short edges once you divide that up. And if we
12 go to Slide 41, Dr. Grove explains this. So when you combine the teachings
13 of Lundahl and Larsen, utilize the light source distribution of Lundahl with
14 the LED panels in Larsen, it results in a higher intensity of light along the
15 second shorter edges, along the top and the bottom. Dr. Grove explains this.
16 The Board rightly agreed with this interpretation during the institution
17 decision.

18 And Dr. Jokerst also made some key admissions here. If we turn
19 to Slide 42, she admitted that the Lundahl device would have a higher
20 intensity of light near the forehead and the chin of a patient. And if we go to
21 Slide 43, she also admitted that if a POSITA divided up the U-shape of
22 Lundahl on the five panels, the short edges would be on the top and bottom
23 where the patient's forehead and chin is.

24 Now, one of the arguments Sun makes, and if we can turn to Slide
25 44. Sun argues that Lundahl's light sources have low output areas along the
26 edges. And therefore, they argue that Lundahl doesn't necessarily meet the

1 higher intensity near the edges where those areas are. What they're talking
2 about here are what's known as Faraday dark spaces. Kind of a lot of people
3 realize when you look at the fluorescent tubes, which you can even see
4 actually above my head, near the edges where the cathodes are, you can see
5 that they're not as bright. There's a dark area there.

6 The problem with this is LEDs don't have those dark spaces. If
7 you created a panel or multiple panels with LEDs across them, they're not
8 going to have those dark spaces at the edge. So they would continue to have
9 the higher intensity of light near the edges as well. And Patent Owner
10 grossly exaggerates those dark spaces of Lundahl.

11 If we turn to Slide 45, we have on the left, we have Patent Owner's
12 depiction there, where you see Patent Owner draws those red oval shapes
13 that, you know, come along the ears and come in front of the ears of a
14 patient. Well, problem with that is the disclosure in Lundahl to the right
15 says that the dark areas are effectively behind the patient's ears. And that's
16 obviously different than what's drawn and depicted there.

17 JUDGE WEATHERLY: And you just make the tubes long
18 enough.

19 MR. LANDMON: I'm sorry?

20 JUDGE WEATHERLY: You just make the tubes long enough so
21 the dark area isn't next to the patient.

22 MR. LANDMON: That is also something a POSITA would have
23 figured out. The problem also with their argument, if you go to the next
24 slide, is it's contrary to the testimony of their own expert, Dr. Heather
25 Roberts. She says that she uses Lundahl's fixed-shape device to treat chests
26 and backs of patients by turning them sideways within the device. If you

1 turn them sideways, essentially their chest or back would be right where
2 those ovals are drawn.

3 So if she's treating patients that way, obviously they have to keep
4 producing the intensity of light that's needed. I want to address one other of
5 Patent Owner's arguments --

6 JUDGE WEATHERLY: I don't love that argument, by the way.
7 And I don't know if you even need it. But I like to try to give people who
8 come in front of us some window into how the things you say strikes us.

9 MR. LANDMON: Yes.

10 JUDGE WEATHERLY: That strikes me as maybe not even
11 relevant. But are you trying to discredit her testimony essentially overall by
12 saying something like that?

13 MR. LANDMON: I guess I'm trying to say one of the experts is
14 right and one of the experts is wrong. If Dr. Roberts actually treats patients
15 that way, then there can't be these large, dark areas along that straight end of
16 the view.

17 JUDGE WEATHERLY: Except you just said that there are and
18 told me to look at the ceiling and notice them.

19 MR. LANDMON: No, no. So I didn't say they were large. I
20 mean, I --

21 JUDGE WEATHERLY: This is a boondoggle. Mostly, I'm
22 questioning you because -- to give you a sense of --

23 MR. LANDMON: Yeah, I appreciate the question --

24 JUDGE WEATHERLY: -- when to take a position on something
25 that matters and when to leave something that doesn't alone.

26 MR. LANDMON: I will leave that alone and move. To get to

1 your point, I wasn't saying there were large areas in the ceiling. They're
2 actually really small --

3 JUDGE WEATHERLY: No, I see that.

4 MR. LANDMON: -- which is my point. If we turn to Slide 47, so
5 Patent Owner also argues that Larsen's scan engine would move the light
6 sources as a way to place higher intensity of light, not along the short edges,
7 but along the long edges. But here's the problem with this. This is
8 completely made up by Patent Owner and Dr. Jokerst. If you look to the left
9 there, the arrows pointing up and down in the whole schematic in the
10 bottom, those were added by Dr. Jokerst and Patent Owner here. Larsen
11 doesn't disclose that. This is simply a red herring argument.

12 Dr. Jokerst actually admits, when I asked her during her
13 deposition, that there is nothing in Larsen that says that the scan engine
14 moves the light sources up and down or whether it moves them side to side.
15 She admits there's nothing about the pattern of movement of the scan engine.
16 There's nothing about the range of movement, the rate of movement, or even
17 the time points. So again, this is just something that Patent Owner has come
18 up with to try and undermine our arguments about the higher intensity of
19 light, and it should be rejected by this Board.

20 So turning to the hinges limitation, if we could turn to Slide 52.
21 There are two basically types of hinges limitations. The first one is five
22 panels connected by a hinge structure on inner side surfaces of adjacent
23 panels. The second one just says, five panels connected by hinge structures.
24 That's Claim 16. I note that because Patent Owner does not seem to contest
25 it. The prior art in Larsen discloses the hinge structure limitation of Claim
26 16, that there's five panels connected by hinge structures.

1 But turning more broadly to the hinges limitation and the broader
2 one, if we want to look at that, I guess the narrow one actually. But if we
3 want to look to Slide 53, Larsen here teaches hinges respectively connecting
4 one edge with the other. We see that in the top there. Frankly, this
5 disclosure is clear on its face that the hinges are located on inner side
6 surfaces between the panels, given that one edge is connected with the other.
7 What you don't say is Larsen saying --

8 JUDGE WEATHERLY: Wait, wait. Say that again.

9 MR. LANDMON: Yeah. This disclosure, we believe is
10 demonstrating, is a disclosure of the hinges being on inner side surface
11 because it says the hinges are respectively connecting one edge with the
12 other. So the hinges are connecting one edge with the other. It does not say
13 hinges on the bottom of the panels.

14 JUDGE WEATHERLY: That's unpacking a lot out of those. How
15 many words is that, eight? Yeah, so I agree with you.

16 MR. LANDMON: Okay. I do believe it's a straightforward
17 reading, but maybe we can get to a couple other issues here. You know,
18 Patent Owner looks over to the figure of Larsen, as we know, and Patent
19 Owner points to number 10 as being in the bottom of the figures. But here's
20 what's key here, and no one really disputes: There's a typo in Larsen. We
21 see the top callout. It says, hinges 10, respectively connecting one edge with
22 the other. On the bottom, it says Figure 1 has the invented device 10.

23 So everyone recognizes that Larsen uses 10 twice. It's more than
24 twice, but he uses it with respect to two different things. There needs to be a
25 -- so it's recognized there's a typo. And really the question is, how would a
26 POSITA interpret that typo, and what would a POSITA take from that? Dr.

1 Grove says that a POSITA would reasonably understand Larsen as
2 disclosing hinges between the panels, as indicated by number 20 here. And
3 if we look on slide --

4 JUDGE WEATHERLY: Is that what 20 indicates, hinges between
5 the panels?

6 MR. LANDMON: That's what Dr. Grove believes, and that's what
7 the patent examiner --

8 JUDGE WEATHERLY: By between, help me understand what
9 you mean by between. I mean, that's a kind of very, very rough drawing,
10 and I think Larsen, frankly, isn't paying very much attention to hinges,
11 because hinges are well-known. A lot of different kinds of hinges are well-
12 known. But that almost looks like panels that overlap each other on the top
13 and bottom edges of that assembly with, like, a pin in them. I'm guessing,
14 just like all of the experts are guessing, about what that is. Is it your position
15 that Larsen clearly or indisputably describes hinges that are actually
16 physically located on the, like, the opposing edges of those panels? Like in
17 the gap between the panels?

18 MR. LANDMON: So, to your broader point, it's obvious that
19 there are only a few places to put hinges. And Dr. Grove takes the position,
20 when looking at this, that that's how a POSITA would understand it. The
21 POSITA would understand that that's what 20 refers to. Also, the patent
22 examiner of the '028 Patent took that same --

23 JUDGE WEATHERLY: I mean, I know the claim requires that
24 the hinges be on the inner side surfaces, which is these surfaces that are
25 between the panels. I don't think that's what Larsen shows directly.

26 MR. LANDMON: Sure.

1 JUDGE WEATHERLY: Whether a person of skill looking at it
2 would say, yeah, hinges, hinges, hinges, hinges. I think you sort of say that
3 in your reply, don't you?

4 MR. LANDMON: Yeah. I mean, actually we say that in a number
5 of places, even in our petition. I mean, I do think it's obvious there are a few
6 places you can put the hinges on.

7 JUDGE WEATHERLY: And different kinds of hinges that you
8 can use.

9 MR. LANDMON: Yeah. You can put it between the panels, you
10 can put it on the top and bottom, you can put them in the back. You know,
11 picking one of three is not inventive. I think courts have been very clear
12 about that when there are only a few options. But I also think the patent
13 examiner here, if you go to Slide 54 --

14 JUDGE WEATHERLY: But other than the location physically of
15 the hinges, the claim doesn't really say anything at all about what kind of
16 hinges. None of the claims say anything at all about what kind of hinges,
17 correct?

18 MR. LANDMON: That's right.

19 JUDGE WEATHERLY: Just that they be on the inner side
20 surfaces of panels.

21 MR. LANDMON: That's correct, Your Honor.

22 JUDGE WEATHERLY: Okay.

23 MR. LANDMON: And the patent examiner here in a related
24 application, same disclosures, came to the conclusion that there was a typo.
25 That Larsen does disclose hinges on inner side surfaces and that Larsen
26 referred them as 20. So I think it's not just Dr. Grove as a POSITA. It's not

1 just us as the Petitioners. It was also the patent examiner.

2 Obviously, Dr. Grove explains that would be the most logical
3 location as well, if you go to Slide 55. You know, as you noted, for
4 generations, that's where people have put hinges. So, you know, he says it'd
5 be the most obvious place. And as I mentioned, just picking one of three
6 certainly is not inventive stuff. It's not inventive.

7 JUDGE HOFFMAN: What do you say in response to Patent
8 Owner's expert who said that a POSITA would be discouraged from putting
9 them on inner side surfaces?

10 MR. LANDMON: Yeah. So, you know, us and Dr. Grove
11 disagree with that. You know, one, it's the most logical place. Two, the
12 basis they say that is because of gaps between panels. But as you noted, the
13 patent doesn't say anything about the type of hinge you use. So you can use
14 the most narrow hinge. Obviously, hinges --

15 JUDGE WEATHERLY: Or whether gaps are excluded.

16 MR. LANDMON: Yeah. Well, gaps certainly aren't excluded as
17 long as you continue to have the uniformity of light and the continuous
18 illumination. So, Dr. Grove takes the position, we take the position that it
19 would be within the scale of the POSITA to both, you know, choose the
20 right hinge, also choose the right configuration of the edges of your panels.
21 I mean, there's nothing here either about what the edges of panels need to
22 look like. So can you embed a hinge within a panel to narrow the gap to
23 continue to do uniformity and continuous illumination? That's our point.
24 That's what Dr. Grove says.

25 JUDGE HOFFMAN: Thank you.

26 JUDGE WEATHERLY: Is there anything important about the

1 way the Claims actually -- the words that the Claims actually use describing
2 these hinges as hinged structures?

3 MR. LANDMON: I don't believe so, Your Honor. Just that it --

4 JUDGE WEATHERLY: And I apologize for some of the
5 questions I'm asking. All three of us are actually somewhat new to the case.
6 You've probably recognized that the original panel members aren't on the
7 case any longer.

8 MR. LANDMON: Yeah.

9 JUDGE WEATHERLY: So I apologize for asking. I'm not afraid
10 of appearing to be wrong.

11 MR. LANDMON: There's been no dispute between the parties of
12 giving any special meaning to hinge structures.

13 JUDGE WEATHERLY: Okay, all right. Everybody's been
14 arguing it as if it just says hinges.

15 MR. LANDMON: Correct, Your Honor.

16 JUDGE WEATHERLY: Okay. Patent Owner will correct you if
17 necessary.

18 MR. LANDMON: Yes. So just very briefly in my next few
19 minutes, I just want to hit the last contested issue that I'm going to deal with
20 and then Ms. Gurule will come up to deal with individually configurable and
21 secondary considerations. That's the continuous illumination claim term.
22 And if we can turn to Slide 65, we see that the '028 Patent recites, five
23 panels connected by hinged structures to allow continuous illumination
24 across the five panels.

25 And if we turn to Slide 66, Larsen discloses five panels connected
26 by hinges and Patent Owner doesn't appear to dispute this. Patent Owner's

1 dispute is simply whether Larsen's hinges allow continuous illumination
2 across the five panels. But Larsen discloses this, because what Larsen says
3 is it's adjustable. It's adjustable to treat different areas, including large areas
4 such as the human back. And it discloses that it has even and gap-free
5 radiation. So Larsen discloses that even when its panels are extended to
6 treat a back or, you know, could be a chest, it's a back here, that there is
7 continuous illumination with its device.

8 Now, Patent Owner tries to rely, if we go to Slide 67, on Dr.
9 Bretschneider's declaration. As you may know, Dr. Bretschneider submitted
10 a declaration in a different IPR proceeding. They quote him as saying there
11 are lower irradiance regions at the junction of two of Larsen's panels. We've
12 got their statement up there. But here's the problem, they take that out of
13 context. What Dr. Bretschneider fully says, if you can see his full quote
14 there, is that Larsen's applicators are designed to provide an even and gap-
15 free radiation. So Dr. Bretschneider doesn't undermine the concept that
16 Larsen teaches the continuous illumination.

17 And as I mentioned before, certainly a POSITA is aware of
18 divergence angles, the Lambertian distribution of LEDs, and a POSITA
19 would have been able to make those changes and position the LEDs as I
20 talked about before.

21 JUDGE HOFFMAN: Question.

22 MR. LANDMON: Yes.

23 JUDGE HOFFMAN: Patent Owner says that a POSITA would
24 understand that those gaps would provide areas, regions of lower irradiance,
25 and that is why there's no continuous illumination. So help me understand,
26 what exactly is continuous illumination? Would lower irradiance regions

1 not be included in illumination -- continuous illumination?

2 MR. LANDMON: It would still be included within continuous
3 illumination. It is not the same, at least I don't believe the party has taken
4 that position. We certainly haven't. It is not the same as uniform
5 illumination. It just means it needs to be continuously illuminated. So even
6 if there's an area of lower radiance, as long as that area is still irradiated by
7 the light, it's our position that that claim term is met by the prior art.

8 JUDGE HOFFMAN: Thank you.

9 MR. LANDMON: So unless you have any other questions about
10 those terms, I will let Ms. Gurule address the last term in secondary
11 considerations.

12 MS. GURULE: So good afternoon, Your Honors. It's Kendall
13 Gurule for Petitioner. I'll plan to take us through two issues today. First,
14 what we've been calling the individually configurable claim limitation,
15 followed by a brief mention of secondary considerations as time permits.
16 Turning the first of those issues into Slide 59 here, Independent Claims 16
17 and 21 in the '028 Patent recite, wherein the five panels are individually
18 configurable to control illumination from each of the five panels.

19 Now, Larsen teaches this limitation and has three key disclosures
20 on this issue. So if we move over to Slide 60 here, we can see the first of
21 those where Larsen discloses that it has a control mechanism 16 connected
22 to each of its panels, such that the invented device is adjustable within a
23 relatively large range with reference to duration, amplitude, and frequency
24 of certain current to its light sources.

25 And flipping down to Slide 63, we can see the second of Larsen's
26 key disclosures on this issue, where Larsen talks about doing feedback

1 control of the light emission from its device based on input from sensors to
2 those on each of the five panels. So taking these two things in combination,
3 first, that radiation is adjustable by a controller, and second, that the device
4 is doing feedback control of radiation using sensors placed on individual
5 panels, these would normally suggest to a POSITA that what Larsen's
6 teaching here is control of light emission at a panel-by-panel level, or at an
7 individual panel level.

8 Dr. Groves opined on this in paragraphs 229-231 of his initial
9 declaration in this case, Exhibit 1015. Now, Patent Owner here argues that
10 Larsen's disclosure can only be interpreted in a very limited fashion, and that
11 is specifically that Larsen's disclosure can only be interpreted as disclosing
12 one single controller that is only operable to do one thing, and that is adjust
13 the entire light output of the device at one time. So essentially, one
14 controller that's operating like an on-off switch, switching the whole device
15 on or the whole device off.

16 But the issue here is that both of those assumptions are incorrect.
17 Initially, although Larsen does refer to its controller in the singular, as we all
18 know here in the patent, part of the singular form encompasses both the
19 singular meaning and the plural meaning, so Larsen's disclosure is
20 necessarily just limited to the one controller. However, even if Larsen did
21 only disclose one controller, a single controller could do more than just a
22 simple on-off switch can.

23 JUDGE WEATHERLY: When you say controller, and since you
24 brought up the singular, Larsen talks about control mechanism 16. Is that
25 the singular, quote-unquote singular, that you're referring to?

26 MS. GURULE: Yes, Larsen talks about a controller or a control

1 mechanism and refers to it as element number 16.

2 JUDGE WEATHERLY: And then controls later. Okay.

3 MS. GURULE: Mm-hm. And so turning over to Slide 61, there's
4 an excerpt from an article here, a 2008 article by Bourget that Dr. Jokerst
5 actually cited, which states what was common knowledge for a POSITA at
6 the time, and that's that LED control systems allowed a brightness of
7 individual LEDs to be set. So that illustrates that a POSITA would have
8 understood that a controller, an LED controller, can do a more granular level
9 of control than flipping an entire device on or off.

10 And while that background information is helpful, if we want some
11 more clarity as to what Larsen's controller can do, we actually need to look
12 within Larsen itself. As you can see up on the slide here, Larsen's claim five
13 is clear that the light sources are individually selected to switch on or off.
14 So via that disclosure, Larsen teaches illuminating or darkening individual
15 light sources on LED panels, which would necessarily change or configure
16 the light intensity emitted from that panel. Now, similarly here --

17 JUDGE WEATHERLY: So the Claim, in your view, doesn't
18 require any sort of granularity, any particular granularity in the adjustability
19 or configurability of illumination? Just on and off, turning individual LEDs
20 on and off is configurable enough to meet the claim limitation?

21 MS. GURULE: So the claim limitation of the '028 Patent, I think,
22 refers to illumination from panels.

23 JUDGE WEATHERLY: Yes.

24 MS. GURULE: And so if you have panels with multiple LEDs
25 and multiple light sources on the panels.

26 JUDGE WEATHERLY: Like Larsen does have.

1 MS. GURULE: Like Larsen does have.

2 JUDGE WEATHERLY: Right.

3 MS. GURULE: And you're able to turn off individual light
4 sources among that multi-LED or multi-light source array within the panel,
5 that would alter the illumination from that panel.

6 JUDGE WEATHERLY: It would alter it.

7 MS. GURULE: Yeah.

8 JUDGE WEATHERLY: And my question is whether any type of
9 alteration is sufficient to meet the limitation. And I think your argument is
10 that, yes, that's --

11 MS. GURULE: Our understanding is that, yes, I don't think there's
12 been any argument by either of the parties that some particular level of
13 alteration --

14 JUDGE WEATHERLY: Well, separate and apart from whether
15 there's been an argument, I'm asking you, what does the claim limitation
16 mean?

17 MS. GURULE: The claim limitation doesn't require any particular
18 level of alteration.

19 JUDGE WEATHERLY: So just turning one LED on a panel off is
20 enough change in illumination to constitute a configurable control of the
21 illumination?

22 MS. GURULE: It should be because the claim doesn't require
23 anything more narrow than just --

24 JUDGE WEATHERLY: Should be?

25 MS. GURULE: It is, because the claim limitation doesn't require
26 anything more narrow or more granular than that.

1 JUDGE WEATHERLY: Okay, that's what I'm asking. Thank
2 you.

3 JUDGE HOFFMAN: Claim 5, which you mentioned, is talking
4 about the light sources being individually selected, switching on or off, what
5 is your response to Patent Owner's argument that that is in reference to
6 activating either the semiconductor diodes or the laser diodes across all the
7 panels, not individually?

8 MS. GURULE: Sure. So there's sort of two parts to Patent
9 Owner's argument there. The first part of it is with reference to Claim 1. As
10 you seem to be aware, Claim 5 depends on Claim 1. And so Patent Owner
11 has argued that because Claim 1 recites the light sources consist of at least
12 one semiconductor diode and or at least one laser diode, then Claim 5 could
13 only refer to switching between the two. However, if you look at the Claim
14 1 closely, I don't think that's supported.

15 JUDGE WEATHERLY: I agree.

16 MS. GURULE: Yeah. The Claim 1 recites and or, which means
17 that Claim 1 would include essentially three types of device.

18 JUDGE WEATHERLY: Right. Both, one or the other.

19 MS. GURULE: Right. One or the other. And if only one or the
20 other light source is included, then it would make sense that Claim 5 would
21 mean switching between the two light source types. I think that's further
22 supported by the fact that Claim 5 doesn't further limit that and or language
23 in Claim 1. So Claim 5 isn't saying wherein the light sources consist of the
24 semiconductor diode and the laser diode.

25 JUDGE WEATHERLY: Right. Or wherein the semiconductor
26 diode or the laser diode can be individually selected. Something like that.

1 MS. GURULE: Right.

2 JUDGE WEATHERLY: Right, I agree with you.

3 MS. GURULE: Yeah. And so, just to fully address the previous
4 question, Patent Owner's argument also encompassed paragraph 74 of
5 Larsen. Paragraph 74 of Larsen discusses a switch select system and the
6 language there is very similar. It says a switch select system for operating
7 different types of semiconductor diodes 17 and or with laser diodes.

8 And so, two points with respect to that. First of all, there's nothing
9 in paragraph 74 that limits the switch select system to only switching
10 between the two light source types for a similar reason that that and or
11 language means the switch select system could be used and presumably
12 would be operable in a device just for the semiconductor diodes. And then
13 just moving to Claim 5 itself again, there's nothing in Claim 5 that limits
14 Claim 5 to only the disclosure in paragraph 74. For instance, Claim 5
15 doesn't recite a switch select system, so there's nothing in Claim 5 that would
16 mean that it's completely limited to the disclosure in paragraph 74.

17 So I think our conclusion here is that basically the easiest reading
18 and what makes the most sense is just simply read Claim 5 to mean what it
19 says, which is that the light sources are individually selected and switch on
20 and off, which as we discussed earlier, would allow for a level of control
21 down to the individual LED, which would include panel level control, which
22 would read on the individually configurable claim limitation. Unless Your
23 Honors have any questions, I'll move over to a brief mention of secondary
24 considerations.

25 JUDGE HOFFMAN: Thank you.

26 MS. GURULE: So as Your Honors may notice, just to start out,

1 we don't have any slides on this issue. We'd initially intended to rely chiefly
2 on our briefing for this issue, and I think we'll continue to do that, but after
3 the LEAP request was approved, decided to make a brief mention here, and
4 so we'll just give a brief overview. So, as we've been discussing for all the
5 reasons in our papers and as we've discussed here, the claims of the '028
6 Patent are obvious, so they're a combination of Lundahl and Larsen.

7 Patent Owner has sort of made a superficial attempt here to argue
8 secondary considerations, but really hasn't done enough with respect to
9 nexus in particular to save it from the obviousness conclusion. As a brief
10 summary, Patent Owner's secondary considerations arguments are based on
11 alleged commercial success and industry praise of two devices, primarily the
12 RhodoLED XL, which is Petitioner's device, and more tangentially, the
13 BLU-U 4170E, which is Patent Owner's device.

14 But regardless of the device they're relying on, it's Patent Owner's
15 burden to establish nexus here, and they just haven't done enough to carry
16 that burden. To briefly mention the BLU-U 4170E, Patent Owner's entire
17 discussion of that device is limited to just a single sentence in its response.
18 In that sentence, Patent Owner asserts the BLU-U 4170E embodies the '028
19 Patent, but doesn't make any attempt to provide any analysis in support of
20 that assertion beyond that single sentence. Accordingly, Patent Owner has
21 fail to carry its burden with respect to its arguments about the device.

22 And arguments with respect to the RhodoLED XL are similar. The
23 bulk of Patent Owner's argument on nexus with respect to RhodoLED XL is,
24 in its response, is just a single paragraph. It incorporated by reference 50
25 paragraphs of expert declaration without any analysis whatsoever, which
26 isn't proper under 37 CFR 42.6(a)(3), which prohibits argumentation by

1 incorporation by reference.

2 Just to touch briefly on the remainder of Patent Owner's arguments
3 there, they rely heavily on features that were well known in the art prior to
4 the '028 Patent, for instance, uniformity and then flexibility provided by five
5 panels which, as we've discussed, although there's debate over how these
6 would be combined, there's really no debate that Lundahl disclosed
7 uniformity in 1998 and Larsen disclosed a five-panel device in 2005.

8 JUDGE WEATHERLY: I'm not sure I know why your mic is
9 cutting on and off --

10 MS. GURULE: Yeah, I'm sorry. I don't know why I did.

11 JUDGE WEATHERLY: I didn't know if you were -- it's a touch-
12 sensitive switch on the base. I don't know if you're touching it inadvertently
13 or not. (CROSSTALK) But the green light is on when it's on.

14 MS. GURULE: Okay. Thank you.

15 JUDGE WEATHERLY: Sure.

16 MS. GURULE: But in sum, for all the reasons discussed here
17 today and in Petitioner's papers, Claims 1, 2, 4-6, 16-17, and 19-21 of the
18 '028 Patent are invalid for obviousness of Lundahl in combination with
19 Larsen. And unless Your Honors have any other questions, we'll reserve the
20 remainder of our time for rebuttal.

21 JUDGE WEATHERLY: No questions from me, believe it or not.

22 JUDGE HOFFMAN: Thank you.

23 MS. GURULE: Thank you.

24 MR. HA: So, Your Honors, we were having a little bit of technical
25 difficulty in terms of getting the PowerPoint up, so we'll try to do this while
26 I continue on with our slides. Hopefully you guys have all of the

1 demonstratives in front of you.

2 JUDGE HOFFMAN: Yes, we will pull them up.

3 MR. HA: Thank you so much.

4 JUDGE HOFFMAN: Okay. Mr. Ha, how much would you like to
5 reserve for rebuttal?

6 MR. HA: So we'll reserve about 15 minutes, Your Honor.

7 JUDGE HOFFMAN: Okay. There's probably an easier way to do
8 this. You may begin your arguments when ready.

9 MR. HA: Thank you very much. Good afternoon, Your Honors.
10 Let me just jump right to Slide 3. So I want to begin by talking about the
11 two related matters that are periodically mentioned throughout the
12 presentation today. The first one is on the top right of the slide. It has to do
13 with IPR2024-874, which was an earlier IPR petition that was denied
14 institution challenging the same '028 Patent.

15 The second related matter is the 1411 ITC investigation where
16 Administrative Law Judge Moore issued his initial determination on
17 September 30, 2025, after hearing essentially the same identical arguments
18 to conclude that the '028 Patent is valid. And I know Petitioner's Counsel
19 just walked through two differences, which was Dr. Grove's discussion
20 about the divergence angles and Dr. Jokerst's discussion regarding
21 fluorescent versus LED. That all has to do with a single limitation, uniform
22 limitation. It does not have anything to do with any of the other disputed
23 issues. I want to make that clear.

24 The other argument that I think the Petitioner is making in terms of
25 their briefing paper is that the ITC applies a different standard, a clear and
26 convincing standard, whereas we're applying -- we're working under the

1 preponderance of the evidence standard. So what I'll try to do here is
2 throughout the presentation only focus on the factual determinations by the
3 ALJ regarding the disputed issues which should be persuasive evidence
4 about what these references teach and how the factual determinations should
5 come out. So with that, let me just jump to a short overview of the '028
6 Patent.

7 JUDGE WEATHERLY: When you say they should be persuasive,
8 what do you mean exactly by that?

9 MR. HA: Well, ALJ Moore heard essentially the identical
10 arguments and very similar evidence throughout the ITC proceeding as those
11 arguments that are presented here. And the factual determinations findings
12 by ALJ --

13 JUDGE WEATHERLY: So let me clarify my question. Should be
14 persuasive could mean that this panel is bound by them, like in a
15 precedential sense. Should be persuasive could mean Judge Moore should
16 have been doing a good job, and you know Judge Moore and you should
17 trust Judge Moore. Should be persuasive could mean you believe they are in
18 fact persuasive. I think Petitioner is arguing that at least in some important
19 ways Judge Moore's findings are well founded and they are arguing that in
20 the ITC currently. When you say should be persuasive, what do you mean?

21 MR. HA: So I do not mean to say that Judge Moore's findings
22 should be binding upon this panel. I also disagree with Petitioner's
23 viewpoint that Judge Moore had inaccuracies or incorrectness in his
24 decision.

25 JUDGE WEATHERLY: Okay.

26 MR. HA: What I mean to say is he looked at the same evidence,

1 the same set of arguments, he made factual determinations before arriving at
2 the final ultimate conclusion of obviousness, and your panel is presented
3 with essentially the same arguments and evidence. And our position here is
4 that it should come out the same way.

5 JUDGE WEATHERLY: Because he got it right?

6 MR. HA: Yes, Your Honor.

7 JUDGE WEATHERLY: Okay.

8 MR. HA: So with that, let me jump to Slide 4 and begin with a
9 short overview of the '028 Patent. The '028 Patent is directed to a
10 photodynamic therapy device, a PDT device, that has adjustable illuminators
11 that provides a uniform distribution of visible light to treat various skin
12 conditions. And you see a picture of that device here on Figure 4 of the '028
13 Patent here on the right.

14 And Slide 5, we also highlighted in the patent itself some of the
15 very important characteristics of the device. At the outset, the overall goal
16 of this device is to provide uniform light distribution where the measured
17 output over the entire active emitting areas within 60 percent of the
18 measured maximum. And that's highlighted on the left side of the slide.
19 Well, how do we achieve that? It's not simply by placing various different
20 LEDs in certain locations. It's about a combination of one or more of the
21 various characteristics that have been claimed in the claims themselves.

22 So let me highlight three of them. First one is, as you see here, sort
23 of in the middle of Slide 5, we've colored in brown the areas where you see
24 emission of higher intensity of light. And those regions are near the shorter
25 edges of each of those panels. Turning to Slide 6, these panels are also
26 configured with hinges on the inner side surfaces of the adjacent panels, and

1 we colored those in light blue. And one of the examples that the patent
2 gives is nested hinges. And those hinges allow the panels to reduce or
3 eliminate optical dead spaces. And that's an important characteristic that I'll
4 talk about later today.

5 And third is the fact that each of these individual panels are
6 individually configurable to provide a specific power output as needed to
7 achieve that overall uniform illumination. So it's not just simply some
8 placement of LEDs, it's the combination of one or more of these
9 characteristics that come together to give you this uniform light distribution
10 as claimed. Turning to Slide 7, and this patented device now appears in
11 Petitioner's RhodoLED XL in remarkably the same fashion.

12 JUDGE WEATHERLY: Counsel?

13 MR. HA: Yes, Your Honor?

14 JUDGE WEATHERLY: Let me ask you a question about this
15 concept of shorter edges and higher intensity. The part of the specification
16 you just went over seemed to indicate that the intensity could be controlled
17 by the current that's being delivered to the light source which is near the
18 shorter edges, probably adjacent to the shorter edges. But the claim says that
19 light sources are arranged such that a higher intensity of light is emitted
20 approximate to the second edges. Until just now, I thought that we were
21 talking about essentially kind of like a spatial density of light sources where
22 the LEDs were closer together essentially at the top and bottom of these
23 panels.

24 MR. HA: Yes. So as with everything, everything can be
25 manipulated or adjusted as needed. So let's say you're applying the same
26 amount of current to all of the LEDs at once that have the same output --

1 JUDGE WEATHERLY: I'm really trying to focus on the Claim
2 language, what does the Claim language mean. I don't need to talk about
3 like what could be done or what might be done. I'd rather focus on what is
4 claimed so that I can do a better job of trying to figure out whether the Claim
5 reads on the prior art.

6 MR. HA: So, just to make sure I understand the question, is your
7 question that the claim requires a specific placement of the LEDs, or is --

8 JUDGE WEATHERLY: Is the claim directed to the physical
9 spacing between LED sources even though the claim doesn't recite LED
10 sources? Or is it -- or is any mechanism of achieving higher intensity light
11 including sending more current to the LEDs near that?

12 MR. HA: It would be the latter, Your Honor.

13 JUDGE WEATHERLY: That's included within the scope of the
14 claim?

15 MR. HA: Yes, Your Honor. And that's included as part of the
16 example in the specification --

17 JUDGE WEATHERLY: Okay. And do the shorter edges of these
18 individual five panels, do they need to be at the top and bottom of the panels
19 as they are presented to a patient, or can they be -- in other words, it seems
20 to me that the Claims require that the panels be rectangular rather than
21 square, and that the shorter edges be at the top and bottom of the rectangle.
22 And by top and bottom, the frame of reference I'm talking about is as the
23 panel is presented to the patient, to the treatment area.

24 MR. HA: Well, I'm not -- so I agree with the first portion.

25 JUDGE WEATHERLY: But not the second part?

26 MR. HA: But the second part, I'm not sure that the claim has any

1 sort of that explicit part.

2 JUDGE WEATHERLY: About the orientation. Just that one of
3 the edges be shorter than the other?

4 MR. HA: Yes, Your Honor.

5 JUDGE WEATHERLY: So the panels do have to be rectangular.

6 MR. HA: I wouldn't say rectangular, but rectangular may -- so it
7 wouldn't be square, right? But it could be rectangular-ish, for example. It's
8 sort of a shorter edge versus a longer edge. It would not be a perfect --

9 JUDGE WEATHERLY: I think that's a rectangle, but --

10 MR. HA: Let's say oval-ish, rectangle-ish. So a rectangle with
11 rounded corners.

12 JUDGE WEATHERLY: With rounded corners?

13 MR. HA: Yeah. Would also work, right?

14 JUDGE WEATHERLY: Well, now we're arguing about where do
15 the edges begin and end.

16 MR. HA: Sure.

17 JUDGE WEATHERLY: This is my favorite and my least favorite
18 thing about what we all do here in this room.

19 MR. HA: Yes, Your Honor. Okay. So continuing on with sort of
20 the important characteristics about the device, I'm on Slide 6 again. We just
21 talked about the hinges and we also talked about the fact that each of the
22 panels are individually configurable to provide a specific power output as
23 needed to achieve uniform illumination.

24 And turning to Slide 7 now, the patented device now appears in
25 Petitioner's RhodoLED XL. And you can see the remarkable similarities
26 between the two by looking at the picture of the RhodoLED XL on the left

1 and then the inset, we have Figure 4 of the '028 panel. And how do we
2 know they're similar? Well, they placed hinges right on the inner side
3 surfaces and we highlighted that using blue arrows. They placed more LEDs
4 near the shorter edges --

5 JUDGE WEATHERLY: Wait a minute. I'm not going to let you
6 get away with that. You can't complain about Larsen's description of hinges
7 and then tell me that just because you put blue arrows on this cartoon that
8 that means that the hinges are on the inner side surfaces of those panels. I'm
9 not going to let you do that.

10 MR. HA: Sure. I can give you additional cites and we'll get these
11 cites ready. These are, for example, at Exhibit 2050. I'll give you the cites
12 where we specifically pointed out what the hinge structure looks like in
13 RhodoLED XL.

14 JUDGE WEATHERLY: Okay. Well, there's a difference between
15 what the hinge structure looks like in an accused device and what the Claims
16 require and what the patent describes. So I'd rather that you focus on the
17 latter. And I don't really care that much unless you're going to give me some
18 really specific reason for me to care, other than the secondary
19 considerations, maybe a copying kind of thing.

20 MR. HA: So this is just to set up the secondary considerations to
21 give some background.

22 JUDGE WEATHERLY: All right. Okay.

23 MR. HA: We do have hinges in the RhodoLED XL. And in fact
24 --

25 JUDGE WEATHERLY: And that's Petitioner's device, correct?

26 MR. HA: Petitioner's device. And in fact, Judge Moore found

1 infringement at the ITC of the RhodoLED XL.

2 JUDGE WEATHERLY: Again, we don't deal with infringement
3 here necessarily.

4 MR. HA: Sure.

5 JUDGE WEATHERLY: Sometimes we care when it comes to
6 things like copying, but even copying is really not copying a Claim. It's
7 copying your commercial device. From a secondary considerations
8 perspective, that's slightly different from an infringement analysis.

9 MR. HA: Understood. So the point here is that, you know, we
10 have in our segmentation --

11 JUDGE WEATHERLY: Also, we're not going to get mad about
12 behavior.

13 MR. HA: Absolutely.

14 JUDGE WEATHERLY: You know, that's not going to be part of
15 our decision-making process, whether we should be mad or, like, somebody
16 stole something.

17 MR. HA: Right, right.

18 JUDGE WEATHERLY: You know what I'm saying?

19 MR. HA: And our whole point here is not about whether they
20 stole anything. We're just trying to set up the fact that all of the claimed
21 features are found in the RhodoLED XL, which has received industry praise
22 and commercial success.

23 JUDGE WEATHERLY: Okay.

24 MR. HA: And that's the real link that I'm trying to draw here.

25 JUDGE WEATHERLY: But Petitioner implied that, and I should
26 know the record better than I do and I apologize for not knowing it better

1 already. But Petitioner implied that you just said that that's true and that you
2 didn't -- like normally, a Patent Owner will present some sort of a claim
3 chart analysis where they point out where all the limitations are shown. Is
4 that in the record?

5 MR. HA: Yes, it is. Well, we don't have a claim chart. We do
6 have a claim chart, sorry. We do have a claim chart, and Ms. Belcher will
7 walk through all of the secondary considerations, including the nexus
8 argument.

9 JUDGE WEATHERLY: And is the claim chart part of what
10 Petitioner's complaining about being incorporated by reference?

11 MR. HA: Yes.

12 JUDGE WEATHERLY: Okay.

13 MR. HA: So it is in the declaration.

14 JUDGE WEATHERLY: Okay.

15 MR. HA: Yes.

16 JUDGE WEATHERLY: Okay. By the way, I think the
17 incorporation by reference argument is often overwrought, relied upon by
18 parties too hard.

19 MR. HA: Yes. And I just want to note that all of the underlying
20 evidence were cited in our briefing papers, except the form of the claim
21 chart was not included.

22 JUDGE WEATHERLY: Well, it couldn't be incorporated by
23 reference if it weren't cited. But at the same time, if it's in the record and it's
24 argued in front of us, on my behalf. I'm just speaking as an individual here.
25 That's usually good enough for me.

26 MR. HA: Great. Then I think we should be good, from Your

1 Honor's perspective. So not to belabor the point here on Slide 7, we're just
2 trying to set up the fact that RhodoLED XL has all of the claim features that
3 are found in the Claims, and it has received industry praise and commercial
4 success. So turning to Slide 8 and 9, we've highlighted in the five
5 independent claims all of the claim terms that are at dispute. In red, we've
6 colored the uniformly illuminating treatment surface limitation. As you can
7 see, that appears in all of the five Claims.

8 Colored in brown are all of the Claims that recite each of the five
9 panels, emitting higher intensity of light near the shorter edges of the panel.
10 That appears in all the claims. Like blue, four out of the five Claims recite
11 pin structures on the inner side surfaces of adjacent panels. In orange, we've
12 colored the two Independent Claims that recite that the five panels are
13 individually configurable to control illumination from each of the five
14 panels. And then finally, one of the Claims we have colored in green, the
15 continuous illumination requirement.

16 And so that's the short overview of the patent. And I wanted to
17 now move on to sort of the disputed issues and the grounds covered by the
18 Petitioner, unless Your Honors have further questions on this.

19 JUDGE WEATHERLY: Not yet.

20 MR. HA: Okay. So, turning to Slide 11, Petitioner initially
21 presented two grounds. And then as shown in Slide 12, they dropped
22 Ground 2. And so I'll focus only on Ground 1, which has to do with
23 Lundahl and Larsen. And so let me give a short, hopefully a short overview
24 of Lundahl and Larsen and their proposed combination before diving into
25 the disputed issues. Slide 13, let's begin with Lundahl. Lundahl is directed
26 to an illuminator that is a single panel made up of U-shaped fluorescent

1 tubes.

2 Those are unevenly spaced apart from each other in the manner
3 shown there on the top right. And because these fluorescent tubes inherently
4 do not output uniform light, there are dark regions near the cathode. And
5 you see that here on the bottom right as we've schematically illustrated. But
6 Lundahl is clearly missing a bunch of features that's reciting their claims.

7 JUDGE WEATHERLY: Let me make sure I understand this
8 device.

9 MR. HA: Yes, Your Honor.

10 JUDGE WEATHERLY: Because I think you just said that those
11 tubes don't emit uniform light because they don't emit uniform light,
12 effectively, which is pretty circular. So there is a portion of those tubes
13 that's relatively dark. I don't think anybody's arguing that that's not true.
14 But otherwise, the rest of -- the great majority of the length of those tubes
15 does emit uniform light, right?

16 MR. HA: Actually, that's not true.

17 JUDGE WEATHERLY: No?

18 MR. HA: So the fluorescent tubes are inherently not uniform.

19 JUDGE WEATHERLY: Okay.

20 MR. HA: So that's why Lundahl has to employ their specific --

21 JUDGE WEATHERLY: And by inherently not uniform, what do
22 you mean?

23 MR. HA: It's just that the way you have fluorescent light emitting
24 it is you have to have fluorescent materials that are coating certain things.

25 JUDGE WEATHERLY: Right.

26 MR. HA: And you get gas injection in there, and you start to emit

1 out light. And depending on, say, the coating thicknesses or how evenly
2 things are done, you actually have a non-uniform light. It is diffuse, and it
3 actually emits out very diffusely, pretty uniformly. Sorry, not uniformly, but
4 sort of in all directions unlike an LED. But if you look at the entirety of the
5 tube, you will have regions of hot and cold spots, and that's why Lundahl
6 needed to employ all of these various cooling systems, heating systems,
7 circuitry, reflectors, and whatnot, to make the overall output light of the
8 fluorescent tube uniform.

9 JUDGE WEATHERLY: Okay. But it did achieve that, right?

10 MR. HA: It did achieve that --

11 JUDGE WEATHERLY: Even by the standards set forth in the
12 challenged patents?

13 MR. HA: Correct. Yes, Your Honor.

14 JUDGE WEATHERLY: Okay.

15 MR. HA: Okay. So Lundahl is missing a bunch of features from
16 the claims, such as five panels, the five panels that are individually
17 configurable, and hinges on the inner side surfaces, right?

18 JUDGE WEATHERLY: Why isn't this case as simple as you all
19 developed a system with Levulan as the drug and a light that depended on
20 fluorescent tubes, and then when LEDs became available, you adapted the
21 light source to just an LED panel, a set of LED panels? I have to tell you
22 that my first impression of this case is that I can't think of something more
23 obvious.

24 MR. HA: So two points on that. We have real-world life
25 examples of inventor testimony that's in the record that specifically talked
26 about how difficult it was to go from fluorescent tubes to LEDs with five

1 panels, et cetera. We also have their own expert submission talking about,
2 in trying to invalidate the claims under enablement at the ITC, how the
3 Claims would require undue experimentation to get enablement, right? And
4 so the fact that they're now relying on a hindsight --

5 JUDGE WEATHERLY: To enable the uniform -- I'm guessing to
6 enable the uniform elimination characteristic, right?

7 MR. HA: Yes, that's right.

8 JUDGE WEATHERLY: Because the rest of it is just screwing
9 panels together and putting LEDs on them --

10 MR. HA: Well, I'd like to push back on that as well as covering
11 the hinge structure on the inner side surfaces.

12 JUDGE WEATHERLY: Okay.

13 MR. HA: We have testimony in the record where people were
14 saying once you start breaking up the single panel of Lundahl into five by
15 introducing gaps between the panels, you're going to have dark regions
16 between them.

17 JUDGE WEATHERLY: But there are gaps between the LEDs --

18 MR. HA: Sure.

19 JUDGE WEATHERLY: -- on every panel. I mean, it's just a
20 simple design, mechanical design of what's the gap. I mean, just because
21 there's a gap between the panel doesn't mean the space between adjacent
22 rows on adjacent panels wouldn't be the same as the gap between adjacent
23 rows intra-panel. Do you follow what I'm saying?

24 MR. HA: I think I do. But I --

25 JUDGE WEATHERLY: I mean, there are columns, more accurate
26 maybe is a better way to describe it, columns of LED sources on each panel,

1 and there's a spacing between them.

2 MR. HA: But I think the --

3 JUDGE WEATHERLY: On one panel, the lateral edge of the
4 panel is going to have the last column of LEDs on that panel, and there's
5 going to be another panel next to it that has a column on an adjacent edge.
6 And it would seem to me to be trivial to design a hinge so that that gap
7 between adjacent rows on different panels is the same as the gap between
8 adjacent -- I said rows, adjacent columns on different panels and adjacent
9 columns on the same panel. So I'm trying to understand, like that doesn't
10 sound like a very big leap or I don't find anything inventive about that unless
11 I'm completely misunderstanding what you're trying to say.

12 MR. HA: So I think what matters is that within a panel, you have
13 degree of control of where you can place the LEDs and where you can
14 actually how to power things up.

15 JUDGE WEATHERLY: You have the same control in terms of
16 the spatial relationship between adjacent columns of LED sources in
17 adjacent panels.

18 MR. HA: And I think that's where I differ with you because, for
19 example, if you look at certain TVs, right? You're going to have boundaries
20 around the TVs, correct?

21 JUDGE WEATHERLY: Yeah. Yeah.

22 MR. HA: And when you're trying to put two different panels
23 together next to one another, depending on how big those boundaries are and
24 how you can change your relative orientation of the hinges, if you've got
25 hinges, let's say, on the top and the bottom that causes too much of a gap,
26 you may never be able to achieve uniform illumination --

1 JUDGE WEATHERLY: You may not. And it depends on the
2 device. I mean, the display devices you're talking about. I mean, micro-
3 LED televisions often, at times, are constructed out of individual sub-panels,
4 and they're physically joined, especially the really large ones. And the gap
5 has to be microns, and they still figure out how to do it. But that's almost
6 irrelevant to this context from my perspective. I don't see anything here that
7 indicates that you need to control these gaps down to a micron kind of
8 accuracy.

9 MR. HA: Right. And we're not saying that we have to --

10 JUDGE WEATHERLY: Or even a millimeter accuracy.

11 MR. HA: Right. And we're not arguing about the distance
12 between the gaps. What I'm saying is when you have these physical
13 dimensions of the applicators that have to be hinged together to give you this
14 control of panel application, such that as a plane construction requires, the
15 treatment surface area achieves an intensity that exceeds -- that is at least
16 within 60 percent of the measured maximum across the entire treatment
17 surface, then those hinged structures matter, right?

18 JUDGE WEATHERLY: I mean, in a lot of ways, this almost
19 seems like -- I mean, those curved fluorescent tubes have a very sort of
20 analog sort of behavior in the way that they present light and how
21 continuous they are around someone's face. It's almost as if these panels are
22 just kind of like a very rough kind of digital representation, if you'll pardon
23 my use of that word, where you've got to figure out how many panels do I
24 need so that the curve is close enough to the curve that we used to have. We
25 got settled on five.

26 It looks like the width of these individual panels in the commercial

1 devices varies a little bit. But to me, that's just all -- it looks like it's all
2 -- none of that's claimed, as far as I can tell. I'm not saying you didn't have
3 to work on it to get it to be uniform, but --

4 MR. HA: And I think that's the point, right? Which is, the
5 evidence in the record is inventor testimony discussing how difficult it was
6 to break up that single panel of a fluorescent tube into five different panels
7 and continue to achieve that continuous -- sorry, uniform --

8 JUDGE WEATHERLY: Well, now I understand why the
9 Petitioner made an enablement argument, or maybe even thought about a
10 written description argument, if the inventors talk about how hard it was but
11 they don't describe in the patent how they solved all these difficult problems
12 or claim the things that they overcame, but instead they just say, put five
13 panels together with hinges.

14 MR. HA: But that's our point. It's not just any hinges. It's hinges
15 on the inner side surfaces, right? So Claim 16, we have a claim that says
16 hinge structures between adjacent panels. We don't talk about on the inner
17 side surfaces. So we are not challenging that. We are pointing out the fact
18 that all the remaining four Independent Claims recite hinge structures on the
19 inner side surfaces, and that was a critical overhaul --

20 JUDGE WEATHERLY: So there's magic about the hinges being
21 on the inner side surfaces?

22 MR. HA: Yes. That's absolutely right, Your Honor.

23 JUDGE WEATHERLY: That is the reason that your client should
24 keep this Claim.

25 MR. HA: That is one of the reasons why the prior arts
26 combination of what Petitioner put together fails to meet it, because this was

1 something that was not --

2 JUDGE WEATHERLY: What did Judge Moore say about that
3 issue specifically?

4 MR. HA: Sure. Let me turn to that. In fact, let me just jump to
5 that no hinge structures on the inner side surfaces issue first, if you don't
6 mind.

7 JUDGE WEATHERLY: Sure.

8 MR. HA: Let's turn to Slide 58. As I just alluded to, we have four
9 independent claims that recite the on the inner side surfaces, right?

10 JUDGE WEATHERLY: Yeah.

11 MR. HA: And the issue here was, well, just to address your --

12 JUDGE WEATHERLY: I'm just curious how he came out on that
13 issue and the basis for his decision. But ultimately, I can find that in the
14 record if -- and I don't want to consume your time.

15 MR. HA: No, I'll turn your attention to Slide 66, Patent Owner
16 Demonstrative 66 --

17 JUDGE WEATHERLY: Sure.

18 MR. HA: -- where Judge Moore said the following. Before 2015,
19 persons of ordinary skill designing PDT illuminators to output uniform light
20 were discouraged from placing hinges between the LED panels because the
21 arrangement was thought to negatively impact the illuminator's uniformity
22 by creating gaps between the panels, interfering with the panel's wiring, and
23 causing panel line issues. So he specifically heard our argument about what
24 the state of the art was before 2015 and said, yeah. People would have been
25 discouraged from doing this.

26 JUDGE WEATHERLY: So help me decode the citation to

1 evidence after that, because I'm not familiar with the conventions used at the
2 ITC. Jokerst is your expert here, and was your expert there at the ITC.

3 MR. HA: Yes, Your Honor. And Luebbert is Petitioner's CEO.

4 JUDGE WEATHERLY: Okay.

5 MR. HA: And in fact, if we want to decode that, I will turn your --

6 JUDGE WEATHERLY: So the first citation is to some sort of
7 declaration? And the second citation to Jokerst is to a deposition transcript
8 or trial transcript, I'm guessing?

9 MR. HA: I will get all of those specific --

10 JUDGE WEATHERLY: If you don't know off the top of your
11 head, that's okay.

12 MR. HA: I do not know, but I will get those to you.

13 JUDGE WEATHERLY: And Luebbert is the CEO of Petitioner?

14 MR. HA: Correct, Your Honor.

15 JUDGE WEATHERLY: Okay.

16 MR. HA: Yes. And we have testimony from the inventors also
17 that talks about how difficult that was. We have Dr. Jokerst testifying how
18 this would be our concept.

19 JUDGE WEATHERLY: By the way, in these LED panel
20 arrangements that are being discussed here and the challenge associated with
21 hinges, are those LED panels -- are those arrangements of multiple panels in
22 a kind of, for lack of a better word, a sort of arc configuration that would
23 surround someone's head, but without hinges? Or is that just --

24 MR. HA: -- Your Honor.

25 JUDGE WEATHERLY: So it says before 2015, persons of
26 ordinary skill designing PDT illuminators to output uniform light were

1 discouraged from placing hinge between the LED panels because that
2 arrangement was thought to negatively impact the illuminator's uniformity.
3 Well, for example, my imagination immediately runs to an LED panel that's
4 3 feet wide 6 inches high, if my face is sitting in front of that and I have
5 Levulan in front of me, well, the front of my face is going to get illuminated,
6 but the side isn't going to be illuminated. That's not uniform on my face.

7 But I can't -- for the life of me, I can't remember what kind of light
8 source I sat in front of because of my experience of what that felt like. But
9 the light source wrapped around my head. You could make LED panels that
10 wrap around someone's head without any hinges.

11 MR. HA: I have not thought of that specific configuration.

12 JUDGE WEATHERLY: And so I'm trying to understand what
13 Judge Moore is saying with his finding here about placing hinges between
14 LED panels. Well, if you don't place hinges between LED panels, they have
15 a fixed relationship.

16 MR. HA: He's actually talking about the proposed combination
17 that the Petitioner has tried to make.

18 JUDGE WEATHERLY: Okay.

19 MR. HA: Which is when you try to make -- break up Lundahl's
20 single panel into five, where would you place hinges? He's saying the --

21 JUDGE WEATHERLY: Well, the Larsen has individual panels,
22 five panels, right?

23 MR. HA: And I think that's the other point --

24 JUDGE WEATHERLY: And they are connected by hinges, yes?

25 MR. HA: But it's not on the inner side surfaces, and that's the
26 point, right? Which is --

1 JUDGE WEATHERLY: Okay. Isn't it the physical arrangement
2 in space of the panels that leads to the uniformity, not the nature of the
3 hinges?

4 MR. HA: Absolutely not, Your Honor. That's one of our claimed
5 features.

6 JUDGE WEATHERLY: I'm having a hard time believing that
7 that's -- that it's hinges on the inner side surface that make the magic for how
8 you get this arrangement of panels around someone's face.

9 MR. HA: And I think you're demonstrating sort of the unexpected
10 nature of this invention. If you look at column 4 in line 48 of our '028 Patent
11 itself, we're actually talking about how the hinges allow uniformity of light.
12 And that's what's kind of novel --

13 JUDGE WEATHERLY: Say that, where? Column where?

14 MR. HA: Column 4 in line 48.

15 JUDGE WEATHERLY: Hinges may take the form of nested
16 hinges, which may include hinges that substantially reduce or eliminate
17 optical dead spaces.

18 MR. HA: Optical dead spaces, right?

19 JUDGE WEATHERLY: May. Again, that doesn't sound like it's
20 all about nested hinges.

21 MR. HA: I'm not saying it's all about nested hinges. That's one of
22 the characteristics that's claimed that overall contribute to the uniform
23 illumination.

24 JUDGE WEATHERLY: What is a nested hinge, by the way? Is
25 that like a hinge that sits inside of a carved out?

26 MR. HA: It's basically a specific type of a hinge that's on the inner

1 surface.

2 JUDGE WEATHERLY: And one that's not claimed because the
3 claim just says a hinge on the inner surface.

4 MR. HA: Correct, yeah. Honestly, I don't actually know exactly
5 what a nested hinge looks like, but it is one of the types --

6 JUDGE WEATHERLY: Is there any other place in your spec that
7 focuses on the magic of the hinges?

8 MR. HA: I'll find that for you and circle back.

9 JUDGE WEATHERLY: Okay.

10 MR. HA: And so -- yes, Your Honor.

11 JUDGE HOFFMAN: Let me jump in. So I was going to say
12 Figure 3A of the patent illustrates the hinge 50.

13 MR. HA: Yes, Your Honor.

14 JUDGE HOFFMAN: But my question is back to the ITC
15 determination. Does putting hinges on the inner side surfaces necessarily
16 create these gaps?

17 MR. HA: So it's the breakup of the panel into five that's causing
18 the gap, and we're ameliorating the gaps that are caused by placing the
19 hinges on the inner side surfaces. Does that make sense?

20 JUDGE HOFFMAN: Not particularly. If we accept your expert's
21 testimony that a POSITA would have been discouraged from placing hinges
22 between the LED panels because that arrangement created gaps, where -- it
23 seems like your position is that putting hinges between LED panels creates
24 gaps.

25 MR. HA: No, Your Honor. I think what Judge Moore is saying
26 here, which is consistent with that argument, is before 2015, what people

1 thought was if you place hinges between the panels, it's going to further
2 create gaps. What we said is, no. We actually did all of the required testing
3 and the experimentation and realized that if you place them on the inner side
4 surfaces, that can actually ameliorate the gaps. So it's really a point of
5 reference of before the invention with after the invention.

6 So what Judge Moore here is saying is before the invention, that's
7 what people thought. But once you came up with the invention, that is the
8 invented feature. And that's the statement here.

9 JUDGE HOFFMAN: Yes, I understand. Thank you.

10 MR. HA: And I think that's the point about Larsen, right? Which
11 is -- and I'm now turning to Slide 60, which is, Petitioner argues that the
12 hinges are shown as element 20 in Figure 1. But if you look at paragraph
13 72, it specifically says the applicators are connected to each other through
14 hinges 10. And Figure 1 already has hinges 10 labeled.

15 JUDGE WEATHERLY: So you're not buying that that's a
16 misprint argument from Petitioner?

17 MR. HA: No, Your Honor.

18 JUDGE WEATHERLY: I am, just so you know --

19 MR. HA: So here's the reason why, right? It has --

20 JUDGE WEATHERLY: So assume that it is a typo. Now what?

21 MR. HA: So if that is a typo, then that's introducing two additional
22 typos to Larsen, which is the discussion of --

23 JUDGE WEATHERLY: You're misunderstanding my
24 hypothetical. Assume that the hinges are located at 20, just like Larsen
25 -- just like Petitioner says, how does that affect your position?

26 MR. HA: So you're saying I have to assume that hinges are

1 located exactly at 20?

2 JUDGE WEATHERLY: At 20, yes.

3 MR. HA: Okay. I do not know where 20 is. 20 is referring to this
4 dotted dashed line. So, for example, if I look at Figure 17 of Larsen, right?
5 I see -- so, paragraph 101 of Larsen talks about a hinge structure, upper part
6 hinged together. And if I look at Figure 17, I see a hinge at the top and the
7 bottom, exactly where element 20 is located, right? That's not on the inner
8 side surfaces.

9 JUDGE WEATHERLY: Give me a moment to find Figure 17.
10 You're trying to say Figure 17 of Larsen?

11 MR. HA: Of Larsen, yes, Your Honor. So starting with --

12 JUDGE WEATHERLY: 17B?

13 MR. HA: Yes, Your Honor. So let's start with Figure 17A, which
14 is sort of the other view, right? And you've got an applicator on top of the
15 patient and an applicator below the patient. And it's talking about a hinge
16 structure where that device is able to open up and down to allow a patient in,
17 right?

18 JUDGE WEATHERLY: Okay.

19 MR. HA: And that circular thing is a hinge structure, because
20 that's what's causing the sort of up and down.

21 JUDGE WEATHERLY: Okay. So the circular thing at the center
22 on the, like, horizontal center line on Figure 17B, that's the circular thing
23 you're talking about?

24 MR. HA: Correct. And on --

25 JUDGE WEATHERLY: And down in Figure 17A, does that
26 correspond to what's shown as a kind of a circle on the right-hand edge?

1 MR. HA: Yes, Your Honor.

2 JUDGE WEATHERLY: Okay.

3 MR. HA: So that would still be consistent where 20 is drawn in
4 Figure 1.

5 JUDGE WEATHERLY: Is that a six-panel arrangement?

6 MR. HA: No, those are two panels.

7 JUDGE WEATHERLY: Okay. I asked about six -- you
8 understand why I'm asking about six panels, right? Because of the way it
9 looks in 17A.

10 MR. HA: I'm sorry?

11 JUDGE WEATHERLY: 17A, when you're looking from above,
12 there are six different planes shown there.

13 MR. HA: I think those are basically just sort of a trapezoidal
14 applicator, another trapezoidal applicator --

15 JUDGE WEATHERLY: So those are like different panels that are
16 connected without hinges?

17 MR. HA: I would just call that a single panel, but --

18 JUDGE WEATHERLY: Okay.

19 MR. HA: Yeah, it's just, you know --

20 JUDGE WEATHERLY: But a panel that has a kind of concave,
21 sort of.

22 MR. HA: Yes. And it's doing this, and the hinge structures are at
23 the --

24 JUDGE WEATHERLY: You realize that doing this, like what you
25 described, does not translate to the record, right?

26 MR. HA: Yes, Your Honor. So it's opening up and down --

1 JUDGE WEATHERLY: Yeah, like a clamshell.

2 MR. HA: Yeah, exactly. And the hinges are located exactly
3 where that line 20 would be, but it would still not be on the inner side
4 surfaces, right? Because that hinge is between the two panels and yet it's on
5 the top and the bottom of the two structures.

6 JUDGE WEATHERLY: Looks like it might, you know. Again,
7 I'm sure you recall that I had a lot of skeptical sort of questions for Petitioner
8 on this particular topic, but at the same time hinges aren't mysterious. A lot
9 of kind of hinges, and hinges that allow you to mount things next to each
10 other without gaps or with gaps or gaps that change as the two things move
11 relative to each other, or gaps that don't change as the two things move
12 relative to each other.

13 MR. HA: Right.

14 JUDGE WEATHERLY: So your claims are very quiet about
15 details on hinges. It just says hinges, the only detail being that they be on
16 the inner --

17 MR. HA: Side surfaces.

18 JUDGE WEATHERLY: -- inner side surfaces.

19 MR. HA: Yes, Your Honor.

20 JUDGE WEATHERLY: And I don't even know necessarily what
21 it means to be on the inner side surfaces, whether it means part of the hinge
22 structure contacts those surfaces but all of it need not, or. Do you see what
23 I'm saying?

24 MR. HA: Yeah. So the ALJ actually provided some explanation
25 of what that means, on the inner side surfaces, because one of their non-
26 infringement arguments was that it has to be mounted on the surface,

1 whereas ALJ just simply said, as long as it fits somewhere in the side
2 surfaces, it's fine.

3 JUDGE WEATHERLY: So it contacts the inner side surface
4 anywhere, then that's on the inner side surfaces.

5 MR. HA: Exactly.

6 JUDGE WEATHERLY: Okay.

7 MR. HA: And so, I think that's a fair representation. And even
8 with that understanding, what Judge Moore found was Larsen doesn't
9 disclose that. It only says hinges 10, which is on the bottom of the panels,
10 not on the inner side surfaces, and that is on our Slide 62, where Judge
11 Moore found that.

12 JUDGE WEATHERLY: Right. I'm not sure that that ends the
13 inquiry about whether Larsen suggests hinges on the inner side surfaces.

14 MR. HA: And you're right, because they do have a backup
15 obviousness argument in the petition, and let me cover that as well. So
16 they're basically making two points on, even if Larsen doesn't disclose
17 hinges on the inner side surfaces, well it would have been obvious to place
18 them on the inner side surfaces. And now I'm on Slide 64. This is from
19 their petition.

20 JUDGE WEATHERLY: Your Slide 64?

21 MR. HA: Yes, our Slide 64. And all they say here is, such a
22 modification would have involved nothing more than the use of a known
23 prior element according to known methods to yield predictable results, and
24 that there were a finite number of known predictable solutions. I want to
25 push back on both of those points, and Judge Moore agreed with us on both
26 of those points as well.

1 First, there's nothing in the record demonstrating hinge structures
2 on the inner side surfaces. Nothing, right? If we take Larsen out as
3 disclosing that, there's nothing else in the record. So they haven't done their
4 job of demonstrating that hinges on the inner side surfaces in this particular
5 context was a known prior element. And my colleague will address in the
6 motion to exclude evidence, their belated attempt to try to bring in additional
7 facts surrounding that. But take the petition at its word, nothing directed to
8 that. And Slide 65, we've highlighted Judge Moore's summary of this thing,
9 Biofrontera fails to identify a single illuminator with hinges on the inner side
10 surfaces.

11 Turning to Slide 66, Petitioner did not articulate what the finite
12 number of known solutions were. But as the evidence developed during trial
13 demonstrated, and as Judge Moore concluded here on the top part of that
14 decision, numerous designs to connect the panels of a PDT device flexibly,
15 including, as you noted, without hinges, or with different hinge designs were
16 available in the art. It's not just simple as like, okay, hinges are known, it's
17 on the inner side surface, so let's go do it. There are a lot of different options
18 available to a POSITA before 2015.

19 And as then Judge Moore concludes, before 2015, people would
20 have actually thought placing the hinges on the inner side surfaces would
21 create gaps. But lo and behold, our inventors came in and realized this is
22 actually the way to solve this problem, by placing hinges on the inner side
23 surfaces. And so, our position here is that it's not obvious in that respect.
24 Does that address all of the questions on the hinge structures?

25 JUDGE YANG: I have a question.

26 MR. HA: Yes, Your Honor.

1 JUDGE YANG: So you said if you take Larsen out of the picture,
2 then there is nothing to show hinges on the inner side. Just so that I
3 understand it correctly, does Larsen show hinges on the inner side?

4 MR. HA: Thank you for that clarification. Larsen does not show
5 hinge structures on the inner side surfaces. And my intent there was, if you
6 take out their position that it included a typographical error and includes it,
7 then there's nothing else.

8 JUDGE YANG: So on this typo, I think Counsel for Petitioner
9 pointed out that Larsen also referred numeral 10 as the device. So 10 could
10 be the device and the hinge. What's your response to that?

11 MR. HA: Yeah. So if we follow their argument about what the
12 typo is, that would introduce three separate typographical errors into Larsen.
13 Whereas if we just take our view, hinge means 10, and element 20 refers to
14 this regular row arrangement of LEDs, as Dr. Grove admitted during his
15 deposition, that only leaves one typographical error in Larsen that says
16 present device 10.

17 And so, it's a much easier -- and Judge Moore agreed with us on
18 this point, we can find a cite to that. It's a much easier way to kind of say,
19 yeah, Larsen has one typographical error instead of these three different
20 typographical errors that the Petitioner is trying to propose.

21 JUDGE YANG: Thank you.

22 MR. HA: Okay. I am going to try to skip through the next issue,
23 which is individually configurable, first, and then I want to return back to the
24 uniformly illuminating very quickly. So I think with the hinge structures,
25 that addresses all but three of the challenged claims. The next issue has to
26 do with the individual configurable, which will address the remaining set of

1 claims. And I think if you find in our favor for both of these issues, it'll be
2 dispositive of the entire case.

3 Turning to Slide 70. Let's start with the claim construction. Judge
4 Moore -- so Petitioner in the petition did not propose any kind of
5 construction. Judge Moore in the ITC said, this is plain and ordinary
6 meaning. And what that means is the power output and or light intensity of
7 each panel can be individually controlled. Not some results, not some effect
8 that would appear if you can somehow turn off one or the other. It has to be
9 actually controlled, and each of the panels has to be controlled.

10 And throughout the record, there's only two instances of the word
11 individually coming up in context of light sources, right? The first one that
12 Petitioner points to is in paragraph 70. That, if you look at that, says, figure
13 -- and now I'm on Slide 71, Figures 2A through 2C show plain surface
14 printed circuit boards with light sources mounted on them. And it says,
15 these, i.e. these printed circuit boards, can be used in working models
16 individually, side by side, or in combination with an applicator.

17 And I think that makes perfect sense, because you have printed
18 circuit boards that are individually used, for example, in Figure 1 of the
19 applicator. Each of those panels have to have individual PCDs. It says
20 nothing about each of the panels being controllable. And in fact, if you look
21 at paragraph 27, what it says is, there's just a single control mechanism that
22 can switch on and off, what, the entire device, the device, not the entire
23 device, not each of the applicator panels.

24 Turning to Slide 72, the second cite that Petitioner relies on is
25 Claim 5. I think Judge Weatherly had some premonition about agreeing
26 with the Petitioner on this, but let me try to convince you otherwise.

1 JUDGE WEATHERLY: I'm not sure I would call it a
2 premonition. I'm guessing you're going to explain to me why it was a
3 mistake.

4 MR. HA: Right. So I think what we have to do is, number one,
5 recognize Claim 5 is dependent on Claim 1. And we have to look at claims
6 in light of the specification, which is on paragraph 74. And so let's do that
7 stepwise, right? Which is --

8 JUDGE WEATHERLY: I'm going to stop you right there.

9 MR. HA: Yes, sir.

10 JUDGE WEATHERLY: Our job is not to interpret the scope of
11 the claims in this reference.

12 MR. HA: True.

13 JUDGE WEATHERLY: Our job is to understand what do these
14 claims describe to a person of skill in the art?

15 MR. HA: Yes, Your Honor. And I think if you read Claim 5 in
16 context of paragraph 72, you'll be able to --

17 JUDGE WEATHERLY: To a patent attorney. You're about to
18 argue what a patent attorney would think the claims mean --

19 MR. HA: Well, I would also say --

20 JUDGE WEATHERLY: -- in terms of their scope.

21 MR. HA: Yeah.

22 JUDGE WEATHERLY: I'm trying to get you to focus on when a
23 person of ordinary skill reads this disclosure, what do they see?

24 MR. HA: And let me just jump then to what Judge ALJ Moore
25 found, right? This is on page 73. His conclusion after hearing both of these
26 --

1 JUDGE WEATHERLY: On Slide 73?

2 MR. HA: On Slide 73. His conclusion after hearing both of these
3 arguments was the entire device is adjustable, not that each of the five
4 applicators is individually configurable to control elimination from each
5 panel.

6 JUDGE WEATHERLY: Did he deal with this Claim 5 issue?

7 MR. HA: Yes. Right above he says, individually in Claim 5 does
8 not refer to panels and Biofrontera has no support to show that the output
9 from each panel can be individually controlled. So he specifically addressed
10 this argument as well. And his conclusion was, entire device is controllable.

11 JUDGE WEATHERLY: I think he's overstating that. I disagree
12 with him.

13 MR. HA: Okay. And let me try to make one last effort to try to
14 convince you why. Because individually selected is dependent on Claim 1,
15 which talks about the light sources consisting of two things, semiconductor
16 diode and or at least one laser diode. And I think --

17 JUDGE WEATHERLY: That includes a device that has only
18 semiconductor diodes, correct?

19 MR. HA: That's right. I think you were focusing on the word or
20 there, right? But I think the key point here is, Claim 5 has to be narrower
21 than Claim 1.

22 JUDGE WEATHERLY: Yes.

23 MR. HA: So if you -- and it has to have in part meaning. So yes,
24 Claim 1 can have a scenario where you have just semiconductor diodes or
25 just laser diodes. But if you want to be able to practice Claim 5, you have to
26 further narrow the situation where that device has both semiconductor

1 diodes and laser diodes.

2 JUDGE WEATHERLY: So your argument that Claim 5 requires
3 us to interpret the phrase, and or, in Claim 1 is not really meaning, and or,
4 but only meaning and?

5 MR. HA: In Claim 5, yes. In Claim 1, no. So in Claim 5, it has to
6 be a specific situation where you have both the semiconductor diodes and
7 the laser diodes --

8 JUDGE WEATHERLY: That's what I just said. I thought you're
9 saying Claim 5 requires us to interpret the phrase, and or, as stated in Claim
10 1 as really meaning and.

11 MR. HA: Correct, Your Honor, for Claim 5. Claim 1, it can mean
12 and or or. So, I think that's a proper interpretation because if you look at
13 Claim 74, again it's talking about the control mechanism of --

14 JUDGE WEATHERLY: Did you say Claim 74?

15 MR. HA: Paragraph 74, sorry.

16 JUDGE WEATHERLY: All right.

17 MR. HA: Which is on the left side of our Slide 72. Because that's
18 talking about the control mechanism of the entire device, the invented
19 device, not the different panels, which then goes and talks about the control
20 mechanism that isn't there. And then it says the switch select system for
21 operating different types of the semiconductor diodes or laser diodes, and or
22 laser diodes. So it's really talking about turning on and off one type of
23 diodes across the entire device, not on each of the individual panels. And
24 again, ALJ Moore --

25 JUDGE WEATHERLY: Seems like an awfully fancy on-off
26 switch control mechanism. You're telling me the control mechanism

1 essentially just lets the operator turn the device on or off?

2 MR. HA: That's right. That's what Larsen's disclosing --

3 JUDGE WEATHERLY: And they call that a control mechanism?

4 MR. HA: Right. It's controlling the on and off of the device, the
5 entire device.

6 JUDGE WEATHERLY: As on the whole, like literally turn the
7 device on and turn the device off?

8 MR. HA: Yes, Your Honor. That's what Larsen's disclosing.

9 JUDGE WEATHERLY: Okay. Well, I understand your position.

10 MR. HA: Thank you.

11 JUDGE HOFFMAN: I just want to make sure I understand.

12 MR. HA: Sure.

13 JUDGE HOFFMAN: So Larsen is saying you can turn on the
14 semiconductor diodes or you could turn on the laser diodes or you could turn
15 both of them on?

16 MR. HA: Yes, Your Honor, yes. And it's across the entire five
17 panels, not on each of the individual panels.

18 JUDGE HOFFMAN: Okay. Thank you.

19 MR. HA: One last point about this before I jump to the uniformly
20 illuminate is Petitioner is trying to now rely on Exhibit 2011. I just want to
21 point out that's not related to the control mechanism of Larsen, nor was it
22 ever presented in the petition itself. So that's the only other thing that I
23 wanted to add on that. I know I have only about ten minutes left, and we
24 need to also have Ms. Bridget Belcher cover the second --

25 JUDGE WEATHERLY: She might not be mad that you've used
26 so much of her time. We'll see.

1 MR. HA: So I think all I want to end on is, uniformly illuminate
2 had a particular construction that was agreed upon by both parties. The
3 petition did not demonstrate this at least within 60 percent requirement
4 anywhere in the petition. That's a deficiency of the petition itself that cannot
5 be --

6 JUDGE WEATHERLY: And why isn't Lundahl's teaching of 60
7 percent enough?

8 MR. HA: Because when she goes from the --

9 JUDGE WEATHERLY: Because using LEDs spoils it?

10 MR. HA: Once you break up into five panels and then switch the
11 light source to LEDs, they have to demonstrate that these LEDs actually get
12 you there. They never did that.

13 JUDGE WEATHERLY: But your patent doesn't really describe
14 how to do that except to use the magic hinges?

15 MR. HA: Well, we do. Because if you look at Figures 7 and 8,
16 we're comparing conventional illuminators with the invented device that
17 have all of these different claim characteristics put together. Five panels,
18 hinges on the inner side surfaces, individual controllable power output, all of
19 these are things that are claimed. And once you put all of those things
20 together, that's what allows you to achieve the uniformly illuminate. They
21 haven't done that in their petition.

22 JUDGE WEATHERLY: Okay.

23 MR. HA: So, with only ten minutes left, I call Ms. Bridget
24 Belcher.

25 MS. BELCHER: Okay. I'm going to start you all on page 81
26 -- Slide 81, sorry. And I'm going to talk to you a little bit about the objective

1 indicia of non-obviousness that are present here. First, the ALJ did not
2 address the objective indicia finding that Biofrontera had failed to show that
3 the claims were obvious over Lundahl and Larsen. And if you agree with us
4 here as well that the Petitioner has not made out a prima facie case of
5 obviousness, there's really nothing to rebut, but I'm still going to go through
6 the objective indicia here.

7 First, I'll explain to you why the RhodoLED XL is coextensive
8 with the claims of the '028 Patent. And I'd also like to point out that because
9 the device is coextensive with the claims, there's a presumption of nexus that
10 applies. If we turn to Slide 83, I have Representative Claim 1 here, along
11 with some images from Biofrontera's marketing materials and their user
12 manual for the RhodoLED XL.

13 JUDGE WEATHERLY: So you're saying that because the
14 competitors -- because the Petitioner's device is coextensive with the claims,
15 you are entitled to a presumption of nexus?

16 MS. BELCHER: So Petitioner's device -- there is case law; it does
17 not have to be your own device. If the device embodies the claims and is
18 commercially successful, has received industry praise, then it does not have
19 to be your own device to show that they are.

20 JUDGE WEATHERLY: Okay. Usually it is.

21 MS. BELCHER: Usually it is. In this case, as of the time these
22 papers were filed, we had not marketed our device yet.

23 JUDGE WEATHERLY: Okay.

24 MS. BELCHER: So if we look at Claim 1, you can see in the
25 bottom image there are hinges that connect five panels on the inner side
26 surfaces. They're represented by the blue arrows, and I think I'm going to

1 anticipate your question. If you look at Exhibit 2059, which is cited on page
2 73 of our POR, this is Biofrontera's '169 Patent, which is the Orange Book
3 Patent for the RhodoLED XL. In column 28, lines 58 to 64, they say that
4 hinges 15 are used between the radiation-emitting units. And if you look at
5 Figures 1 and 2, you can see that the placement of the hinges is on the inner
6 side surface.

7 JUDGE WEATHERLY: I'm sorry, I may not be on the right slide.

8 MS. BELCHER: Oh, sorry. This image is not on the slide. I was
9 just anticipating that you were going to --

10 JUDGE WEATHERLY: Yeah, I don't see any hinges in these
11 cartoons.

12 MS. BELCHER: Yeah, so if you look at Exhibit 2059 --

13 JUDGE WEATHERLY: Okay.

14 MS. BELCHER: Yeah, sorry. That's Biofrontera's '169 Patent that
15 covers the RhodoLED XL.

16 JUDGE WEATHERLY: Well, does it?

17 MS. BELCHER: Yes, it does. So if you look at Exhibit --

18 JUDGE WEATHERLY: Who says that?

19 MS. BELCHER: Biofrontera does.

20 JUDGE WEATHERLY: Okay.

21 MS. BELCHER: So if you look at Exhibit 2058, it explains that
22 the '169 Patent is the Orange Book patent for the RhodoLED XL.

23 JUDGE WEATHERLY: Okay.

24 MS. BELCHER: And so that shows the hinges on the inner side
25 surface. And just to add that our expert, Dr. Jokerst, had examined the
26 device and that is in Appendix B, which is her claim chart mapping this

1 against --

2 JUDGE WEATHERLY: The part that the Petitioner says you
3 incorporated by reference?

4 MS. BELCHER: Yeah, and unfortunately our claim chart is in her
5 declaration, which we did --

6 JUDGE WEATHERLY: It is what it is.

7 MS. BELCHER: Yeah. Okay, so that covers the hinges. And
8 also, again, if you look in the top image, boxed in red, it emits a uniform
9 light, the RhodoLED XL. And if you look in the bottom image again, you
10 can see that one of the panels is configured to face a treatment surface, and
11 the other panels are angled relative to that panel. The treatment distance for
12 the RhodoLED XL is within approximately 4 inches of the treatment surface
13 at 4.9 plus or minus 0.59 inches. And if you -- I boxed it in brown, the LED
14 arrangement allows for a higher intensity of light to be emitted.

15 JUDGE WEATHERLY: Which slide are you on right now?

16 MS. BELCHER: Sorry, I'm on Slide 83.

17 JUDGE WEATHERLY: Okay, yeah.

18 MS. BELCHER: Sorry. It allows for a higher intensity of light to
19 be emitted proximate the second shorter edges of the panel with that LED
20 arrangement boxed in brown.

21 JUDGE WEATHERLY: Okay.

22 MS. BELCHER: And then to cover any limitations that are
23 missing from Claim 1, I also have mapped Claim 16 here. You can see that
24 the panels are connected by hinged structures to allow for continuous
25 illumination. And if you look at the image on the right-hand side, the
26 RhodoLED XL meets the more structural limitations in Claim 16, and I can

1 walk you through those if you want, but because we're running out of time.

2 JUDGE WEATHERLY: Yeah.

3 MS. BELCHER: And then in the bottom image, they say that each
4 panel can be independently controlled and turned on and off, and so the five
5 panels are individually configurable to control the illumination.

6 And now if we turn to Slide 85, you can see that these features are
7 not incidental, and Biofrontera actually markets the RhodoLED XL by
8 emphasizing the claimed features. So on the right-hand side, that screenshot
9 is from a presentation by Mark Baldyga, who's Biofrontera's VP of Sales,
10 and he emphasizes the five-panel design, the higher intensity at the top and
11 bottom that's enabled by the -- sorry, at the shorter edges that's enabled by
12 the LED arrangement, and the uniform light. And he also emphasizes the
13 treatment distance within approximately 4 inches here.

14 JUDGE WEATHERLY: And why isn't there an analysis of one of
15 your own clients' products again?

16 MS. BELCHER: I believe that was confidential business
17 information at the time.

18 JUDGE WEATHERLY: At the time. At what time?

19 MS. BELCHER: When we filed the Patent Owner response in
20 May.

21 JUDGE WEATHERLY: Okay. So --

22 MS. BELCHER: And we do have an analysis, actually, of it
23 mapping onto the BLU-U 4170E device on page 77 of the POR. Exhibit
24 2014 is our ITC domestic industry claim chart that maps the '028 Patent
25 against the BLU-U 4170E.

26 JUDGE WEATHERLY: Okay. We'll look at that in the record. It

1 sounds like your showing on that front was a little bit different from -- you
2 spent more -- you all spent more attention mapping these claim elements to
3 the accused device.

4 MS. BELCHER: And we did that on purpose because we're able
5 to show commercial success of this device, which ties into the objective
6 indicia of the whole process.

7 JUDGE WEATHERLY: Because Petitioner's selling one, but
8 you're not.

9 MS. BELCHER: It's being tested, I believe.

10 JUDGE WEATHERLY: Okay. I think that's a yes.

11 MS. BELCHER: As of right now.

12 JUDGE WEATHERLY: You don't have enough -- you didn't have
13 enough evidence?

14 MS. BELCHER: We didn't have enough evidence at the time that
15 we submitted this.

16 JUDGE WEATHERLY: Okay. Which is, you know, again, it is
17 what it is.

18 MS. BELCHER: So if we turn to Slide 87, I can talk a little bit
19 about the industry praise. So we've given you a bunch of examples on page
20 77 of the POR of industry praise for the RhodoLED XL. But I've
21 highlighted two here from two dermatologists who both emphasize the
22 larger illumination area that has enhanced the overall quality of care and the
23 patient experience. And these are enabled by the RhodoLED XL's five-
24 panel design, uniform illumination, and the LED configuration that allowed
25 for higher intensity at the second shorter edge.

26 And if we talk a little bit about the commercial success of the

1 RhodoLED XL, it was commercially successful by -- on 18.5 percent growth
2 in Q4 2024 compared to Q4 2023. And they stated that --

3 JUDGE WEATHERLY: So to what extent does your reliance on
4 secondary considerations depend upon us finding that you're entitled to a
5 presumption of nexus?

6 MS. BELCHER: We did do a nexus analysis in the POR. I don't
7 have the page number off the top of my head right now.

8 JUDGE WEATHERLY: By nexus analysis, do you mean like a
9 nexus -- I refer to it as like a nexus in fact kind of analysis. In other words,
10 not based on a presumption, but a showing that's -- an affirmative showing
11 of nexus.

12 MS. BELCHER: Yes, we do do that in the POR. I think it's on the
13 last page of the PR. I can't remember the page number off the top of my
14 head.

15 JUDGE WEATHERLY: Okay. Well, the fact that it's on one page
16 already causes me to be a little suspicious about whether it carries the day.

17 MS. BELCHER: So earlier when we were talking about -- when
18 we were mapping the device, and also when we were talking about industry
19 praise and the commercial success, we already had walked through the
20 nexus and had explained it. And so it kind of just sums it up right at the end
21 there.

22 JUDGE WEATHERLY: Okay.

23 MS. BELCHER: But the nexus analysis is present throughout the
24 discussion of secondary --

25 JUDGE WEATHERLY: No, but I mean there's a difference
26 between a presumption -- being entitled to a presumption of nexus and --

1 MS. BELCHER: Yeah.

2 JUDGE WEATHERLY: -- and an affirmative showing of nexus.
3 And my question really is to what extent? And then this industry praise, for
4 example, if you're entitled to a presumption of nexus and you have this
5 doctor saying that the RhodoLED XL is fantastic. I'm not sure that he's
6 identifying anything about a claimed feature that makes it fantastic. But if
7 you're entitled to a presumption of nexus, maybe we have to weigh that
8 evidence differently.

9 If you're not entitled to a presumption of nexus, then we have to
10 ask ourselves whether this evidence constitutes an affirmative showing of
11 nexus. I'm not sure that it does. I'm not sure that it doesn't either. But I'm
12 trying to get a sense from you --

13 MS. BELCHER: Yeah.

14 JUDGE WEATHERLY: What do you need us -- where is your --

15 MS. BELCHER: So, again, I don't have the page number set off
16 the top of my head, but we have Mr. Baldyga's deposition transcript in the
17 record where he does talk a little bit about the nexus, and he talks about this
18 --

19 JUDGE WEATHERLY: And that's the Petitioner's VP?

20 MS. BELCHER: Yes, of sales.

21 JUDGE WEATHERLY: Okay.

22 MS. BELCHER: And we've looked at -- so it's Exhibit 2039. I,
23 again, don't have the line number cites, I apologize. But --

24 JUDGE WEATHERLY: What is Ameluz? Is that the drug that --

25 MS. BELCHER: Ameluz is the topical --

26 JUDGE WEATHERLY: The topical.

1 MS. BELCHER: -- that Biofrontera markets.

2 JUDGE WEATHERLY: The evil topical solution.

3 MS. BELCHER: Yeah, it's that one.

4 JUDGE WEATHERLY: Trust me.

5 MS. BELCHER: And so we have his deposition in the record
6 where he does tie these statements to the claimed features of the '028 Patent.
7 So these statements by dermatologists that are touting the praise, or touting
8 the product, he does tie them to the claimed features of the '028 Patent.

9 JUDGE WEATHERLY: Okay.

10 MS. BELCHER: And that is in our --

11 JUDGE WEATHERLY: I mean, the papers will speak for
12 themselves, but I'll take your word for it for now.

13 MS. BELCHER: Yeah. Sorry, I have the cite right here. It's
14 Exhibit 2039, page 44, line 9 through 45, 11. And he says -- he's saying
15 that, which is what I have again on this Slide 85, on the left-hand side, this
16 quote from him. And then he is also testifying at page 40, line 6 through 11,
17 that the purpose of the presentation was to encourage the customers to
18 purchase the RhodoLED XL. And he, again, he's saying that there's the
19 uniform light with all five panels that allow for the full face and full scalp
20 illumination. So the dermatologist --

21 JUDGE WEATHERLY: I'm a little skeptical about how the
22 Petitioner's VP of sales statements can be interpreted as industry praise --

23 MS. BELCHER: Well, he was interpreting the things that these
24 dermatologists -- he was interpreting what these dermatologists were saying
25 here.

26 JUDGE WEATHERLY: Okay.

1 MS. BELCHER: If you look at that quote from Dr. Ted Lane,
2 Biofrontera uses this in their marketing materials.

3 JUDGE WEATHERLY: I'm trying to sell this device. Everybody
4 says it's great.

5 MS. BELCHER: Right. But, I mean, the dermatologists aren't
6 going to like -- they've tested the device and they're going to give their
7 honest feedback about the device. And they've purchased them. At least Dr.
8 Cooper apparently has purchased it himself. On this quote, he's purchased
9 two of the devices after testing.

10 JUDGE HOFFMAN: I just want to make sure that you're paying
11 attention to the time.

12 MS. BELCHER: Yeah, I see. Okay.

13 MR. HA: We'll eat up the five --

14 MS. BELCHER: Yeah, thank you. If I could direct your attention
15 quickly to Slide 89, just briefly go over the commercial success of the
16 RhodoLED XL. So, Biofrontera has said a couple of times publicly that the
17 growth in 2024 can be attributed to the successful launch of the RhodoLED
18 XL. And the graph that I'm showing here is the cumulative sales of the
19 original RhodoLED device versus the sales of the RhodoLED XL device.
20 You can see that until the RhodoLED XL launched, there was a steady
21 increase in sales between quarter one and quarter two of the RhodoLED
22 original device.

23 And then when the RhodoLED XL launched, it saw skyrocketing
24 growth and outpaced the sales of the original RhodoLED. And this is
25 notable because the differences between the original RhodoLED and the
26 RhodoLED XL are the claimed features of the '028 Patent. The five-panel

1 design with a higher intensity of light emitted proximate to second shorter
2 edges, that emits a uniform intensity of light, and that hinges on inter-site
3 surfaces of adjacent panels.

4 JUDGE WEATHERLY: Am I understanding the y-axis on this
5 graph to be -- does 100 mean 100 units?

6 MS. BELCHER: Yeah, so 100 is 100 units sold in 2024.

7 JUDGE WEATHERLY: Okay.

8 MS. BELCHER: So these are the cumulative sales.

9 JUDGE WEATHERLY: Cumulative for the year?

10 MS. BELCHER: Yeah, so like the difference between quarter
11 three and quarter four for the XL is --

12 JUDGE WEATHERLY: Is 100 minus 48 or so.

13 MS. BELCHER: Yeah, so about 50.

14 JUDGE WEATHERLY: Okay, all right. Just want to make sure
15 I'm understanding this part correctly.

16 MS. BELCHER: Yeah. And then in case there's any doubt about
17 commercial success, if you flip to Slide 90, Petitioner's CEO Hermann
18 Luebbert says that the first and foremost contributor to the annual sales
19 growth in quarter four of 2024 was the placement of the newly launched
20 RhodoLED XL plants. And yeah, unless Your Honors have any other
21 questions, we'll rest on the papers for the rest and reserve anything we have
22 left.

23 JUDGE HOFFMAN: Thank you very much, Ms. Gurule. You
24 have ten minutes remaining for rebuttal. And Mr. Landmon, you have 20
25 minutes of rebuttal, and I'll start the timer when you begin speaking.

26 MR. LANDMON: Sorry, just getting my slides up. Perfect, thank

1 you. May I begin? Thank you. I'll be jumping around a little bit, but
2 hopefully making the points clear as I do that. I just wanted to start really
3 quickly with Larsen. Counsel for Patent Owner pointed to figure 17A and
4 17B in Larsen. Just want to quickly say a couple things about that. I mean,
5 first, the parties have never made any arguments about these figures. This
6 has been the first time the Patent Owner has brought it up. It appears to us
7 that the figures cover something totally different. I mean, it looks to be
8 some sort of large, full-body applicator. Certainly, it's not figure 1 of
9 Larsen. That's the figure we've largely been talking about and relying on.

10 And also, he talked about that in relation to the hinge placement.
11 ALJ Moore basically said any hinge that appeared to touch the inner side
12 was sufficient to meet that claim limitation. So even if those figures
13 somehow did relate to the issues before you, those figures seem to
14 demonstrate hinges that meet at least Judge Moore's construction
15 interpretation of the claim term.

16 And if I can turn you to Petitioner, Petitioner's counsel -- I want to
17 focus on their slides first. Just one slide, I think Slide 64. Petitioner's
18 counsel was stating -- was asked about -- made a statement that there's no
19 single --

20 JUDGE WEATHERLY: You mean Patent Owner's counsel?

21 MR. LANDMON: Patent Owner's counsel.

22 JUDGE WEATHERLY: Okay.

23 MR. LANDMON: Thank you. The slide starts with Petitioner's.

24 JUDGE WEATHERLY: Is that mic over there hot again? Is that
25 why we're getting the feedback? No, it was off. Okay.

26 MR. LANDMON: Thank you. Apologies for that.

1 JUDGE WEATHERLY: No, no problem.

2 MR. LANDMON: Patent Owner's counsel said that we have
3 pointed to nothing in the record demonstrating a hinge structure on an inner
4 side surfaces. So a couple of things about that. Obviously, Larsen's there.
5 And you know it's our position, it's Dr. Grove's position, that Larsen does, in
6 fact, have a hinge on the inner side surface. Also, Dr. Grove, in his first
7 declaration, paragraph 151, he talks about there being a finite number of
8 locations where to put them. Paragraph 155, he talks about it being obvious
9 to put them in the inner side surfaces. That's all in the petition in his original
10 declaration.

11 So it's just not true that there's nothing in the record that points to
12 that. I did want to -- if we could put up Slide 24. One of the points that
13 Patent Owner's counsel has pointed to has been about the gaps, including the
14 gaps between the panels. Wanted to put, and we've talked a lot about this
15 -- I've talked a lot about this before about the divergence angles, the known
16 divergence angles, Dr. Grove's testimony. The bottom part of that slide, the
17 bottom part of that demonstrative, demonstrates why the positioning of the
18 LEDs can compensate and the divergence angles known as the LEDs would
19 compensate for any gap between the panels.

20 JUDGE WEATHERLY: This is what I was trying to say before,
21 that the gap can be controlled for by just putting the column of LEDs closer
22 to the edge.

23 MR. LANDMON: Yes, and that's our position, Your Honor.

24 JUDGE WEATHERLY: Although this time I managed to say it in
25 six words instead of 100.

26 MR. LANDMON: If I could have us turn to Slide 57. So Patent

1 Owner's Counsel, again, this was in discussion and in response to questions
2 about what number 20 is in the figure of Larsen that we have to the left.
3 Patent Owner's counsel said it, they say in their papers too, that somehow
4 figure 20 and the pointing of 20 is pointing to regular row arrangements.
5 And they point to figures 2A and 2D in the patent where the regular row
6 arrangements are shown.

7 So stating the obvious, but it's also what Dr. Jokerst submitted to,
8 if you look at figures 2A through 2D, you will not see a reference to 20
9 because there is none. And it also wouldn't make any sense to draw 20 in
10 the gap between the two panels where the area where the hinges would go
11 because regular row arrangements are the LED rows that would be on the
12 face of the panels. They wouldn't be between the panels as is shown in 20 in
13 figure 1 of Larsen.

14 Counsel, when he started as well, counsel for Patent Owner, when
15 he started, talked about the ALJ's initial determination, and he said when I
16 was talking, I only pointed to issues relating to uniform illumination. In our
17 papers we submitted here, and certainly in our petition to the Commission,
18 we have pointed to errors and things that the ALJ got wrong throughout his
19 opinion on all of the disputed issues that we have disputed here. I did want
20 to point out one, because it's not only where I think ALJ Moore went wrong.
21 I think it's also where Patent Owner goes wrong.

22 And if we could turn to Slide 49. And this is in relation to the
23 higher intensity limitation. We see in the bottom left, this comes from the
24 initial determination. But frankly, it actually really comes from Patent
25 Owner, where they draw the light spacing of Lundahl in the other orientation
26 to say that Lundahl would have said put a higher intensity on the long side of

1 the panels in Larsen. And that is what ALJ Moore found. The problem with
2 Patent Owner's position there --

3 JUDGE WEATHERLY: I really disagree with that. Strongly
4 disagree with that. That's not what Lundahl is showing the spacing in. The
5 fact that that's like taking advantage of the weird orientation that Lundahl
6 shows that panel. Yeah.

7 MR. LANDMON: We obviously totally agree with that, Your
8 Honor. We also believe that it is inconsistent with KSR and its progeny.

9 JUDGE WEATHERLY: Yeah.

10 MR. LANDMON: Basically, it's treating a POSA as an
11 automaton. As you know, and I don't mean to belabor the point on the law,
12 but a POSA has creativity --

13 JUDGE WEATHERLY: I mean, all you have to do is read
14 Lundahl to understand that the image is drawn and rotated 90 degrees from
15 the discussion.

16 MR. LANDMON: That's correct, Your Honor. Sorry, I may be
17 done. If you just give me a moment to look at my notes. Sorry, I'm not
18 done. I should have looked at my notes first.

19 One last point. You heard Patent Owner's counsel talk repeatedly
20 about inventor testimony and inventors, you know, saying that they had
21 difficulty. The law is pretty clear that the perspective is from a POSITA, not
22 from the inventors. And there's a lot of law we cite to in our papers, the
23 Standard Oil case, the Intercontinental Great Brands case. There are other
24 cases as well.

25 And one of the interesting things too, one of the inventors here
26 doesn't even qualify under the definition of POSITA that the Board's

1 adopted here. So I think for all of those reasons, for the reasons in our
2 petition, for the reasons set forth in all the papers and the evidence before
3 you, we believe the challenged claim should be rendered invalid as obvious.
4 If you have no other questions, I --

5 JUDGE WEATHERLY: We're a stickler for making findings on
6 patentability, whether it's patentable or -- unpatentable or not unpatentable.

7 MR. LANDMON: Apologies, Your Honor.

8 JUDGE WEATHERLY: I don't expect you to share the same sort
9 of peccadillo that we do on that, but we're not going to be entering any
10 findings on validity or invalidity.

11 MR. LANDMON: Yes. No, I should have used the right
12 terminology. Apologies for that, and thank you for the correction.

13 JUDGE WEATHERLY: We play with words, all of us.

14 MR. LANDMON: Yeah, thank you. I'm happy to answer more
15 questions.

16 JUDGE HOFFMAN: Further question.

17 MR. LANDMON: Yes.

18 JUDGE HOFFMAN: Not to belabor the point on 20 and 10 and
19 the typo, but I'm not convinced that 20 is pointing to the hinge structure. I
20 mean, it could be pointing to the axis, for example, that's illustrated there.
21 And clearly, there's some kind of typo, but we just don't know what it is.
22 And so I wanted to give you another opportunity to address the ALJ's
23 determination regarding the discouraged from placing the hinges between
24 the panels before 2015. I just want to hear one more time what your position
25 is.

26 MR. LANDMON: Yeah. Thank you, Your Honor. Patent Owner'

1 s counsel talked about that in relation to Slide 66 where they cite the
2 opinion. A couple things about that. What the ALJ Moore cited to there is
3 Dr. Jokerst's testimony, which is just her statements. She's not citing any
4 prior art devices. She's not citing -- I think Judge Weatherly asked, you
5 know, were there other prior art devices that we were talking about that
6 would have discouraged one from doing that?

7 She's not doing that. She's just saying that, listen, if you create a
8 gap, you have light shining out here and light shining out here. You need to
9 fill in that gap, and a POSITA needs to know how to fill in that gap. She
10 doesn't address prior art teaching away. It's her own statements that the
11 judge is relying on.

12 And I think at the heart of this, this is that Lundahl teaches that
13 uniformity is important. A POSITA looks at that, realizes that uniformity is
14 important, and then says, okay, I want to create a flexible design. I've got
15 that in Larsen. Where do I put the hinges? I mean, frankly, and we have a
16 lot of testimony, I know we had a lot of discussion the first time I was up
17 about the most obvious place that we see on every door frankly is a hinge
18 between the two items, so between the two panels.

19 And then on the discouragement point, it's, okay, well, then I need
20 to do this in a way that the gap is not so large that I can't overcome that by
21 my placement of the LEDs. Dr. Grove submitted testimony here that a
22 POSITA would have known how to do that, would have known how to place
23 the LEDs, and would have used a hinge. Very notably, and there's been
24 discussion, when both sides have been discussing, the claims don't require a
25 specific kind of hinge. They have another patent on whatever a nested hinge
26 is.

1 The claims just require some hinge structure. So a POSITA, using
2 their normal creativity, would say, okay, I need uniformity because Lundahl
3 tells me I need uniformity. I'm going to use a type of hinge between the
4 panels to keep them as close together. Maybe that's embedding them within
5 the panel. Maybe that's using just a hinge that's pretty small. There are all
6 kinds of different ways to do it. And Larsen itself talks about creating or the
7 fact that he did have continuous illumination between the panels.

8 So I think you put all of that together, and whether you say, well,
9 20 is the hinge. And I know you had some questions when I talked before
10 that the disclosure of respectively connecting one edge with the other, we do
11 believe that's strong enough to support the hinge being there. But also,
12 there's only a few places to put them. And, you know, one of a few is
13 certainly not something to overcome obviousness.

14 JUDGE WEATHERLY: It's an unexpectedly spicy issue. We
15 have an advantage here, that Judge Moore would admit probably that there
16 are three of us and we get to talk about this case and figure out where we go
17 in a consensus way. And don't misinterpret my questions as being
18 representative by the way of what my colleagues think about this case. I
19 don't have any other questions. It looks like you're about to wrap up.

20 JUDGE HOFFMAN: Any further questions? Well, thank you
21 very much for your time.

22 MR. LANDMON: Thank you.

23 JUDGE HOFFMAN: Patent Owner, you have ten minutes for
24 your sur-rebuttal.

25 MR. HA: Thank you, Your Honor.

26 JUDGE HOFFMAN: Give me one moment to start the clock.

1 And I will start your time when you begin speaking.

2 MR. HA: Thank you very much. I'll start with the divergence
3 angle issue, and I'll actually turn to our Slide 31 through 33 for that
4 particular point. So a couple of points I want to make is, they locked
5 themselves in the petition into incorporating, and this is now on Slide 31 of
6 our demonstratives, incorporating the uneven spacing of light sources of
7 Lundahl in making this proposed combination. That's that series of lights
8 that are various different centimeters, like 3.5, 5, and 7 centimeters apart
9 from each other.

10 Now, what Dr. Jokerst is explaining, and this is on Slide 32, is
11 when you have that uneven spacing that the Petitioner's proposed
12 combination actually put forth in the petition, well, if you look at the hot
13 spots of the LEDs, most of those hot spots are going to appear right directly
14 below the LEDs themselves. So the regions in between may or may not
15 actually meet that required at least within 60 percent of the measured
16 maximum. Their proposed combination and their petition had to
17 demonstrate that, but it didn't, and that's the issue. And I think Petitioner's
18 counsel said Dr. Grove sort of rebutted Dr. Jokerst's position on this.

19 JUDGE WEATHERLY: Let me ask you a question about Dr.
20 Jokerst's depiction here.

21 MR. HA: Yes.

22 JUDGE WEATHERLY: And the papers will bear this out, so
23 almost regardless of what you answer, we'll figure out what she means.
24 Does she mean -- she depicts these LED sources as throwing a relatively
25 narrow angle cone of light energy?

26 MR. HA: So this is -- so Dr. Jokerst's --

1 JUDGE WEATHERLY: Is this her saying it might be like this,
2 therefore Petitioner's failed to make out a case? Or is this her saying, no,
3 this is how LEDs project light?

4 MR. HA: Her point on paragraph 128 is spacing LEDs as taught
5 by Lundahl's uneven spacing of light sources would create gaps. That's her
6 explicit statement.

7 JUDGE WEATHERLY: And how does she know that? She has
8 no idea what the scale of those spaces are.

9 MR. HA: So we do know what the scale is because you see the
10 dimensions here on Slide 31, for example --

11 JUDGE WEATHERLY: Oh, I see. Those are dimensions from
12 Lundahl?

13 MR. HA: Correct.

14 JUDGE WEATHERLY: Okay.

15 MR. HA: And so --

16 JUDGE WEATHERLY: But again, that's the combination. That's
17 your characterization of Petitioner's combination --

18 MR. HA: Correct.

19 JUDGE WEATHERLY: -- is a perfect bodily incorporation of
20 take the LED tubes -- the fluorescent tubes out of Lundahl and plug in LEDs
21 in exactly the same physical gap of spacing.

22 MR. HA: And it's their wording that we're looking at, right? This
23 is paragraph 179 of Dr. Grove's declaration that incorporates the uneven
24 spacing of light sources of Lundahl. So we're taking what they presented in
25 the petition and we're rebutting what they presented.

26 JUDGE WEATHERLY: Yeah. Well, again, usually it's about

1 teachings between references, not bodily incorporation. And a reference to
2 the uneven spacing of light sources, what you're asking us to find is that Dr.
3 Grove is saying the specific three and a half centimeter, 5 cm, 7 cm gaps
4 shown in Lundahl, right? That's what the uneven spacing means from your
5 perspective?

6 MR. HA: That's correct.

7 JUDGE WEATHERLY: Now, was there any cross-examination
8 on that point?

9 MR. HA: Yes, Your Honor.

10 JUDGE WEATHERLY: So what did he say?

11 MR. HA: He said -- so let me explain this a little bit further. So
12 he submitted an ITC expert report. He submitted another declaration that
13 both says you're incorporating the uneven spacing. We then took the
14 deposition --

15 JUDGE WEATHERLY: Yeah, but my point is I'm not sure that
16 incorporating the uneven spacing means what you say it means.

17 MR. HA: And so the deposition, the cross-examination testimony
18 at the ITC, we locked him in and asked him the question, are you relying
19 specifically on that spacing? And he said, yes. And the IPR deposition --

20 JUDGE WEATHERLY: That spacing meaning three and a half
21 millimeters.

22 MR. HA: Correct.

23 JUDGE WEATHERLY: But do you talk about three and a half
24 centimeters and 5 cm in the depo?

25 MR. HA: Yes, we do.

26 JUDGE WEATHERLY: And is that a record in our case?

1 MR. HA: Yes, Your Honor.

2 JUDGE WEATHERLY: And it's ITC cross-examination?

3 MR. HA: It's both ITC cross-examination as well as IPR cross-
4 examination.

5 JUDGE WEATHERLY: Okay. The ITC cross-examination that
6 was on the stand in front of Judge Moore, right?

7 MR. HA: That's a deposition --

8 JUDGE WEATHERLY: Okay, all right.

9 MR. HA: -- for the ITC proceeding.

10 JUDGE WEATHERLY: And is there any evidence that goes
11 against you on this specific point?

12 MR. HA: Well, in the -- so after he admitted in the ITC deposition
13 that he is relying on the spacing, when we tried to confirm that in the IPR
14 deposition a couple of months later, he then says, no, I'm just relying on the
15 various teachings, despite the fact that his ITC expert report and the IPR
16 declaration used identical verbatim words. So that's the issue that we're
17 raising in the motion to exclude evidence, where he's now trying to give
18 himself more flexibility in making the change despite the fact that the
19 original declaration presented should have locked himself into --

20 JUDGE WEATHERLY: Doing that with a supplemental
21 declaration of some kind that was submitted with the reply?

22 MR. HA: Yes, Your Honor.

23 JUDGE WEATHERLY: Just as a point of practice for you in the
24 future, I'm not sure that it's -- to try to get us to exclude evidence on a Rule
25 403 basis is a really, really tall, really tough challenge.

26 MR. HA: We understand.

1 JUDGE WEATHERLY: Right.

2 MR. HA: Yes, Your Honor.

3 JUDGE WEATHERLY: I hope that I've demonstrated, at least by
4 the questions I'm asking, that we're not really worried about evidence being
5 prejudicial or misunderstanding the evidence --

6 MR. HA: Understood, Your Honor.

7 JUDGE WEATHERLY: -- on the bench here.

8 MR. HA: Yes. And I think Your Honors are totally capable of
9 deciphering which arguments are new and which ones are ones that are
10 presented --

11 JUDGE WEATHERLY: Well, if an argument's new though, that's
12 a different issue. And I will just refer to it as kind of a Rule 23 issue, where
13 your argument would be that the Petitioner has exceeded the proper scope of
14 a reply.

15 MR. HA: Yes, Your Honor.

16 JUDGE WEATHERLY: And that we should disregard to the
17 extent that they've exceeded that scope. But you really haven't presented
18 that argument for us, have you?

19 MR. HA: Well, only because I think the panels have routinely
20 discarded new arguments of improper scope.

21 JUDGE WEATHERLY: I just had a decision I wrote vacated
22 because I didn't consider someone's declaration testimony on reply.

23 MR. HA: Understood. Which is why we're --

24 JUDGE WEATHERLY: And it's reversible error for me to not
25 consider something that the Federal Circuit thinks I should consider.

26 MR. HA: Right. Which is exactly the reason why we're moving to

1 exclude the evidence.

2 JUDGE WEATHERLY: Well, it's also reversible error for me to
3 exclude evidence if the Federal Circuit thinks it's something that I should
4 have considered.

5 MR. HA: Understood.

6 JUDGE WEATHERLY: If we do consider the evidence, then
7 what? What does that do to your position? Does it --

8 MR. HA: Well, it still has the overall defect of, number one, not
9 presenting or demonstrating the required construction. So regardless of what
10 the spacing is, they still haven't demonstrated it needs to be at least within 60
11 percent of the maximum.

12 JUDGE WEATHERLY: To some extent, doesn't that depend on
13 us agreeing with Dr. Jokerst that these LEDs emit light in this really tight
14 cone pattern?

15 MR. HA: I think it's just a procedural defect. They have no
16 discussion whatsoever. And I'll point you to our demonstrative Slide 41,
17 which is their entire discussion of this uniformly illuminating in the petition.
18 So we've presented here on Slide 41, and we've color coded their individual
19 discussion of Lundahl in blue and their individual discussion of Larsen in
20 pink. No where did they ever talk about these two things in combination
21 with one another.

22 JUDGE WEATHERLY: Which two things are you talking about?

23 MR. HA: How the proposed combination of Lundahl --

24 JUDGE WEATHERLY: Right. What the spacing precisely
25 should be on the LED sources?

26 MR. HA: Including the at least within 60 percent maximum,

1 including how you actually apply the teachings of one to the other and --

2 JUDGE WEATHERLY: Yeah, that's tough for you because, I
3 mean, there's no argument that Lundahl doesn't say that uniformity is
4 important. There's no argument that Larsen says that uniformity is
5 important. The question ends up being whether Petitioner's showing about
6 uniformity in the combination that they propose is sufficient.

7 MR. HA: Yeah, so I want to push back on Larsen's teaching that
8 uniformity matters, right? Which is Larsen only talks about gap-free
9 illumination, which is not uniform as required by the construction. It's
10 similar to our figure 7, which has a conventional illuminator where you can
11 have a gap-free illumination that falls below 60 percent. When they make
12 the proposed combination of breaking up the panel, placing these LEDs in
13 this specific uneven spacing, they have to go and demonstrate that the
14 greater than 60 percent is met. They haven't done any of that.

15 JUDGE HOFFMAN: On that point, the challenged patent, column
16 3, talks about the lighted hinge, which really refers to the U-shape. It talks
17 about the nested hinges. It talks about the individual configurable aspect.
18 And it seems to suggest those three things in combination are what results in
19 this uniform illumination. Is that not correct? If we found a combination
20 -- if we determined the combination with those three things was obvious,
21 wouldn't it not have uniform illumination?

22 MR. HA: And I'm sorry I missed the three things. I just want to
23 make sure I have that exactly right.

24 JUDGE HOFFMAN: Sure. It's in column 3. And it refers to it as
25 the lighted hinge, which seems to refer to the U-shape of the device. It talks
26 about the nested hinges, which goes to the gap-free, and it talks about the

1 individually configurable aspect of the panels.

2 MR. HA: So I want to push back on that. The lighted hinge is an
3 embodiment that's not a disputed issue because literally that embodiment
4 actually uses a light at the hinge, so that's a lighted hinge. Nested hinge, as
5 we noted earlier, is one type of a hinge that's on the inner side surface.
6 You're right about the individually configurable, but we also have additional
7 characteristics like the higher intensity of light near the shorter edges relative
8 to the non-shorter edges. It's these various combinations of technologies that
9 are put together that makes the claim inventive. And I think your point
10 about these three is just slightly off.

11 JUDGE HOFFMAN: Okay. Thank you.

12 MR. HA: I think I'm over my time, so I will sit down.

13 JUDGE HOFFMAN: Okay. Are there any further questions from
14 the panel? Counsel, thank you so very much. We appreciate your level of
15 preparedness today. I believe it was very helpful for us. And we will take
16 this case under advisement and issue our final written decision in due course.
17 The panel will be leaving now, but please remain in the room to confer with
18 the court reporter to ensure that there are no questions regarding the spelling
19 of names or terms. Thank you again.

20 (Whereupon, the above-entitled matter went off the record at 4:04
21 p.m.)

IPR2024-01312
Patent 11,697,028 B2

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Exhibit B

**SUPPLEMENTAL EXPERT DECLARATION OF ROBERT E. GROVE, PH.D., FOR
INTER PARTES REVIEW OF U.S. PATENT NO. 11,697,028**

I. INTRODUCTION

1. I, Robert E. Grove, submit this supplemental declaration in support of Petitioner's Reply to Patent Owner's Response in *Inter Partes* Review Proceeding No. IPR2024-01312 of United States Patent No. 11,697,028 ("the '028 Patent"), owned by Sun Pharmaceuticals, Inc., ("Patent Owner" or "Sun").

2. I have been retained in this matter by Polsinelli ("Counsel") on behalf of Biofrontera Inc., Biofrontera BioScience GmbH, Biofrontera Pharma GmbH, and Biofrontera AG (collectively, "Petitioner" or "Biofrontera").

3. I make this declaration based upon my personal knowledge. I am over the age of 21 and am competent to make this declaration.

4. I incorporate by reference my opinions set forth in my declaration signed on August 21, 2024, submitted in this proceeding as Ex. 1015.

5. My materials considered for forming my opinions herein are listed in Ex. 1015 and below in Appendix A in view of my specialized knowledge provided by my education, training, research, and experience, as summarized in Ex. 1015 and described in detail in my CV, which was provided as Appendix B to Ex. 1015.

6. I understand that Petitioner retained me using Rubin Anders Scientific, Inc. ("RAS"), and that RAS is being compensated at a rate of \$1,000 per hour for my time spent in preparing this declaration. Regardless of my compensation in this matter, the opinions herein are my own, and I have no stake in the outcome of the review proceeding. My compensation does not depend in any way on the outcome of Petitioner's petition.

II. RELATED PROCEEDINGS

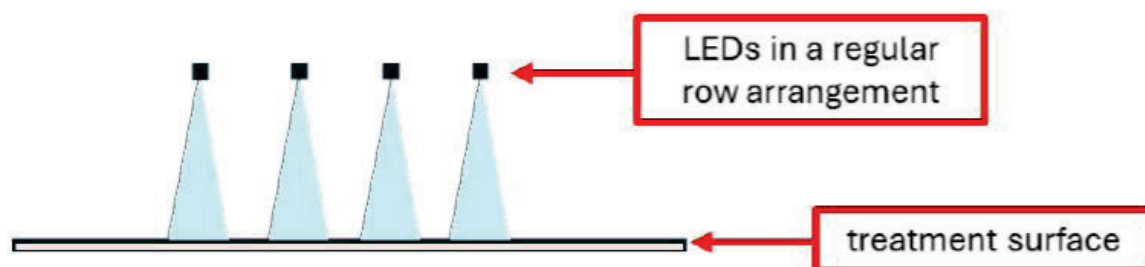
7. The '028 Patent is involved in a related ITC matter, *In Re Certain Photodynamic Therapy Systems, Components Thereof, And Pharmaceutical Products Used In Combination With The Same*, Investigation No. 337-TA-1411, that may affect or be affected by this proceeding. See EX1020 (ITC Complaint).

8. I have applied the construction of the claims as ordered in the related ITC matter. See EX2033 (ITC Order No. 18).

III. REPLY TO DR. JOKERST'S TESTIMONY

A. LED Light Emission

9. In her declaration in support of the Patent Owner Response, Dr. Jokerst includes a discussion of the "Technology Background," in which she discusses the technology underlying fluorescent tubes, as well as LEDs. See EX2050, ¶¶37-48. In particular, Dr. Jokerst states that LEDs "are discrete, point source, directional illuminators with a Lambertian output characteristic" (emphasis added). EX2050, ¶46. While I agree with this statement, I disagree with how Dr. Jokerst has illustrated and characterized the light distribution pattern from LEDs. Dr. Jokerst states that "LEDs emit light in a specific direction in a 'noncoherent, narrow band.'" *Id.* Additionally, Dr. Jokerst states that "LEDs placed in a regular row arrangement are not a continuous light source," and provides the following illustration:



EX2050, ¶46.

10. Again, while I agree that LEDs are discrete, point source, directional illuminators, Dr. Jokerst's discussion and illustration of the illumination profile for LEDs mischaracterizes what is known in the art. As an initial matter, Dr. Jokerst relies on EX2011, a 2008 article entitled "An Introduction to Light-emitting Diodes" by Bourget. EX2050, ¶44, 46-47. The only support for Dr. Jokerst's discussion and illustration of the LEDs having a "noncoherent, narrow band" is provided in the Bourget article (EX2011), and the discussion in the Bourget article is in reference to the wavelength of the emission from an LED light, *not* the light distribution. *See* EX2011, 1 ("Light-emitting diodes (LEDs) are semiconductor devices that produce noncoherent, narrow-spectrum light when forward voltage is applied. LEDs range in wavelength from the UVC band to infrared (IR) and are available in packages ranging from milliwatts to more than 10 W;" "LED light is of a noncoherent, narrow band (Wikipedia LED, 2008). In general, LEDs are not dangerous. However, care should be taken if LEDs in the UVB and UVC range are used, because those wavelengths can be dangerous to the eyes and skin in sufficient power levels"). Consequently, a POSA reading Bourget would conclude that the discussion of a "noncoherent, narrow band" refers to the wavelength of emission from the LED, and has nothing to do with the divergence (*i.e.*, spread) of light from the LED.

11. Further, Dr. Jokerst correctly notes that LEDs have a "Lambertian output characteristic." EX2050, ¶46. Exhibit 2013 cited in Dr. Jokerst's declaration, a 2015 article entitled "Visible Light Communications (VLC) Technology" by Ndjiongue, describes Lambertian LED light emission profiles. EX2013, 8. Specifically, Figure 6 of EX2013 illustrates a Lambertian distribution of light from LEDs.

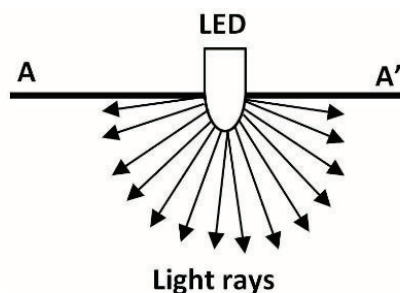
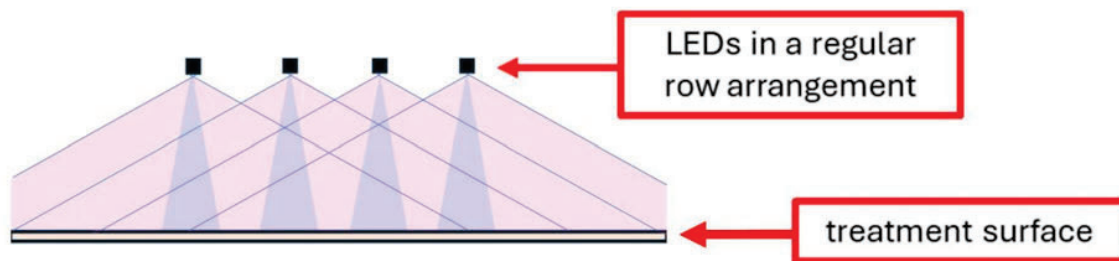


Figure 6: Scattering of the light from LEDs (Lambertian distribution); ($A - A'$) represents the Lambertian surface in the profile view

EX2013, 8.

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

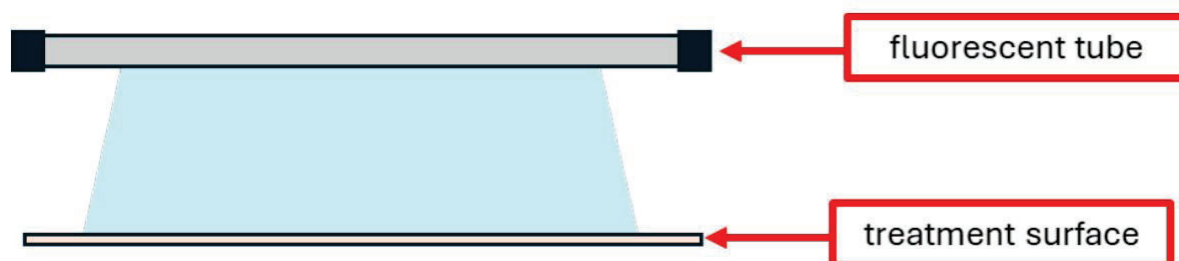


13. As can be seen from the modified illustration above, a POSA would understand that, while LEDs placed in a regular row arrangement are discrete light sources, unlike a fluorescent tube, a row of individual LEDs would not be expected to have the gaps in illumination that are illustrated by Dr. Jokerst.

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

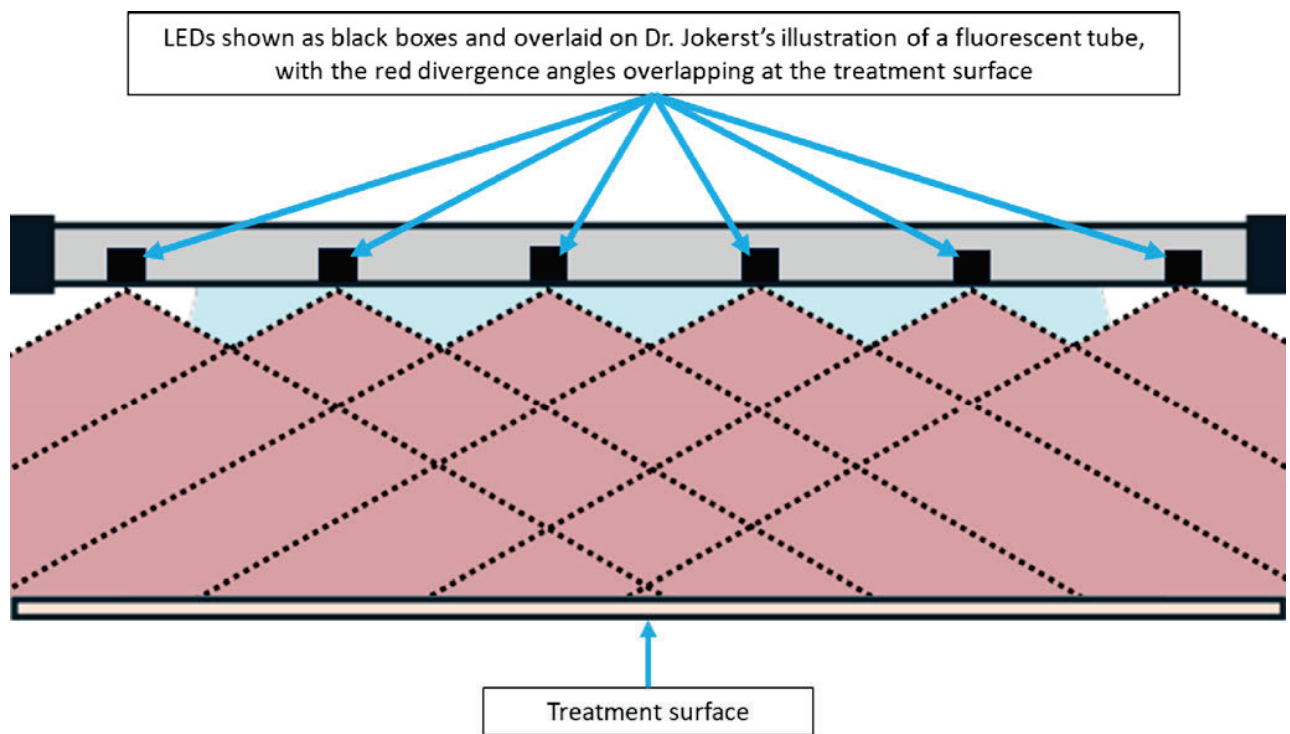
15. In particular, as I discussed in my original declaration (EX1015), based on the teachings of Lundahl and Larsen, a POSA would be motivated to replace the fluorescent tubes of

Lundahl with the LEDs taught by Larsen for a number of reasons. EX1015, ¶¶129-131. As described by Dr. Jokerst, fluorescent tubes are a continuous light source, as illustrated below:



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

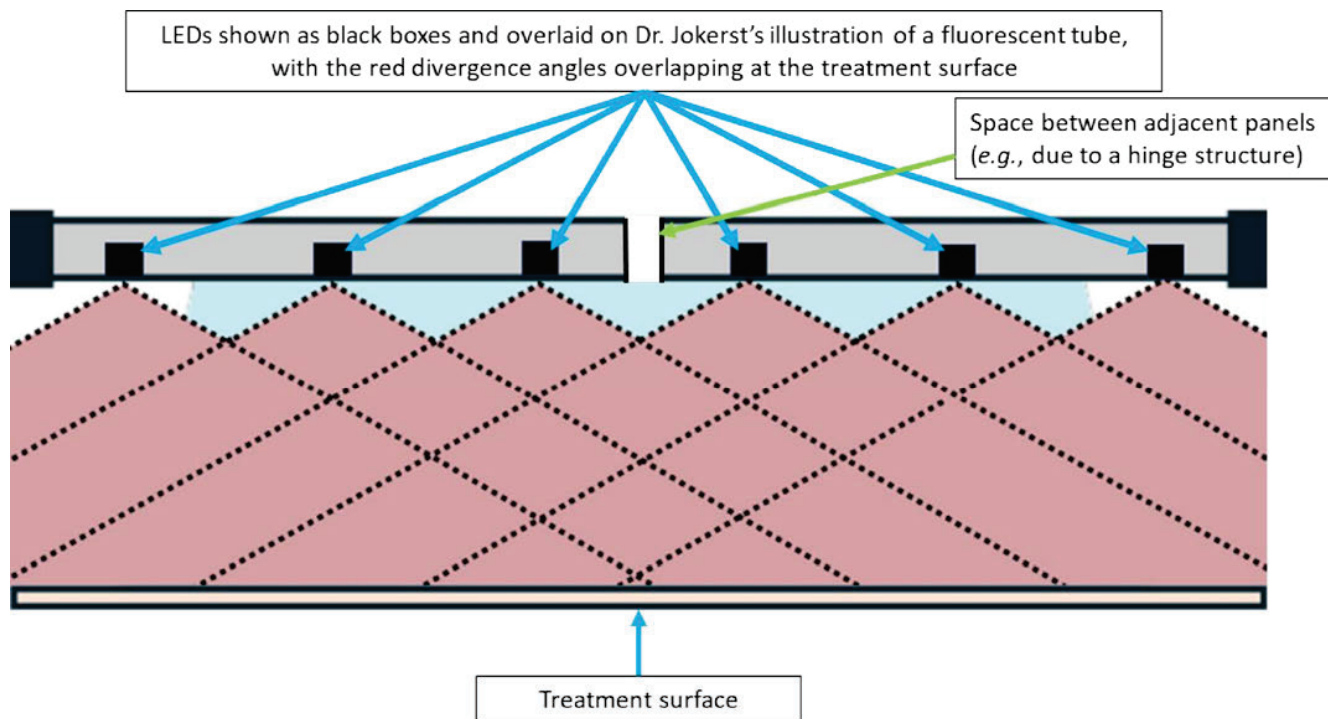
¹ The overlap of adjacent divergence angles would increase at distances from the treatment surface greater than the minimum of two inches, including at four inches.



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

17. Additionally, even the physical space between adjacent panels resulting from the attachment of adjacent panels via hinges (or other means) is easily addressed by accounting for the

overlap of divergence angles at a distance from the treatment surface of a minimum of two inches², as I have illustrated below:



18. In fact, this common understanding is also reflected in the disclosure of the '028 Patent. The '028 Patent reports that “Fig. 8, on the other hand, illustrates the light uniformity produced by an embodiment of the present invention.” EX1001, 8:43-44.

² The overlap of adjacent divergence angles would increase at distances from the treatment surface greater than the minimum of two inches, including at four inches.

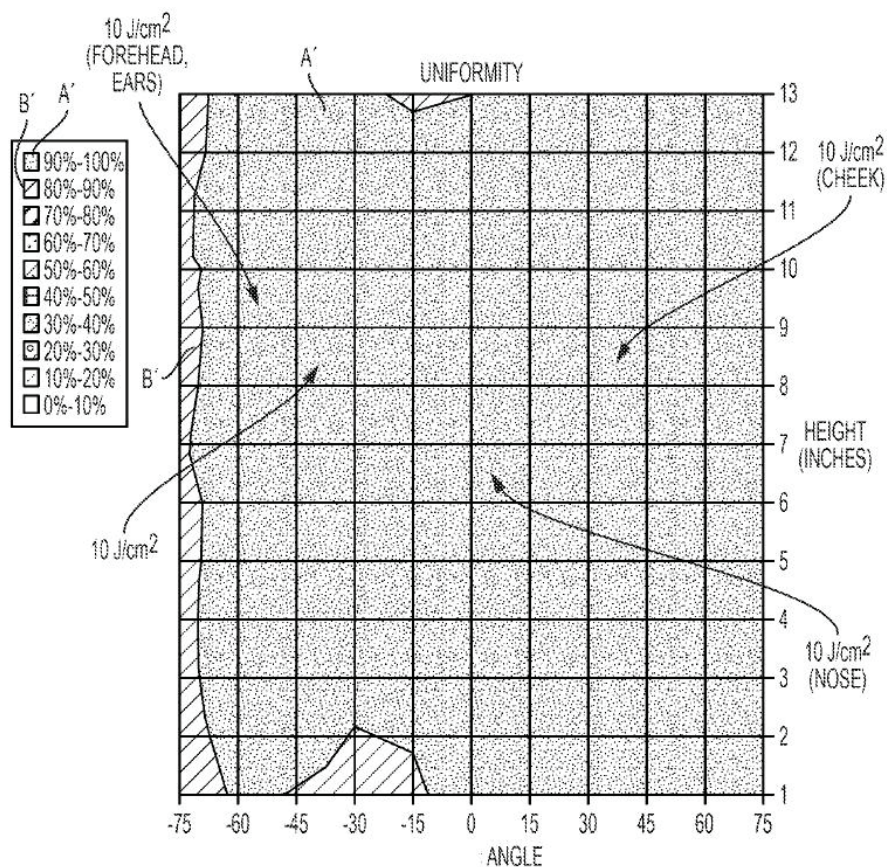


FIG. 8

EX1001, FIG. 8.

19. The uniformity of 90-100% provided in the '028 Patent is significantly higher than the 60% standard required by the claims. EX2033, 15. Notably, these uniformity values of 90-100% were achieved, yet the '028 Patent does not once describe the specific spacing of LEDs on the illuminator tested in Fig. 8. EX1001, 3:59-60. While the '028 Patent references “addressable strings” included in areas 1, 3, and 5, and 2, 4, and 6 (as illustrated in Fig. 5), the '028 Patent includes no disclosure as to the specific spacing of LEDs within each of these strings. *See* EX1001, 6:24-37. Additionally, the '028 Patent states that, “[e]ach panel contains an array of light emitting diodes (LED) 60, which may be configured in an evenly spaced pattern across the face of the panel[,] [t]he number of individual LEDs arranged in a given array is not particularly limited[.]”

EX1001, 3:56-60, but once again provides no discussion of the specific spacing of the LEDs on the panel. This is because a POSA would find the determination of the specific spacing between LEDs in a row to be a straightforward task given the understanding in the art, accounting for divergence angles and the Lambertian distribution.

20. Consequently, despite Dr. Jokerst's assertions that "[b]y replacing the continuous, diffuse light of the fluorescent tubes with discrete, directional point source LEDs with Lambertian outputs, Dr. Grove is creating gaps (between the LEDs) that were not in Lundahl's light distribution," (EX2050, ¶121), a POSA would understand that these alleged "gaps" would not be present in the combined device, because a POSA would know to account for the divergence angles of the LEDs, and space the lights accordingly.

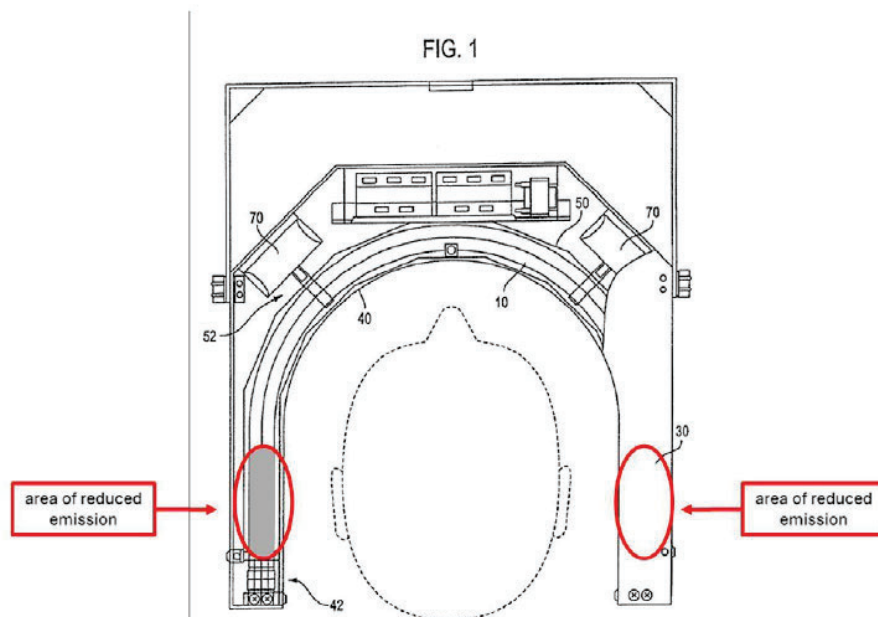
21. Dr. Jokerst's arguments mischaracterize the teachings in the art, and ignore the basic and standard knowledge of a POSA having a M.D. and/or a Ph.D. in an electrical engineering, physics, optical sciences, optical engineering, or a related scientific or engineering field, and at least one to two years of work or research experience in optical engineering, optics, optoelectronics, phototherapy ("PT"), PDT, or a related field.³ Thus, as outlined in my initial declaration, Lundahl in view of Larsen renders obvious the combined illuminator I described in my previous declaration, and a POSA would have at least a reasonable expectation that the combined illuminator would provide the claimed "uniform illumination," which the parties have agreed to be construed in the related ITC proceeding (and subsequently adopted by the Administrative Law Judge) as "irradiating light over the active emitting area such that the

³ This definition of a POSA is the definition provided in the Decision Granting Institution of *Inter Partes* Review dated February 24, 2025. While this definition differs from the definition I provided in my previous declaration, I nonetheless qualify as a POSA under this definition.

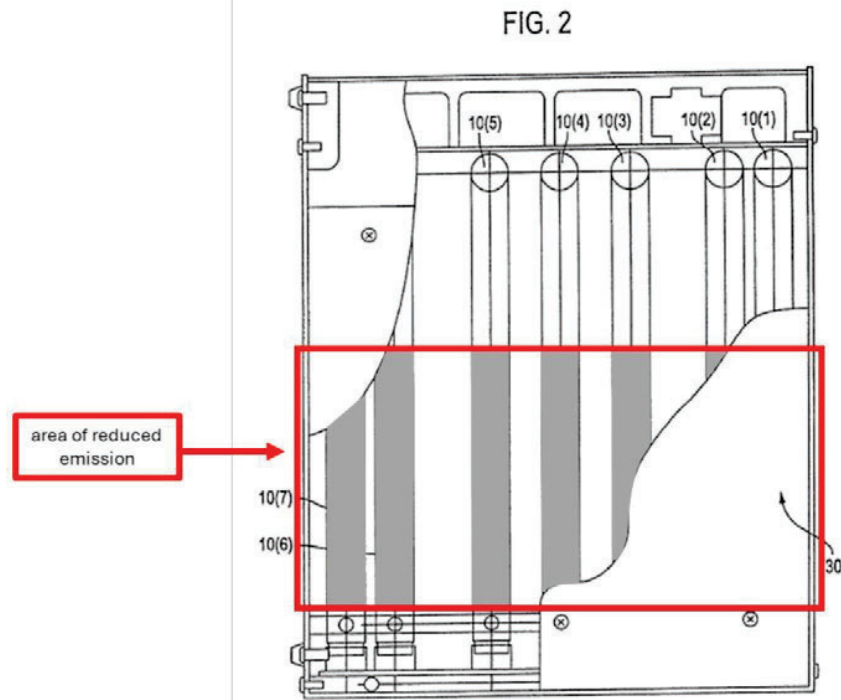
measured irradiance at a treatment surface of the patient is at least within 60% of the measured maximum.” See EX1015, ¶¶178-179; *see also* EX2033, 15.

B. LED Light Source Properties

22. As acknowledged by Dr. Jokerst, Lundahl teaches that a fluorescent tube has an area of reduced emission near the cathode known as the Faraday dark space. EX1014, 5:66-6:4; EX2050, ¶40. Dr. Jokerst explains that this “area of reduced emission” is reflected in multiple illustrations included in her declaration, including the following:

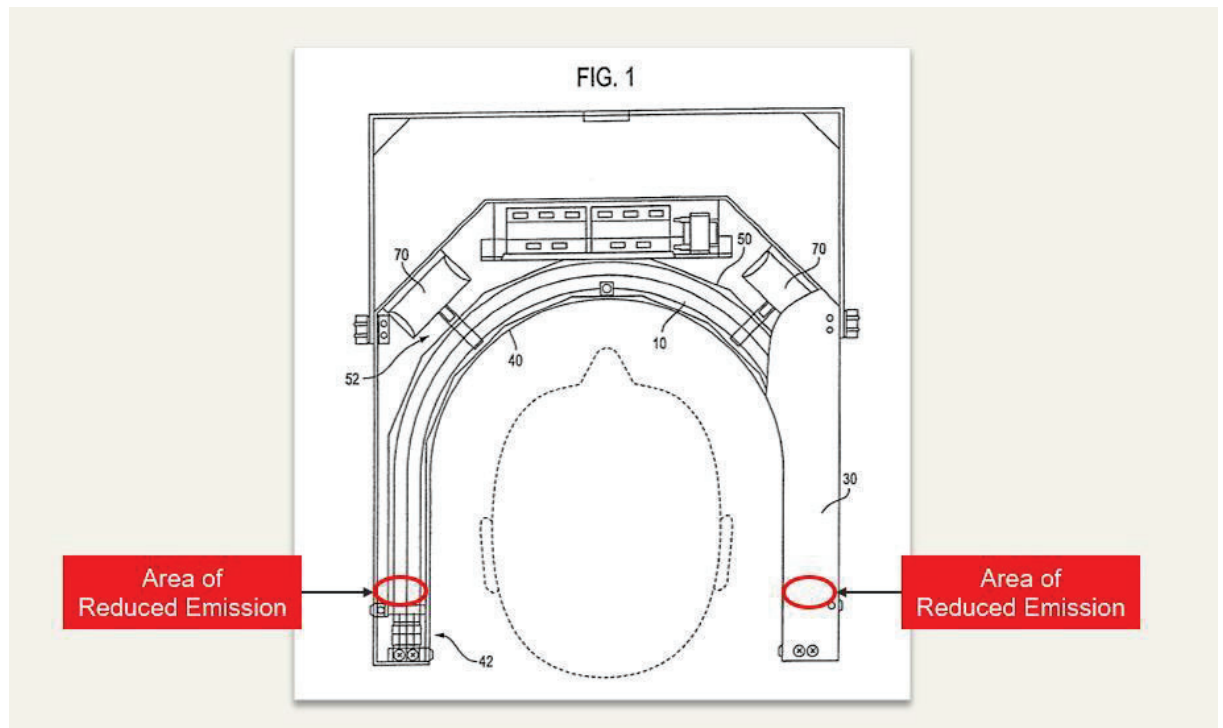


EX2050, ¶145.



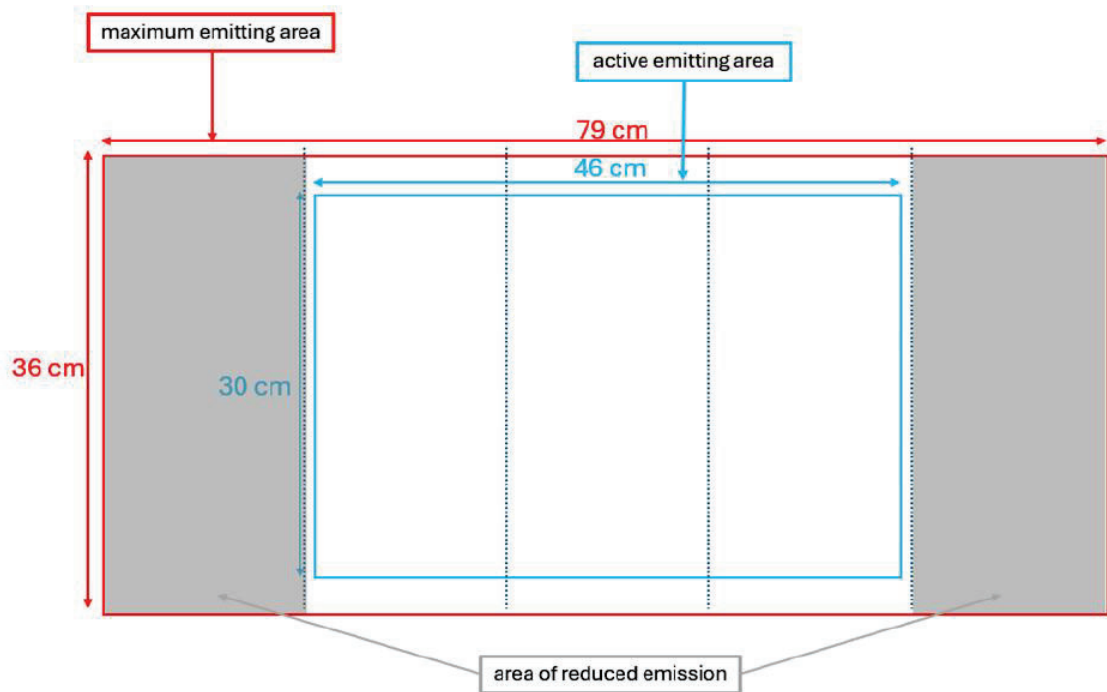
EX2050, ¶145.

23. However, these illustrations are inconsistent with Lundahl’s own description of the location of the Faraday dark space. Lundahl states that “the cathodes and their low output area [are] located outside the active emitting area (*effectively behind the patient’s ears*).” EX1014, 6:10-20 (emphasis added). The portion of the fluorescent tubes shown in Fig. 1 of Lundahl behind the ears is a very small portion of the tube immediately adjacent the metal couplings, as I have illustrated below.



24. Conversely, the illustration provided by Dr. Jokerst shows an area of reduced emission that is *next to* and even *in front of* the ears. This is not what Lundahl discloses. Lundahl states that the reduced emission is *behind* the ears. Consequently, it is my opinion that Dr. Jokerst's positions on the areas of reduced emission mischaracterize the teachings of Lundahl, and I disagree with these positions.

25. Moreover, when describing the "maximum emitting area" and the "active emitting area," Dr. Jokerst provides the following illustration:



EX2050, 98.

26. However, Dr. Jokerst conveniently omits that Lundahl describes the “active emitting area” that is denoted by the 30 cm x 46 cm portion of her illustration above, as the “*minimum* therapeutically active area.” EX1014, 5:38-46 (emphasis added). Consequently, a POSA would recognize that this “therapeutically active area” (i.e., “active emitting area”) could be larger than the region Dr. Jokerst has noted in her illustration.

IV. CONCLUSION

27. In my opinion, claims 1, 2, 4-6, 16, 17, 19, 20, and 21 of the '028 Patent are invalid for at least the reasons stated above, in addition to the reasons I have stated in my previous declaration, as well as the reasons I have provided in my expert reports, witness statements and demonstratives, and hearing testimony provided in ITC Investigation No. 337-TA-1411, redacted copies of which are provided as exhibits to this supplemental declaration.

28. I reserve the right to supplement my opinions in the future to respond to any arguments raised by the owner of the '028 Patent and to take into account new information that becomes available to me.

29. I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code. Signed on this 13th day of August, 2025.

Respectfully submitted,

Signed by:

76704E026020400
Robert E. Grove, Ph.D.

APPENDIX A

APPENDIX A
MATERIALS CONSIDERED

All Materials Referenced in this Declaration, and other Relevant Materials, Including the Following:

Exhibit No.	Description
1001	U.S. Patent No. 11,697,028
1002	File history for U.S. Patent No. 11,697,028
1023	Levulan® Kerastick® (aminolevulinic acid HCl) for Topical Solution, 20%, Initial U.S. Approval: 1999, Revised 3/2010
1017	U.S. Patent No. 5,079,262
1014	U.S. Patent No. 6,223,071
1008	U.S. Patent No. 7,033,381
1009	Office Action dated March 23, 2021, from file history of Application No. 17/009,871
1010	Office Action dated October 25, 2021, from file history of Application No. 16/791,004
1004	U.S. Patent Publication No. 2005/0075703
1005	U.S. Patent Publication No. 2004/0068305
1016	Declaration of Michael Ehrenreich, MD
1021	Agostinis, P et al. Photodynamic Therapy of Cancer: An Update. CA Cancer J Clin.2011; 61(4): 250-281
1023	M. Gold, “Lasers and Light Treatments for Acne Vulgaris, Promising Therapies,” J. of Clinical Aesthetic Dermatology, Vol. 1, No. 3, pp. 28-34, at 29 (Sept. 2008)
Petition	April 30, 2024, Petition for <i>Inter Partes</i> Review of U.S. Patent No. 11,697,028
2033	<i>In Re Certain Photodynamic Therapy Systems, Components Thereof, And Pharmaceutical Products Used In Combination With The Same</i> , Investigation No. 337-TA-1411, Order No. 18: Construing Certain Claim Terms (March 4, 2025)
2050	Declaration of Nan Marie Jokerst, Ph.D.
2011	C. Michael Bourget, <i>An Introduction to Light-emitting Diodes</i> , HortScience, Vol. 43(7), pp. 1944-1946 (December 2008)
2013	Ndjiongue, Alain R. et al., <i>Visible Light Communications (VLC) Technology</i> , pp. 1-23 (June 2015)

APPENDIX B

CURRICULUM VITAE

ROBERT E. GROVE, PH.D.

28 GREY EAGLE CT.
PLEASANTON, CA 94566

EXECUTIVE SUMMARY

Business executive and entrepreneur with a career of over forty years in the medical laser industry. Proven ability to build successful companies from concept through acquisition. Exceptionally strong technical background combined with CEO-level business management experience. Global consultant to diverse clients including private equity, law firms and medical device companies. Particular expertise in implementing recent trends in the med-device space toward recurring revenues with both Rx and OTC dermatologic devices. Public and private Board experience as well as IP litigation and deposition.

PROFESSIONAL CORPORATE EXPERIENCE

ON Light Sciences, Inc. (2013 – 2016)

Executive Chairman

Directed start-up developing transparent gel patches for accelerated tattoo removal with short-pulse lasers. Raised seed-round funding and recruited world-renowned dermatologists for clinical trials. Acquired by Merz North America in August of 2016.

Intellectual Light, Inc. (2012 – 2017)

President and CEO

Founded start-up to develop and patent a novel low-cost laser diode source for OTC devices for medical and other applications, with emphasis on patent portfolio.

Once Again Me, Inc. (2011)

President and CEO

Founded start-up, raised \$300k in seed capital, developed an innovative OTC laser beauty device and associated patent applications. Acquired by TRIA Beauty, Inc. in Dec. 2011.

TRIA Beauty Inc. (2003 – 2010)**CEO '03-'08; CTO '09-'10**

Co-founded start-up to develop, manufacture and market consumer laser devices for permanent hair removal, acne and facial wrinkle treatment at home. Directed venture capital raise, grew worldwide sales to ~\$20M while CEO.

Coherent Star, Inc. (1999 – 2001)**President**

Expanded *LightSheer™* business as part of Coherent Medical. Managed over 100 employees with revenues in excess of \$50 million.

Star Medical Technologies, Inc. (1993 – 1999)**President and CEO**

Co-founded start-up to develop, manufacture and market the first successful Rx laser hair removal system (*LightSheer™*) that remains the gold standard today. Negotiated acquisition by Coherent in 1999 for \$65 million.

DermaCare, Inc. (1987 – 1990)**President and CEO**

Co-founded one of the first laser med-spas in the US; over \$2.5 million in domestic and foreign investment. Directed operation of two clinics in S. CA with over 400 patients/month.

Cooper LaserSonics, Inc. (1984 – 1987)**President, Laser Products Division**

Integrated copper lasers into newly formed Scientific and Industrial Division; identified research clinicians to spur new product development (e.g., laser treatment of port-wine hemangiomas).

Plasma Kinetics, Inc. (1981 – 1984)**President and CEO**

Co-founded world's first commercial copper vapor laser company. Raised funding, established manufacturing operations and led global marketing effort. Negotiated acquisition by Cooper LaserSonics in 1984.

Lawrence Livermore National Laboratory (1976 – 1981)**Project Leader**

Directed Copper Laser Development for the Atomic Vapor Laser Isotope Separation Program. Managed Ph.D. scientists and engineers developing world's largest laser pump source for pulsed dye laser uranium enrichment efforts at LLNL.

CONSULTING EXPERIENCE

QPC, Inc. (2024)

Business and technical consultant for high-power diode laser manufacturer, exploring opportunities for 1726-nm acne treatment systems.

Zerigo Health, Inc. (2021 - 2023)

Technical consultant for company with innovative UVB-LED home-use devices for treatment of psoriasis, eczema and vitiligo.

Arbonne International LLC (2014 – 2018)

Conceived, designed and developed, with outside firm, a novel home-use ultrasound device for enhanced application of topicals. Achieved over \$50 million in revenues during first two years on the market with \$2.5 M investment.

Apax Partners, LLP (2017)

Assisted private equity firm in evaluation of Syneron-Candela prior to its acquisition by Apax Partners.

JLE Associates (1990 – 1993)

Worked with two other laser experts to formulate plan for new laser business to be founded and owned by Hoya Corporation of Japan.

EXPERT WITNESS/DEPOSITION EXPERIENCE

Solta Medical, Inc. v. Lumenis Ltd. and Lumenis, Inc., 19-11600 (D. Mass 2021)

Served as technical expert witness in patent infringement litigation relating to aesthetic laser technologies, including providing deposition testimony, formal written opinions on claim construction, in-depth inspections of implicated laser systems and non-infringement and invalidity analyses regarding the same.

Lumenis LTD. and Pollogen LTD. (2019)

IPR2019-01180 and -01181. IPR proceedings before the Patent Trial and Appeal Board at the U.S. Patent and Trademark Office involving patents related to RF energy skin treatment apparatus and method.

Lutronic, Inc. (2018)

ITC Investigation 337-TA-1112. Certain Radio Frequency Micro-Needle Dermatological Treatment Devices and Components Thereof. Lead technical witness for company. Consulted on all aspects of invalidity and non-infringement, including developing theories of anticipation based on inherency and developing strategies related to obviousness.

Lumenis LTD. (2013)

Labor File 30125-07-10 (Tel Aviv – Jaffa), *Lumenis Ltd. vs. Karni et al.* Suit involved alleged theft of trade secrets relating to IPL devices for dermatology.

TRIA Beauty, Inc. (2009)

Deposed during litigation between Palomar Medical Technologies and TRIA Beauty alleging infringement of Palomar/MGH hair removal patents.

INDEPENDENT CORPORATE BOARD EXPERIENCE

Candesant Corporation (March 2019 – March 2023)

Independent Director for a venture-funded biotech company developing a safe, in-office, non-drug solution to excessive sweating.

IRIDEX Corporation [NASDAQ: IRIX] (Oct. 2018 – present)

Independent Director for an industry-leading ophthalmic laser manufacturer.
Member of Compensation Committee and Audit Committee.

Ellman International, Inc. (Dec. 2013 – Sept. 2014 acquisition by Cynosure, Inc.)

Independent Director for manufacturer of advanced radio-frequency products utilized around the world for precision surgical and aesthetic procedures.

CORPORATE ADVISOR/ADVISORY BOARD EXPERIENCE

American Society for Laser Medicine and Surgery, Inc.

Appointed to the Membership Committee (2020 and 2021). Appointed to the Nominating Committee by the ASLMS president, Eric Bernstein, MD (2018).

Elected to position of Industry Research and Development Representative (1995 – 1998); Elected to second term (2008 – 2011)

Appointed Exhibits Chairperson (1994 – 1998).

Joylux, Inc. (2017 – present)

Advisor to the CEO, shareholder of company developing and marketing through physicians the world's first home-use device for women's intimate wellness incorporating photobiomodulation and thermal energy.

RECENT PRESENTATIONS AND AWARDS AT PROFESSIONAL MEETINGS

American Society for Laser Medicine and Surgery Annual Meeting, Baltimore, April, 2024.

Recipient of the *Presidential Citation Award*, presented at the 2024 Annual Meeting.

American Society for Laser Medicine and Surgery Annual Meeting, Denver, February 2019.
Recipient of the *Presidential Citation Award*, presented at the 2019 Annual Meeting.

9th 5-Continent Congress, Lasers and Aesthetic Medicine, Barcelona, August 2018. "Will Vaginal Rejuvenation become the Largest Home-Use Device Market?"

American Academy of Dermatology Annual Meeting, San Diego, February 2018. "Lessons in Entrepreneurship: What I've Learned as Founder or Co-founder of Seven Companies".

EDUCATION

Postdoctoral training:

Head research associate, Research laboratory of Prof. Shaoul Ezekiel; MIT, 1976.

University: Ph.D. in Instrumentation (Field of laser applications); MIT, 1975.

M.S. in Aeronautics and Astronautics; MIT, 1971.

B.S. With Distinction in Engineering Physics; Cornell University, 1970. Graduated as salutatorian of engineering class (all EP, EE, ME, ChemE, CivE students).

PUBLICATIONS

1. R. E. Grove, F. Y. Wu, L. A. Hackel, D. G. Youmans and S. Ezekiel, "Jet-stream CW Dye Laser for High Resolution Spectroscopy", *Appl. Phys. Lett.* **23**, 442 (1973).
2. F. Y. Wu, R. E. Grove and S. Ezekiel, "CW Dye Laser for Ultra-High Resolution Spectroscopy", *Appl. Phys. Lett.* **25**, 73 (1974).
3. R. E. Grove, F. Y. Wu, and S. Ezekiel, "Frequency Stabilization of a CW Dye Laser", *Opt. Engr.* **13**, 531 (1974).
4. F. Y. Wu, R. E. Grove and S. Ezekiel, "Measurement of the Resonance Fluorescence Spectrum under Monochromatic Excitation", *Phys. Rev. Lett.* **35**, 1426 (1975).
5. R. E. Grove, F. Y. Wu, and S. Ezekiel, "Measurement of the Spectrum of Resonance Fluorescence from a Two-level Atom in an Intense Monochromatic Field", *Phys. Rev. A* **15**, 227 (1977).

6. R.S. Hargrove, R. E. Grove and T. Kan, "Copper Vapor Laser Unstable Resonator Oscillator and Oscillator-Amplifier Characteristics", IEEE J. Quantum E. QE-15, 1228 (1979).
7. B. E. Warner, R. S. Anderson and R. E. Grove, "Large Bore Copper Vapor Laser", Digest of Technical Papers, Opt. Soc. of America, CLEOS Conf., 90, Feb. (1980).
8. R. E. Grove, "Copper Lasers Come of Age", Laser Focus 18, 45 (1982). Reprinted in Frontiers of Laser Technology, PennWell, Tulsa, OK (1985).

PATENTS

	Patent No.	Patent Title	Issue Date
1.	10,342,618	Self-contained, eye-safe hair-regrowth-inhibition apparatus and method	July 9, 2019
2.	10,342,617	Phototherapy device thermal control apparatus and method	July 9, 2019
3.	D794,784	Skin care device	August 15, 2017
4.	9,687,671	Optical sensor and method for identifying the presence of skin and the pigmentation of skin	June 27, 2017
5.	9,302,118	Phototherapy device thermal control apparatus and method	April 5, 2016
6.	9,172,210	Mount for semiconductor devices using conformable conductive layers, and method	October 27, 2015
7.	8,965,214	Manufacturing system and method using IR communications link	February 24, 2015
8.	8,792,527	Mount for semiconductor devices using conformable conductive layers, and method	July 29, 2014
9.	8,777,935	Optical sensor and method for identifying the presence of skin	July 15, 2014
10.	8,755,420	Failure protection apparatus and system	June 17, 2014
11.	8,728,063	Antimicrobial layer for optical output window	May 20, 2014
12.	8,681,829	Compression mount for semiconductor devices, and method	March 25, 2014
13.	8,551,104	Self-contained, diode-laser-based dermatologic treatment apparatus	October 8, 2013

14.	8,518,027	Phototherapy device thermal control apparatus and method	August 27, 2013
15.	8,512,322	Antimicrobial layer for optical output window	August 20, 2013
16.	8,340,144	Compression mount for semiconductor devices, and method	December 25, 2012
17.	7,981,111	Method and apparatus for the treatment of benign pigmented lesions	July 19, 2011
18.	7,452,356	Eye-safe dermatologic treatment apparatus	November 18, 2008
19.	7,413,567	Optical sensor and method for identifying the presence of skin	August 19, 2008
20.	7,250,045	Self-contained, eye-safe hair-regrowth-inhibition apparatus and method	July 31, 2007
21.	D535,746	Portable hair removal device	January 23, 2007
22.	7,118,563	Self-contained, diode-laser-based dermatologic treatment apparatus	October 10, 2006
23.	6,758,845	Automatic firing apparatus and methods for laser skin treatment over large areas	July 6, 2004
24.	5,835,518	Laser diode array packaging	November 10, 1998
25.	5,743,901	High fluence diode laser device and method for the fabrication and use thereof	April 28, 1998
26.	5,707,403	Method for the laser treatment of subsurface blood vessels	January 13, 1998
27.	5,527,350	Pulsed infrared laser treatment of psoriasis	June 18, 1996

Exhibit C

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

v.

SUN PHARMACEUTICAL INDUSTRIES, INC.
Patent Owner.

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

REPLY TO PATENT OWNER'S RESPONSE

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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 provided in Application No. 17/942,353
1003	Reserved
1004	U.S. Patent Publication No. 2005/0075703 by Eric Larsen entitled “Photodynamic Stimulation Device and Methods” (“Larsen”)
1005	U.S. Patent Publication No. 2004/0068305 by Vineet Bansal et al. entitled “Phototherapy System and Device” (“Bansal”)
1006	Reserved
1007	Reserved
1008	U.S. Patent No. 7,033,381 (“Lundahl ’381”)
1009	Office Action dated March 23, 2021, from file history of Application No. 17/009,871
1010	Office Action dated October 25, 2021, from file history of Application No. 16/791,004
1011	WO 99/56827 by Scott Lundahl et al. entitled “Illuminator for Photodynamic Therapy”
1012	Reserved
1013	U.S. Patent No. 11,179,574 by Thomas Boyajian et al. entitled “Method of administering 5-aminolevulinic acid (ALA) to a patient”
1014	U.S. Patent No. 6,223,071 (“Lundahl”)
1015	Declaration of Dr. Robert Grove
1016	Declaration of Dr. Michael Ehrenreich
1017	U.S. Pat. No. 5,079,262 (“Kennedy”)
1018	Complaint filed in <i>Sun Pharmaceutical Industries, Inc. v. Biofrontera Bioscience GmbH, Biofrontera Pharma GmbH, Biofrontera AG, and Biofrontera Inc.</i> , Civil Action No. 1:24-cv-11637 (D. Mass) (filed on June 25, 2024)
1019	Plaintiff’s Infringement Contentions submitted as Exhibit 4 attached to complaint filed in <i>Sun Pharmaceutical Industries, Inc. v. Biofrontera Bioscience GmbH, Biofrontera Pharma GmbH,</i>

Exhibit No.	Description
	<i>Biofrontera AG, and Biofrontera Inc.</i> , Civil Action No. 1:24-cv-11637 (D. Mass) (filed on June 25, 2024)
1020	<i>In Re Certain Photodynamic Therapy Systems, Components Thereof, And Pharmaceutical Products Used In Combination With The Same</i> , Investigation No. 337-TA-1411 (complaint filed on June 25, 2024)
1021	Agostinis et. al., <i>Photodynamic Therapy of Cancer: An Update</i> , <i>CA Cancer J Clin.</i> Author manuscript; available in PMC 2012 July 1 (also published in final edited form at <i>CA Cancer J Clin.</i> 2011 ; 61(4): 250–281)
1022	Levulan® Kerastick® (aminolevulinic acid HCl) for Topical Solution, 20% Initial U.S. Approval: 1999, Revised 3/2010
1023	Michael H. Gold, <i>Therapeutic and Aesthetic Uses of Photodynamic Therapy, Part Two of a Five-Part Series, Lasers and Light Treatments for Acne Vulgaris, Promising Therapies</i> , <i>Journal of Clinical and Aesthetic Dermatology</i> , Vol. 1(3), pp. 28-34 (September 2008)
1024	Declaration of Brian Larivee in Support of Pro Hac Vice Motion
1025	Declaration of Chad Landmon in Support of Pro Hac Vice Motion
1026	Supplemental Declaration of Dr. Robert Grove
1027	Deposition Transcript of Nan Marie Jokerst, Ph.D., taken July 22, 2025
1028	Deposition Transcript of Heather J. Roberts, M.D., FAAD, taken July 25, 2025
1029	Deposition Transcript of Thomas D. Vander Veen, Ph.D., taken July 29, 2025
1030	Complainant’s Post-Hearing Brief (Public Version) filed in <i>In Re Certain Photodynamic Therapy Systems, Components Thereof, And Pharmaceutical Products Used In Combination With The Same</i> , Investigation No. 337-TA-1411 ¹

¹ All exhibits provided from the related ITC proceeding are publicly accessible redacted versions of those filings.

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

Exhibit No.	Description
1031	Trial Transcript Day 3 (Open Sessions) for <i>In Re Certain Photodynamic Therapy Systems, Components Thereof, And Pharmaceutical Products Used In Combination With The Same</i> , Investigation No. 337-TA-1411
1032	Trial Transcript Day 4 (Open Sessions) for <i>In Re Certain Photodynamic Therapy Systems, Components Thereof, And Pharmaceutical Products Used In Combination With The Same</i> , Investigation No. 337-TA-1411
1033	Trial Transcript Day 2 (Open Sessions) for <i>In Re Certain Photodynamic Therapy Systems, Components Thereof, And Pharmaceutical Products Used In Combination With The Same</i> , Investigation No. 337-TA-1411

I. INTRODUCTION

In its Patent Owner's Response (POR), Patent Owner relies on a shotgun approach that raises many arguments but fails to provide persuasive evidence supporting these arguments. Most of Patent Owner's arguments rely on the legally impermissible theory that a POSITA is an automaton incapable of applying ordinary creativity. *KSR Intern. Co. v. Teleflex Inc.*, 550 U.S. 398, 420-21 (2007) ("A person of ordinary skill is also a person of ordinary creativity, not an automaton.").

For example, Patent Owner argues that the prior art fails to render obvious the "uniform illumination" limitation because Petitioner fails to account for the various "engineered components" discussed in Lundahl that are specific to fluorescent tubes. POR, 21-28. However, a POSITA would not incorporate components for fluorescent tubes into a device using LEDs as in Petitioner's proposed combination. In addition, Patent Owner argues that using discrete LEDs would result in "gaps" compared to fluorescent tubes (POR, 24), but this overlooks that a POSITA would have been well aware how to space LEDs so that their light output overlaps to eliminate any gaps at the treatment surface.

Likewise, Patent Owner argues that the prior art fails to render obvious the "higher intensity" limitation because the fluorescent tubes of Lundahl have areas of lower output (known as Faraday dark spaces). POR, 33-38. Again, Patent Owner

ignores that eliminating these dark spaces (which are not present in LEDs) was part of the motivation to move away from fluorescent tubes to LEDs.

Moreover, Patent Owner alleges the prior art fails to teach “hinged structures on inner side surfaces of adjacent panels,” based on labeling inconsistencies in Larsen (POR, 48-52), but fails to acknowledge there are only three places that a hinge can be located: between panels, on the top/bottom of panels, and behind the panels, and a POSITA would know that the most common option is to put “hinges between the two panels.” EX1031, 591:5-7, 592:2-8.

These arguments, as well as others raised by Patent Owner in its response, are addressed below.

II. REPLY ON GROUND 1²

A. Lundahl in View of Larsen Renders Obvious the “Uniform Illumination Limitation” of All Challenged Claims

1. A POSITA would not need to use the fluorescent specific components of Lundahl for an LED device.

Patent Owner does not dispute that Lundahl teaches uniform illumination where “the measured output over the active emitting area is within 70% of the

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

measured maximum” at distances of 2” and 4”, which is greater uniformity than required under the ITC’s claim construction. EX1014, 15:22-27; EX1030, 97; *see* EX2033, 15 (ITC construction). Rather, Patent Owner argues that Lundahl is only able to achieve this uniformity via integration of at least four components specific to fluorescent tubes including: U-shaped fluorescent tubes, fluorescent tube reflectors, a fluorescent tube electrical system, and a fluorescent tube cooling system. POR, 10. This is factually incorrect but also legally irrelevant given that the proposed combination relies on LED light sources rather than fluorescent tubes.

First, Patent Owner’s attempt to elevate the importance of these features to achieve uniformity is contradicted by Lundahl itself, which teaches the spacing of light sources is the primary factor in uniformity. As noted in the Petition, Lundahl explains that “uniformity can also be adjusted by varying the lateral spacing of the tubes.” EX1014, 6:22-30, 6:43-57(“[t]he number of tubes used and the spacing between them were chosen to achieve desired uniformity and power output specifications” with greater density of lighting near the top and bottom edges); EX1015, ¶¶160-162.

Second, the features Patent Owner cites as contributing to uniformity are only needed to solve uniformity issues specific to fluorescent tubes, meaning that they would be rendered unnecessary once fluorescent tubes are replaced by panels with

LEDs as set out for the proposed combination. Each feature is addressed in turn below.

With regards to the U-shaped fluorescent tubes, this same functionality is achieved in a superior way using the adjustable hinged panels taught by Larsen. As explained by Dr. Grove, the combination would utilize Larsen's hinged panels instead of the U-shape fluorescent tubes because the panels can be "individually adjusted to account for variations" in anatomy while "provid[ing] the desired irradiance and irradiance uniformity to all target areas during PDT." EX1015, ¶¶126-127; EX1004, [0072]; EX1027, 35:14-36:5. Consequently, the device formed by combining the design principles of Larsen related to hinged panels and LED lights with the PDT device and light distribution of Lundahl, can provide a U-shape around a patient's face and scalp, contributing to the desired uniformity of illumination. EX1015, ¶¶126-127; EX1027, 31:5-18, 35:3-36:5.

Next, Lundahl provides a reflector positioned behind "the rear surface of the tubes" (EX1014, 8:65-67) because "fluorescent tubes put out light 360 degrees around the circumference of the tube." EX1031, 593:9-22. However, a POSITA would have appreciated that "LEDs put out light in basically one direction." *Id.*; EX2050, ¶46; EX1027, 59:12-60:9. Consequently, reflectors to re-direct the light going away from the intended illumination surface are unnecessary when using LEDs.

Similarly, Lundahl discloses an electrical control system tailored to address flaws in fluorescents. EX1014, 7:11-8:59. This electrical system is necessary in Lunahl because “[f]luorescent tubes, being gas discharge devices, are particularly sensitive to the electrical voltages and currents used to drive them.” EX1014, 7:14-31. In contrast, as Dr. Jokerst admits, a POSITA would have been aware that LEDs “do not face the same [electrical] challenges as fluorescent tubes.” EX1027, 37:17-39:2, 47:12-21. Accordingly, a POSITA would have known that an LED device did not need to utilize Lundahl’s electrical control system. As Dr. Jokerst further admits, a POSITA would have known how to construct an electrical system appropriate for operating LEDs. EX1027, 40:12-42:3, 45:17-48:6.

Lastly, Lundahl explains that “[s]ince cathode and tube wall temperatures strongly affect the output distribution, a cooling system is provided to ensure proper bulb operation” particularly due to variations in “phosphor coating thickness caused by the bending process” of the tube. EX1014, 9:13-15 and 9:39-54. LEDs do not utilize tubes with walls having variable phosphor coating thickness. EX1027, 47:12-21. Accordingly, a POSITA would not have used Lundahl’s cooling system for fluorescent tubes for the combination that relies on LEDs. EX1031, 594:17-595:6.

In sum, a POSITA would not incorporate design strategies intended to address the shortcomings of fluorescent tubes into a device that used LEDs. *PGS Geophysical AS v. Iancu*, 891 F.3d 1354, 1366 (Fed. Cir. 2018) (“[Plaintiff’s]

argument relies on the presumption that one of ordinary skill would blindly incorporate [secondary reference's] exact methodology into [primary reference]. But the Board *properly* did not view [defendant's] proposed combination to be so limited.")³. Instead, a POSITA would use their knowledge to retain only those teachings that still provide utility in the combination – in this case, Lundahl's light source distribution (via LEDs on adjustable panels instead of U-shaped fluorescent tubes) to achieve uniformity where “the measured output over the active emitting area is within 70% of the measured maximum.” EX1014, 15:22-27, 6:16-30.

2. A POSITA would know how to position the LED light sources so that the “measured irradiance at a treatment surface...is at least within 60% of the measured maximum.”

Contrary to Patent Owner's unsupported allegations, ample evidence and analysis shows that the combination of Lundahl and Larsen would meet the ITC construction of “uniformly illuminate a treatment surface” including the requirement that the “measured irradiance at a treatment surface...is at least within 60% of the measured maximum.” *See* EX2033, 15.

Lundahl reports that “the measured output over the active emitting area is within 70% of the measured maximum” on a treatment surface 2-4 inches away,

³ Emphasis always added unless otherwise noted.

meaning that a higher degree of uniformity than that required by the '028 Patent was achieved with the fluorescent tubes of the Lundahl device. EX1014, 15:22-27. This is despite the fact that “fluorescents tubes are known to have inconsistent light output within the tube itself.” EX1015, ¶129; EX1027, 36:14-37:4 (Dr. Jokerst admitting that “achieving satisfactory performance from a fluorescent tube...includes many challenges.”). LEDs, on the other hand, provide better control of light output characteristics in comparison to earlier technologies like fluorescents. EX1015, ¶129. Here, a POSITA would have reasonably expected to achieve at least the same uniformity using LEDs than had already been achieved by Lundahl using fluorescent tubes. *Tyco Healthcare Group LP v. Ethicon Endo-Surgery, Inc.*, 774 F.3d 968, 978 (Fed. Cir. 2014) (“One of ordinary skill knows how to combine familiar prior art elements to achieve the same functions.”).

While Patent Owner argues that a reasonable expectation of success has not been adequately shown because Dr. Grove did not conduct uniformity measurements for his combination (POR, 20-21), there is no “law-required minimum for what can support a ‘reasonable’ expectation of success,” and the Federal Circuit has stated that testing is not required. *Acorda Therapeutics, Inc. v. Roxane Labs, Inc.*, 903 F.3d 1310, 1333 (Fed. Cir. 2018). That is particularly true here, where the combination of Lundahl and Larsen substitutes the more predictable light output from LEDs for “output from a fluorescent tube [which is] not inherently uniform.” EX1014, 6:9-11.

Furthermore, Patent Owner argues that Larsen *on its own* does not teach the required uniformity, but this is legally irrelevant. EX2050, ¶134; POR, 29; *Bradium Techs. LLC v. Iancu*, 923 F.3d 1032, 1050 (Fed. Cir. 2019) (cannot overcome obviousness of a combination “by attacking references individually”). Petitioner has not relied on Larsen (or Lundahl) *separately* to achieve uniformity. Petition, 39-40. Rather Petitioner’s argument relies on combining the teachings of Lundahl and Larsen to produce a device with adjustable LED panels that achieves at least the same level of uniformity that Lundahl’s fluorescent tube device did. EX1014, 15:22-27; EX1015, ¶160.

What is more, Patent Owner’s argument that LED’s have narrow divergence angles that would not be able to meet the claimed uniformity requirement contradicts the evidence. As acknowledged by Dr. Jokerst, LEDs “are discrete, point source, directional illuminators *with a Lambertian output characteristic*”. EX2050, ¶46; EX1026, ¶9. Figure 6 of EX2013, a 2015 article relied on by Dr. Jokerst to describe LED light emission (EX2050, ¶44), illustrates a *Lambertian* emission profile as shown below. EX2013, 8; EX1026, ¶11.

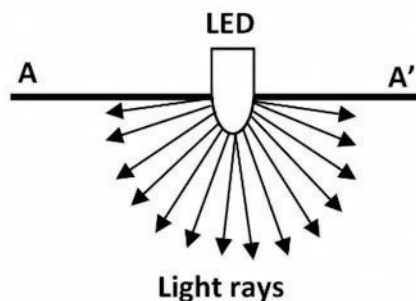
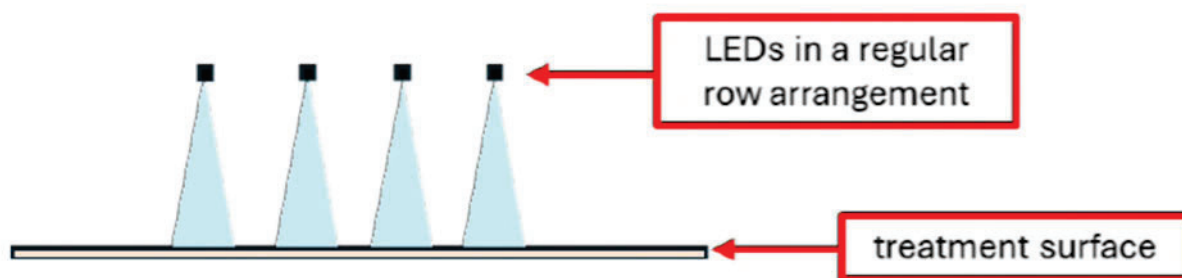


Figure 6: Scattering of the light from LEDs (Lambertian distribution); (A – A') represents the Lambertian surface in the profile view

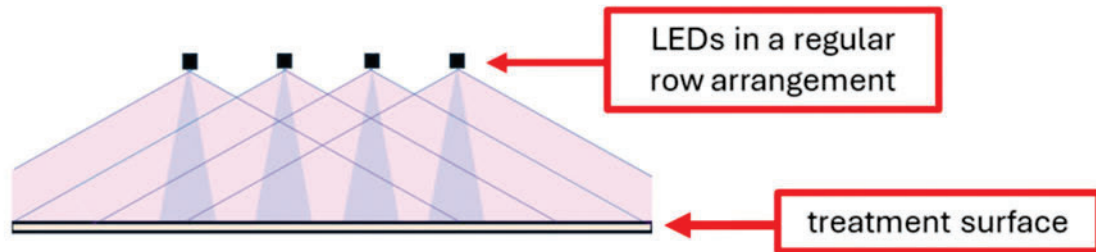
EX2013, 8.

This evidence directly contradicts the below drawing provided by Dr. Jokerst that inaccurately portrays narrow cones of light (shown as light blue) emitted from each LED instead of the actual Lambertian output of an LED. EX2050, ¶46; EX1026, ¶9-11.



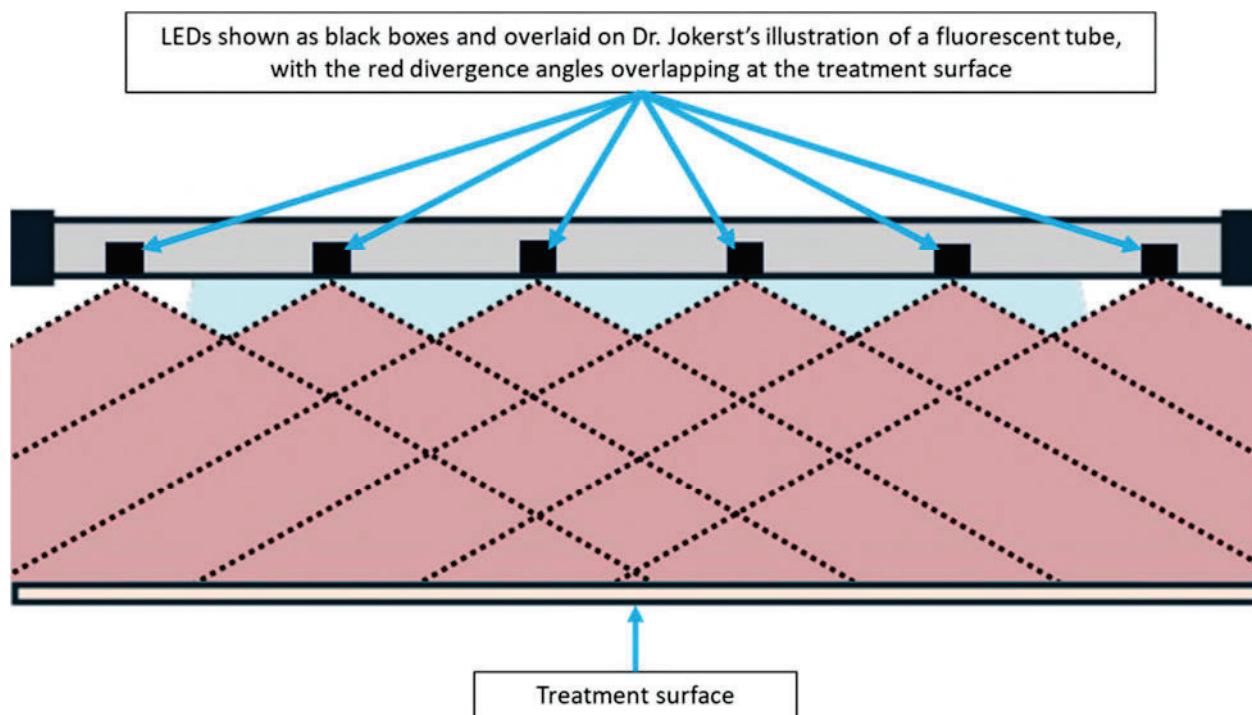
EX2050, ¶46. The only support for this drawing that Dr. Jokerst cites to is a statement in the Bourget article that “LED light is of a noncoherent, narrow band.” EX2050, ¶46; EX2011, 1; EX1026, ¶10. However, this statement refers to the *wavelength* of the emission from an LED light (*i.e.*, color), not the light emission. EX2011, 1; EX1026, ¶10.

A revised drawing showing a more accurate divergence angle for each LED, where the rays shown represent $I = I_o/2$ as required by a Lambertian distribution, is below. EX1026, ¶12.



EX1026, ¶12. As shown in the drawing above, a POSITA would understand that while LEDs may have gaps between where the light is *emitted* from each LED, the row of LEDs can still uniformly *illuminate* a treatment surface of a patient some distance away, where the divergence angles of the LEDs overlap. EX1026, ¶13-17. More specifically, achieving a desired uniformity of *illumination* with LEDs is based on (a) spacing between individual LEDs, (b) spacing between rows of individual LEDs, and (c) spacing between the LEDs and the treatment surface. EX1026, ¶14. Lundahl provides guidance as to (b), teaching that distance between light source rows can be manipulated to increase uniformity (EX1014, 6:43-57), and as to (c), teaching illumination of a treatment surface 2-4" away (EX1014, 15:22-28). EX1026, ¶14. Accordingly, only (a) spacing between individual LEDs need be addressed. EX1026, ¶14. It would have been straightforward for a POSITA to space

adjacent LEDs in a manner that allows the divergence angles to overlap to prevent gaps in illumination. EX1026, ¶14-15.



EX1026, ¶15. Tellingly, the '028 Patent does not discuss how to arrange LEDs to achieve the claimed uniformity or identify any problem in spacing LEDs to do so. EX1026, ¶19. This is further evidence that appropriate LED spacing to achieve uniform illumination was well known to a POSITA at the time of the invention. *McRO, Inc. v. Bandai Namco Games America Inc.*, 959 F.3d 1091, 1102 (Fed. Cir. 2020) (“[A] patent need not teach, and preferably omits, what is well known in the art.”); *see also In re Buchner*, 929 F.2d 660, 661 (Fed. Cir. 1991) (“Sec. 112 requires that, unless the information is well known in the art, the application itself must contain this information”). Specifically, the '028 Patent reports that “Fig.

8...illustrates the light uniformity produced by an embodiment of the present invention....” EX1001, 8:43-44.

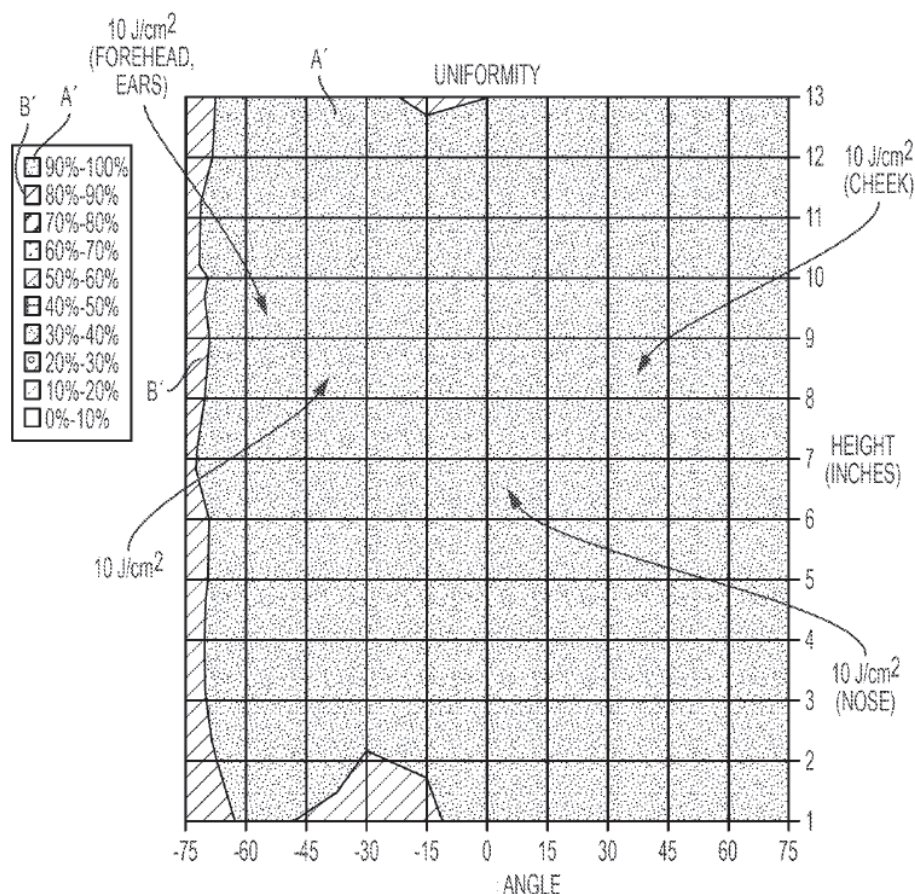


FIG. 8

EX1001, Fig. 8. As shown in Fig. 8, the '028 Patent reports that uniformity of 90-100% was achieved over the vast majority of the illuminated surface – uniformity values significantly higher than the 60% standard claimed. EX1026, ¶18-19. Yet, despite these high uniformity values, not once does the '028 Patent describe the specific spacing between the LEDs of the illuminator tested in Fig. 8. The '028 Patent references “addressable strings” included in areas 1, 3, and 5, and 2, 4, and 6

(*see* EX1001, Fig. 5, 6:24-37), but, again, the '028 Patent includes no disclosure as to the specific spacing of LEDs within each of these areas. EX1026, ¶19. This is because a POSITA would consider the determination of LED spacing a straightforward task in light of the understanding in the art of divergence angles and Lambertian distribution, and Lundahl's teachings regarding manipulation of lateral spacing to account for illumination drop off at the forehead and chin. EX1026, ¶19.

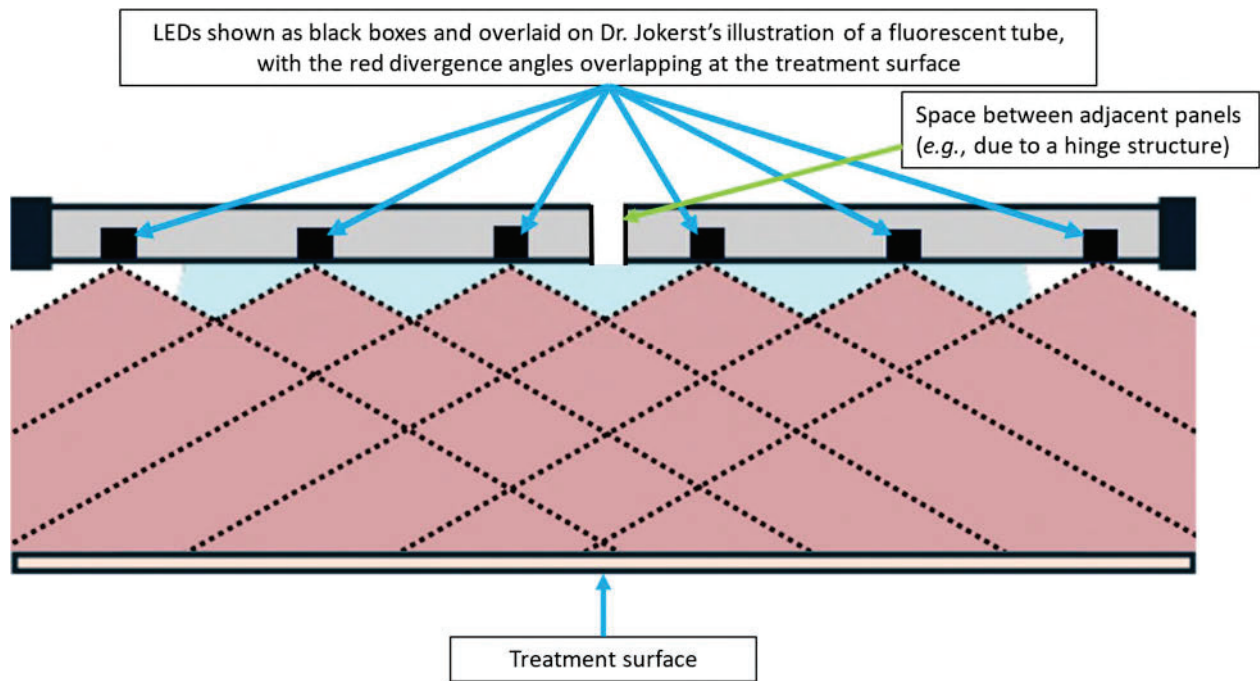
Lastly, Patent Owner argues that Dr. Grove himself admitted that achieving uniform illumination was not routine, citing a statement that a "POSA would be required to perform undue experimentation to make and use an illuminator that provides 'uniform illumination.'" POR, 32 (citing EX2034, ¶186). But this quote is taken out of context. Dr. Grove's statement was in relation to the difficulty of providing uniform illumination to the far reaches of the claim scope – *e.g.*, providing uniform illumination to a patient's extremities and torso. EX1031, 587:4-588:21. This statement was not made in relation to providing uniform illumination of, *e.g.*, the face, which is both within the claim scope and disclosed in Lundahl. EX2034, ¶186; EX1014, 2:35-40, 2:60-67, 3:29-38.

Accordingly, a POSITA would know how to position the LED light sources to achieve the desired illumination uniformity. EX1026, ¶13-21.

3. **A POSITA would understand that modifying Lundahl's U-shaped tubes to incorporate panels would not affect the illumination uniformity.**

While Patent Owner argues that a POSITA would not have been motivated to modify Lundahl's U-shape with panels because such modification "would create gaps between the panels," (POR, 24) this argument does not comport with the law, which states that "[t]he fact that the motivating benefit comes at the expense of another benefit, however, should not nullify its use as a basis to modify." *Medichem, S.A. v. Rolabo, S.L.*, 437 F.3d 1157, 1165 (Fed. Cir. 2006); *In re Fulton*, 391 F.3d 1195, 1200 (Fed. Cir. 2004).

Further, at the time of invention, it was feasible to create a paneled device that provided uniform illumination, notwithstanding gaps between panels. As discussed above, gaps in light emission do not require gaps in the illumination of a treatment surface. *Supra*, Section II(A)(2). Rather, as with gaps between individual LEDs on a panel, gaps in emission between adjacent panels are easily addressed by accounting for the overlap of divergence angles as Dr. Grove illustrates below. EX1026, ¶17.



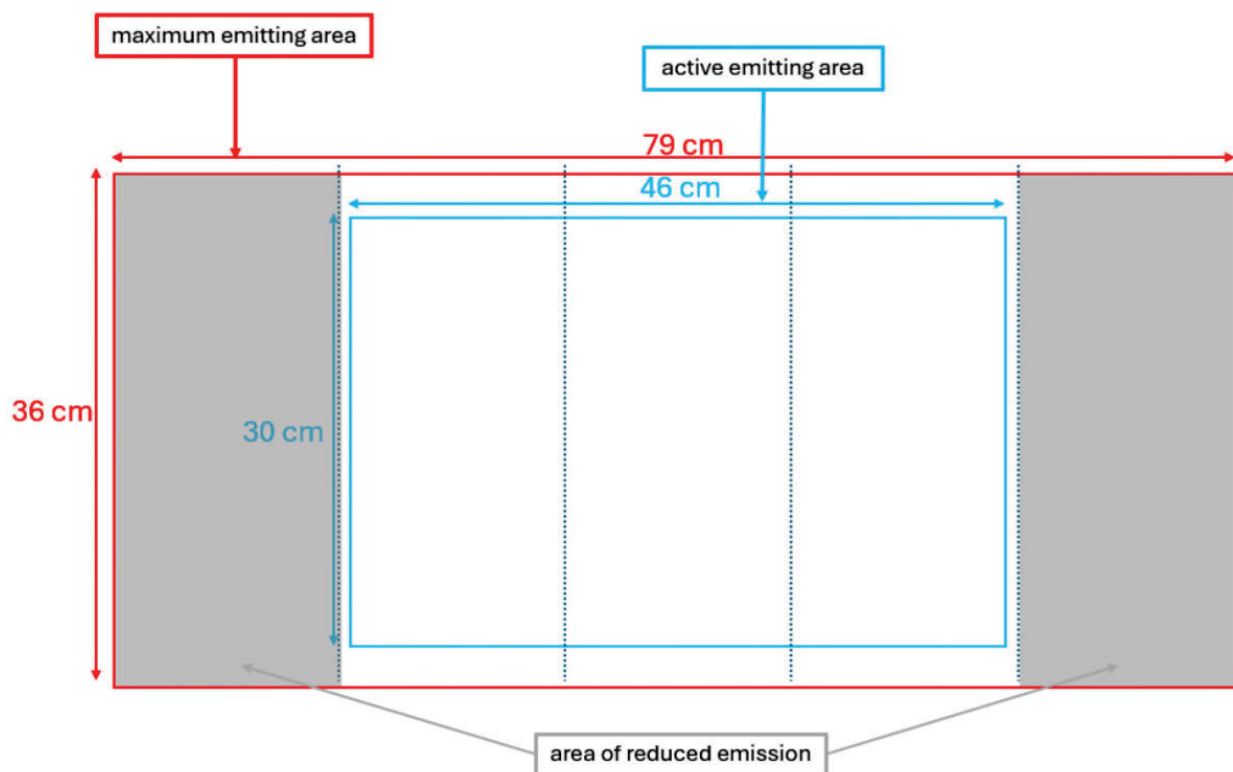
EX1026, ¶17.

B. Lundahl in View of Larsen Renders Obvious the “Higher Intensity Limitation” of All Challenged Claims

Patent Owner’s argument that the “higher intensity close to the second shorter edges” limitation is not obvious rests on two main assertions: (1) a POSITA would replicate Lundahl’s low output areas in a combination with Larsen; and (2) Lundahl would lead a POSITA to increase intensity near the *longer* edges. POR, 33-47. These assertions rest on the false assumption that a POSITA is an automaton, lacking capacity for normal creativity and logical interpretation of the teachings in the art. *KSR*, 550 U.S. at 420-21. A POSITA would not blindly follow every teaching of the prior art, especially when doing so makes no sense in the context of the proposed combination.

With respect to the first point, Patent Owner points out that Lundahl's light sources have "low output area[s]" or "areas of reduced emission." POR, 34-37. Patent Owner is correct on this point – Lundahl discloses that its fluorescent tubes have what are known as "Faraday dark space[s]" near their cathodes. EX1014, 6:9-22. Patent Owner is not correct, however, that a POSITA would incorporate these dark spaces into a combination using LEDs. It was well-known that Faraday dark spaces were a problem specific to fluorescents. *Id.*; EX1032, 732:7-10. LEDs did not have such dark spaces, and, as Dr. Jokerst noted, a POSITA "wouldn't typically incorporate the shortcomings of a prior device when developing a new device." EX1032, 768:10-13.

Further, Dr. Jokerst's description of the dark areas of the fluorescent tubes is exaggerated. Specifically, Dr. Jokerst asserts that Lundahl's "active emitting area" does not include the "low output area[s]," which, according Dr. Jokerst's illustration provided below, constitute a significant portion of the length of the tubes:



EX2050, ¶146. However, Dr. Jokerst omits that Lundahl describes the above dimensions as the “minimum” active emitting area, meaning that the actual “active emitting area” may be much larger. EX1032, 737:19-738:12. In any case, variations in size (i.e., of the emitting area) are not a basis for patentability absent unexpected results. *American Infra-Red Radiant Co. v. Lambert Indus.*, 360 F.2d 977, 987 (Fed. Cir. 1966) .

Moreover, Dr. Jokerst’s description of the dark areas of the fluorescent tubes is inconsistent with the testimony of Patent Owner’s other expert, Dr. Heather Roberts. Dr. Jokerst argued that only the curved central portion of Lundahl’s device is appropriate for patient treatment, while the straight portions underneath the dotted

line in FIG. 4A are not (i.e., because they are areas of reduced emission). EX1027, 91:3-92:17, 100:15-101:13.

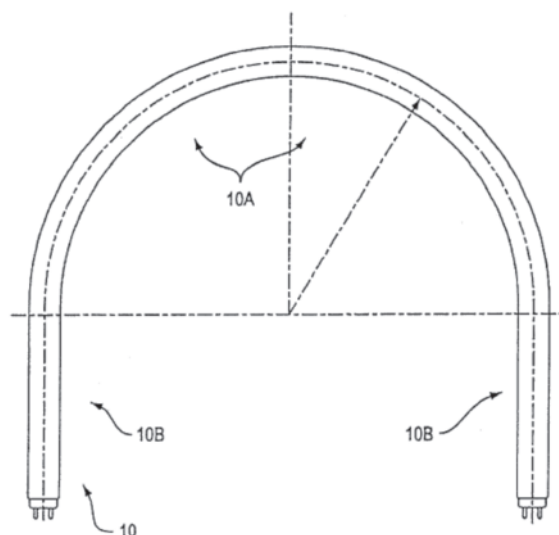


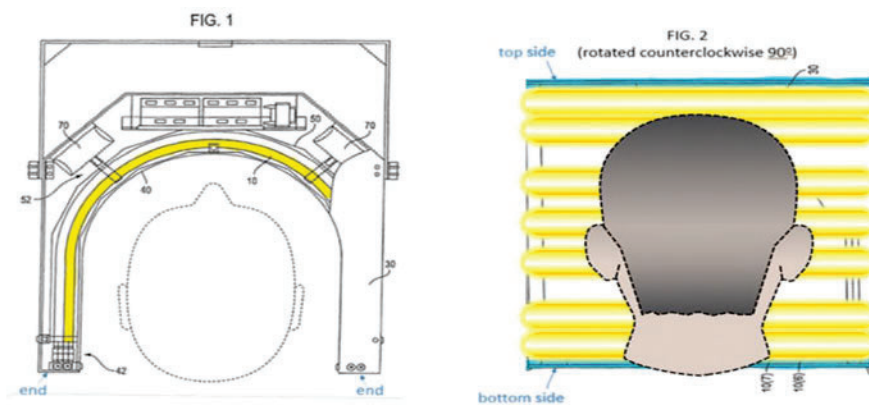
FIG. 4A

EX1014, FIG. 4A. However, Dr. Roberts testified that she treats patients' chest and backs with the BLU-U 4170D⁴, by having "the patient turn to the right so the 'U' of the device wraps halfway around their chest and back. Then, I have turned them to the left so the 'U' of the device wraps around the other half of their chest and back." EX2015, ¶36. Consequently, Dr. Roberts makes clear that the straight portions of the "U" shape, which correspond to the "low output areas," emit light and are used

⁴ Dr. Jokerst has admitted that the BLU-U 4170D device is an embodiment of Lundahl. EX1032, 731:24-732:3.

to illuminate a treatment surface, thereby undercutting the factual foundation of Dr. Jokerst's opinion.

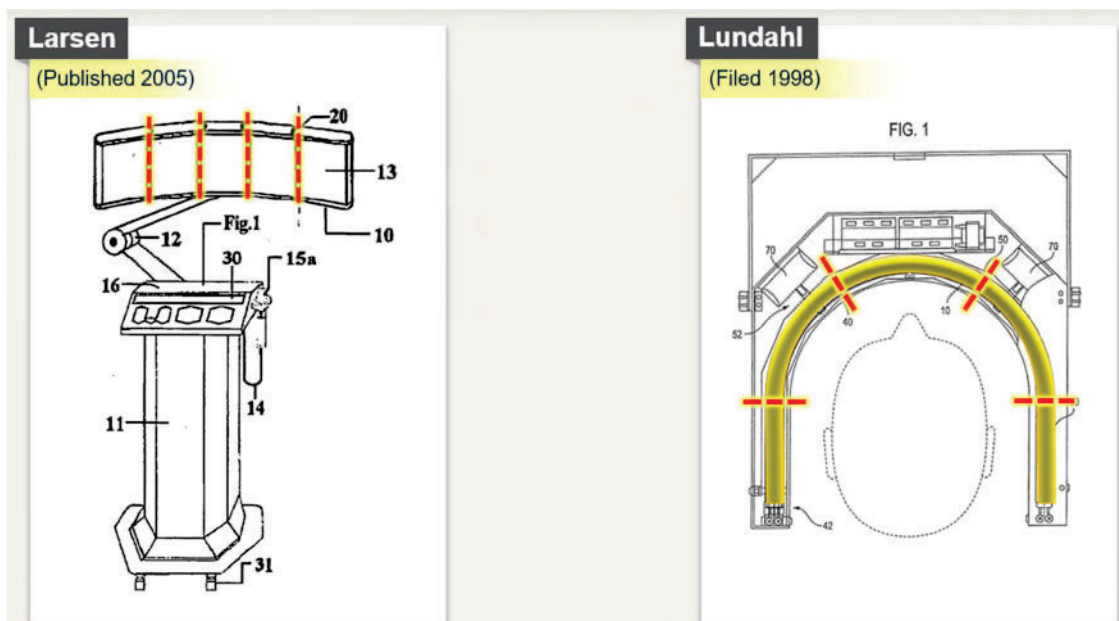
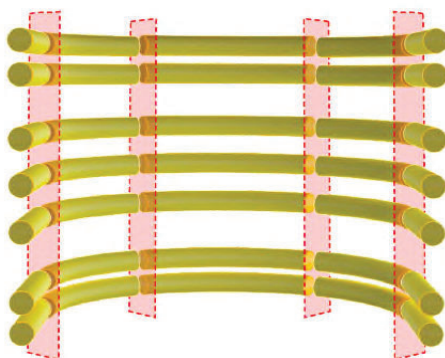
Patent Owner's second point, i.e., that Lundahl would lead a POSITA to increase intensity near the *longer* edges, is also incorrect. As fully explained in the Petition (Petition, 17-20, 39-41), Lundahl teaches that the uniformity benefits provided by its light distribution are realized by providing increased intensity at the edges corresponding to a patient's forehead and chin, when the device is used as shown in Figure 1. EX1014, 6:25-30; EX1015, ¶¶77-78, 83-84. Dr. Jokerst similarly admits that Lundahl teaches a light source distribution that increases intensity near the forehead and chin, when the device is used as shown in Figure 1. EX1032, 740:25-741:5, 748:10-21; EX1014, Fig. 1.

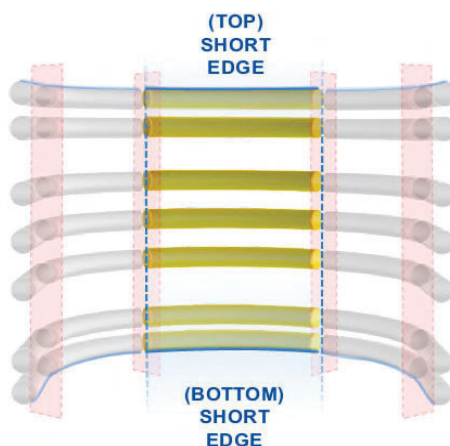


EX1014, Figs. 1-2 (annotated).

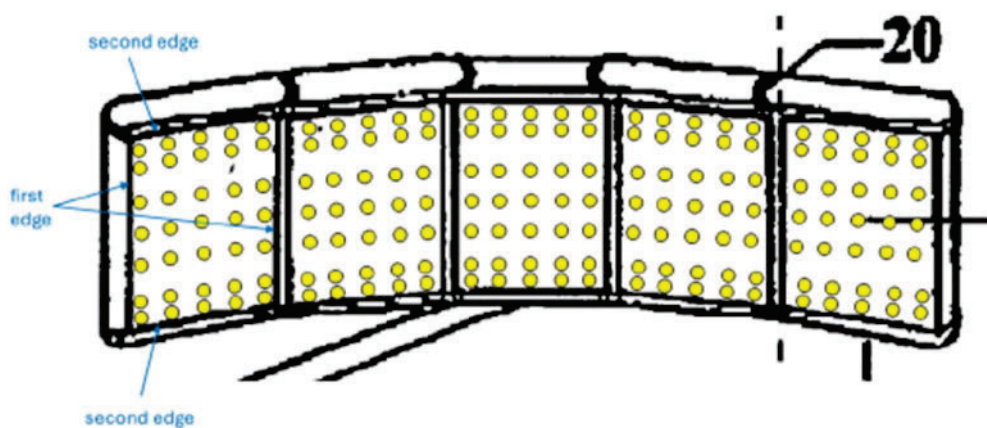
A POSITA would be able to understand this and apply this principle in combining Larsen with Lundahl. As Dr. Jokerst admits, if Lundahl's device were

divided into five panels, the edges near the patient's forehead and chin would be the shorter edges (EX1032, 748:22-749:7), which is further illustrated below:





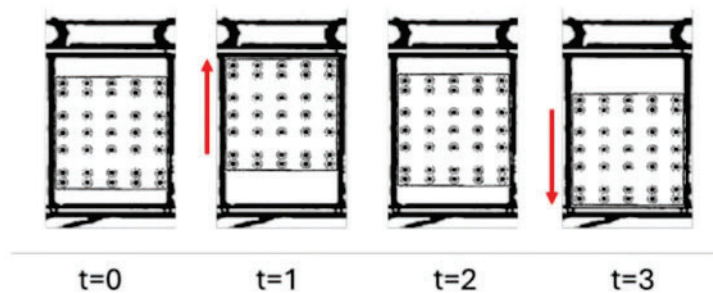
Accordingly, a POSITA applying ordinary creativity would arrive at a combination providing higher intensity (via increased density of LEDs) along these shorter edges corresponding to the forehead and chin as shown in Dr. Grove's illustration below. EX1015, ¶178-179.



Finally, Patent Owner's argument that "Petitioner relies on Larsen's disclosure of a scan engine in its combination...[that] would move the light sources linearly up and down" is unsupported. POR, 38-41. First, Petitioner has never argued

that Larsen's scan engine *must* be incorporated into the combination to achieve uniformity since the Petition relies on Lundahl's teaching of light source spacing for that aspect. *See* EX1015, 172. Rather, Petitioner merely cited the scan engine for the proposition that Larsen also taught the benefits of uniform light distribution which further supported the reason to combine Larsen's LED panels with Lundahl's positioning of light sources. Petition, 40-44.

Second, while Dr. Jokerst imagines hypothetical movements of a scan engine that would supposedly cause "the light sources [to] move up and down from $t=0$ to $t=3$, as shown below," she admitted that none of these imaginings is actually disclosed in Larsen.

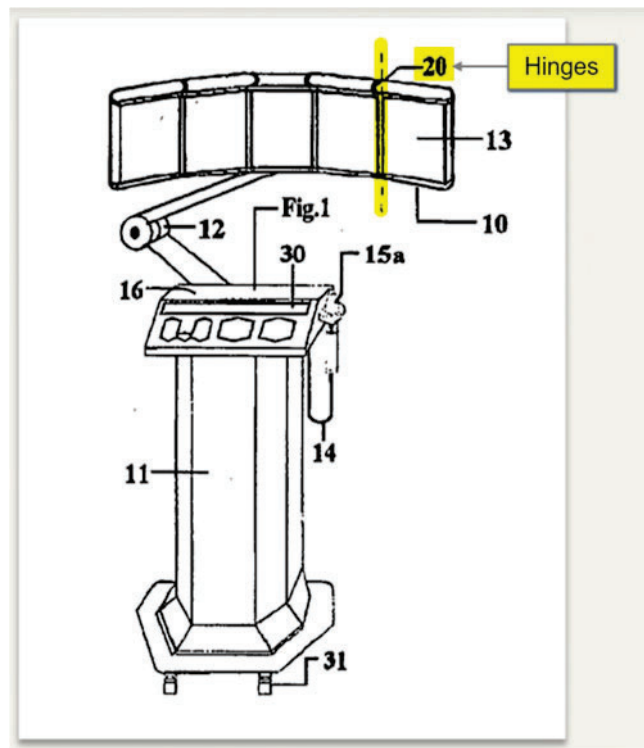


EX2050, ¶152. For example, Dr. Jokerst admitted that Larsen fails to disclose whether the scan engine causes movement up or down or side to side, any pattern of movement for the scan engine, any range of movement for the scan engine, any rate of movement for the scan engine, or any specific time points. EX1032, 741:22-

743:5. As a result, Patent Owner’s argument regarding the scan engine is a construct that is unsupported by any evidence. Petition, 40-44; EX1015, 172.

C. Larsen Discloses and Renders Obvious the “Hinges Limitation” of Claims 1, 5, 20, and 21

Although Patent Owner notes that Larsen teaches “several applicators 13 are flexibly connected to each other through *hinges 10*...on the bottom of the applicator 13,” (POR, 48-49), Larsen also identifies element number 10 as corresponding to “the *invented device 10*.” EX1004, [0069]; EX1032, 743:14-21. Accordingly, it is clear that one of these passages must contain a typographical error.



The specification taken as a whole indicates that the most reasonable understanding is that the reference to “hinges 10” was the typographical error, as the

hinges are properly indicated by element number 20. EX1015, ¶154. For instance, Larsen notes that its panels “are flexibly connected to each other through hinges... *connecting one edge with the other.*” EX1004, [0027]. The description of hinges as *connecting edges* of adjacent panels indicates that the hinge is located between the inner side surfaces – which is exactly where element number 20 is illustrated in Figure 1. EX1015, ¶154. Indeed, this sentence alone is sufficient to establish obviousness even if it were somehow a mistake (which it is not). *Beckman Instruments, Inc. v. LKB Produkter AB*, 892 F.2d 1547, 1551 (Fed. Cir. 1989) (reference used for obviousness “is prior art for all that it teaches”).

The examiner of the '028 Patent concurred with this conclusion. During prosecution of the parent of the '028 Patent, the examiner explicitly noted that Larsen's hinges had been erroneously labeled as element number 10 in the specification while being correctly shown as element number 20 in the Figures. EX1009, 3 (“*hinges 20* (indicated as 10 in the specification, but shown as element 20 in the Figures)...”); EX1032, 744:6-15; EX1015, ¶154. Further, as Dr. Grove testified, a POSITA would understand that the most logical location for hinges connecting panels would be between the panels in the location identified by number element 20. EX1015, ¶155; EX1031, 592:2-5.

Moreover, even if Figure 1 does not explicitly teach hinges 20, it would have been obvious for a POSITA to arrive at hinges located on inner side surfaces.

EX1015, ¶155. There are only three reasonable options for placing hinges to connect adjacent panels – (1) between adjacent panels; (2) on the top or bottom of the panels; or (3) on the rear surface of the panels. EX1031, 591:5-7 (“Yeah, in general, there are three locations to connect adjacent panels.”). Among these three, the most common option is to put “hinges between the two panels.” EX1031, 592:2-8. People have been doing this for generations prior to 2015. *Id.* This would be especially obvious where Larsen teaches “hinges... *connecting one [panel] edge with the other.*” EX1004, [0027]. The choice of whether to place hinges between panels, on the top or bottom, or on the back is not an act of invention. EX1015, ¶155; *see Teva Pharms. U.S.A., Inc. v. Sandoz, Inc.*, 906 F.3d 1013, 1025 (Fed. Cir. 2018) (finding claims obvious where “a POSITA had only a limited number of permutations...to explore”).

Patent Owner’s additional arguments do not change this conclusion. Although Patent Owner argues that Larsen’s element number 20 identifies regular row arrangements in Figs. 2a-d (as opposed to hinges between panels) (POR, 49-50), Dr. Jokerst admitted that Figs. 2a-d do not list the element number 20. EX1032, 746:6-19; EX1004, Figs. 2a-d. Further, element number 20 indicates a location between panels, which does not make sense as a location for “regular row arrangements” of light sources – which would necessarily be on the front of the panels.

Patent Owner's reliance on Fig. 3 of EX2004 similarly fails to move the needle. POR, 50-51. EX2004 is a different patent, with a different disclosure, from a different family, in a different jurisdiction than Larsen and therefore of dubious relevance. Further, although Patent Owner points out that the parent of the '028 Patent was allowed over Larsen, such allowance was not based solely on the absence of hinges in the prior art. EX2061, 1731. In fact, earlier in prosecution, the examiner cited Larsen as anticipatory to claims including the term "nested hinges" - which, Patent Owner has asserted in the related ITC investigation mean hinges "on inner side surfaces of adjacent panels." EX2061, 555; EX2033, 29-34.

D. Larsen Discloses the "Individually Configurable Limitation" of Claims 16 and 21

Larsen teaches that "the invented device is adjustable within a relatively large range with reference to duration, amplitude and frequency of surge of current...." EX1004, [0074]. While Patent Owner argues that this refers to the device as a whole rather than to each of the five panels "being individually configurable to control illumination from each of the five panels" (POR, 59), this argument ignores Larsen's disclosure as a whole.

Larsen discloses applicators (*i.e.*, panels), with each panel containing multiple light sources. EX1004, [0070]-[0072]; EX1015, ¶157-158. Claim 5 of Larsen recites "wherein the light sources are *individually selected*—switched **ON** or **OFF**."

EX1004, claim 5 (emphasis added). Thus, Larsen teaches illuminating or darkening individual light sources within a panel, which necessarily alters or configures the power output and/or light intensity of the panel – i.e., by allowing for brightening or dimming of the panel. Accordingly, a POSITA reading Larsen’s disclosure that “the invented device is adjustable” would understand that to include adjustability of light output from each individual panel. EX1004, [0074].

Although Patent Owner argues that Larsen allegedly discloses only a single controller for the device (POR, 60-61), this argument ignores the basic functionality of a controller. It was known as early as 2008 that “LED control systems allow the user to set various parameters of system operation including *brightness*, time on or off, photo periods, *light quality*...Controls are usually interfaced to the driver circuitry to *allow the brightness of the individual LEDs to be set.*” EX2011, 2. Accordingly, a POSITA would understand that a single controller can control multiple individual LEDs.

E. Larsen Discloses the “Continuous Illumination Limitation” of Claim 16

Initially, Patent Owner argues that the combination of Lundahl and Larsen does not render obvious “continuous illumination across the five panels” because Larsen allegedly does not teach “hinged structures on inner side surfaces of adjacent

panels.” POR, 63. However, Larsen does teach and render obvious hinged structures on inner side surfaces as discussed above. Supra, Section II(C).

Patent Owner further argues that Larsen does not teach continuous illumination because “there are lower irradiance regions at the junction of two of Larsen’s panels.” POR, 64. To the extent that Patent Owner is suggesting that the “continuous illumination” requirement would not be rendered obvious for the same reason as the “uniform illumination” requirement, this is incorrect for all the reasons discussed above. Supra, Section II(A). A POSITA was aware of the divergence angles and Lambertian distribution of LEDs, and would have positioned the LEDs in a manner to provide continuous illumination across panels. EX1026, ¶¶9-17. To the extent Patent Owner is suggesting that a five-panel device *cannot* provide “continuous illumination” because of the junctions of the adjacent panels, this position is entirely contrary to the positions set forth in Dr. Jokerst’s declaration, where she asserts that the RhodoLED®XL (a five-panel LED device) meets this claim limitation. EX2050, 178-182. Further, this is contrary to the ’028 Patent itself, which claims both a paneled device and uniform illumination. *See e.g.*, EX1001, claim 1.

III. SECONDARY CONSIDERATIONS SUPPORT OBVIOUSNESS GROUNDS OF REJECTION

A. Lack of Nexus Between the '028 Patent Claimed Invention and the Objective Evidence of Non-Obviousness

Patent Owner devotes a single paragraph to its argument for allegedly establishing nexus. POR at 78.⁵ This single paragraph fails to satisfy Patent Owner's burden to establish nexus to any claim of the '028 Patent, let alone for all challenged claims. *See Fox Factory, Inc. v. SRAM, LLC*, 944 F.3d 1366, 1373 (Fed. Cir. 2019) (“[t]he patentee bears the burden of showing that a nexus exists”).

Even if the Board looked outside this single paragraph, it would find only conclusory and contradictory statements about nexus. For example, on commercial success, Patent Owner provides conclusory statements that “RhodoLED® XL practices at least exemplary claim 1 of the '028 Patent” and that RhodoLED®XL is “coextensive” with all claims. But, Patent Owner provides no explanation, merely citing various exhibits, including Dr. Jokerst's declaration. POR, 73. Dr. Jokerst's declaration does not address claim 1, but instead addresses “exemplary claim 16”, which notably does not recite “hinged structures on inner side surfaces of adjacent

⁵ Patent Owner improperly incorporates by reference fifty paragraphs of expert declaration citations without analysis of the expert declarations into a single paragraph of its response and should not be considered. 37 CFR § 42.6(a)(3).

panels” as the other independent claims do. EX2050, ¶229 and Appendix B. Additionally, Dr. Jokerst’s conclusory chart for claim 16 merely identifies various excerpts of marketing material discussing the RhodoLED®XL without providing analysis for how claim 16 reads on those marketing excerpts. EX2050, Appendix B. Patent Owner wrongly assumes RhodoLED®XL infringes the claims of the ’028 Patent, but provides no analysis or evidence for why that is true.

Finally, Patent Owner relies on a RhodoLED®XL press release, but Patent Owner cites features indisputably known in the art, as both Lundahl and Larsen taught uniform light and Larsen taught using five panels with LEDs. Patent Owner willfully ignores unclaimed features touted by Petitioner about RhodoLED®XL in the same press release, including a “robust but sleek construction,” “intuitive user interface,” “simple to maneuver,” “able to accommodate various patient treatment positions,” and “positioning sensors.” EX2045, 1. Patent Owner has not shown how the limited features it self-selected (even when considered together) establish a nexus to the claims of the ’028 Patent.

B. The ’028 Patented Invention Has Not Achieved Commercial Success

Patent Owner fails to show that the sales volume of the RhodoLED®XL is significant enough to meet the standard of commercial success. *See J.T. Eaton & Co. v. Atl. Paste & Glue Co.*, 106 F.3d 1563, 1571 (Fed. Cir. 1997). Patent Owner

merely states that Biofrontera sold more RhodoLED®XL lamps than its older RhodoLED® over the same time period. POR, 77. This one data point merely establishes that RhodoLED®XL generated more revenue than RhodoLED®, but that is a far cry from establishing commercial success. Additionally, Biofrontera's CFO found the increase in revenue from the RhodoLED®XL unremarkable, describing Biofrontera's revenue as "flat." EX1033, 410:3-8. As such, the owner of the RhodoLED®XL did not find it a commercial success, contrary to Patent Owner's assertions.

Finally, Dr. Vander Veen, who Patent Owner relies on for commercial success of the RhodoLED®XL, testified that he compared the alleged evidence of commercial success to the "features of the product" provided to him by Dr. Jokerst, rather than compare the evidence to the '028 Patent claims. EX1029, 9:18-21, 31:20-32:4; EX2050, ¶230; EX2048, 16. Dr. Vander Veen also testified he was unable to "assess[] or opin[e] on the extent to which claims are or are not practiced by" the RhodoLED®XL, giving his testimony on this issue no weight. EX1029, 33:9-14.

C. The '028 Patented Invention Has Not Received Industry Praise

Patent Owner cites statements about the RhodoLED®XL's "elegant design," "maneuverability," "adjustability," and its "advanced features. POR, 77. Yet, these are not claimed features of the '028 Patent. For instance, the "elegant design" of the RhodoLED®XL includes aspects such as material choice, color, touch pad design,

and the design of the maneuverable arm holding the LED panels, which are not within the scope of the '028 Patent. Indeed, the reticulating arm holding the LED panels and wheels added to the base of the RhodoLED[®]XL would make the lamp highly maneuverable and adjustable for clinical use and are not claimed by the '028 Patent. *See* EX2041, 6.

With regards to Patent Owner's BLU-U 4170E device, Patent Owner does not even attempt to explain its single conclusory sentence on how this device "embodies the 028 Patent" or why the quoted statement about being a "step forward" has a nexus to the claimed invention. POR, 77.

IV. CONCLUSION

Patent Owner fails to overcome the strong showing of obviousness presented in the Petition and the Board should find claims 1, 2, 4-6, 16, 17, and 19-21 obvious over the prior art.

Dated: August 13, 2025

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

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CERTIFICATION OF WORD COUNT

Petitioner certifies that the word count in this Reply, including all footnotes, is 5,583 words as counted by the word-processing program (Microsoft Word for Office 365) used to generate this Reply, where such word count excludes the table of contents, mandatory notices, certificate of service, list of exhibits, and this certificate of word count. This Petition is in compliance with the 5,600 word limit set forth in 37 C.F.R. § 42.24(c)(1).

CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of the foregoing Petitioner's Reply to Patent Owner's Response, is being served on August 13, 2025, via email directed to the following counsel of record for the Patent Owner:

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Exhibit D

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

v.

SUN PHARMACEUTICAL INDUSTRIES, INC.
Patent Owner.¹

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

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

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

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PETITIONER’S EXHIBITS²

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

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

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

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

I. INTRODUCTION

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

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

II. MANDATORY NOTICES

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

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

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

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

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

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

PTAB IPR Parallel Petition

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

ITC COMPLAINT

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

DISTRICT COURT LITIGATION

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

V. THE CONTESTED PATENT

A. Effective Filing Date of the '028 Patent

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

B. Overview of the '028 Patent

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

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

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

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

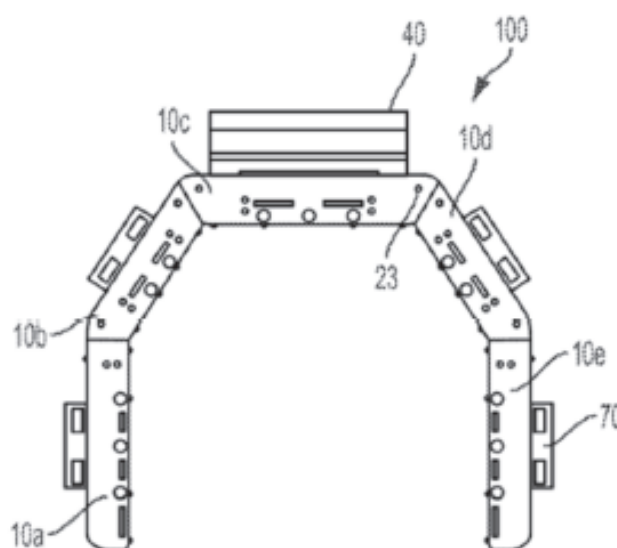


FIG. 1A

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

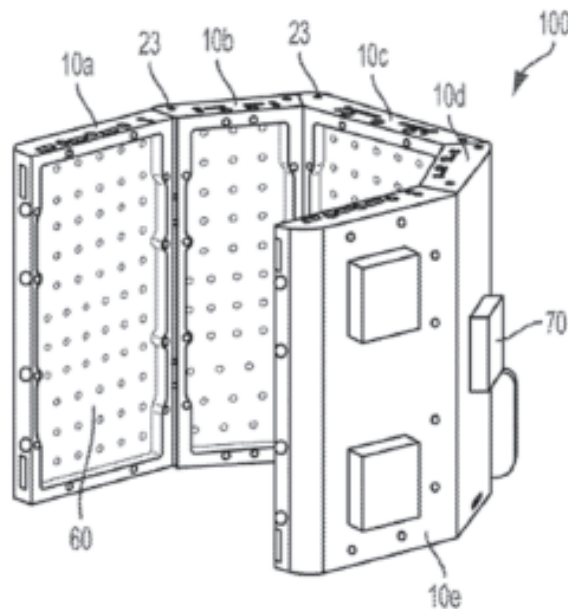


FIG. 2A

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

C. Prosecution History

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

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

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

D. Claim Construction

For the purposes of this IPR, Petitioner has taken a view of the scope of the claims consistent with Patent Owner’s infringement allegations. *See e.g.*, Ex.1019. In view of Patent Owner’s infringement allegations, Petitioner does not believe any term needs to be construed to determine the claims are rendered obvious over the prior art cited herein. *Wellman, Inc. v. Eastman Chem. Co.*, 642 F.3d 1355, 1361 (Fed.Cir.2011) (“claim terms need only be construed to the extent necessary to resolve the controversy”) (internal quotations removed). Petitioner does not agree the accused products infringe the ’028 Patent and reserves the right to present its own interpretation of the claim scope of the ’028 Patent in the related ITC, district

court litigation or later in this IPR proceeding, including claim scope that disagrees with Patent Owner's infringement allegations and/or claim scope that fails to meet statutory requirements under 35 U.S.C. §112.

VI. STATE OF TECHNOLOGY AT THE TIME OF THE INVENTION

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

A. Actinic Keratosis

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

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

B. Photodynamic therapy

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

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

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

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

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

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

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

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

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

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

VII. SUMMARY OF PRIOR ART

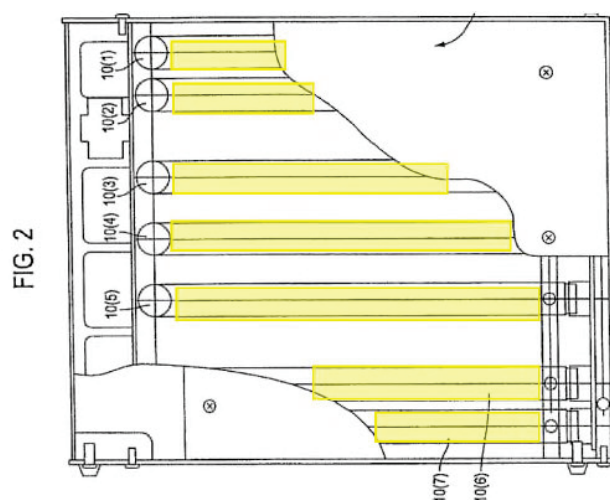
The prior art discloses and teaches the claimed subject matter of the '028 Patent as explained below. All the references are prior art under 35 U.S.C. § 102(a)(1). These references are directed to the same field as the '028 Patent and/or the same problems. Ex.1015, ¶¶113, 122, 137-138,144-146, 149. Petitioner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

A. Lundahl (Ex.1014)

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

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

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

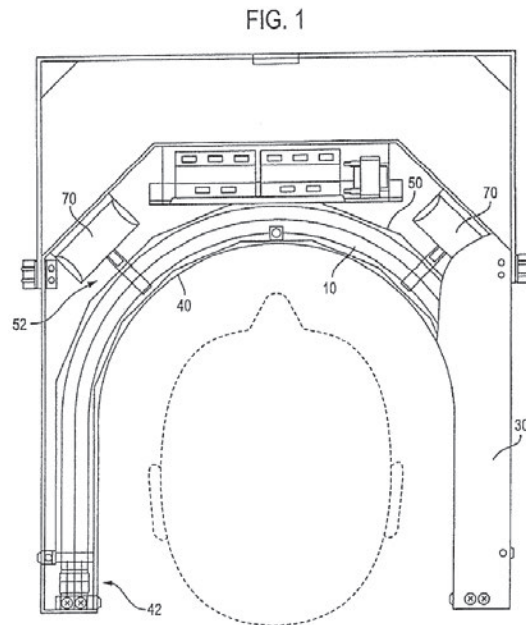


Lundahl explains that “[t]o avoid uniformity problems, one embodiment, of the present invention utilizes a plurality of U-shaped tubes 10(1)-10(7)...[An] advantage of the arrangement is that uniformity can also be adjusted by varying the

lateral spacing of the tubes (relative [vertical] spacing as shown in Figure 2).⁴ This is important since it is necessary to compensate for the fact that the output from a flat plane emitting light source drops near the edges. Ex.1014, 6:16-30. Lundahl states that the spacing of lights and greater density of lighting near the top and bottom of the panel provide for uniform illumination. Ex.1014, 6:43-57 (“[t]he number of tubes used and the spacing between them were chosen to achieve desired uniformity and power output specifications.”).

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

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



Ex.1014, Fig. 1.

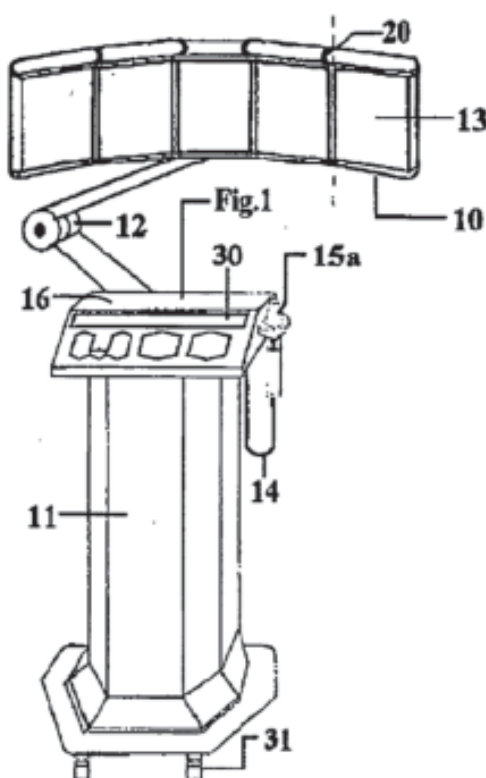
Additionally, in its discussion of the background on PDT treatment, Lundahl states “[g]eneral background information on PDT using 5-aminolevulinic acid (“ALA”) as the precursor of a photoactivatable agent can be found in U.S. Pat. No. 5,079,262, entitled “Method of Detection and Treatment of Malignant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

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

B. Larsen (Ex.1004)

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

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



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

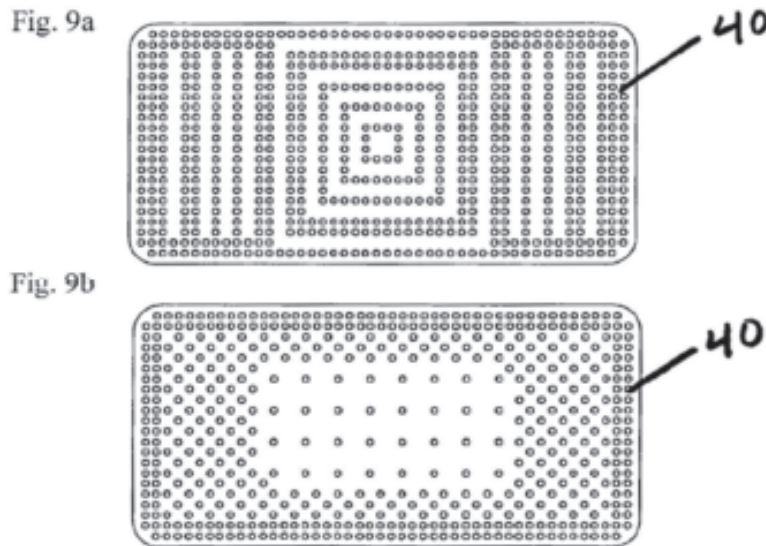
hinges. *Id.*, [0069]-[0070]. Each applicator includes printed circuit boards with multiple light sources for irradiating the treatment surface of a patient's skin using light at various wavelengths. *Id.*, [0070]-[0072], Figs. 2a-2c.

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

C. Bansal (Ex.1005)

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

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



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

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

VIII. LEVEL OF SKILL IN THE ART

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

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

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

IX. PROPOSED GROUNDS OF REJECTION

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

1. Motivation to Combine

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

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

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

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

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

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

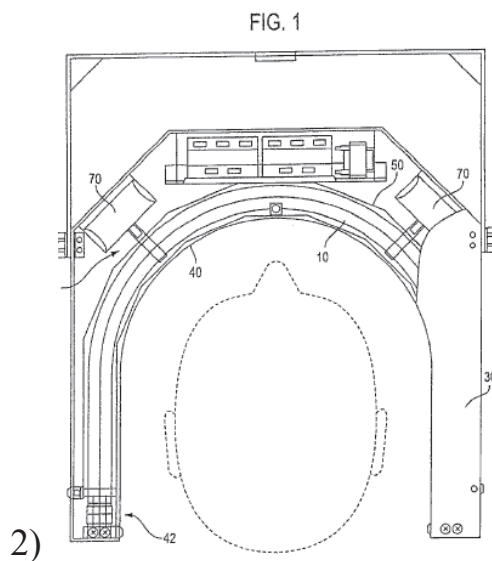
known problems outlined in Dr. Ehrenreich's declaration include: (1) the inflexibility of the fixed U-shape of Lundahl not only created issues ensuring the proper 2-4" treatment distance for the wide variety of patient head sizes and shapes, but also would not allow for proper treatment of other parts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

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

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

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

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



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

⁵ Unless otherwise indicated, all emphasis added.

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

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

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

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

Larsen teaches that “[f]or the treatment of large-area tissues according to Fig. 1, **several applicators 13 are flexibly connected to each other through hinges 10, respectively connecting one edge with the other**, whereby the applicators are suitable for the treatment of for example, the backs of humans and so become adjustable for an equidistant positioning of the applicators 13 above the skin.” Ex.1004, [0072]. These teachings would have motivated POSITA to incorporate Larsen’s solution of connecting light applicators by hinges, to allow for adjustability of Lundahl’s device to provide the desired irradiance and irradiance uniformity to all target areas during PDT. Ex.1015, ¶127.

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

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

POSITA was also motivated to modify Lundahl to incorporate LEDs as taught by Larsen, rather than the fluorescent tubes. Lundahl discloses horizontally oriented fluorescent tube lights. However, by the late 2000's and early 2010's, POSITA would have been motivated to use solid-state light-emitting diodes (LEDs) as the illumination source for three reasons. First, LEDs have a lower cost and a longer lifetime than fluorescent tubes. Second, fluorescent tubes are known to have inconsistent light output within the tube itself, as acknowledged in Lundahl (the tubes have "non-emitting area at their ends" (Ex. 1014, 6:31-42) and that "tube output may vary over its length" (Ex. 1014, 4:41-42). Third, by moving to adjustable panels connected by hinges to increase flexibility, the use of LEDs would be more practical to reduce spacing between light sources and the edges of the panels, as opposed to the bulky metal couplings at the end of fluorescent tubes, to reduce optical dead space across the light surface. Ex.1015, ¶129.

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

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

POSITA would have had a reasonable expectation of success in combining Lundahl with Larsen, because both references describe similar illuminators and the conversion from fluorescent tubes to LEDs was a routine practice prior to 2015. Ex.1015, ¶131.

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

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

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

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

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

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

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

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

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

2. Claim 1

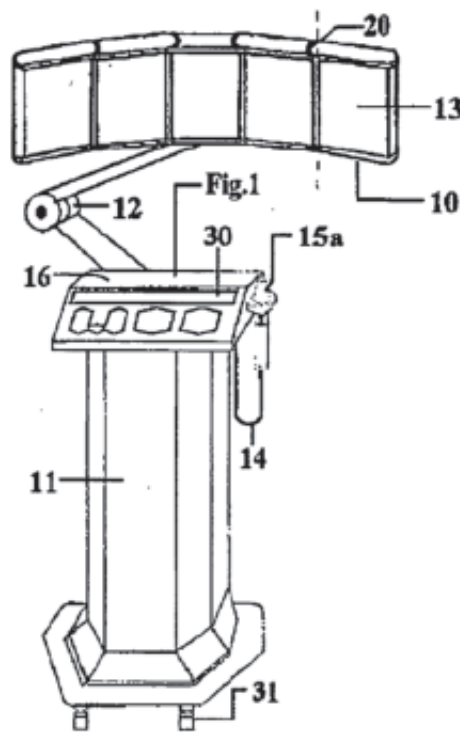
Claim 1[preamble]: *“A system for photodynamically diagnosing or treating a patient, comprising:”*

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

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

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

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



Ex.1004, Fig. 1; Ex.1015, ¶152.

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

Ex.1004, [0072]; Ex.1015, ¶153.

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

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

Even if the Board determines that Larsen’s hinges are not expressly (or inherently) disclosed on the inner side surfaces of the panels, POSITA would have found it obvious and would have been motivated with a reasonable expectation of success to locate Larsen’s hinges on the inner side surfaces of adjacent panels. Ex.1015, ¶154. First, Figure 1 of Larsen shows that the inner edges of each of the panels (13) are nearly flush with each other. This disclosure would have motivated POSITA to place the hinges on the inner side surfaces of Larsen’s panels in order to facilitate this nearly flush arrangement. *Id.* Such a modification would have involved

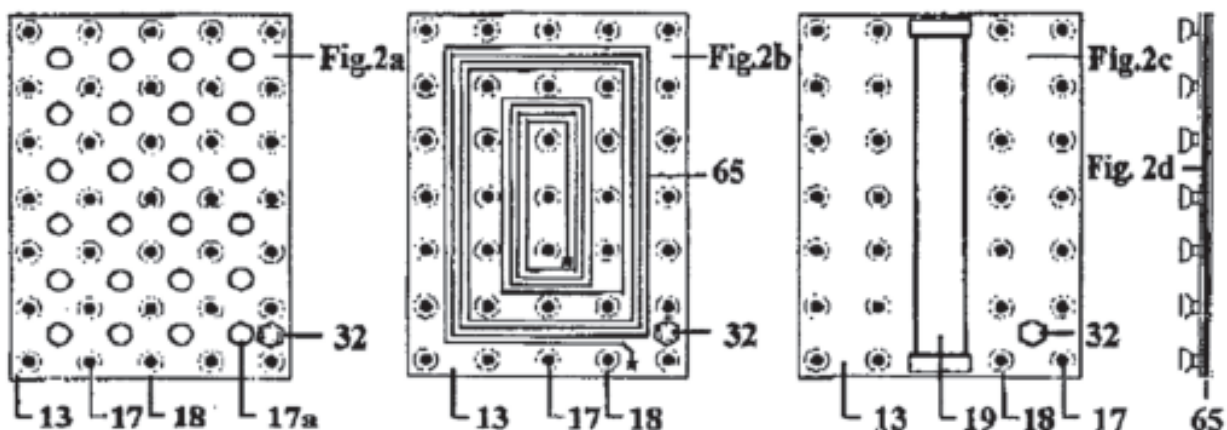
⁶ This application is a continuation of patent application no. 16/791,004 (the direct parent of the ‘028 Patent) and includes substantially the same specification as the ‘028 Patent. *Compare* Ex.1001 *with* Ex.1013.

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

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

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

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



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

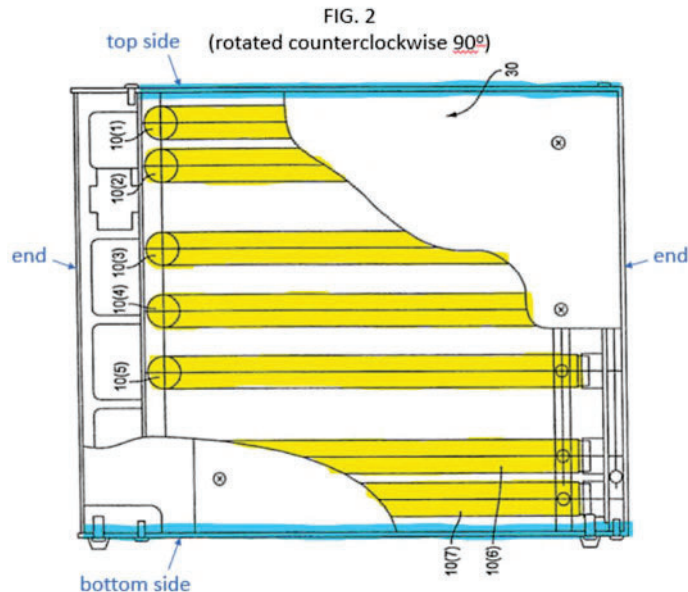
Thus, Larsen teaches the limitations of claim 1(b). Ex.1015, ¶158.

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

Lundahl teaches uniform illumination of the head of a patient via photodynamic therapy. Lundahl states “[t]he present invention is directed to photodynamic therapy using an illuminator that provides a uniform distribution of visible light.” Ex.1014, at 1:9-11. To achieve this uniformity, Lundahl utilizes the

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

light distribution pattern illustrated in Figure 2 (which has been rotated 90° to better illustrate):



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

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

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

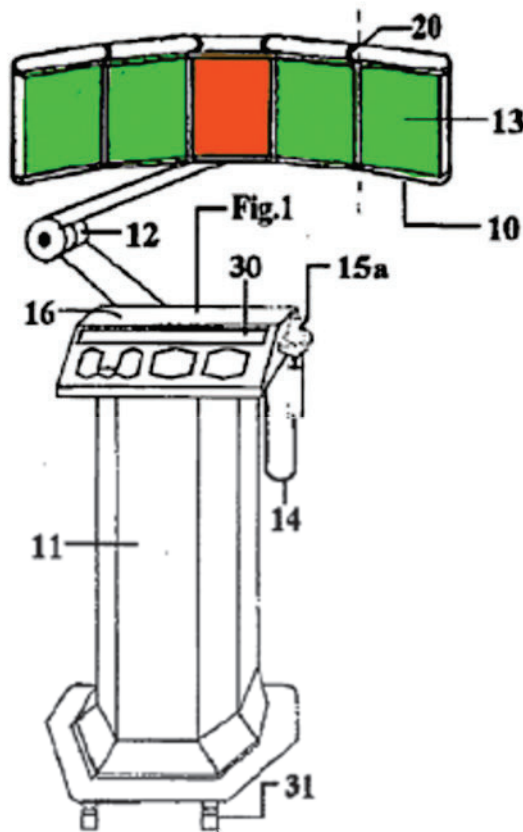
Larsen also teaches that its applicators “*permit[] an even and gap-free radiation* of the surface with multiple wavelengths of light.” Ex.1004, [0028]. An “even and gap-free radiation of the surface” would uniformly illuminate the

treatment surface. Ex.1015, ¶163. Larsen also describes measurements taken by sensors 32 that measure “the amount of energy radiated away from the skin surface, which is indicative of the total energy penetrating into the tissue.” Ex.1004, [0079]. Larsen teaches that “[t]aking into account individual variations from patient to patient, the exposure can be determined according to the measurements taken by the sensors 32 so that the correct amount of therapeutic energy (Joule/cm²) reaches the tissue.” *Id.* POSITA would have understood that Larsen’s applicator is configured to uniformly illuminate a treatment surface of the patient. Ex.1015, ¶164.

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

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

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

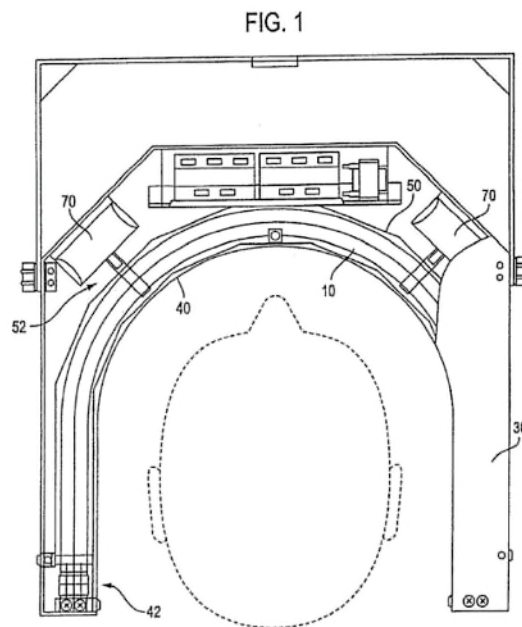


Ex.1004, Fig. 1; Ex.1015, ¶166. Larsen teaches that “the applicators are suitable for the treatment of, for example, the backs of humans and so become adjustable for an equidistant positioning of the applicators 13 above the skin.” *Id.*, [0072]. As shown above, the center panel (annotated in red) is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

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

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

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



Ex.1014, Fig. 1; Ex.1015, ¶169.

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

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

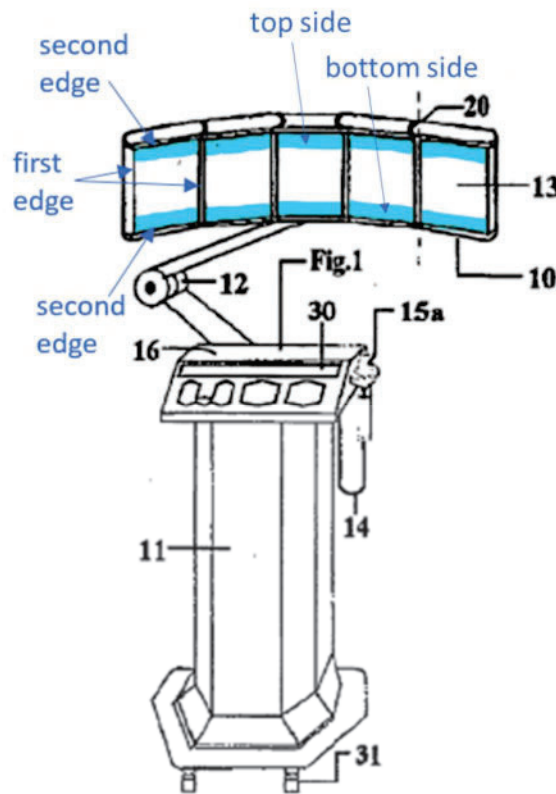
Lundahl further teaches that the light-emitting surface of the PDT device is positioned at distances of 2” and 4” from the treatment surface (i.e., the skin on the patient’s head), stating that “according to a preferred embodiment of the present invention, the measured output over the active emitting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

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

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

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

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



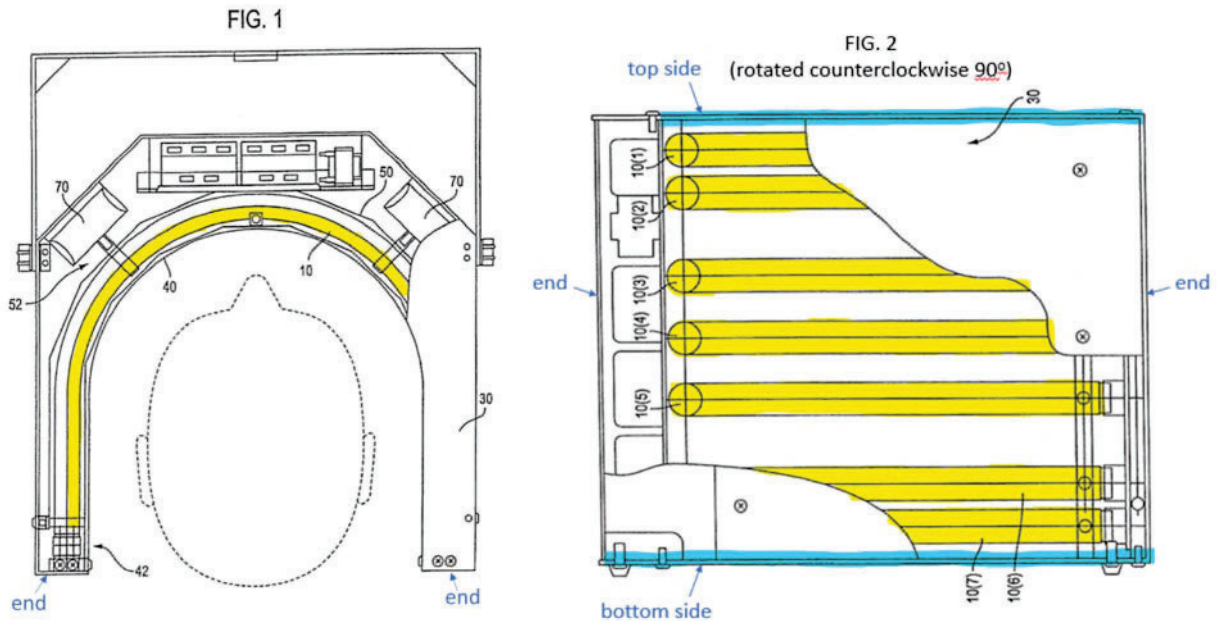
Thus, Larsen teaches the limitations of claim 1(f). Ex.1015, ¶174.

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

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

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

Ex.1014, 6:45-48.

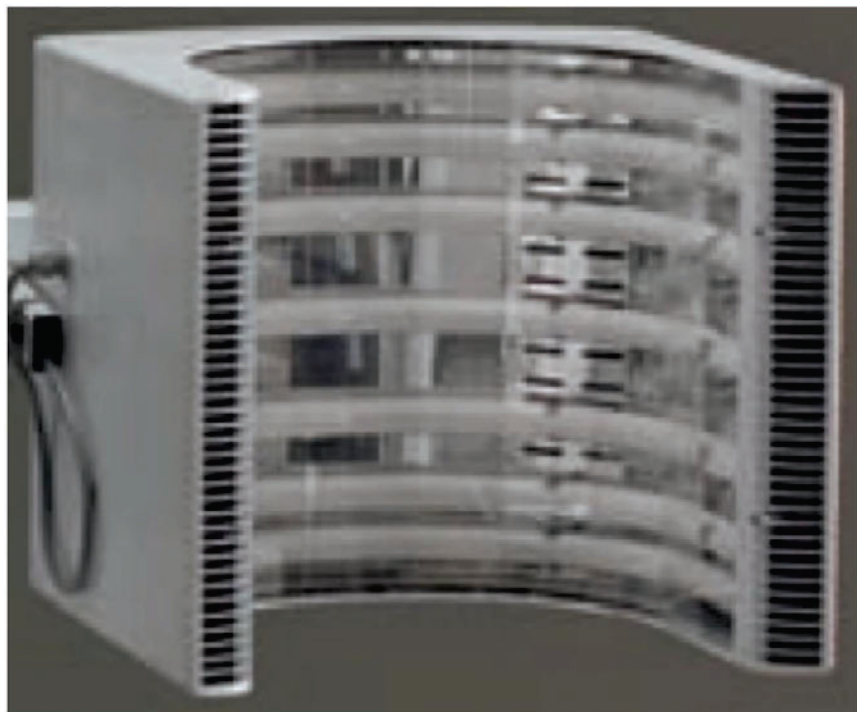


Ex.1014, Figs, 1, 2; Ex.1015, ¶175.

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

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

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



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

As shown in the annotated figures of Larsen and Lundahl above with respect to claim 1(f) and claim 1(g), POSITA would have found it obvious and would have been motivated with a reasonable expectation of success to incorporate the uneven spacing of light sources of Lundahl to increase the intensity of light emitted from the second edges (e.g., extending along the top and bottom sides of the panel arrangement) of the panels of Larson compared to regions not proximate to the second edges, for all the reasons described above at Section XI(A)(1). Ex.1015, ¶¶178-180.

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

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

3. Claim 2

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

The combination of Lundahl in view of Larsen renders obvious the system of claim 1, for all the reasons given above. Lundahl also teaches and renders obvious the use of red light *at a dose of 30 J/cm² to 150 J/cm²*. Ex.1015, ¶182.

Lundahl teaches that “[s]ince total light Dose (J/cm²)=Irradiance (W/cm²) ×Time (sec), the only additional parameter that needs to be controlled for delivery of the correct treatment light dose is exposure time”, which is “accomplished in a

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

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

more successful if it strongly absorbs red light. PpIX does strongly absorb red light.”

Ex. 1015, ¶185; Ex.1017, 4:60-69.

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

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

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

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

4. Claim 4

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

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

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

5. Claim 5

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

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

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

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

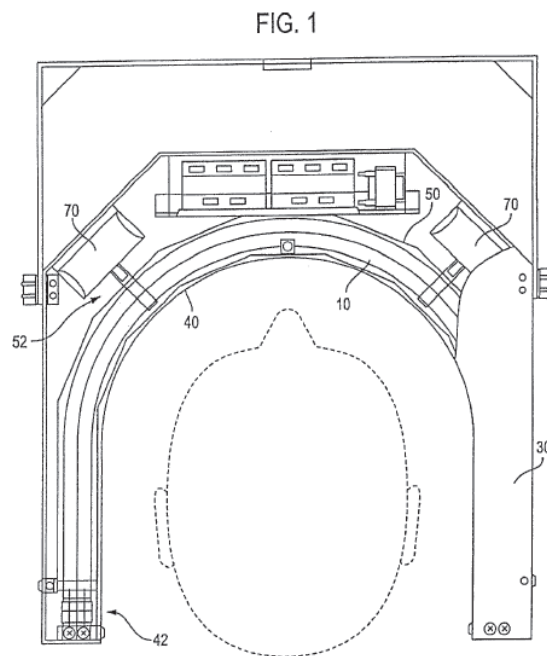
Claim 5(a): “administering 5-aminolevulinic acid (ALA) to the patient;”

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

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

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

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



Ex.1014, Fig. 1; Ex. 1015, ¶195-196.

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

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

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

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

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

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

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

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

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

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

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

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

Claim 5(h): “the light sources are arranged such that a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges.”

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

6. Claim 6

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

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

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

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

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

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

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

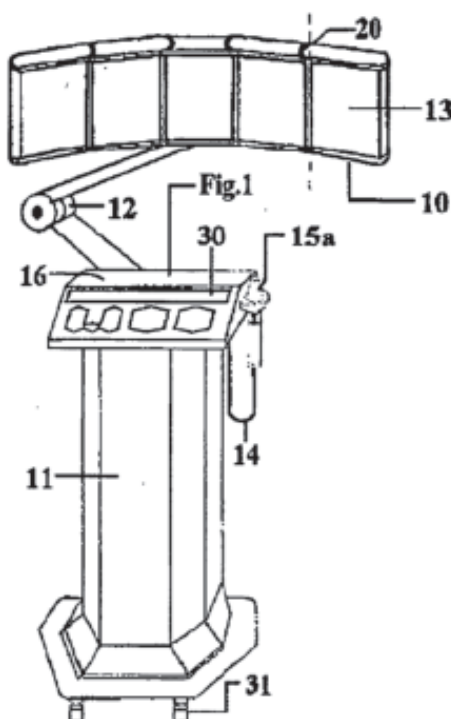
7. Claim 16

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

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

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

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



Ex.1004, Fig. 1; Ex.1015, ¶213.

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

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

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

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

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

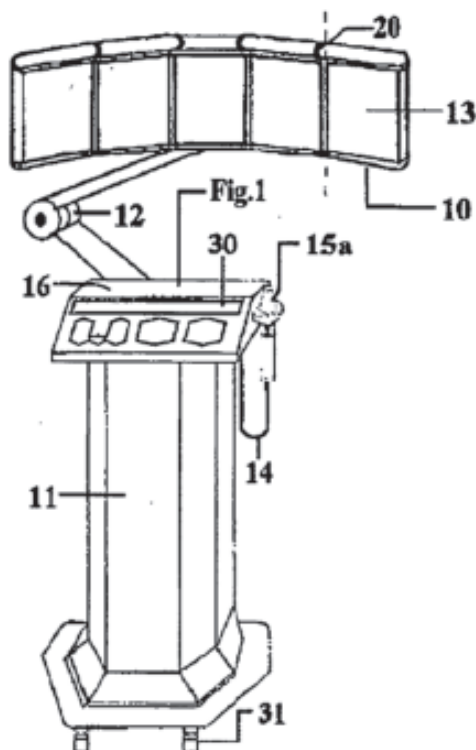
Larsen’s “stand 11” is perpendicular to the base, as shown in Figure 1. Ex.1004, Fig. 1, [0069]; *see also* Ex.1002, 328 (finding claim 16(b) disclosed by “a pillar 11” in Larsen ‘381); Ex.1015, ¶217.

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

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

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

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

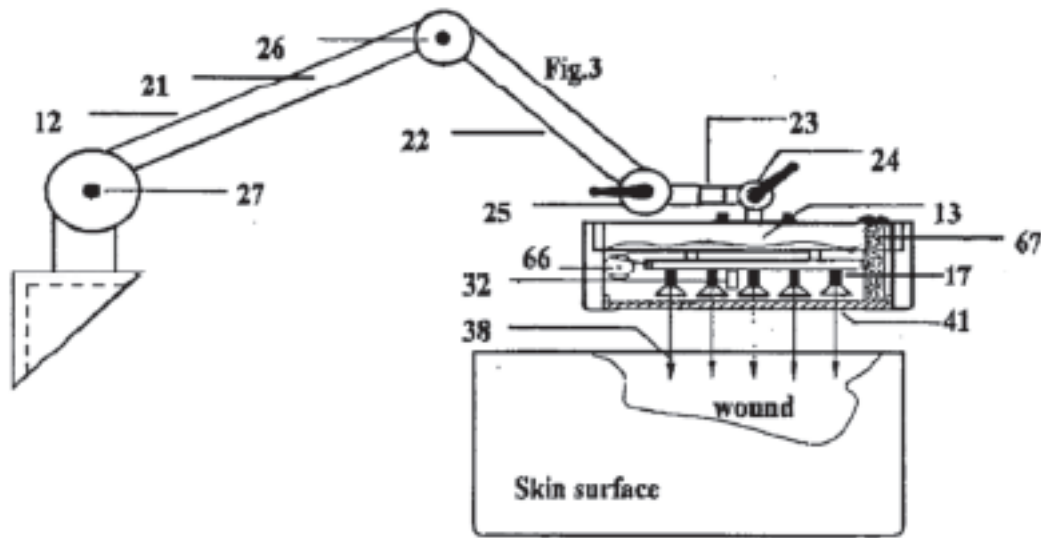


Ex.1004, Fig. 1, [0074]; *see also* Ex.1002, 328 (finding claim 16(c) disclosed by “a controller 16” in Larsen ’381); Ex.1015, ¶220.

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

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

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



Ex.1004, Fig. 3; Ex.1015, ¶222.

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

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

Claim 16(e): “an illuminator connected at an end of the arm, the arm being hinged to allow adjustment of a position of the illuminator relative to the base, the illuminator comprising:”

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

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

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

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

Claim 16(f): “five panels connected by hinged structures to allow continuous illumination across the five panels, wherein the five panels are individually configurable to control illumination from each of the five panels,”

Larsen discloses five panels connected by hinged structures to allow continuous illumination across the five panels, wherein the five panels are individually configurable to control illumination from each of the five panels. Larsen’s five panels are connected by hinged structures, for all the reasons given at claim 1(a) above. Larsen also provides continuous illumination across the five panels

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

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

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

Furthermore, each applicator includes sensors that “measure the amount of energy radiated away from the skin surface, which is indicative of the total energy penetrating into the tissue.” Ex.1004, [0079], Figs. 2a-2c. A “sensor 32a is also contained in at least one of the machine applicators, measuring the temperature change of the radiated tissue, whereby the control unit can react with a feedback regulation of the radiation parameters depending on the therapy indication, location and (PDT) light sensitive substance used.” *Id.*, [0080]. Thus, each applicator is individually configurable, since each one can be adjusted by the controller based on feedback from its own sensors. Ex.1015, ¶230.

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

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

Larsen discloses “light sources disposed on surfaces of the five panels, the illuminator being configured to uniformly illuminate a treatment surface of the patient via the light sources,” for all the reasons given with respect to claim 1(b) above. Ex.1015, ¶232.

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

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

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

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

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

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

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

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

Claim 16(k): “the light sources arranged such that a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges, and”

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

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

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

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

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

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

8. Claim 17

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

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

9. Claim 19

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

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

10. Claim 20

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Claim 20(g): *“the light sources are arranged such that a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges.”*

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

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

11. Claim 21

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Claim 21(h): *“the light sources are arranged such that a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges.”*

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

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

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

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

1. Motivation to Combine

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

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

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

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

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

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

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

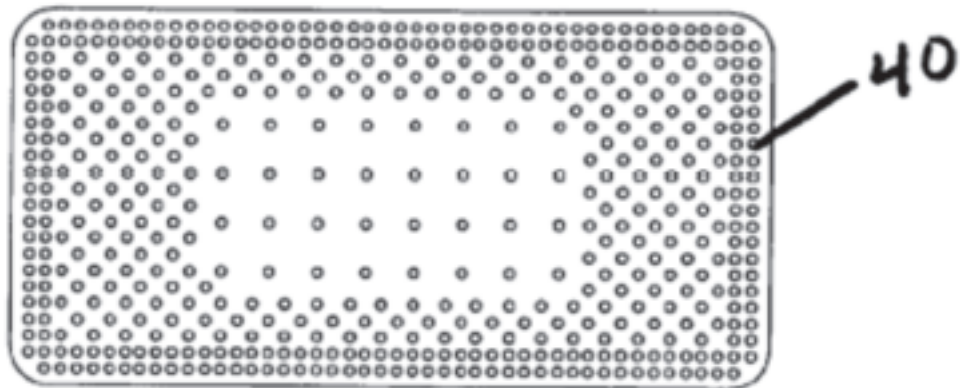
3. Bansal further teaches “a higher intensity of light is emitted proximate the second edges” recited in limitations 1(g), 5(h), 16(k), 20(g), and 21(h)

Limitations 1(g), 5(h), 16(k), 20(g), and 21(h) recite the light sources are “arranged such that a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges.” Ex.1001, 10:40-44 (claim 1), 10:66-11:3 (claim 5), 12:1-5 (claim 16), 12:37-40 (claim 20) and 12:59-63 (claim 21). For these limitations Bansal’s teachings are in addition to what Lundahl and Larsen teach, as discussed in Ground 1. Ex.1015, ¶271

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

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

Fig. 9b



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

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

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

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

4. Remaining limitations and dependent claims

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

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

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

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

A. 35 U.S.C. § 325(d)

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

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

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

Further, under part two of *Advanced Bionics*, assuming the examiner was aware of the relevant teachings in the cited prior art, then the examiner erred in a manner material to the patentability. For example, as discussed below, both Lundahl (which is part of Grounds 1 and 2) and Bansal (Ground 2) when viewed in combination with Larsen teach all the claim limitations, including “wherein each of the five panels has two first edges and two second edges shorter than the two first edges, and the light sources are arranged such that a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges.” *Supra* Sections XI(A)(2) and XI(B)(3). In the Notice of Allowance, the Examiner found that none of the prior art of record taught this limitation. *Supra* Section V(C). Thus, the arguments presented in this IPR demonstrate the Office materially erred in issuing the Challenged Claims.

B. *Fintiv*

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

XI. CONCLUSION

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

Dated: August 21, 2024

Respectfully submitted,
/James P. Murphy/

¹⁰ Available at:

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

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

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CERTIFICATE OF SERVICE

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

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CERTIFICATE OF SERVICE

I, Antoine R. Bland, hereby certify that on March 16, 2026, copies of the foregoing were served upon the following as indicated:

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PUBLIC VERSION

**UNITED STATES INTERNATIONAL TRADE COMMISSION
WASHINGTON, DC**

In the Matter of

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

Investigation No. 337-TA-1411

**RESPONDENTS BIOFRONTERA INC., BIOFRONTERA PHARMA GMBH,
BIOFRONTERA BIOSCIENCE GMBH, AND BIOFRONTERA AG'S
RESPONSIVE SUBMISSION TO COMPLAINANT'S RESPONSE TO THE
COMMISSION REQUEST FOR ADDITIONAL BRIEFING**

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Abbreviation	Meaning
CX-	Complainant's Exhibit
CX-xxxxC	Confidential Complainant's Exhibit
RX-	Respondents' Exhibit
RX-xxxxC	Confidential Respondents' Exhibit
JX-	Joint Exhibit
JX-xxxxC	Confidential Joint Exhibit
'512 Patent	U.S. Patent No. 11,446,512
'028 Patent	U.S. Patent No. 11,697,028
4170D	BLU-U® 4170 or BLU-U® 4170D
4170E	BLU-U® 4170E
Asserted Patents	The '512 Patent and the '028 Patent
Complainant <i>or</i> Sun Pharma	Sun Pharmaceutical Industries, Inc.
Respondents <i>or</i> Biofrontera	Biofrontera Inc., Biofrontera Pharma GMBH, Biofrontera Bioscience GMBH, & Biofrontera AG
ITC	International Trade Commission
FID	Final Initial Determination
USPTAB or PTAB or the Board	United States Patent Trial and Appeal Board
USPTO <i>or</i> PTO	United States Patent and Trademark Office
IPR	<i>Inter Partes</i> Review
POSA or POSITA	Person of Ordinary Skill in the Art at the time of the invention
CMIB	Complainant's Initial Markman Brief
CMRB	Complainant's Reply Markman Brief
RMIB	Respondents' Initial Markman Brief
RMRB	Respondents' Reply Markman Brief
PD	Photodynamic diagnosis
PDT	Photodynamic therapy
ALA	5-aminolevulinic acid
CPHB	Complainant's Pre-Hearing Brief
RPHB	Respondent's Pre-Hearing Brief

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CIB	Complainant's Initial Post-Hearing Brief
RIB	Respondent's Initial Post-Hearing Brief
CRB	Complainant's Responsive Post-Hearing Brief
RRB	Respondent's Responsive Post-Hearing Brief
ITC Tr.	ITC Evidentiary Hearing Transcript
IPR Tr.	IPR2024-01312 Oral Hearing Transcript
FWD	IPR2024-01312 Final Written Decision
RPR	Respondent's Petition for Review
CCPR	Complainant's Contingent Petition for Review
CIUCL	Complainant's Identification of Undisputed Claim Limitations Pursuant to Ground Rule 14.1
CIS	Complainant's Initial Submission in Response to Commission Request for Additional Briefing
RIS	Respondent's Initial Submission in Response to Commission Request for Additional Briefing
Petition	Biofrontera's Petition for Inter Partes Review of U.S. Pat. No. 11,697,028 (IPR2024-01312)
Reply	Biofrontera's Reply to Patent Owner's Response in IPR2024-01312
POR	Sun Pharma's Patent Owner's Reply in IPR2024-01312
POAB	Patent Owner's Additional Briefing Explaining Similarities and Differences Presented in the Related ITC Proceeding and in this Proceeding in IPR2024-01312
Prior Art References	
Lundahl	U.S. Patent No. 6,223,071 to Lundahl, et al.
Larsen	U.S. Patent Publication No. 2005/0075703 to Larsen
Kennedy	U.S. Patent No. 5,079,262 to Kennedy, et al.
Hente	U.S. Patent Publication No. 2010/0118522 to Hente
Perutz	U.S. Patent No. 4,823,858 to Perutz
'902 prov.	U.S. Provisional Application No. 62/241,902

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I. INTRODUCTION

Countless courts have held that the views of the PTAB can be helpful to a tribunal like the Commission. *See* RIS, 3-4. As Biofrontera explained in its opening brief (“RIS”), the PTAB’s FWD illuminates clear errors of law and fact in the FID, including errors where, at Sun Pharma’s urging, the FID ignores the factual record or misapplies the law of obviousness. The Commission need not and cannot adopt the FWD’s record, but it can and should look to the FWD to help identify the errors present in the FID and as persuasive weight on the obviousness of the Asserted Patents.

In response to the Commission’s question, Sun Pharma responds with a legal treatise on the difference between the clear and convincing and preponderance standards. As it must, the PTAB’s FWD applies the preponderance standard, but the PTAB’s decision showed it believed there was a “strong case of obviousness,” with a seasoned PTAB judge stating that “*I can't think of something more obvious*” than the ’028 Patent. *See* RIS, 1 (citing FWD 33-34, Ex. A). Moreover, Sun Pharma’s arguments about live testimony are undermined by the fact that all direct testimony in this proceeding was submitted in writing, not live.

Ultimately, Sun Pharma’s attorney argument is severely undermined by its own conflicting statements. To this Commission, Sun Pharma offers a brief replete with references to *different* records, *different* arguments, and *different* evidence. In presenting the ALJ’s FID to the PTAB in November, however, Sun Pharma told a completely different story:

Petitioner relied on the *same art, the same experts, and the same grounds* when it attempted to invalidate the ’028 Patent in the related ITC proceeding....The parties thoroughly briefed *near-identical arguments as presented in this instant IPR*.

Ex. 1. POAB, 1 (emphasis added). Sun Pharma followed these statements with 9 pages of single-spaced text comparing the FID to the arguments made in the PTAB. Sun Pharma’s polar opposite arguments to the PTAB and the Commission means that its submission here should be given little weight. On the individual elements, Sun Pharma’s discussion relies on mistaken arguments of a

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different claim construction belied by the record, unsupported claims of “waiver” or “attorney argument,” false claims of “material differences,” and other red herrings.

II. THE EVIDENCE BEFORE THE COMMISSION AND PTAB SHOW CLEAR AND CONVINCING EVIDENCE OF INVALIDITY

A. The PTAB’s Treatment of the “Uniformity” Is Consistent with Order 18’s Construction and Supportive of an Obviousness Finding by the Commission

Sun Pharma is mistaken when it argues the PTAB used a different claim construction of uniformity. CIS, 12. The application of the ITC’s agreed-to construction for uniformity was not in controversy and was acknowledged by all parties – including the Board itself. For instance, Sun Pharma urged the Board to apply the “60%” construction (Ex. 2 (POR), 18-19), and Biofrontera argued that “the combination of Lundahl and Larsen would meet *the ITC construction* of ‘uniformly illuminate a treatment surface.’” Reply, 6 (emphasis added). The FWD states that:

A claim construction order was issued in the related ITC proceeding...including adopting the parties' agreed-to construction of the term “uniformly illuminate/illuminating a treatment surface” (i.e., to require “irradiating light over the active emitting area such that the measured irradiance at a treatment surface of the patient is at least within 60% of the measured maximum”)...Although we decline to expressly construe claim terms, we note that our Decision is not inconsistent with the claim constructions set forth in the ID.

FWD, 13 n. 7.

While Sun Pharma takes issue with the Board’s observation that “the recited ‘treatment area’ is unspecified, and therefore includes very small and/or flat areas of a patient’s body...” (FWD, 27), this analysis is in no way inconsistent with the claim term itself or the agreed construction applied at the ITC. As the Board correctly recognized, both the claim term (“uniformly illuminate ***a treatment surface***”) and its agreed construction (“the measured irradiance at ***a treatment surface*** of the patient is at least within 60% of the measured maximum”) broadly

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recite “a treatment surface” without further limitation.¹ Had Sun Pharma wished to narrow its claim scope, it could have recited a particular treatment surface in the claims or argued for a specific definition of “treatment surface” at the *Markman* stage. It did not do either of these things.

Although Sun Pharma accuses the FWD of lowering the bar to “some unspecified uniformity” from “a single panel,” (CIS, 12-13), this is a plain mischaracterization. During the hearing, the Board acknowledged the 60% standard as a matter of course. IPR Tr., 18:11-20, 73:1-7 (Mr. Ha: “... uniformly illuminate had a particular construction that was agreed upon by both parties...at least within 60 percent requirement...Judge Weatherly: And why isn't Lundahl's teaching of 60 percent enough?”). Similarly, the FWD’s reference to a “single panel” does not pertain to the number of illuminated panels required by the claims, as Sun argues. CIS, 12-13. Instead, the FWD was merely describing the type of small treatment area that the claims could encompass – *i.e.*, “a small, flat treatment area covered by a single panel.” FWD, 28. Thus, the PTAB’s conclusion was not made under “a different and broader claim construction.” CIS, 14.

Although Sun Pharma urges the Commission to credit the FID’s reliance on “live testimony heard by the ALJ” (FID,106-107), this is a red herring. CIS, 14. First, the direct testimony before the ALJ was entered via written witness statement. Further, the live testimony Sun Pharma does cite repeatedly leaves out important context. For instance, Sun Pharma refers to testimony from Mr. Boyajian regarding the challenges the inventors faced, but fails to acknowledge that (i) the

¹ Sun Pharma also points to the FWD’s citation to *In re Blue Buffalo Enters., Inc.*, No. 2024-1611, 2026 WL 100470 (Fed. Cir. Jan. 14, 2026), to imply that the PTAB applied the “broadest reasonable interpretation” standard. CIS, 12-13. This mischaracterizes the FWD’s use of the case, which was merely cited to support the proposition that “configured to” means “capable of.” FWD, 27. In direct contradiction to Sun Pharma’s vague implications, the FWD explicitly noted that “the Board construes the terms of a patent ‘in accordance with the ordinary and customary meaning....’” FWD, 12-13.

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challenge Mr. Boyajian was referring to was much narrower than the claims at issue² and (ii) Mr. Boyajian is not a POSA. Sun Pharma then continues to argue that Dr. Grove opined that “uniformity requires ‘undue experimentation,’” while ignoring the fact that “Dr. Grove’s testimony only referred to achieving uniform illumination over large or non-flat treatment areas (e.g., torso and extremities).” FWD, 28; *see also* ITC Tr. (Grove), 579:15-25 (Q: you said that in your opening expert report, right? A: *In a different context, I did, yes.*”); RRB, 19-20. As the FWD correctly recognized, while such treatment areas would fall within the unspecified recited “treatment area,” the limitation may be satisfied by less for obviousness purposes.

B. The PTAB’s Conclusion on the Obviousness of the “Hinges” Limitation Corrects Legal Error by the FID and Should Be Given Weight.

Initially, Sun Pharma incorrectly focuses on the implications of Dr. Jokerst’s declaration that “a POSITA [] would have understood that the hinges are not necessarily on inner side surfaces.” CIS, 14-15 (citing FWD, 23). At bottom, it is a matter of judicial notice that “a three-dimensional rectangular panel,” as disclosed in Larsen, has at most six sides for hinge attachment (inclusive of the inner side surfaces). FWD, 25-26. The PTAB recognized this³, Dr. Grove recognized this⁴, and Dr. Jokerst recognized this. CX-0014C (Jokerst), Q/A 236 (only listing “on the top, bottom, and back of the panels” as alternate hinge placements). Choosing one out of six places to attach hinges is not inventive, and the FWD sheds light on the FID’s legal error in finding otherwise.⁵ *See* FWD, 26 (citing *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398 (2007)).

² JX-0014C (Boyajian), 73:21-74:9, 75:11-22 (explaining that the inventors’ goal was to “produce something that was on label” and noting that “what got into the patent is disjoint [sic] from what I did”).

³ FWD, 25-26.

⁴ RX-0006C (Grove), Q/A 157; Tr. (Grove), 591:5-7 (“There are three locations to connect adjacent panels.”).

⁵ Although Sun Pharma points out that the Examiner of the ’028 Patent eventually allowed the application over Larsen (CIS, 15), such allowance was not based solely on the supposed

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Second, while Sun Pharma correctly notes that for noninfringement purposes, Dr. Grove examined the detailed structure of the RhodoLED®XL's hinges, it incorrectly concludes that the prior art must depict the same detail for obviousness. CIS, 15-16. For infringement, the FID found “[t]he claims require only that the ‘panels’ be ‘connected by’ hinges; they *do not specify where or how the hinges are connected to the panels.*” FID, 19 (emphasis added). Because this binding claim interpretation does not recite hinge structure or location in any detail, Sun Pharma’s observation that Larsen fails to disclose hinge structure in any detail is inapposite.⁶ Indeed, the fact that the FID found otherwise highlights a fundamental legal error: application of different claim interpretations depending on whether infringement or validity is at stake.

Finally, while Sun Pharma acknowledges that the “FWD rejected...the written testimony from Dr. Jokerst that a POSITA would have been discouraged from placing hinges between panels because uniform illumination would be degraded by the resultant gaps,” it urges the Commission to discount this finding. CIS, 16. However, its reasoning for this request fails. Sun Pharma notes that the FWD credited Dr. Grove’s supplemental declaration (Ex. 1026), which was not submitted before the ITC. CIS, 16. But Sun Pharma downplayed this difference in its briefing before the PTAB, stating that “Petitioner relied on the same art, the same experts, and the same grounds when it attempted to invalidate the ’028 Patent in the related ITC proceeding.” Ex. 1 (POAB), 1. Sun Pharma cannot have it both ways – either this testimony is important or it is not. While the PTAB did credit this testimony (FWD, 25), the FWD also relied on additional evidence available to the Commission, including Dr. Grove’s testimony that a POSA would have known that hinges on

absence of hinges in the prior art. JX-0004.1731. In fact, earlier in prosecution, the Examiner cited Larsen as anticipatory to claims including the term “nested hinges” - which, according to Sun and Order No. 18, mean hinges “that fit on inner side surfaces of adjacent panels.”

⁶ *TVIIM, LLC v. McAfee, Inc.*, 851 F.3d 1356, 1362 (Fed. Cir. 2017) (holding claim terms construed the same way for purposes of infringement and invalidity).

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inner side surfaces could be arranged so as to allow for nearly flush positioning of the panels. FWD, 24-25; RX-0006C (Grove), Q/A 157; RIB, 44. Accordingly, the FWD recognizes what any POSA would have known and what Dr. Jokerst admitted – that there are very limited options for where to attach a hinge to a panel and selecting one of them is not an act of invention.

C. Biofrontera Argued That “Continuous Illumination” Was Obvious at Both the PTAB and the ITC, and the PTAB’s Obviousness Finding Is Instructive Here

Sun Pharma’s statement that “Biofrontera failed to argue in its post-hearing brief that the ‘continuous illumination’ element of claim 16 of the ’028 Patent was obvious” is incorrect. CIS, 17. Biofrontera made it clear throughout its post-hearing briefs that it was challenging the validity of claim 16 of the ’028 patent as obvious. RIB, 40, 62-64, 72-74; RRB, 2, 28-30. In post-hearing briefing, Biofrontera argued “continuous illumination” was obvious in view of Larsen. Biofrontera addressed “continuous illumination” as part of the “hinges limitation” for all Asserted Claims, including claim 16. *See* RIB, 40-41 (listing limitations), 44-45 (discussing continuous illumination in connection with hinges limitation and citing RX-0006C Q/A158-59 (Grove)); RPR 39-40 (citing Grove testimony and noting the FID’s legal error in disparate treatment for infringement and invalidity). “Continuous illumination” is repeated in claim 16’s “individually configurable” limitation. RIB, 62-64 (“individually configurable”). Biofrontera argued that this whole limitation was obvious over Larsen. *Id.* In addressing “continuous illumination,” the PTAB, was persuaded that, even if it accepted Sun Pharma’s arguments that there could be lower illumination at the juncture between panels, Larsen would still provide “continuous illumination” and thus still taught the limitation. *See* FWD, 44. While this discussion is in a section of Biofrontera’s brief referencing the ’512 Patent, this is not a meaningful distinction given that Sun Pharma’s allegation that the “continuous illumination” language of the ’512 Patent is “materially different” is also incorrect. CIS, 17. The two limitations are as follows:

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Claim 20 of the '512 Patent	Claim 16 of the '028 Patent
“at least five panels connected by nested hinges on inner side surfaces of adjacent panels, the nested hinges being configured so as <i>to allow continuous illumination across the at least five panels</i> ”	“five panels connected by hinged structures <i>to allow continuous illumination across the five panels</i> ”

As explained above, to the extent the Commission affirms the ALJ’s construction of “nested hinges,” the only difference here is that claim 16 of the ’028 Patent is broader than claim 20 of the ’512 patent because it does not require that the hinged structures be on inner side surfaces. This difference is not material and any disclosure rendering “continuous illumination” obvious under the ’028 patent’s more permissive hinge location language would also render “continuous illumination” obvious under the ’512 Patent. Second, Sun Pharma’s argument that “the PTAB’s decision does not support finding invalidity under the clear and convincing standard” goes too far. CIS, 17. Sun Pharma argues that continuous illumination is a consequence of the hinges, “as recited in the claims.” CIS, 17. But the claims do not recite any detailed structure for the hinges, and that breadth was the basis for the FID’s infringement finding. *Supra*, II.B.

D. The FWD’s Finding that “Higher Intensity Proximate Second Edges” Was Obvious Regardless of Larsen’s Scan Engine Should Be Illuminating Here

Sun Pharma argues that the FWD’s conclusions as to the “higher intensity proximate the second edges” limitation should be discounted because it found that “Larsen’s scan engine is not required in the combination” whereas, at the ITC, “Biofrontera explicitly and continuously relied on Larsen’s scan engine in the combination....” CIS, 18. This is false. Biofrontera made clear in its post-hearing briefing that “*Biofrontera has never argued that Larsen’s scan engine need be incorporated* in a combination to achieve uniformity.” RRB, 24.

Regardless of the inclusion of Larsen’s scan engine, there is no evidence to support Sun Pharma’s argument that Larsen’s scan engine would interfere with higher intensity proximate the short edges. RRB, 24-25. Dr. Jokerst admitted that Larsen fails to disclose whether the scan engine

causes movement up or down or side to side, any pattern, range, or rate of movement for the scan engine, any specific time points, or any units, dimensions, or measurements related to her speculations as to the scan engine's movements. ITC Tr. (Jokerst), 741:22-743:5. The FWD reviewed this testimony and correctly concluded that it "confirmed that Larsen's scan engine...would not affect light intensity at the second edges." FWD, 32.

E. In Finding the "Individually Configurable" Limitation Obvious, The FWD Relied on Arguments and Evidence Overlooked by the FID

Sun Pharma argues that the FWD's conclusion of obviousness as to the "individually configurable" limitation "should be given no weight" because "the PTAB credited arguments Biofrontera did not make in this proceeding." CIS, 20-21. However, Sun Pharma ignores the fact that the FWD also credited arguments that Biofrontera *did* make in this proceeding. RIB, 62-64; RRB, 25-26; RPR, 29-31. Specifically, the FWD stated that "we agree with Petitioner... particularly in light of the teaching of Larsen's claim 5..." which "recites that light sources, such as laser diodes, 'are individually selected—switched ON or OFF.' Claim 5's teaching that laser diodes are individually switched supports Petitioner's position that Larsen's teachings go beyond simply adjustability/switching across all applicators." FWD, 46-47.

Further, the FWD found that "we also agree with Petitioner that a POSITA would have understood that a single controller can control multiple applicators and/or LEDs...citing Ex. 2011, 2...." FWD, 45. That evidence, CX-1231, is also before the Commission but was ignored by the FID. *See* RIS, 20. Although Sun Pharma incorrectly asserts that "Biofrontera belatedly attempted to introduce CX-1231 as new prior art," its own expert introduced this reference to illustrate what was understood in the art as of the 2015 priority date. CIS, 20; CX-0014C.119. Biofrontera simply cites CX-1231 for the same purpose – to highlight how a POSA would have understood Larsen's disclosure of "controller." The FID did not consider this evidence, but the PTAB credited it.

F. The FWD’s Legal Analysis of Motivation to Combine Was Correct and Should Be Instructive Here

Sun Pharma’s argument to discount the FWD’s finding of a motivation to combine because the PTAB was not able to consider Dr. Ehrenreich’s live cross-examination (CIS, 9-12) is simply an invitation to the Commission to perpetuate legal error in the FID. Specifically, the FWD credited Dr. Ehrenreich’s testimony detailing the limitations of Lundahl’s fixed-shape device for treating different patients and areas (FWD, 19-20 (citing Ex. 1016 (Ehrenreich Declaration))), which would have motivated incorporation of hinged panels for greater flexibility. Sun Pharma’s argument that this conclusion would be undermined by Dr. Ehrenreich’s live testimony that he still uses the older 4170D fixed-U shape device to treat patients (CIS, 11) is based on a misunderstanding of the law. Motivation to modify does not require that the prior art be impossible to use or inoperable. *See DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co.*, 464 F.3d 1356, 1368 (Fed. Cir. 2006). Thus, under the proper legal framework, the fact that it is still possible to use a fixed-shaped device is irrelevant to the FWD’s conclusion.

III. EVIDENCE OF SECONDARY CONSIDERATIONS CANNOT DEFEAT SUCH A STRONG PRIMA FACIE SHOWING OF OBVIOUSNESS.

The FID does “not consider any secondary considerations of nonobviousness,” FID, 124, which is itself legal error. *See* FWD, 33 (citing *Adapt Pharma Operations Ltd. v. Teva Pharms. USA, Inc.*, 25 F.4th 1354, 1372 (Fed. Cir. 2022)). Noting a “strong case of obviousness in view of Lundahl and Larsen,” the PTAB stated that “we determine that any evidence of secondary considerations would need to be given substantial weight in order to determine that the claims have not been shown to be unpatentable by a preponderance of the evidence.” FWD, 33. While the FID left little for Biofrontera to respond to, both the FWD, which spends 10 pages analyzing secondary considerations, and Biofrontera’s briefing demonstrate that secondary considerations are weak. With respect to commercial success, even 8 months after trial, Sun Pharma has provided virtually

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no evidence of sales of its domestic industry product. The FWD concludes that “many claimed features that drove the success of the RhodoLED®XL were known, at least separately, in the prior art,” FWD, 37-38 (noting Larsen teaches larger illumination area and five adjustable LED panels and both Larsen and Lundahl taught using uniform light). The PTAB found Biofrontera’s self-referential praise of the RhodoLED®XL was entitled to little weight. FWD, 41 (citing *Bayer Healthcare Pharms., Inc. v. Watson Pharms., Inc.*, 713 F.3d 1369, 1377 (Fed. Cir. 2013)). The PTAB spent pages analyzing the Vander Veen declaration and concluded that, “[e]ven assuming we determined a presumption of nexus or actual nexus existed, we find Patent Owner’s weak to moderate evidence of commercial success and praise does not overcome the strong showing of obviousness established by [Biofrontera].” FWD, 43. Given the lack of analysis in the FID, the FWD’s secondary consideration analysis should be persuasive to the Commission.

IV. SUN PHARMA CONTRADICTS ITS PREVIOUS ARGUMENTS TO ASSERT THAT THE ‘512 PATENT IS MATERIALLY DIFFERENT.

As explained in Biofrontera’s RIS, the FID’s construction of the “nested hinges” limitation essentially erases the differences with the “hinged structures” claim language of the ‘028 Patent. *See* RIS, 8. Now, contrary to its arguments and Order No. 18, Sun Pharma claims “nested hinges” to be “materially different.” *See* CIS, 25. In any event, the PTAB was highly skeptical that hinges could convey inventiveness. *See* Ex. A, 50:21-22 (“JUDGE WEATHERLY: So there's magic about the hinges being on the inner side surfaces?”); RIS, 10.⁷

V. CONCLUSION

For the foregoing reasons, the Commission should grant the relief sought in Biofrontera’s Petition for Review.

⁷ With respect to Hente and Perutz, Biofrontera relies on its obviousness arguments as laid out in its Petition for Review. *See* RPR, 40-41; RIB, 69-71, RRB, 27-28.

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Dated: March 19, 2026

Respectfully submitted,

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Exhibit 1

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

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

v.

SUN PHARMACEUTICAL INDUSTRIES, INC.
Patent Owner

Case IPR2024-01312

U.S. Patent No. 11,697,028

**PATENT OWNER'S ADDITIONAL BRIEFING EXPLAINING
SIMILARITIES AND DIFFERENCES PRESENTED IN THE RELATED
ITC PROCEEDING AND IN THIS PROCEEDING**

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Patent Trial and Appeal Board
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PATENT OWNER'S EXHIBIT LIST

EX #	DESCRIPTION
2001	Declaration of Dr. Jose Sasian
2002	<i>Curriculum Vitae</i> of Dr. Jose Sasian
2003	Complainant's Initial Statement Regarding The Public Interest filed in ITC Investigation No. 337-TA-1411, dated June 25, 2024
2004	Australian Patent Application Publication No. AU 200143869 published September 6, 2001 to Eric Larsen entitled <i>Device and methods for the stimulation of body cells through electromagnetic radiation</i> ("Larsen Publication")
2005	United States Trademark Serial No. 78214595 Statement of Use and correspondence for BEAUTYLIGHT ("BEAUTYLIGHT")
2006	United States Patent No. 4,832,294 issued May 23, 1989 to John C. Eldem entitled <i>Portable I.V. Stand</i> ("the '294 patent")
2007	Inventor Tom Boyajian LinkedIn profile at https://www.linkedin.com/in/tom-boyajian-404286307/
2008	Inventor Mark Carota LinkedIn profile at https://www.linkedin.com/in/mark-c-366911a/
2009	Inventor Brian Mazejka LinkedIn profile at https://www.linkedin.com/in/brianmazejka/
2010	Lighting-Gallery.net – My lights/completely clear/uncoated Sylvania 28W T5 HE demonstration tube at https://www.lighting-gallery.net/gallery/displayimage.php?album=1601&pos=188&pid=211863
2011	Bourget, C. Michael, <i>An Introduction to Light-emitting Diodes</i> , HortScience, Vol. 43(7), pp. 1944-1946 (December 2008)
2012	United States Patent No. 6,979,101, issued December 27, 2005 to Christian Sauska et al., entitled <i>Fluorescent Lamp Providing Uniform Backlight Illumination for Displays</i> ("the '101 patent")
2013	Ndjiongue, Alain R. et al., <i>Visible Light Communications (VLC) Technology</i> , pp. 1-23 (June 2015)
2014	Technical Domestic Industry Claim Chart for U.S. Patent No. 11,697,028 (Ex. 10C Public Version) filed in ITC Investigation No. 337-TA-1411, dated July 9, 2024
2015	Declaration of Heather J Roberts, MD, FAAD
2016	<i>Curriculum Vitae</i> of Heather J Roberts, MD, FAAD
2017	https://www.levulanhcp.com/

EX #	DESCRIPTION
2018	https://www.levulanhcp.com/how-to-use
2019	https://www.levulanhcp.com/how-it-works
2020	https://www.levulanhcp.com/treatment-landscape
2021	https://www.levulanhcp.com/efficacy
2022	https://www.levulanhcp.com/assets/pdf/levulan-patient-brochure.pdf
2023	https://drheatherroberts.com/procedures-and-treatments/photodynamic-therapy-pdt-for-skin-cancer/
2024	https://www.mydrugrep.com/mobile-campaigns/Levulan V13a 01a/space requirements.html
2025	https://somalaser.com/dr-michael-ehrenreich-md-millburn-dermatologist/
2026	https://somalaser.com/blu-for-acne/
2027	https://somalaser.com/photodynamic-therapy/
2028	https://somalaser.com/photodynamic-therapy-for-actinic-keratoses-and-skin-cancer/
2029	https://somalaser.com/photodynamic-therapy-for-skin-conditions/
2030	https://somalaser.com/skin-conditions/actinic-keratosis/
2031	[RESERVED]
2032	[RESERVED]
2033	<i>In Re Certain Photodynamic Therapy Systems, Components Thereof, And Pharmaceutical Products Used In Combination With The Same</i> Investigation No. 337-TA-1411 (Order No. 18 – Construing Certain Claim Terms, dated March 4, 2025 (Public Version))
2034	<i>In Re Certain Photodynamic Therapy Systems, Components Thereof, And Pharmaceutical Products Used In Combination With The Same</i> Investigation No. 337-TA-1411 (Redacted Expert Report of Dr. Robert E. Grove, Ph.D. on behalf of Respondents, dated January 22, 2025)
2035	United States Patent No. 8,216,289 issued July 10, 2012 to Scott Lundahl, et al., entitled <i>Illuminator for Photodynamic Therapy</i> (“the ’289 patent”)
2036	<i>In Re Certain Photodynamic Therapy Systems, Components Thereof, And Pharmaceutical Products Used In Combination With The Same</i> Investigation No. 337-TA-1411 (Redacted Deposition Transcript of Dr. Robert E. Grove, taken February 26, 2025)
2037	BLU-U® Optical Specification
2038	<i>In Re Certain Photodynamic Therapy Systems, Components Thereof, And Pharmaceutical Products Used In Combination With The Same</i>

EX #	DESCRIPTION
	Investigation No. 337-TA-1411 (Sun Pharma's Redacted Final Validity Contentions dated December 18, 2024)
2039	Redacted Deposition Transcript of Mark Baldyga in ITC Inv. No. 337-TA-1411, taken December 19, 2024
2040	Ex. 6 to Baldyga Deposition Transcript in ITC Inv. No. 337-TA-1411 (Marketing Presentation Slides)
2041	Ex. 5 to Baldyga Deposition Transcript in ITC Inv. No. 337-TA-1411 (Ameluz Marketing Materials)
2042	Ex. 4 to Baldyga Deposition Transcript in ITC Inv. No. 337-TA-1411 (RhodoLED® XL Trifold)
2043	RhodoLED® XL User Manual, Version 1.7SW_G2
2044	" <i>Biofrontera AG receives FDA-approval of the BF-RhodoLED® XL lamp,</i> " GlobalNewswire, https://www.globenewswire.com/news-release/2021/10/22/2319235/0/en/Biofrontera-AG-receives-FDA-approval-of-the-BF-RhodoLED-XL-lamp.html , dated October 22, 2021
2045	" <i>Biofrontera Announces the Launch of a New, FDA-Approved Red Light Source, the RhodoLED® XL Lamp,</i> " BioSpace, https://www.biospace.com/biofrontera-announces-the-launch-of-a-new-fda-approved-red-light-source-the-rhodoled-xl-lamp , dated June 24, 2024
2046	" <i>Biofrontera Inc. Announces 100 RhodoLED®XL Machines Now Placed in US Market,</i> " GlobalNewswire, https://www.globenewswire.com/news-release/2024/12/23/3001296/0/en/Biofrontera-Inc-Announces-100-RhodoLED-XL-Machines-Now-Placed-in-US-Market.html , dated December 23, 2024
2047	" <i>Biofrontera Inc. Reports Record Fiscal Year 2024 Financial Results and Provides a Business Update,</i> " Biofrontera, Inc., dated March 21, 2025
2048	Declaration of Thomas Vander Veen
2049	Supplemental Declaration of Heather J Roberts, MD, FAAD
2050	Declaration of Dr. Nan Jokerst
2051	<i>Curriculum Vitae</i> of Dr. Nan Jokerst
2052	Excerpted Deposition Transcript of Mark Carota in ITC Inv. No. 337-TA-1411, taken December 5, 2024
2053	Excerpted Deposition Transcript of Thomas Boyajian in ITC Inv. No. 337-TA-1411, taken December 10, 2024
2054	" <i>FDA Approves RhodoLED XL Lamp Red Light Source for Use in Actinic Keratosis Treatment,</i> " Dermatology Times, dated July 2, 2024

EX #	DESCRIPTION
	https://www.dermatologytimes.com/view/icymi-fda-approves-rhodoled-xl-lamp-red-light-source-for-use-in-actinic-keratosis-treatment
2055	Biofrontera Form 10-K, dated March 20, 2025
2056	BF-RhodoLED®, https://us.ameluz.com/hcp/activate-with-rhodoled-lamp/
2057	Biofrontera Q4 2024 Earnings Call Transcript
2058	<i>“Biofrontera Inc. Announces FDA Orange Book Listing of U.S. Patent for BF-RhodoLED® XL, Extends Protection of Ameuluz® PDT Through October 2040,”</i> BioSpace, dated March 14, 2022
2059	U.S. Pat. No.11,235,169 issued February 1, 2022 to Markus Osterloh, et al., entitled <i>Illumination Device for Photodynamic Therapy, Method for Treating a Skin Disease and Method for Operating an Illumination Device</i> (“the ’169 patent”)
2060	AMELUZ Prescribing Information, December 2021
2061	File History of U.S. Patent No. 11,446,512
2062	<i>“Actinic Keratosis,”</i> Cleveland Clinic, https://my.clevelandclinic.org/health/diseases/14148-actinickeratosis
2063	<i>“Actinic Keratosis: Diagnosis and Treatment”</i> American Academy of Dermatology Association, https://www.aad.org/public/diseases/skin-cancer/actinic-keratosistreatment
2064	<i>“Biofrontera Announces U.S. FDA Approval of Ameluz® and Activating BF-RhodoLED® Device for Treatment of Actinic Keratosis”</i> Biofrontera News Release, https://www.biofrontera.com/fileadmin/files/PDFs/Corporate_news/2016/EN/20160511 , May 11, 2016
2065	<i>“Biofrontera Bioscience GmbH,”</i> www.medicines.ie
2066	<i>“Biofrontera Inc. (BFRI) Q2 2024 Earnings Call Transcript”</i> https://seekingalpha.com/article/4714932-biofrontera-inc-bfri-q2-2024-earnings-call-transcript , August 15, 2024
2067	<i>“Biofrontera Inc. (BFRI) Q4 2023 Earnings Call Transcript”</i> https://finance.yahoo.com/news/biofrontera-inc-nasdaq-bfri-q4-132209594.html , March 18, 2024
2068	<i>“Biofrontera Inc. Reports First Quarter 2024 Financial Results and Provides a Business Update”</i> https://www.biospace.com/biofrontera-inc-reports-first-quarter-2024-financial-results-and-provides-a-business-update , May 15, 2024
2069	<i>“Biofrontera Inc. Reports Third Quarter and Nine-Month 2024 Financial results and Provides Business Update”</i> https://www.biospace.com/press-

EX #	DESCRIPTION
	releases/biofrontera-inc-reports-third-quarter-and-nine-month-2024-financial-results-and-provides-business-update, November 14, 2024
2070	Biofrontera Inc., Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 for the Fiscal Year Ended December 31, 2023 (Form 10-K)
2071	“Biofrontera Pharma GmbH,” https://www.medicines.org.uk/emc/product/3158/smpc
2072	“ <i>Photodynamic Therapy Market Size, Share, and Trends 2025 to 2034</i> ” Precedence Research, https://www.precedenceresearch.com/photodynamic-therapy-market
2073	“ <i>Photodynamic Therapy Market to Grow by USD 2.35 Billion (2024-2028), Driven by Rising Cancer Prevalence, AI-Powered Report Highlights Market Trends – Technavio</i> ” PR Newswire, https://www.prnewswire.com/news-releases/photodynamic-therapy-market-to-grow-by-usd-2-35-billion-2024-2028-driven-by-rising-cancer-prevalence-ai-powered-report-highlights-market-trends---technavio-302305410.html , November 14, 2024
2074	“ <i>Photodynamic Therapy</i> ” Mayo Clinic https://www.mayoclinic.org/tests-procedures/photodynamic-therapy/about/pac-20385027
2075	“ <i>U.S. Actinic Keratosis Treatment Market Size Industry Analysis 2033</i> ” BioSpace, https://www.biospace.com/u-s-actinic-keratosis-treatment-market-size-industry-analysis-2033 , April 25, 2024
2076	“ <i>Why Levulan® Kerastick® + BLU-U®</i> ,” https://www.levulan.com/why-levulan-kerastick
2077	Tim Smith, “ <i>FDA-Approved Red-Light LED Lamp Released for Patients With Actinic Keratosis</i> ,” AJMC, https://www.ajmc.com/view/fda-approved-red-light-led-lamp-released-for-patients-with-actinic-keratosis , June 28, 2024
2078	ROTH MKM, Biofrontera, Inc, “BFRI 3Q24: Hurricane Milton Impacted 3Q Revs, But 4Q Is Already Compensating,” Jonathan Aschoff, Ph.D., November 14, 2024
2079	FDA letter regarding BLU-U Model 4170E, dated May 1, 2025
2080	“ <i>Gas Discharge Tubes – Introduction</i> ”, G3YNH.info, https://www.g3ynh.info/disch_tube/intro.html
2081	[RESERVED]
2082	IPR2024-00874 EX1003 Declaration Eric Bretschneider, Ph.D.
2083	[RESERVED]

EX #	DESCRIPTION
2084	Deposition Transcript of Robert E. Grove, Ph.D., taken May 13, 2025
2085	Dermatology Times, “ <i>FDA Approves Sun Pharma’s New LED BLU-U Device for AK</i> ”, May 16, 2025 https://www.dermatologytimes.com/view/fda-approves-sun-pharma-s-new-led-blu-u-device-for-ak
2086	Declaration of Raymond Habbaz in Support of Motion for Admission <i>Pro Hac Vice</i>
2087	Deposition Transcript of Robert E. Grove, Ph.D., taken September 11, 2025
2088	Dr. Grove’s Deposition Exhibit 2088 (Excerpted Redacted Deposition Transcript of Hermann Luebbert in ITC Inv. No. 337-TA-1411, taken December 13, 2024)
2089	Notice of Initial Determination filed in ITC Investigation No. 337-TA1411, dated September 30, 2025
2090	Public Version of Initial Determination filed in ITC Investigation No. 337-TA1411, dated September 30, 2025

Petitioner relied on the same art, the same experts, and the same grounds when it attempted to invalidate the '028 Patent in the related ITC proceeding. Administrative Law Judge Bryan F. Moore ("ALJ") heard live testimony from both sides' experts, subject to extensive cross-examination. The parties thoroughly briefed near-identical arguments as presented in this instant IPR. Ultimately, the ALJ found that the '028 Patent was not invalid in a detailed Initial Determination ("ID") (EX2090). The ID rejected every argument from Petitioner and credited Patent Owner's ("PO's") expert, Dr. Jokerst's, analysis over Dr. Grove's assertions on every contested issue.¹ The overlapping issues already disposed of in the ID are summarized below.

I. The Combination Does Not Meet "Uniformly Illuminate/Illuminating A Treatment Surface"

All Challenged Claims require "uniformly illuminate/illuminating a treatment surface." ALJ construed that limitation as "irradiating light over the active emitting area such that measured irradiance at a treatment surface of the patient is at least within 60% of the measured maximum," consistent with *both parties'* proposed construction in the ITC. EX2033, 13. The Petition did not propose an explicit construction for this term. Pet., 12-13. Nor did the Petition even attempt to

¹ The ID did not reach the extensive evidence of secondary considerations because "[Biofrontera] ha[s] not made out a prima facie case of obviousness." ID, 124.

demonstrate how this construction is met, despite Petitioner’s expert, Dr. Grove’s, admission that he understood the term to have that same construction. Pet., 39-42, 55, 65, 70, 72; Patent Owner’s Response (“POR”), 19-20; EX2084, 80:20-81:3. Consistent with PO’s arguments, the ALJ found that the combination of Lundahl with Larsen does not meet this limitation:

PO’s Argument	ITC ID
“Petitioner and Dr. Grove <i>have not shown that the combination of Lundahl and Larsen “uniformly illuminates a treatment surface” under the parties’ agreed-to construction.</i> ” POR, 26-29.	“Biofrontera’s ‘uniformity’ analysis is based on <i>the wrong assumption that spacing LEDs according to Lundahl’s fluorescent tube spacing leads to the claimed 60% uniformity. Biofrontera offers only speculation in support because it did no analysis and provided no evidence showing spacing alone is enough.</i> I am not persuaded by Biofrontera’s reliance on a single conclusory statement that it would ‘adapt[] an existing device to achieve the same goal.’” ID, 108.
“[M]odifying Lundahl’s U-shaped tubes <i>to incorporate panels would create gaps between the panels, affecting uniformity.</i> ” POR, 24.	“Biofrontera also ignores the <i>optical dead spaces created by breaking Lundahl’s device into five panels.</i> ... Dr. Luebbert, Biofrontera’s CEO, testified that multiple-panel illuminators had <i>known issues in homogeneity because of ‘gaps between individual connected panels’</i> that are not present in a ‘single curved structure.’ <i>Neither Lundahl nor Larsen teaches how to maintain uniformity when introducing multi-panel gaps.</i> ” ID, 107.

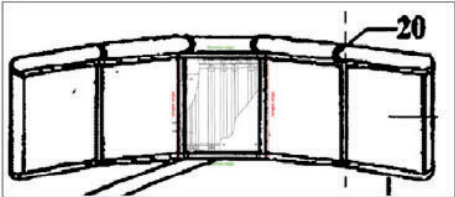
	<p>“Biofrontera acknowledges hinged panels would introduce gaps ... Moreover, <i>introducing gaps would destroy Lundahl’s goal of uniform illumination</i>, undermining any motivation for flexibility....” ID, 120.</p>
<p>“<i>[R]eplacing</i> Lundahl’s diffuse <i>fluorescent tube</i> illuminators <i>with</i> discrete, point-source <i>LEDs would also create gaps</i> between the LEDs, impacting the uniformity.” POR, 24.</p>	<p>“That theory assumes that (1) Lundahl’s vertical spacing of fluorescent tubes is unrelated to fluorescent technology, and (2) LEDs illuminate uniformly with that same spacing. These assumptions are not persuasive, as the different light sources have different optical emission properties. One cannot assume identical illumination given Lundahl’s spacing but different light sources. Fluorescent tubes are continuous, diffuse light sources, whereas LEDs are directional point-source with Lambertian outputs. Thus, <i>switching to LEDs would create gaps</i> and would completely change the light distribution pattern emitted from the illuminator.” ID, 105-106.</p>
<p>“<i>Lundahl emphasizes ‘[a] much higher degree of precision and integration is required for the components of the present invention.</i> ... To achieve this, each functional block within the present invention comprises carefully selected and engineered components’ including (1) the U-shaped tubes, (2) the reflector, (3) the electrical control system, and (4) the cooling system.” Sur-Reply, 7.</p>	<p>“<i>Lundahl warns that his components required a ‘much higher degree of precision and integration’ to control the ‘irradiance uniformity’</i> to ‘assure that the properties of the device are suitable to deliver light to the target lesions and drive the photodynamic reaction.’ ... <i>Lundahl’s Abstract lists several components for improving uniformity</i>; there is no disclosure that the spacing alone achieves ‘the desired uniform illumination,’ as Biofrontera argues.” ID, 105.</p>

<p>“Petitioner provides <i>no basis to support</i> that a POSITA combining Lundahl in view of Larsen would have had a <i>reasonable expectation of success</i> in achieving [uniform illumination].” POR, 31.</p>	<p>“Biofrontera has not shown sufficiently that a skilled artisan would <i>reasonably expect success in achieving the claimed uniformity</i> given those modifications all affect uniformity.” ID, 104-105.</p>
<p>“Dr. Grove argued a ‘<i>POSA would be required to perform undue experimentation to make and use an illuminator that provides ‘uniform illumination.’</i>” POR, 32.</p>	<p>“Biofrontera fails to show a reasonable expectation that its combination of Lundahl and Larsen would meet the uniform illumination limitation as discussed above. ... Its expert previously claimed achieving uniformity would require ‘undue experimentation.’” ID, 122.</p>
<p>“<i>In an attempt to reconstruct the claimed invention using hindsight</i>, Petitioner proposes numerous modifications to the design of Lundahl’s system.” POR, 22.</p>	<p>“<i>First, ‘hindsight reconstruction to pick and choose among isolated disclosures in the prior art’ is improper.</i> ... Biofrontera has not shown sufficiently that a skilled artisan would reasonably expect success in achieving the claimed uniformity given those modifications all affect uniformity.” ID, 104.</p>
<p>“Because Petitioner only addresses Lundahl and Larsen individually with no analysis of the combination, and because that combination will not ‘yield the claimed invention’ with the required uniformity, its argument fails.” Sur-Reply, 6-7.</p>	<p>“Biofrontera admits that the claims require uniform illumination ‘via the light sources’ which are ‘disposed on the surfaces of the five panels.’ ... However, throughout its analysis, Biofrontera relies on separate disclosures from Lundahl (lacking five panels) and Larsen (lacking uniform illumination) for pieces of this limitation and never demonstrates that the combination—Lundahl’s light distribution with Larsen’s five LED panels—teaches the whole ‘uniformly illuminate’ limitation.... Biofrontera’s analysis fails to</p>

	sufficiently show that it is free of improper hindsight.” ID, 103.
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II. The Combination Does Not Meet A “Each Of The Five Panels Has ... A Higher Intensity Of Light Emitted Proximate The Second [Shorter] Edges” As Claimed

All Challenged Claims require “*each* of the five panels has ... two edges shorter than the two first edges, and the light sources are arranged such that a higher intensity of light emitted *proximate the second [i.e., shorter] edges*.” The Petition relies on the combination of Lundahl with Larsen. *See* Pet., 45-49, 55-56, 66-67, 71-73. Consistent with PO’s arguments, the ALJ found that the combination of Lundahl with Larsen does not meet this limitation:

PO’s Argument	ITC ID
“In context, the plain language of the claims requires that the intensity of light emitted proximate the shorter second edges is higher than the intensity of light emitting not proximate the shorter second edges. ... Dr. Grove’s ‘top side’ and ‘bottom side’ are <i>the longer edges—not the shorter second edges required by the claims</i> .” POR, 45.	“It is undisputed that neither Larson [<i>sic</i>] nor Lundahl teaches the full limitation. ... However, the ‘top and bottom edges’ that Biofrontera <i>alleges emit a higher intensity of light, are the longer edges, not the shorter second edges, as required by the claims</i> Applying Lundahl’s light distribution to Larsen’s five panels yields a higher intensity of light on the longer edges of each panel. ... In sum, Biofrontera’s reading of Lundahl requires improper hindsight...” 

	ID, 109-110.
<p>“A POSITA reading Larsen would have understood that in Petitioner’s alleged ‘resulting device’ ..., the scan engine 66 would move the light sources linearly up and down, as shown below: When taken as a time lapse, e.g., from t=0 to t=3, there <i>would be more light sources in the center portion of each panel than near the shorter edges of each panel.</i>” POR, 40-41.</p>	<p>“Additionally, incorporating Larsen’s scan engine in <i>the Lundahl/Larsen combination would lead to higher intensity of light emitted from the center of the panels, not near the second shorter edges as claimed.</i>” ID, 114.</p>
<p>“Petitioner fails to read the <i>claim language as a whole</i>, which requires that ‘<i>each of the five panels</i>’ has ‘<i>a higher intensity of light [] emitted proximate the second edges....</i>’ Petitioner argues the combination of Lundahl and Larsen ‘maintain[s] the same light distribution pattern Lundahl utilized for the fluorescent bulbs’ ..., but <i>ignores Lundahl’s teachings of ‘area[s] of reduced emission’....</i>” POR, 34</p>	<p>“Biofrontera’s hindsight combination fails to meet <i>the whole limitation. Each of the five panels needs higher intensity near the shorter edges.</i> The proposed combination with Lundahl’s light distribution does not have higher intensity for each panel because Lundahl teaches <i>areas of reduced emission. ...</i>” ID, 111-114.</p> <p>“...But Lundahl’s curved center is the only portion with higher intensity at the top and bottom as ‘[o]nly the more uniform center portion of the tube output is used for patient treatment.’ ... Combining Lundahl’s light distribution with Larsen’s five panels yields higher intensity at the shorter edges only in the center of the device, not on each of the five panels.” ID, 111-112.</p>

III. Larsen Does Not Teach Or Suggest “Hinged Structures On Inner Side Surfaces Of Adjacent Panels”

Challenged Claims 1, 2, 4, 5, 6, 20, and 21 require “hinged structures on inner *side surfaces* of adjacent panels.” Petitioner relies solely on Larsen for these limitations.² See Pet., 35-38, 55, 69-71. Consistent with PO’s arguments, the ALJ found that Larsen does not meet this limitation:

PO’s Argument	ITC ID
“Larsen states ‘several applicators 13 are flexibly connected to each other through hinges 10.’ ... As shown in Fig. 1 below, <i>element ‘10’ points to the bottom of the applicator 13</i> , not to the inner side surface of the adjacent panels.” POR, 48-49.	<p>“As an initial matter, in its only disclosure of hinges, Larsen cites Figure 1 and explains that ‘several applicators 13 are flexibly connected to each other through hinges 10.’ ... As shown in Figure 1 below, <i>element ‘10’ points to the bottom of applicator 13</i>, not the inner side surfaces of adjacent panels.” ID, 94.</p> <p>“Larsen’s <i>express disclosure of hinges on the bottom of the applicator</i>, not on the inner side surfaces, is corroborated by the prosecution histories of the Asserted Patents and related applications.” ID, 95.</p>
“Petitioner argues that, despite Larsen’s clear labeling of ‘hinges’ as ‘10,’ the hinges are ‘shown as element 20 in Figure 1.’ <i>However, Larsen identifies ‘20’ as the regular</i>	“Contrary to Biofrontera’s arguments, <i>element 20</i> refers not to the location ‘between the panels.’ Rather, <i>it is the location of the ‘regular row arrangement’ of light sources</i> , which are

² Petitioner purports to rely on the combination of Lundahl and Larsen for claim 21, but only refers back to claim 1, which relied solely on Larsen.

<p><i>row arrangements of light sources</i> in the applicator 13, which are shown below, for example, in <i>Figs. 2b and 2c.</i> POR, 49-50.</p>	<p>‘mounted in’ the applicators 13. <i>While Dr. Jokerst agreed there is no label ‘20’ in Figures 2b-c,</i> a skilled artisan would not expect there to be because Figure 1’s dotted line indicates <i>a more detailed view shown in those figures.</i> ID, 97.</p>
<p>“Petitioner continues to argue that ‘hinges 10’ is a typo and Larsen’s hinges are instead element 20, despite Dr. Grove admitting he understood ‘what 20 means’ only if Larsen is ‘referring to rows of light sources as is shown in, for example, Figure 2a.” Sur-Reply, 2</p>	<p>“I find that there is no persuasive evidence that one of ordinary skill would recognize the label ‘10’ as a typographical error and disregard it and mentally ‘correct’ Larsen by assuming label ‘20’ refers to the location of the hinges as on the inner side surface of the panel.” ID, 99.</p>
<p><i>“Petitioner does not identify a single prior art reference that discloses a ‘hinged structure on inner side surfaces of adjacent panels.’</i> Nor does Petitioner provide any evidence that the claimed hinge was known at the time of the invention or that it would work for its intended purpose in an illuminator to output uniform light for PDT.” POR, 53-54.</p> <p><i>“...a POSITA designing an illuminator to output uniform light for PDT would have been discouraged from placing the hinges on the front of the panels, which would have blocked light from reaching the patient, or between the panels, which can create gaps between the panels, interfere with</i></p>	<p><i>“...Biofrontera fails to identify a single illuminator with hinges on inner side surfaces of panels—the only references of record with that arrangement are the Asserted Patents. Before 2015, persons of ordinary skill designing PDT illuminators to output uniform light were discouraged from placing hinge[s] between the LED panels because that arrangement was thought to negatively impact the illuminator’s uniformity by creating gaps between the panels, interfering with panels’ wiring, and causing panel alignment issues.”</i> ID, 100-101.</p>

<i>the panels’ wiring, and create issues with the use and alignment of the PDT panels—all of those issues would frustrate the goal of providing uniform illumination.”</i> POR, 55-56.	
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IV. Larsen Does Not Teach Or Suggest “The Five Panels Are Individually Configurable”

Challenged Claims 16, 17, and 21 require “the five panels are individually configurable to control illumination from each of the five panels.” The Petition relies solely on Larsen for these limitations.³ Pet., 63-65, 72. The ALJ rejected Petitioners’ argument that each panel in Larsen is individually configurable, because the only control mechanism in Larsen adjusts the entire device, not individual panels:

PO’s Argument	ITC ID
“... Petitioner relies on Larsen’s disclosure that ‘[u]sing the control mechanism, ‘the invented device is adjustable...’ ... However, <i>this passage discloses only that ‘the invented device is adjustable,’ not that each of the five applicators is individually configurable</i> to control illumination from each of the five panels.” POR, 59.	“Biofrontera has no support to show that the output from each panel can be individually controlled. ... Moreover, Larsen states that ‘[w]ith the help of the control mechanism 16, the invented device is adjustable.’ ... <i>The entire device is adjustable, not that each of the five applicators is individually configurable</i> to control

³ Petitioner purports to rely on the combination of Lundahl and Larsen, but never cites to any portion of Lundahl as support.

	illumination from each panel.” ID, 115.
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V. Larsen Does Not Teach Or Suggest “Continuous Illumination Across The Five Panels”

Challenged Claims 16 and 17 require “five panels connected by hinged structures to allow continuous illumination across the five panels.” The Petition relies solely on Larsen for these limitations. Pet., 63-64. The ALJ credited PO’s argument that Petitioner’s expert confirmed Larsen cannot have “continuous illumination across the five panels,” when he argued there is a “lower irradiance region” at the junction of the panels:

PO’s Argument	ITC ID
<i>“Petitioner’s own expert, Dr. Bretschneider, admitted in the first IPR [against the ’028 Patent] that Larsen does not provide continuous illumination across the five panels—he stated there are ‘lower irradiance regions at the junction of two of Larsen’s panels.’ ... A POSITA would understand that with ‘lower irradiance regions at the junction’ of Larsen’s panels, Larsen does not provide continuous illumination across its five panels.”</i> POR, 64.	<i>“Because ‘Larsen doesn’t provide a description of the physical structure of the hinges...,’ Tr. (Grove) at 563:1-23, Larsen cannot teach those hinges ‘allow continuous illumination across the five panels.’ ... Moreover, Biofrontera’s expert confirmed Larsen cannot have ‘continuous illumination’ because it has ‘lower irradiance regions at the junction of two of Larsen’s panels.’”</i> ID, 102-103.

VI. Conclusion

For the reasons set forth herein and in Patent Owner’s Response and Sur-Reply, the Board should find all claims to be patentable.

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

Dated: November 14, 2025

Respectfully submitted,

/Yung-Hoon Ha/

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CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6(e), the undersigned certifies that a complete copy of the foregoing was caused to be served on counsel of record for the Petitioner by filing this document through PTACTS and by sending this document via electronic mail to the following addresses:

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

Dated: November 14, 2025

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Exhibit 2

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

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

v.

SUN PHARMACEUTICAL INDUSTRIES, INC.
Patent Owner

Case IPR2024-01312

U.S. Patent No. 11,697,028

PATENT OWNER'S RESPONSE

Mail Stop Patent Board
Patent Trial and Appeal Board
U.S. Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

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All emphases are added unless otherwise noted.

PATENT OWNER'S EXHIBIT LIST

EX #	DESCRIPTION
2001	Declaration of Dr. Jose Sasian
2002	<i>Curriculum Vitae</i> of Dr. Jose Sasian
2003	Complainant's Initial Statement Regarding The Public Interest filed in ITC Investigation No. 337-TA-1411, dated June 25, 2024
2004	Australian Patent Application Publication No. AU 200143869 published September 6, 2001 to Eric Larsen entitled <i>Device and methods for the stimulation of body cells through electromagnetic radiation</i> ("Larsen Publication")
2005	United States Trademark Serial No. 78214595 Statement of Use and correspondence for BEAUTYLIGHT ("BEAUTYLIGHT")
2006	United States Patent No. 4,832,294 issued May 23, 1989 to John C. Eldem entitled <i>Portable I.V. Stand</i> ("the '294 patent")
2007	Inventor Tom Boyajian LinkedIn profile at https://www.linkedin.com/in/tom-boyajian-404286307/
2008	Inventor Mark Carota LinkedIn profile at https://www.linkedin.com/in/mark-c-366911a/
2009	Inventor Brian Mazejka LinkedIn profile at https://www.linkedin.com/in/brianmazejka/
2010	Lighting-Gallery.net – My lights/completely clear/uncoated Sylvania 28W T5 HE demonstration tube at https://www.lighting-gallery.net/gallery/displayimage.php?album=1601&pos=188&pid=211863
2011	Bourget, C. Michael, <i>An Introduction to Light-emitting Diodes</i> , HortScience, Vol. 43(7), pp. 1944-1946 (December 2008)
2012	United States Patent No. 6,979,101, issued December 27, 2005 to Christian Sauska et al., entitled <i>Fluorescent Lamp Providing Uniform Backlight Illumination for Displays</i> ("the '101 patent")
2013	Ndjiongue, Alain R. et al., <i>Visible Light Communications (VLC) Technology</i> , pp. 1-23 (June 2015)
2014	Technical Domestic Industry Claim Chart for U.S. Patent No. 11,697,028 (Ex. 10C Public Version) filed in ITC Investigation No. 337-TA-1411, dated July 9, 2024
2015	Declaration of Heather J Roberts, MD, FAAD
2016	<i>Curriculum Vitae</i> of Heather J Roberts, MD, FAAD
2017	https://www.levulanhcp.com/

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2018	https://www.levulanhcp.com/how-to-use
2019	https://www.levulanhcp.com/how-it-works
2020	https://www.levulanhcp.com/treatment-landscape
2021	https://www.levulanhcp.com/efficacy
2022	https://www.levulanhcp.com/assets/pdf/levulan-patient-brochure.pdf
2023	https://drheatherroberts.com/procedures-and-treatments/photodynamic-therapy-pdt-for-skin-cancer/
2024	https://www.mydrugrep.com/mobile-campaigns/Levulan V13a 01a/space requirements.html
2025	https://somalaser.com/dr-michael-ehrenreich-md-millburn-dermatologist/
2026	https://somalaser.com/blu-for-acne/
2027	https://somalaser.com/photodynamic-therapy/
2028	https://somalaser.com/photodynamic-therapy-for-actinic-keratoses-and-skin-cancer/
2029	https://somalaser.com/photodynamic-therapy-for-skin-conditions/
2030	https://somalaser.com/skin-conditions/actinic-keratosis/
2031	[RESERVED]
2032	[RESERVED]
2033	<i>In Re Certain Photodynamic Therapy Systems, Components Thereof, And Pharmaceutical Products Used In Combination With The Same</i> Investigation No. 337-TA-1411 (Order No. 18 – Construing Certain Claim Terms, dated March 4, 2025 (Public Version))
2034	<i>In Re Certain Photodynamic Therapy Systems, Components Thereof, And Pharmaceutical Products Used In Combination With The Same</i> Investigation No. 337-TA-1411 (Redacted Expert Report of Dr. Robert E. Grove, Ph.D. on behalf of Respondents, dated January 22, 2025)
2035	United States Patent No. 8,216,289 issued July 10, 2012 to Scott Lundahl, et al., entitled <i>Illuminator for Photodynamic Therapy</i> (“the ’289 patent”)
2036	<i>In Re Certain Photodynamic Therapy Systems, Components Thereof, And Pharmaceutical Products Used In Combination With The Same</i> Investigation No. 337-TA-1411 (Redacted Deposition Transcript of Dr. Robert E. Grove, taken February 26, 2025)
2037	BLU-U® Optical Specification
2038	<i>In Re Certain Photodynamic Therapy Systems, Components Thereof, And Pharmaceutical Products Used In Combination With The Same</i>

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2039	Redacted Deposition Transcript of Mark Baldyga in ITC Inv. No. 337-TA-1411, taken December 19, 2024
2040	Ex. 6 to Baldyga Deposition Transcript in ITC Inv. No. 337-TA-1411 (Marketing Presentation Slides)
2041	Ex. 5 to Baldyga Deposition Transcript in ITC Inv. No. 337-TA-1411 (Ameluz Marketing Materials)
2042	Ex. 4 to Baldyga Deposition Transcript in ITC Inv. No. 337-TA-1411 (RhodoLED® XL Trifold)
2043	RhodoLED® XL User Manual, Version 1.7SW G2
2044	"Biofrontera AG receives FDA-approval of the BF-RhodoLED® XL lamp," GlobalNewswire, https://www.globenewswire.com/news-release/2021/10/22/2319235/0/en/Biofrontera-AG-receives-FDA-approval-of-the-BF-RhodoLED-XL-lamp.html , dated October 22, 2021
2045	"Biofrontera Announces the Launch of a New, FDA-Approved Red Light Source, the RhodoLED® XL Lamp," BioSpace, https://www.biospace.com/biofrontera-announces-the-launch-of-a-new-fda-approved-red-light-source-the-rhodoled-xl-lamp , dated June 24, 2024
2046	"Biofrontera Inc. Announces 100 RhodoLED®XL Machines Now Placed in US Market," GlobalNewswire, https://www.globenewswire.com/news-release/2024/12/23/3001296/0/en/Biofrontera-Inc-Announces-100-RhodoLED-XL-Machines-Now-Placed-in-US-Market.html , dated December 23, 2024
2047	"Biofrontera Inc. Reports Record Fiscal Year 2024 Financial Results and Provides a Business Update," Biofrontera, Inc., dated March 21, 2025
2048	Declaration of Thomas Vander Veen
2049	Supplemental Declaration of Heather J Roberts, MD, FAAD
2050	Declaration of Dr. Nan Jokerst
2051	Curriculum Vitae of Dr. Nan Jokerst
2052	Excerpted Deposition Transcript of Mark Carota in ITC Inv. No. 337-TA-1411, taken December 5, 2024
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2054	<i>“FDA Approves RhodoLED XL Lamp Red Light Source for Use in Actinic Keratosis Treatment,”</i> Dermatology Times, dated July 2, 2024 https://www.dermatologytimes.com/view/icymi-fda-approves-rhodoled-xl-lamp-red-light-source-for-use-in-actinic-keratosis-treatment
2055	Biofrontera Form 10-K, dated March 20, 2025
2056	BF-RhodoLED®, https://us.ameluz.com/hcp/activate-with-rhodoled-lamp/
2057	Biofrontera Q4 2024 Earnings Call Transcript
2058	<i>“Biofrontera Inc. Announces FDA Orange Book Listing of U.S. Patent for BF-RhodoLED® XL, Extends Protection of Ameuluz® PDT Through October 2040,”</i> BioSpace, dated March 14, 2022
2059	U.S. Pat. No.11,235,169 issued February 1, 2022 to Markus Osterloh, et al., entitled <i>Illumination Device for Photodynamic Therapy, Method for Treating a Skin Disease and Method for Operating an Illumination Device</i> (“the ’169 patent”)
2060	AMELUZ Prescribing Information, December 2021
2061	File History of U.S. Patent No. 11,446,512
2062	<i>“Actinic Keratosis,”</i> Cleveland Clinic, https://my.clevelandclinic.org/health/diseases/14148-actinickeratosis
2063	<i>“Actinic Keratosis: Diagnosis and Treatment”</i> American Academy of Dermatology Association, https://www.aad.org/public/diseases/skin-cancer/actinic-keratosistreatment
2064	<i>“Biofrontera Announces U.S. FDA Approval of Ameluz® and Activating BF-RhodoLED® Device for Treatment of Actinic Keratosis”</i> Biofrontera News Release, https://www.biofrontera.com/fileadmin/files/PDFs/Corporate_news/2016/EN/20160511 , May 11, 2016
2065	<i>“Biofrontera Bioscience GmbH,”</i> www.medicines.ie
2066	<i>“Biofrontera Inc. (BFRI) Q2 2024 Earnings Call Transcript”</i> https://seekingalpha.com/article/4714932-biofrontera-inc-bfri-q2-2024-earnings-call-transcript , August 15, 2024
2067	<i>“Biofrontera Inc. (BFRI) Q4 2023 Earnings Call Transcript”</i> https://finance.yahoo.com/news/biofrontera-inc-nasdaq-bfri-q4-132209594.html , March 18, 2024
2068	<i>“Biofrontera Inc. Reports First Quarter 2024 Financial Results and Provides a Business Update”</i> https://www.biospace.com/biofrontera-inc-

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2070	Biofrontera Inc., Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 for the Fiscal Year Ended December 31, 2023 (Form 10-K)
2071	“Biofrontera Pharma GmbH,” https://www.medicines.org.uk/emc/product/3158/smpc
2072	<i>“Photodynamic Therapy Market Size, Share, and Trends 2025 to 2034”</i> Precedence Research, https://www.precedenceresearch.com/photodynamic-therapy-market
2073	<i>“Photodynamic Therapy Market to Grow by USD 2.35 Billion (2024-2028), Driven by Rising Cancer Prevalence, AI-Powered Report Highlights Market Trends – Technavio”</i> PR Newswire, https://www.prnewswire.com/news-releases/photodynamic-therapy-market-to-grow-by-usd-2-35-billion-2024-2028-driven-by-rising-cancer-prevalence-ai-powered-report-highlights-market-trends---technavio-302305410.html , November 14, 2024
2074	<i>“Photodynamic Therapy”</i> Mayo Clinic https://www.mayoclinic.org/tests-procedures/photodynamic-therapy/about/pac-20385027
2075	<i>“U.S. Actinic Keratosis Treatment Market Size Industry Analysis 2033”</i> BioSpace, https://www.biospace.com/u-s-actinic-keratosis-treatment-market-size-industry-analysis-2033 , April 25, 2024
2076	<i>“Why Levulan® Kerastick® + BLU-U®,”</i> https://www.levulan.com/why-levulan-kerastick
2077	Tim Smith, <i>“FDA-Approved Red-Light LED Lamp Released for Patients With Actinic Keratosis,”</i> AJMC, https://www.ajmc.com/view/fda-approved-red-light-led-lamp-released-for-patients-with-actinic-keratosis , June 28, 2024
2078	ROTH MKM, Biofrontera, Inc, “BFRI 3Q24: Hurricane Milton Impacted 3Q Revs, But 4Q Is Already Compensating,” Jonathan Aschoff, Ph.D., November 14, 2024
2079	FDA letter regarding BLU-U Model 4170E, dated May 1, 2025

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2080	“ <i>Gas Discharge Tubes – Introduction</i> ”, G3YNH.info, https://www.g3ynh.info/disch_tube/intro.html
2081	[RESERVED]
2082	IPR2024-00874 EX1003 Declaration Eric Bretschneider, Ph.D.
2083	[RESERVED]
2084	Deposition Transcript of Robert E. Grove, Ph.D., taken May 13, 2025
2085	Dermatology Times, “ <i>FDA Approves Sun Pharma’s New LED BLU-U Device for AK</i> ”, May 16, 2025 https://www.dermatologytimes.com/view/fda-approves-sun-pharma-s-new-led-blu-u-device-for-ak

I. Introduction

U.S. Patent No. 11,697,028 (the “’028 Patent”) covers significant advances in the field of photodynamic therapy (PDT). Prior to the ’028 Patent, conventional PDT devices left “optical dead space[s]” near the edges of the device panels, which “reduce[d] the uniformity of the light along the treatment area, thereby reducing the effectiveness of PDT.” EX1001, 2:41-44, 2:52-56. Sun Pharma developed a five-panel PDT device that provides uniform illumination during PDT treatment without optical dead spaces. *Id.*; EX1001, 2:52-3:21. In particular, the PDT device of the ’028 Patent uses hinges on “the inner side surfaces of adjacent panels,” which “reduc[e] the area in which no light source is present on the illuminator.” EX1001, 3:11-21, 4:65-5:1, FIG. 3A. The light sources are arranged on the panels such that those close to the shorter edges of the panels emit a higher intensity of light than those close to the longer edges of the panels. EX1001, 6:18-40, FIG. 5. Sun Pharma’s novel configuration produces “light output uniformity” that is “greatly enhanced across the patient’s face and exhibits little to no deviation from the light output measured in the center of the patient’s face to the light output measured at the edges of the patient’s face.” EX1001, 8:44-64, FIG. 8. Sun Pharma’s BLU-U® and Levulan® are the “#1-prescribed photodynamic therapy.” EX2017-EX2022. The BLU-U® 4170E, which embodies the ’028 Patent, has been hailed by the industry as “a step forward in photodynamic therapy.” EX2085, 3.

Petitioner cannot prevail on any of its grounds. For Ground 1 that relies on Lundahl in view of Larsen, Petitioner (1) fails to show the combination renders obvious the “uniformly illuminates a treatment surface” limitations under the parties’ agreed-to claim construction of “irradiating light over the active emitting area such that the measured irradiance at a treatment surface of the patient is at least within 60% of the measured maximum,” and fails to show a POSITA would have had a reasonable expectation of success in combining the references to meet those limitations; (2) fails to show the combination renders obvious “each” of the five panels have “a higher intensity of light [] emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges”; (3) fails to show Larsen discloses or renders obvious the “hinges” limitation; (4) fails to show Larsen teaches or suggests the “individually configurable” limitation; and (5) fails to show Larsen teaches or suggests the “continuous illumination” limitation.

For Ground 2 that relies on Lundahl, Larsen, and Bansal, Petitioner cannot prevail for all the same reasons set forth for Ground 1. Additionally, Petitioner has not shown Lundahl in view of Larsen and further in view of Bansal renders obvious the “uniformly illuminates” and “higher intensity” limitations. In particular, the Board has already determined “Petitioner has not sufficiently shown for institution that Bansal teaches or suggests arranging light sources ‘such that a higher intensity of light is emitted proximate the second edges compared to the intensity of light

emitted not proximate the second edges.” IPR2024-00874, Paper 9, 12-13, 17-18; Institution Decision, 22 (citing decision denying institution in IPR2024-00874). Here, Petitioner makes the same arguments regarding Bansal, and the Board should find Ground 2 deficient for the same reasons: the claims distinguish between first edges and second edges of the panels. But, as Petitioner and its experts have admitted, “Bansal’s solution provides higher intensity (or density) of lights around all edges of the panel.” Bansal does not disclose this limitation because it requires a higher intensity of light emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges, which includes at least the first edges. Petitioner’s failure to meet its burden with respect to this limitation, which is present in all the independent claims, is alone sufficient for the Board to find Petitioner has not met its burden with respect to Ground 2.

Additionally, secondary considerations strongly support non-obviousness for both Grounds: the commercial success of Petitioner’s RhodoLED® XL device is a result of the combined features of the patented inventions and the benefits enabled by those features, which have received industry praise. Petitioner’s subsequent recognition and adoption of Sun Pharma’s inventions must be considered as a check against the hindsight-driven reasoning Petitioner applies in its flawed obviousness analyses.

Accordingly, Petitioner cannot prevail on Ground 1 or 2, and claims 1, 2, 4-6, 16, 17, and 19-21 (“Challenged Claims”) are patentable.

II. Background

A. Overview Of The '028 Patent

The '028 Patent relates to an “adjustable illuminator that provides a uniform distribution of visible light” and “is suitable for use in photodynamic therapy [PDT] and diagnosis.” EX1001, 1:19-22.

The '028 Patent addressed the problem of “optical dead space that can occur at or near the hinges of conventional adjustable illuminators,” which “reduces the uniformity of the light along the treatment area, thereby reducing the effectiveness of PDT.” EX1001, 2:41-44. The illuminator panels of an embodiment of the present invention are “coupled together using nested hinges, thereby reducing the area in which no light source is present on the illuminator” and “the light sources on each of the panels are individually configurable to provide specific power output to certain areas of the light sources on the panels to compensate for decreased uniformity.” EX1001, 3:11-21.

As shown below in FIG. 2B, the illuminator “preferably has five individual panels 10a-10e, each of which are connected in a rotatable manner via nested hinges 50.” EX1001, 3:52-56. Each of the five panels contains an array of light emitting

diodes (LED) 60, which preferably “extend[] as far to the edges as possible.”

EX1001, 3:56-64.

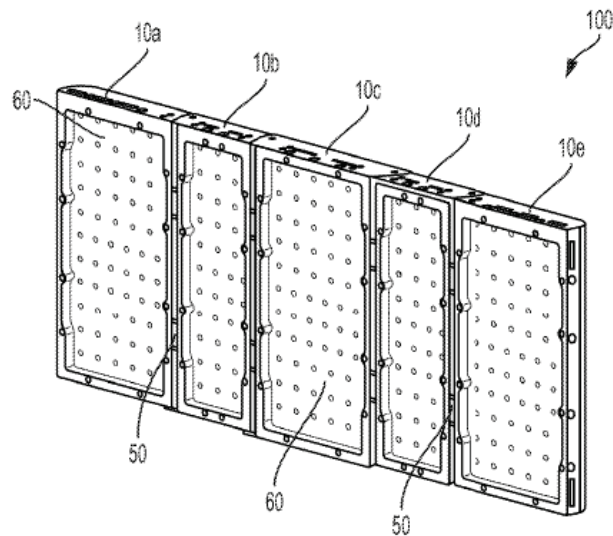


FIG. 2B

EX1001, Fig. 2B. The “nested hinges 50” (shown in blue) are “mounted to the inner side surfaces of adjacent panels (e.g., 10a, 10b),” as shown in FIG. 3A below.

EX1001, 4:65-5:1.

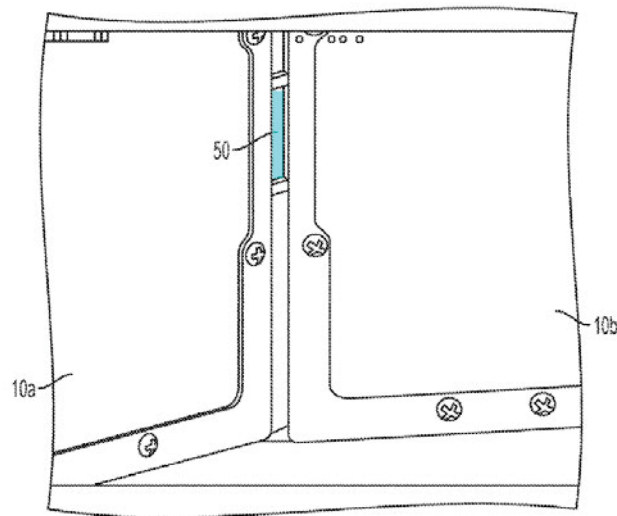


FIG. 3A

EX1001, Fig. 3A.

As shown in FIG. 5, the LED arrays “are divided into three general areas.”
EX1001, 6:24-31. A higher current is supplied to areas 1 and 2 (shown in red) than
areas 3 and 4 (shown in yellow) “such that areas 1 and 2 emit a higher intensity of
light than areas 3 and 4.” EX1001, 6:32-40.

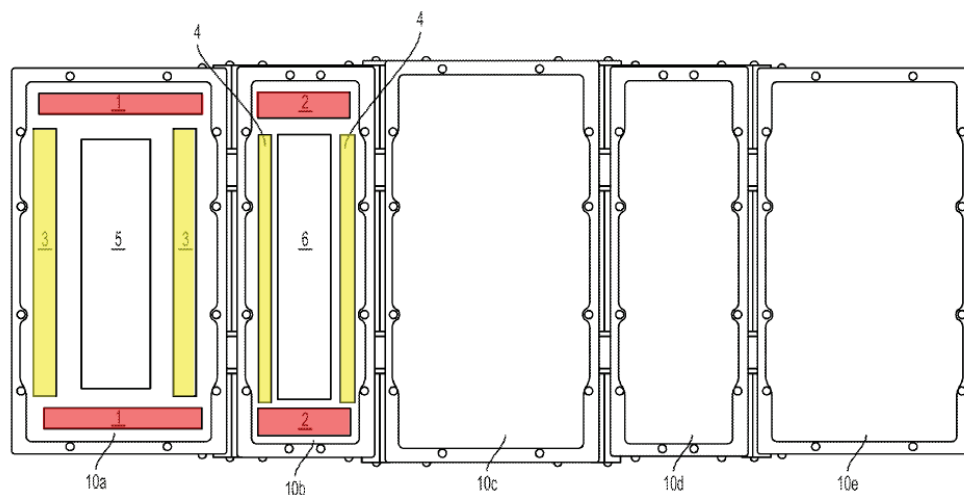


FIG. 5

EX1001, FIG. 5.

As shown in FIG. 4, the illuminator’s main body 100 with the five LED panels
is “mounted to a movable stand 80,” which includes a base 81 and vertical pillar 82.
EX1001, 5:15-21. Each of the five LED panels “may have a dedicated control unit
to regulate power to the individual LED array on a given panel.” EX1001, 5:57-62.

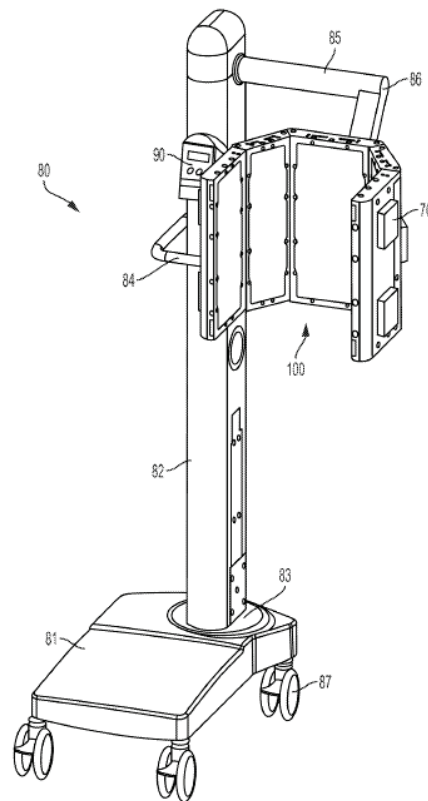


FIG. 4

EX1001, FIG. 4. The '028 Patent discloses that the “light output uniformity” produced by an embodiment of the illuminator of the present invention is “greatly enhanced across the patient’s face and exhibits little to no deviation from the light output measured in the center of the patient’s face to the light output measured at the edges of the patient’s face” over an operating “distance of two and four inches.” EX1001, 8:43-67 (comparing light uniformity produced by a conventional illuminator in FIG. 7 to the light uniformity produced by an embodiment of the present invention in FIG. 8), FIG. 8. EX2050, ¶¶49-71.

B. Overview Of The '028 File History

The application that issued as the '028 Patent was filed on September 12, 2022 and claimed priority to a provisional application filed on October 15, 2015. EX1001, 1:8-15.

In an Office Action dated November 18, 2022, the Examiner rejected pending claims 18 and 20-22 as unpatentable over the Larsen '381 patent (EX1008) in view of Fan (U.S. 2006/0253175). EX1002, 328-330. The Examiner stated claims 3, 6, 9, and 19 would be allowable if rewritten in independent form. EX1002, 333.

In response, on February 16, 2023, Applicant amended pending claim 18 to recite the subject matter of claim 19: “each of the five panels having two first edges and two second edges shorter than the two first edges, the light sources arranged such that a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges.” EX1002, 203-204, 207.

Following the amendment, the Examiner issued a Notice of Allowance on March 1, 2023. EX1002, 114. The Examiner stated in the reasons for allowance that “the art of record neither anticipates nor renders 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' in combination with the rest of the claimed limitations set forth in the independent claim.” EX1002, 120. EX2050, ¶¶72-79.

III. Overview Of The References

A. Lundahl (EX1014)

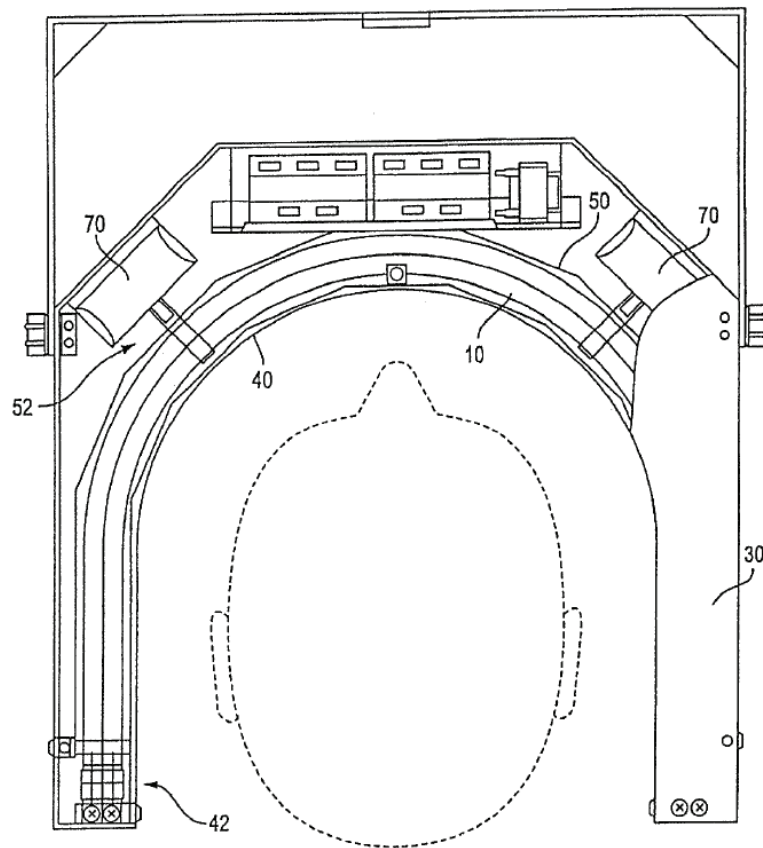
Lundahl discloses “an improved illuminator for PDT and/or PD.” EX1014, 2:33-38. Lundahl teaches its “invention differs from conventional light sources because of the biological requirements imposed on a PDT light source” and “[a] much higher degree of precision and *integration is required for the components of the present invention.*” EX1014, 4:12-16. Lundahl stresses uniformity “must be controlled to assure that the properties of the device are suitable to deliver light to the target lesions and drive the photodynamic reaction.” EX1014, 4:16-19. To achieve this uniformity, Lundahl teaches “each functional block within the present invention comprises carefully selected and engineered components.” EX1014, 4:19-21. These include:

- **U-shaped tubes**: to “ameliorate” the problem of “flat emitting surface[s that] would not deliver a uniform light dose” the “invention uses a U-shaped emitting surface,” which “*provides the desired...uniformity*” and “ensures that the proper visible light dosage is applied to all target areas during PDT.” EX1014, 4:27-38, 6:31-42, Abstract, 2:62-67, 3:62-67, claim 1, FIG. 1, FIG. 4A.

- **reflector**: “to *increase the uniformity* of the output distribution” the invention uses “reflector 50...which is bent to approximately conform to the configuration of the tubes.” EX1014, 8:62-67, 5:30-32, Abstract, FIG. 5B.
- **electrical system**: “[T]he U-shaped tubes” “are driven by electronic ballasts” and “[a]djustment of the ballast voltage controls the output power of the tubes.” EX1014, Abstract, claim 26, 7:10-35, 8:10-59, FIGS. 3, 7, 8, 9A. The ballasts “correct[] output of said light from said plurality of light sources so as to *maintain said substantially uniform intensity*.” *Id.*
- **cooling system**: “modulation of the temperature distribution may be used to *control irradiance uniformity*.” EX1014, 4:39-44, Abstract, 2:46-48, 3:22-28, 9:13-53, claim 34, FIGS. 1, 3.

FIG. 1 shows “a partial cross-section, front elevation view of an illuminator according to the present invention.” EX1014, 4:60-61.

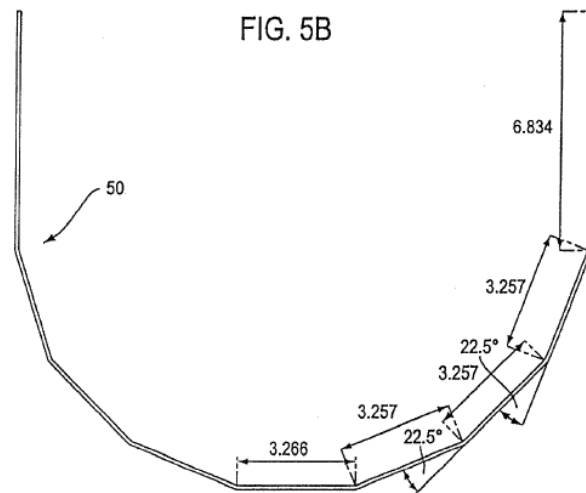
FIG. 1



EX1014, FIG. 1. Lundahl discloses an illuminator with a “*U-shape*” that “*provides the desired irradiance and irradiance uniformity* for scalp and facial irradiation, and thus ensures that the proper visible light dosage is applied to all target areas during PDT.” EX1014, 6:31-42, 4:33-38. Lundahl also discloses the invention is “directed to...other areas of the patient (e.g., arms, legs, etc.).” EX1014, 1:14-17; *see also* EX2015.

As shown in Fig. 5B, *reflector 50* located behind the fluorescent tubes is “bent to approximately conform to the configuration of the tubes” and “*increases both the*

output irradiance and the uniformity of the output distribution.” EX1014, 5:30-32, 8:65-67.



EX1014, FIG. 5B.

As shown in FIG. 4A, the fluorescent tubes “have a generally arcuate *central region* 10A and arms 10B extending from respective ends of the central region,” which “*produces higher output irradiances than the rest of the tube.*” EX1014, 5:43-46, 9:43-54. Lundahl discloses the tubes have “*area[s] of reduced emission*” and “[t]he output measured in the immediate vicinity of the cathode is typically much lower than the output over the rest of the tube.” EX1014, 6:10-16.

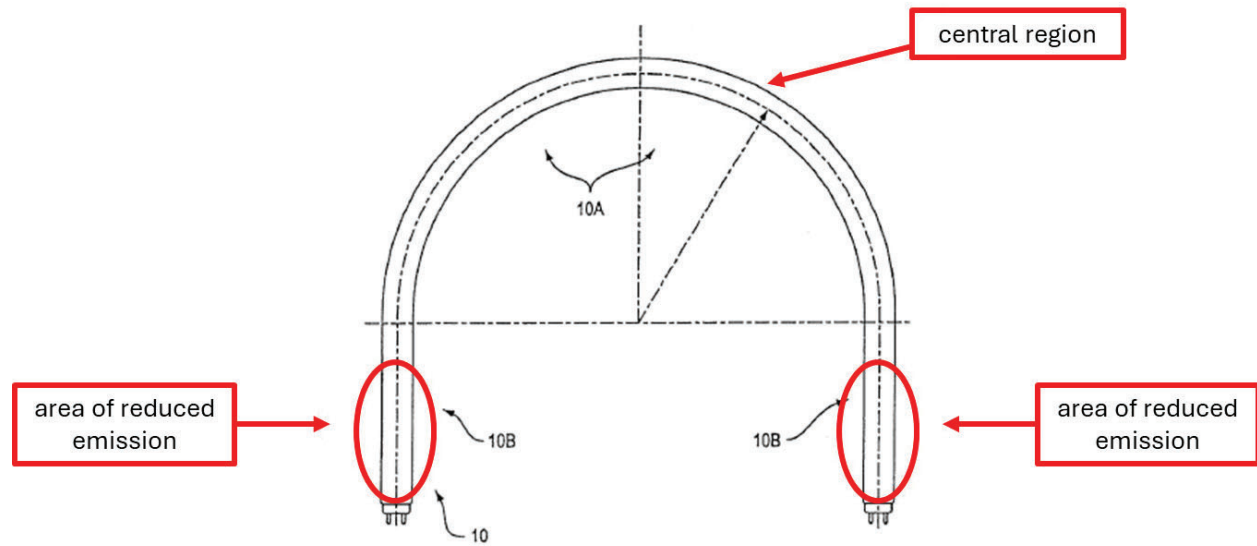


FIG. 4A

EX1014, FIG. 4A.

Lundahl also discloses “[t]o avoid uniformity problems, one embodiment of the present invention utilizes a plurality of U-shaped tubes 10(1)-10(7). This arrangement allows the cathodes and their *low output area to be located outside the active emitting area (effectively behind the patient’s ears). Only the more uniform center portion of the tube output is used for patient treatment.*” EX1014, 6:16-22.

Lundahl further discloses “[c]ontrol of the voltage and/or tube current characteristics, as well as heating of the cathodes is accomplished with external electronic circuitry which is usually engineered and packaged into a single device commonly referred to as a ‘ballast’.” EX1014, 7:28-32, 8:46–54, 11:6–18, FIGS. 7, 8, and 9A. Lundahl’s *electronic circuitry “correct[s] output of said light from said*

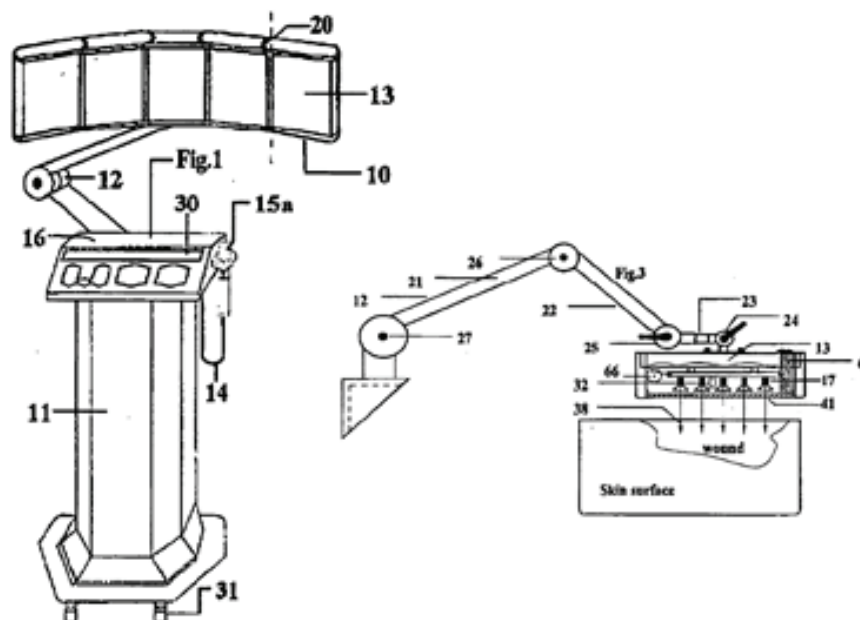
plurality of light sources so as to maintain said substantially uniform intensity.”

EX1014, claim 26. EX2050, ¶¶83-98.

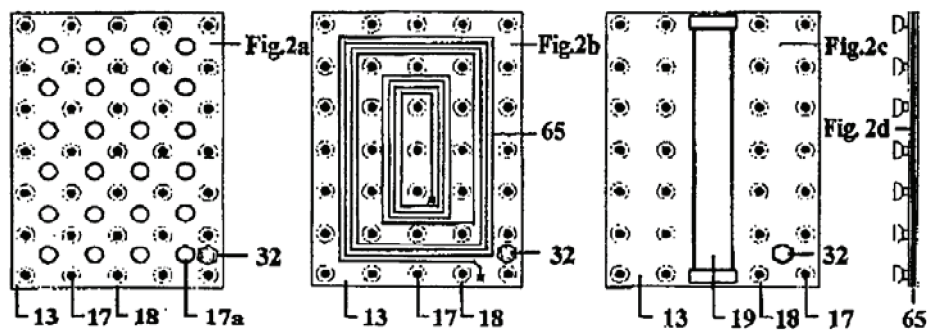
B. Larsen (EX1004)

Larsen discloses a device for photodynamic therapy (PDT) with “changeable applicators using a light and/or laser radiation of several wavelength ranges suited for the photodynamic stimulation of the cell energy in living cells.” EX1004, Abstract, [0026].

Figure 1 illustrates the device, “consist[ing] of a stand 11, with which machine applicators 13...are connected through a jointed arm 12.” EX1004, [0069], [0040]. The “*applicators 13 are flexibly connected to each other through hinges 10, respectively connecting one edge with the other.*” EX1004, [0072], [0027].



EX1004, FIGS. 1, 3. “In each applicator the printed circuit board carrying the light sources is connected to a small electrical *scan engine 66, which can move the light sources with linear movements.*” EX1004, [0072], FIG. 3. The applicators 13 have printed circuit boards with *light sources 17 “placed in regular row arrangements, i.e., 20 equidistant from each other, whereby, according to FIG. 2c, one applicator 13, in addition to the diodes 17, has a light source 19.”* EX1004, [0071].



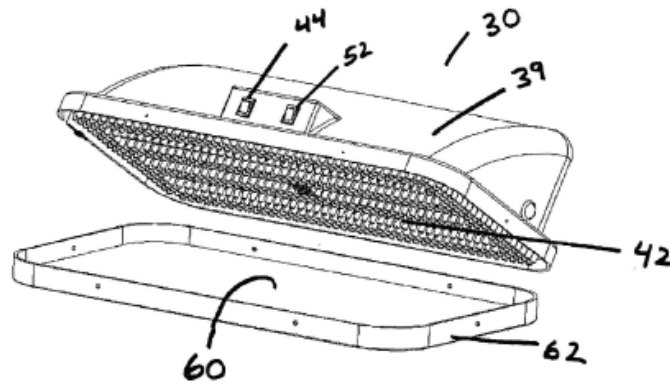
EX1004, FIGS. 2a, 2b, 2c, and 2d.

As shown in FIGS. 2a, 2b, and 2c, the applicators 13 “are equipped with sensors 32 arranged between the semiconductor and/or laser diodes 17.” EX1004, [0079]. Larsen discloses “[w]ith the help of the control mechanism 16, *the invented device is adjustable* within a relatively large range with reference to duration, amplitude and frequency of surge of current, so that the semiconductor diodes 17, 17a and 18, as well as laser 17 diodes with the same realisation as semiconductor diode 17, can be used as light sources.” EX1004, [0074]. EX2050, ¶¶99-108.

C. Bansal (EX1005)

Bansal discloses a “phototherapy system including a non-uniform array of light sources.” EX1005, [0010]. Shown below in Figure 2, Bansal’s device has an enclosure 30 that supports the LED board 42. EX1005, [0023], [0012].

Fig. 2

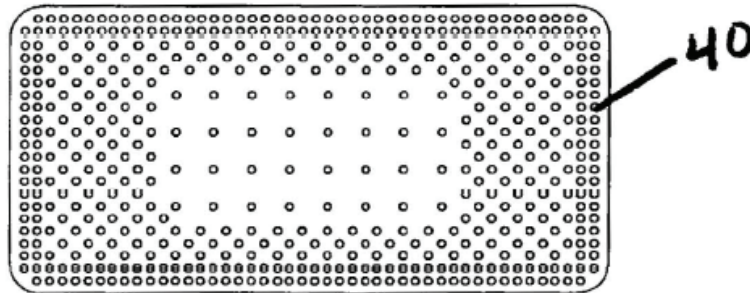


EX1005, FIG. 2. Bansal also has “a light diffusing panel 60 placed between the array 40 and a subject.” EX1005, [0021].

Bansal discloses the array of light sources “can take a number of different non-uniform forms to achieve the goal of even exposure on the subject’s skin.” EX1005, [0025]. In one embodiment, “the density of light source distribution would vary throughout the array, such as with higher density in the periphery and a lower density in the center. In yet another version of the invention, 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....Some exemplary light source configurations are provided in FIGS. 9a-9d.” *Id.* Fig. 9b of Bansal is shown below.

Fig. 9b



EX1005, FIG. 9b.

Bansal further discloses PDT devices with light sources arranged in “uniform arrays” that are “suspended 12 inches above a subject” can “produce sufficient intensity...to be a clinically useful phototherapy device.” EX1005, [0007]. EX2050, ¶¶109-113.

IV. The Level Of Ordinary Skill In The Art

The Board should apply the same definition of a POSITA adopted in the Institution Decision, 8-10. Regardless, the Petition is deficient under either party’s definition. EX2050, ¶¶30-36.

V. Claim Construction

Claim terms in IPRs are construed according to their “ordinary and customary meaning” to those of skill in the art. 37 C.F.R. § 42.100(b); *see also Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-1313 (Fed. Cir. 2005) (*en banc*). In the parallel ITC

investigation, the ALJ issued a claim construction order adopting the parties' agreed-to construction of the "uniformly illuminate" limitations:

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

EX2033, 13. In addition, the ALJ construed the following claim terms, which were based on Patent Owner's constructions:

Claim Term	Construction
"a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges"	"a higher intensity of light is emitted close to the second shorter edges compared to the intensity of light emitted not close to the second shorter edges"
"the five panels are individually configurable to control illumination from each of the five panels"	"the power output and/or light intensity of each panel can be individually controlled"

EX2033, 14-23, 35-40. Because these constructions are supported by the claims and specification, and because *Petitioner* "[f]or purposes of this IPR" took a "*view of the scope of the claims consistent with Patent Owner's infringement allegations,*"

the Board should apply these same constructions. EX2033, 13-23, 35-40; Petition, 12; EX2050, ¶¶80-82.

VI. Ground 1: The Challenged Claims Are Patentable Over Lundahl And Larsen

A. Lundahl In View Of Larsen Does Not Render Obvious The “Uniformly Illuminate” Limitations (All Claims)

Petitioner argues “Lundahl and Larsen teaches” “uniformly illuminate a treatment surface” and “uniformly illuminating a treatment surface.” Petition, 39-42, 55, 65, 70, 72; EX1015, ¶¶160-165, 200, 234, 250. However, Petitioner fails to meet its burden of showing obviousness because the Petition only addresses the teachings of the references separately. Petitioner does not show that Lundahl and Larsen, as *combined together*, render obvious “uniformly illuminate a treatment surface” and “uniformly illuminating a treatment surface.” See *Unigene Labs., Inc. v. Apotex, Inc.*, 655 F.3d 1352, 1360 (Fed. Cir. 2011) (“Obviousness requires more than a mere showing that the prior art includes separate references covering each separate limitation in a claim....”). EX2050, ¶¶116-117.

As explained (Section V), the ALJ in the related ITC proceeding adopted the parties’ agreed-to construction of “uniformly illuminate a treatment surface” and “uniformly illuminating a treatment surface,” construing these limitations as “irradiating light over the active emitting area such that the measured irradiance at a treatment surface of the patient is at least within 60% of the measured maximum.”

EX2033, 13. Petitioner’s expert agreed this is the construction he is applying in this proceeding. EX2084, 80:20-81:3. Petitioner fails to show the *combination* of Lundahl in view Larsen renders obvious the “uniformly illuminate” limitations for each of the reasons set forth below. EX2050, ¶118.

1. Petitioner’s reliance on Lundahl’s disclosure does not show the combination is obvious

Petitioner argues Lundahl discloses the “uniformly illuminate” limitations because Lundahl’s “invention is directed to photodynamic therapy using an illuminator that provides a uniform distribution of visible light” and “highly uniform output irradiance.” Petition, 39-41 (citing EX1014, 1:9-11, 6:16-57; EX1015, ¶¶160-162). However, Petitioner’s reliance on Lundahl’s *separate* references to “highly uniform output irradiance” does not inform the POSITA what the *measured output* would be for the *combination* of Lundahl and Larsen. *Unigene*, 655 F.3d at 1360; EX2050, ¶119.

Petitioner presents no supporting evidence or analysis to show that the alleged *combination* of Lundahl and Larsen would “irradiat[e] light over the active emitting area such that the measured irradiance at a treatment surface of the patient is at least within 60% of the measured maximum.” Petitioner’s assertion that Lundahl and Larsen teach the limitations is based on Dr. Grove’s declaration (EX1015, ¶¶160-165), *which contains neither supporting evidence nor analysis by comparison to a*

maximum “over the active emitting area” for the proposed combination. Petition, 39-42. Dr. Grove addresses only the *individual* teachings of Lundahl (EX1015, ¶¶160-162) and Larsen (EX1015, ¶¶163-164). For the proposed *combination*, Dr. Grove provides no comparison of outputs to the maximum output at the alleged operation distances of “2-4” of the entire treatment surface.” EX1015, ¶125 (“ensure the light panels could be maintained at a distance of 2-4” of the entire treatment surface”), ¶126 (“POSITA would have been motivated to change the design of the system of Lundahl to...ensure a 2-4” distance”). EX2050, ¶120. Dr. Grove does not identify what the measured maximum is for the *combination* of Lundahl and Larsen, nor does he explain how a POSITA would have achieved the same measured results as Lundahl after combining Lundahl with Larsen. *Id.* Petitioner fails to meet its burden of showing obviousness because Petitioner does not explain how the *combination* of prior art references is mapped to the claim limitations under the agreed-to construction or articulate its reasoning for why the subject matter of the claim would have been obvious. *Id.*; *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007) (“Rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, *there must be some articulated reasoning with some rational underpinning* to support the legal conclusion of obviousness.”).

Additionally, Petitioner ignores Lundahl’s teachings that multiple “*carefully selected and engineered components*” *together affect irradiance uniformity*,

including (1) the U-shaped tubes, (2) the reflector, (3) the electrical control system, and (4) the cooling system. EX1014, 4:12-22, 4:39-44, Abstract, 2:46-48, 3:22-28, 7:10-8:59, 9:13-53, claims 26, 34, FIGS. 1-11; EX2050, ¶¶121-123. For example, Lundahl teaches (1) “the ‘U’ shape *provides the desired irradiance and irradiance uniformity*” (EX1014, 6:39-42); (2) the reflector “*increases* both the output irradiance and the *uniformity of the output distribution*” (EX1014, Abstract); (3) the electrical system corrects the output of light from the light sources “so as to *maintain said substantially uniform intensity*” (EX1014, claim 26); and (4) the cooling system “modulat[es]” “temperature distribution...to *control irradiance uniformity*” (EX1014, 4:39-44). Lundahl teaches a “*much higher degree of precision and integration*” is required for these components to *achieve “irradiance uniformity*” and “to assure that the properties of the device are suitable to deliver light to the target lesions and drive the photodynamic reaction.” EX1014, 4:12-22; *see also* EX1015, ¶47 (Dr. Grove acknowledging “[t]he design of the light source plays an important role in achieving an irradiance that is as uniform as possible”). EX2050, ¶¶121-124.

In an attempt to reconstruct the claimed invention using hindsight, Petitioner proposes numerous *modifications* to the design of Lundahl’s system. Petition, 30 (“...POSITA would have been motivated to change the design of the system of Lundahl...” (“...the easiest way to modify the fixed, curved U-shape of Lundahl

would be to incorporate hinged panels...”), 31 (“POSITA was also motivated to modify Lundahl to incorporate LEDs...”); EX1015, ¶¶178, 126, 129 (“a motivation existed to combine the teachings of Lundahl and Larsen to: (1) incorporate the hinged panels of Larsen *into the PDT device* of Lundahl to increase the adaptability of the device; and (2) replace the *fluorescent bulbs* of Lundahl *with LEDs*”); EX2034, ¶268 (“...*the electrical needs and design of Lundahl’s system* for operating fluorescent tubes would need to be changed to accommodate the electrical needs and design of Larsen’s LED panels...”). EX2050, ¶125. However, Petitioner does not present any supporting evidence or analysis to show that the device resulting from the combined teaching and numerous modifications would “irradiat[e] light over the active emitting area such that the measured irradiance at a treatment surface of the patient is at least within 60% of the measured maximum.” Petitioner does not identify what the measured maximum is for the alleged combination, nor does Petitioner explain how a POSITA would have achieved the same measured results as Lundahl after changing the U-shaped fluorescent tubes, changing the reflector, changing the electrical system, and changing the cooling system. *Id.* The extent of the modifications proposed by Petitioner and whether there would be a reasonable expectation of success that the combination would “irradiat[e] light over the active emitting area such that the measured irradiance at a treatment surface of the patient is at least within 60% of the measured maximum”

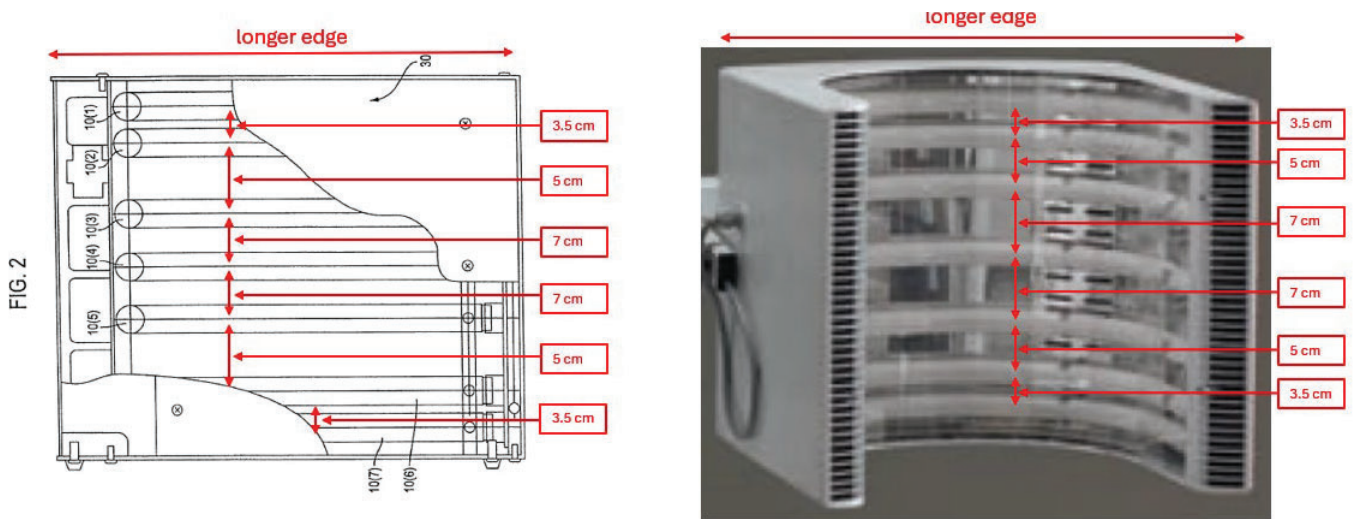
are not adequately supported. By failing to address numerous modifications that impact uniformity and failing to show a reasonable expectation of success, Petitioner has not shown the **combination** of Lundahl in view Larsen renders obvious the “uniformly illuminate” limitations. EX2050, ¶¶124-125.

First, Petitioner argues a “POSITA would have been motivated to **change the design of the system of Lundahl**” and “the easiest way to **modify the fixed, curved U-shape of Lundahl** would be to incorporate hinged panels.” Petition, 30; EX1015, ¶126. However, modifying Lundahl’s U-shaped tubes to incorporate panels would create gaps between the panels, affecting uniformity. EX2050, ¶¶126-128; EX2082, ¶151 (Petitioner’s expert, Dr. Bretschneider, acknowledging “lower irradiance regions at the junction of two of Larsen’s panels”); EX2052, 88:8-89:1 (Mr. Carota explaining the “difficulty” the inventors had “because of the gap between the lights at the place where there was a hinge”).

Dr. Grove also argues a POSITA would “**replace the fluorescent bulbs of Lundahl with LEDs.**” EX1015, ¶¶178, 129. But, replacing Lundahl’s diffuse fluorescent tube illuminators with discrete, point-source LEDs would also create gaps between the LEDs, impacting the uniformity. EX2050, ¶¶127, 38-48; EX2053, 100:22-101:15 (Mr. Boyajian explaining the difference between fluorescent tubes with “no gaps” and LEDs with “points of light” that “give an area that you can’t have light”). Dr. Grove states he “**incorporate[s] the uneven spacing of light**

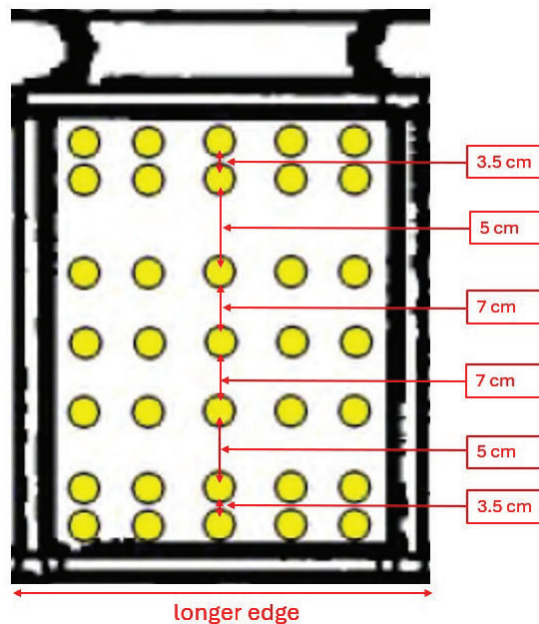
sources of Lundahl” in his alleged combination (EX1015, ¶¶178-179), but applying Lundahl’s teaching of spacing of the light sources to LEDs would not result in the claimed uniform illumination. EX2050, ¶127; Petition 47-48; EX1015, ¶¶176-177 (Dr. Grove relying on express teaching of Lundahl’s spacing); EX2036, 149:24-150:4 (Dr. Grove testifying he is relying on Lundahl’s spacing, not Larsen’s spacing).

Lundahl teaches the “lateral spacing” is “3.5 cm between tubes 10(2),10(1) and 10(6),10 (7)”; “5 cm between the tubes 10(3),10(2) and 10(5),10 (6)”; and “7 cm between the center tube 10(4) and each of the two tubes 10(3),10(5) adjacent to the center tube,” as shown below (EX1014, 6:48-57):



Left: EX1014 (Lundahl Fig. 2 rotated counterclockwise 90° and annotated to show the distances between light sources); Right: EX1023, 29 (Lundahl Blu-U® annotated to show distances between light sources). EX2050, ¶127.

Spacing LEDs as taught by Lundahl would create gaps (“optical dead spaces”) in areas of the target treatment area that would impact the uniform illumination, because LEDs and fluorescent tubes have different light output characteristics. EX2050, ¶¶127-128, 38-48.



EX1015, ¶¶178-179 (Dr. Grove’s alleged panel, annotated to show the distance between light sources). By changing Lundahl’s continuous diffuse fluorescent tubes to discrete, point-source LEDs, and failing to address the impact this change has on the uniformity, Petitioner and Dr. Grove have not shown that the **combination** of Lundahl and Larsen “uniformly illuminates a treatment surface” under the parties’ agreed-to construction. EX2050, ¶128.

Second, Dr. Grove argues a POSA “*would not seek to replicate the design ... of Lundahl with nine sections,*” but would instead include “*five reflectors,* matching

the number of panels disclosed by Larsen.” EX2034, ¶265. However, Dr. Grove’s modification ignores Lundahl’s teaching that the nine-section reflector “***increase[s] the uniformity*** of the output distribution” by “conform[ing] to the configuration of the tubes” and contains vents “so that cooling air flows primarily over the straight section and the end portions of the curved section.” EX1014, 8:62-67, 9:43-46, FIG. 5B. Dr. Grove also does not explain why a POSITA would have incorporated Larsen’s LEDs, but not Larsen’s reflectors. *See* EX1004 (Larsen), [0070]. Whether Dr. Grove’s combination uses five reflectors or none at all, changing Lundahl’s reflector would impact the combination’s uniformity. EX2050, ¶129. Because Petitioner fails to address the impact that would have on uniformity, Petitioner has not shown the ***combination*** of Lundahl and Larsen “uniformly illuminate[s] a treatment surface” under the parties’ agreed-to construction. *Id.*

Third, Petitioner changes Lundahl’s electrical system that “correct[s] output of said light from said plurality of light sources so as to ***maintain said substantially uniform intensity***.” EX1014, Abstract, claim 26. Dr. Grove argued “***the electrical needs and design of Lundahl’s system for operating fluorescent tubes would need to be changed*** to accommodate the electrical needs and design of Larsen’s LED panels.” EX2034, ¶268. However, changing Lundahl’s electrical control system to drive LEDs at lower voltage would necessarily affect uniformity. EX2050, ¶130; EX1014, 5:58-61, 8:46-54; EX2011, 1944. Because Petitioner fails to address the

impact a change to the electrical control system would have on uniformity, Petitioner has not shown the **combination** of Lundahl and Larsen “uniformly illuminate[s] a treatment surface” under the parties’ agreed-to construction. EX2050, ¶130.

Fourth, Petitioner does not address Lundahl’s cooling system that “control[s] irradiance uniformity,” despite acknowledging that Lundahl’s uniformity is “affected by heat and the ability to cool the Lundahl device.” EX1014, 4:39-44; Petition, 26; EX1015, ¶121; EX1016, ¶¶68-69. Lundahl discloses a complex cooling system that includes zones, intake vents, fans, reflector vents, and exhaust vents at specific locations. EX1014, 9:13-54. Changing Lundahl’s cooling system to simply incorporate one or more fans as Dr. Grove proposes (EX1015, ¶240), without Lundahl’s zones, vents, shield, and reflector, would also necessarily affect uniformity. EX2050, ¶¶131, 46-47; EX2011, 1944, 1945. Because Petitioner fails to address the impact the change to the cooling system would have on uniformity, Petitioner has not shown the **combination** of Lundahl and Larsen “uniformly illuminate[s] a treatment surface” under the parties’ agreed-to construction. *Id.*

Because Petitioner modifies and/or replaces multiple carefully selected and engineered components that Lundahl teaches must work together to achieve uniformity (EX1014, 4:14-22), and does not address the affects those changes have on uniform illumination, Petitioner has not shown the **combination** of Lundahl and

Larsen renders obvious the “uniformly illuminate” limitations under the parties’ agreed-to construction. EX2050, ¶¶119-132.

2. Petitioner’s reliance on Larsen’s disclosure does not show the combination is obvious

Petitioner argues Larsen’s use of a scan engine teaches “uniformly illuminate a treatment surface.” Petition, 41-42, 66; EX1015, ¶¶163, 235 (citing EX1004, [0072]). However, again Petitioner relies on Larsen’s disclosure *separately* and does not show that the *combination* of Lundahl and Larsen renders obvious the “uniformly illuminate” limitations. *Unigene*, 655 F.3d at 1360; EX2050, ¶133.

Larsen does not disclose “irradiating light over the active emitting area such that the measured irradiance at a treatment surface of the patient is at least within 60% of the measured maximum.” EX2050, ¶134. Indeed, Dr. Grove admitted “*Larsen doesn’t disclose how to achieve uniformity meeting the requirements of 60 percent of the measured maximum at all points.*” EX2036, 139:9-14. Moreover, Petitioner’s expert, Dr. Bretschneider, opined there are “lower irradiance regions at the junction of two of Larsen’s panels.” EX2082, ¶151. He acknowledged “the scan engine would have been a less effective way to achieve more uniform illumination” because “the scan engine can only move lights linearly in one direction at a time, which *would only decrease unradiated gaps on the portion of the*

treatment surface towards which the light sources are being moved.” EX2082, ¶154; *see also* EX2052, 118:10-119:17.¹

Petitioner’s argument that “Larsen also describes measurements taken by sensors 32” also fails. Petition, 42; EX1015, ¶164. Larsen’s sensors 32 “measure the amount of energy radiated away from the skin surface, which is indicative of the *total energy* penetrating into the tissue” (EX1004, [0079]). A POSITA would have understood that *indicative of the total energy* (measured in Joules) measured by Larsen’s sensors is *not* equivalent to the *measured irradiance* (measured in W/cm²). EX2050, ¶135. Larsen *does not* teach or suggest “irradiating light over the active emitting area such that the *measured irradiance* at a treatment surface of the patient is at least within *60% of the measured maximum.*” *Id.*

Therefore, Petitioner has not shown Larsen discloses the “uniformly illuminate” limitations. Nor has Petitioner shown the combination of Lundahl and Larsen renders obvious these limitations. EX2050, ¶¶133-136.

¹ Petitioner argues that during prosecution of the ’512 Patent, the Examiner stated Larsen discloses “the illuminator being configured to uniformly illuminate a treatment surface of the patient via the light sources (see EX1004 [0072]).” Petition, 41. However, the Examiner’s statement is conclusory, incorrect, and addresses Larsen’s disclosure *separately, not* the alleged combination of Lundahl and Larsen.

3. The evidence demonstrates no reasonable expectation of success

Petitioner fails to show a POSITA would have had a reasonable expectation of success that the combination of Lundahl and Larsen would “irradiat[e] light over the active emitting area such that the measured irradiance at a treatment surface of the patient is at least within 60% of the measured maximum.” Petitioner argues a “POSITA would have had a reasonable expectation of success in combining Lundahl with Larsen, because both references describe similar illuminators for using light to treat conditions on a patient’s skin” and “the conversion from fluorescent tubes to LEDs was a routine practice.” Petition, 31-32; (citing EX1015, ¶¶128, 131). However, “[t]he reasonable expectation of success requirement refers to the likelihood of success in combining references to *meet the limitations of the claimed invention*.” *Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1367 (Fed. Cir. 2016). Petitioner provides no basis to support that a POSITA combining Lundahl in view of Larsen would have had a reasonable expectation of success in achieving “irradiating light over the active emitting area such that the measured irradiance at a treatment surface of the patient is at least within 60% of the measured maximum.” EX2050, ¶¶137, 121-132. On this basis alone, Petitioner cannot meet its burden.

Significantly, Petitioner's own expert argued that achieving uniform illumination was *not routine* at the time of the invention. Dr. Grove argued a "*POSA would be required to perform undue experimentation to make and use an illuminator that provides 'uniform illumination.'*" EX2034, ¶186. Dr. Grove explained "[i]t is well-known that the field of optics and illumination is complex, and in some cases requires extensive measurement and experimentation. *A POSA will expect that the amount of experimentation and testing necessary to achieve a specific design goal increases where the treatment surface is not flat, a challenge further compounded by the fact that the shape of the illuminator does not follow the contours of a face or other treatment area. Moreover, there is a range of distances between the illuminator and the treatment surface, and this variance can dramatically affect irradiance of the skin. And, finally, much of the targeted skin area is not in the same plane as the emitting source; the irradiance falls off rapidly if the treatment surface is not orthogonal to the light emitted from the illuminator.*" EX2034, ¶191; EX2084, 66:1-67:14.

Dr. Grove's assertions in IPR2025-00287 also support no reasonable expectation of success; he argued "based on the teachings of Lundahl and Larsen, uniformity of illumination is *still a key design motivation*, as a POSITA would want to minimize *gaps between the adjacent panels (appreciable gaps between panels might impact the ability to produce uniform illumination).*" IPR2025-00287,

EX1015, ¶139. Furthermore, the inventors of the '028 Patent testified that achieving uniform illumination was “one of the *more difficult challenges* that [they] had,” and they conducted numerous tests because “LEDs don’t act like fluorescents.” EX2052, 73:20-74:14; EX2053, 87:3-89:12, 100:7-12, 100:22-101:15. A POSITA would have understood that replacing fluorescent tubes with LEDs creates problems unique to LEDs, due at least in part to the different optical and electrical characteristics of LEDs and fluorescent tubes. EX2050, ¶¶138-139, 38-48. Therefore, the evidence demonstrates that a POSITA would have had no reasonable expectation of success that the combination of Lundahl in view of Larsen would “irradiat[e] light over the active emitting area such that the measured irradiance at a treatment surface of the patient is at least within 60% of the measured maximum.” EX2050, ¶¶137-140.

Accordingly, for each of the above reasons, Lundahl in view of Larsen does not render obvious the “uniformly illuminate” limitations. Petitioner has not met its burden for all Challenged Claims.

B. Lundahl In View Of Larsen Does Not Render Obvious The “Higher Intensity” Limitation (All Claims)

Petitioner argues Lundahl in view of Larsen renders obvious “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.”

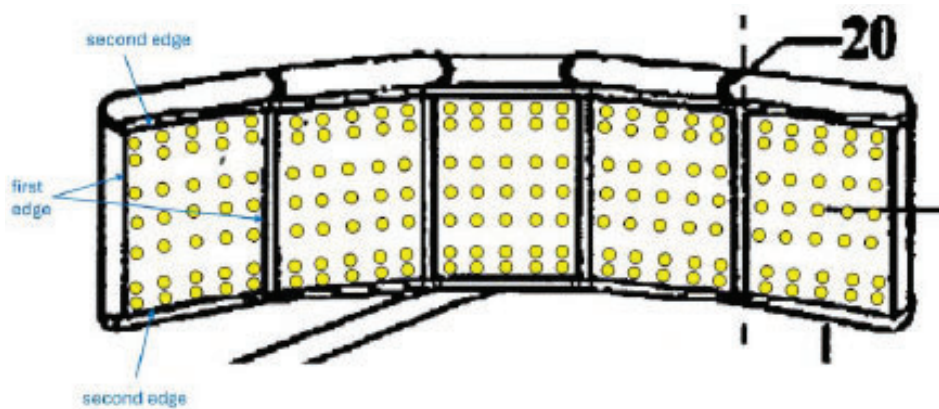
Petition, 46-49, 56, 67, 71, 73; EX1015, ¶¶175-181, 204-205, 238, 254-255, 264-265. However, Lundahl in view of Larsen does not render obvious this limitation for each of the reasons set forth below. EX2050, ¶¶141-142.

First, Petitioner argues “the PDT device and light distribution of Lundahl” combined with “the “hinged panels and LED lights” of Larsen renders obvious this limitation. Petition, 49; EX1015, ¶¶178-180. However, Petitioner fails to read the claim language as a whole, which requires that “each of the five panels” has “a higher intensity of light [] emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges.” *See, e.g.*, EX1001, 10:39-44 (“wherein each of the five panels has two first edges and two second edges shorter than the first two 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”). EX2050, ¶¶144-145.

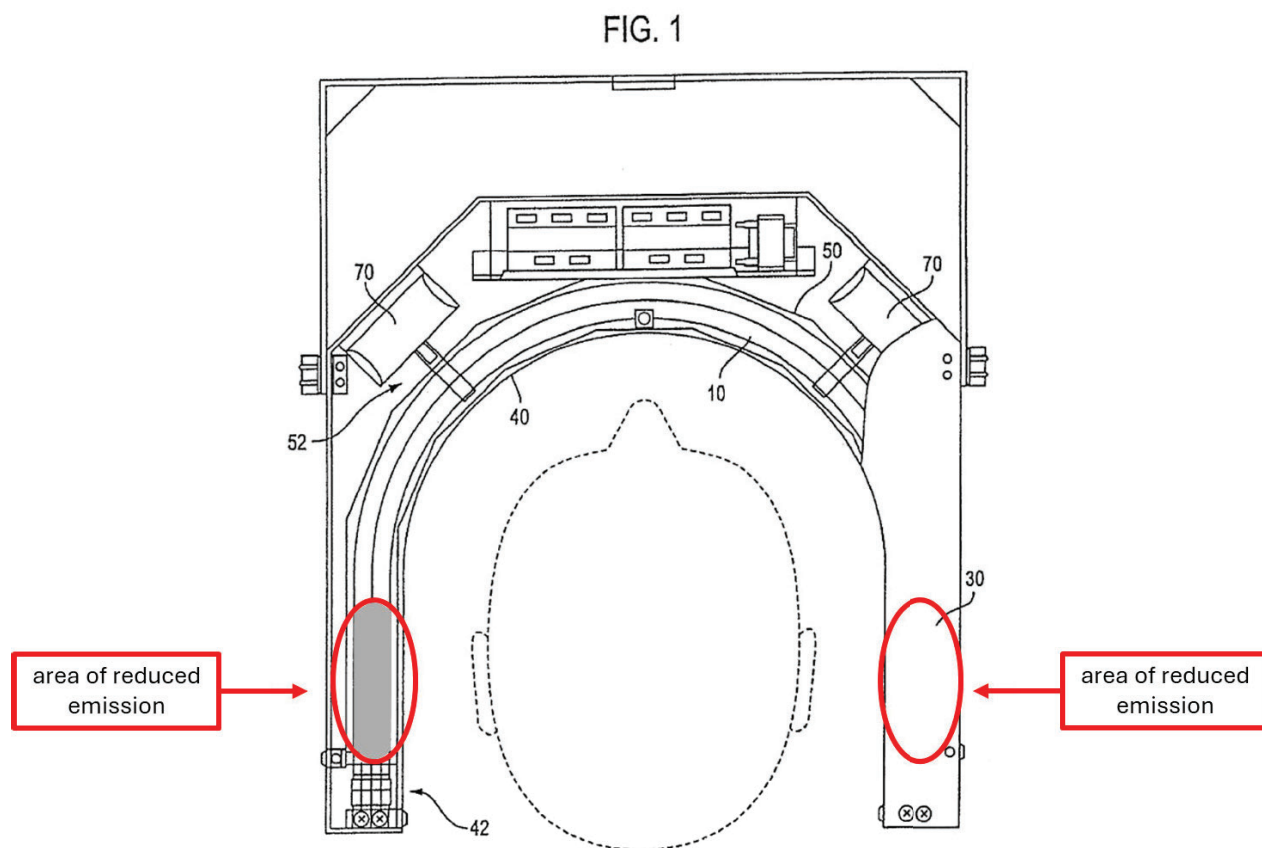
Petitioner argues the combination of Lundahl and Larsen “maintain[s] the same light distribution pattern Lundahl utilized for the fluorescent bulbs” (EX1015, ¶179; Petition, 49), but *ignores Lundahl’s teachings* of “*area[s] of reduced emission*” and “[o]nly the more uniform center portion of the tube output is used for patient treatment.” (EX1014, 6:10-22). When the claim language and Lundahl are properly read as a whole, a POSITA would understand in applying Lundahl’s

teachings that “***each*** of the five panels” would ***not*** have “a higher intensity of light [] emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges.” EX2050, ¶¶145-149.

Dr. Grove alleges “a POSITA would expect the resulting device to have a design similar to the below (yellow circles representing LEDs).” EX1015, ¶¶178-179; Petition, 48-49.

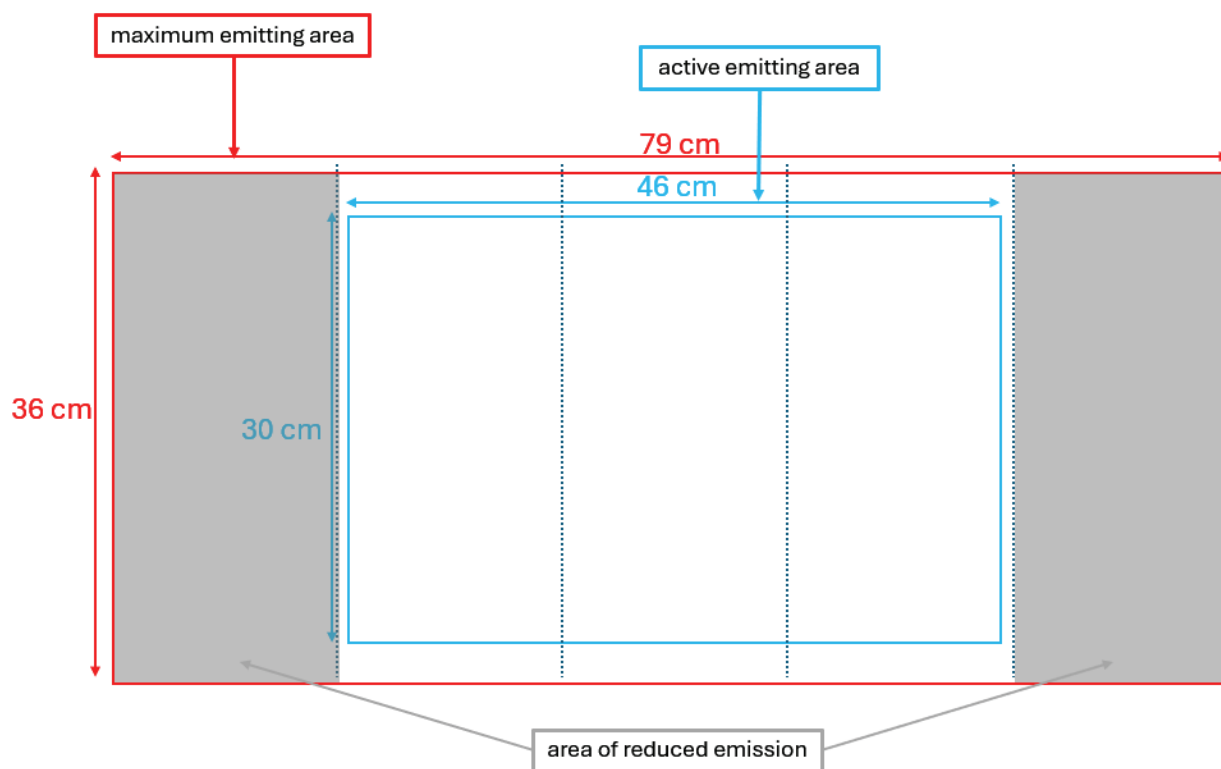


However, Dr. Grove’s alleged “resulting device” contradicts Lundahl’s teachings. Lundahl teaches “***[t]he output from a fluorescent tube is not inherently uniform.***” EX1014, 6:10-11. The light sources have “***low output area[s]***” (i.e., “***area[s] of reduced emission***”), which are “***located outside the active emitting area (effectively behind the patient's ears),***” and therefore ***[o]nly the more uniform center portion of the tube output is used for patient treatment.***” EX1014, 6:10-22. Dr. Grove ignores Lundahl’s express teachings of “area[s] of reduced emission,” as illustrated below in red:



EX1014, FIG. 1. A POSITA purporting to apply Lundahl’s express teachings of “light distribution” would have understood the alleged “resulting device” would have had “*area[s] of reduced emission*” as shown in FIG. 1 above. EX2050, ¶145.

In fact, a POSITA would have understood that if Larsen’s five panels were incorporated into the PDT device of Lundahl (as Dr. Grove proposes, EX1015, ¶178), the *combination would not result* in Dr. Grove’s alleged design. Instead, the “resulting device” would have “*area[s] of reduced emission*” “*located outside the active emitting area,*” as illustrated below:



EX2050, ¶146; EX1014, 6:10-22; EX2036, 151:17-152:6 (Dr. Grove agreed he is taking “the single long U-shaped panel of Lundahl and dividing it into five sections”). Lundahl teaches the “therapeutically active area” (shown in blue) is “30 cm high by 46 cm wide,” and the “maximum visible light-emitting area” (shown in red) is “36 cm high by [79] cm wide.” EX1014, 5:38-43; EX2037 (“Total Emitting Area” is “36 cm H X 79 cm W”). Based on Lundahl’s teachings, the light emitted proximate the second edges of *each of the five panels* would not be a higher intensity than the light emitted not proximate the second edges, at least because there would be “*area[s] of reduced emission*” “located *outside the active emitting area*” on at least the outer panels (shown in gray). EX2050, ¶¶146-147; EX1014, 6:10-22,

FIGS. 1, 4A, 5:43-46 (discussing and showing an “active emitting” “central region” and “low output” “arms”).

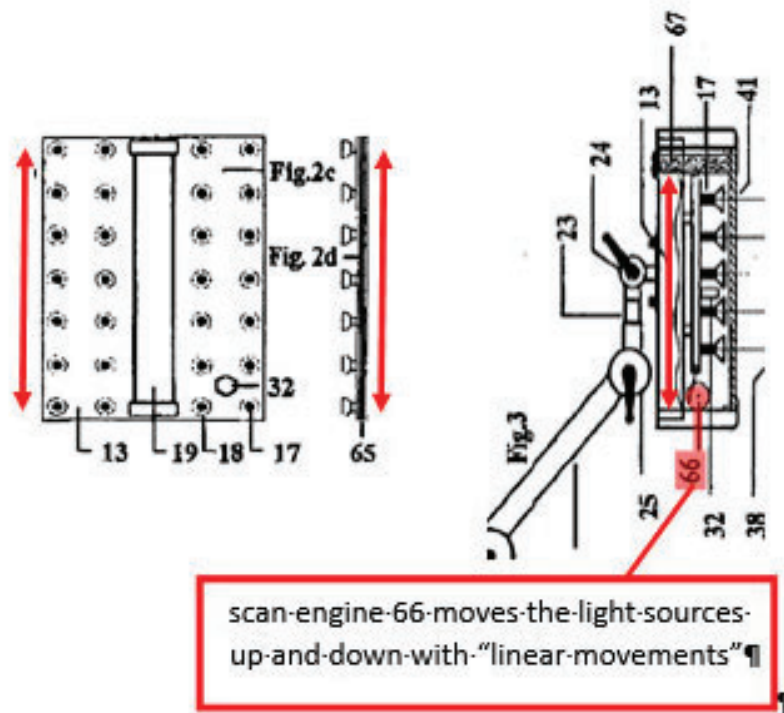
Further, Dr. Grove’s proposal to apply “Larsen’s solution” regarding LEDs (EX1015, ¶130) would not meet the “higher intensity” limitation, because Larsen’s “regular row arrangements” of LEDs do not have higher intensity proximate the shorter edges. EX1004, [0071], FIGS. 2a-2d; EX2050, ¶148. In fact, Petitioner admitted “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.” IPR2024-00874, Paper 1, 36. And, as discussed below, neither Lundahl nor Larsen teaches or suggests higher intensity proximate the shorter edges.

Accordingly, when the claim language and references are properly read as a whole, the combination of Lundahl in view of Larsen does not render obvious “wherein each of the five panels has two first edges and two second edges shorter than the first two 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.” EX2050, ¶¶141-149.

Second, Petitioner relies on Larsen’s disclosure of a scan engine that “move[s] the light sources with linear movements” in its alleged combination. Petition, 41-42, 66 (citing EX1004, [0072]); EX1015, ¶¶163-164, 235. However, a POSITA would have understood the combination applying Larsen’s teaching of “*electrical*

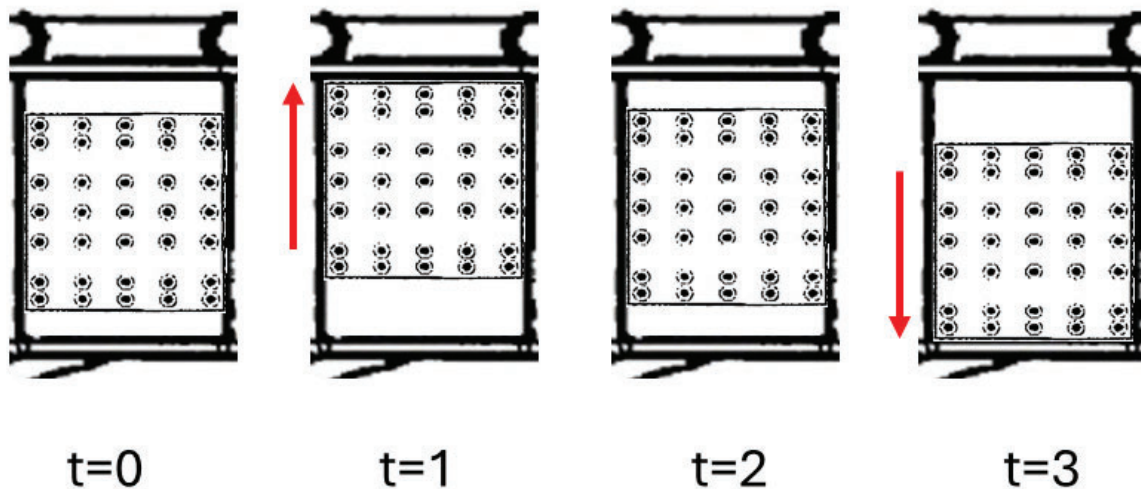
scan engine 66” that “*move[s] the light sources with linear movements*” would not result in a device that renders obvious “the light sources are arranged such that a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges.” EX2050, ¶150.

Larsen teaches “[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.” EX1004, [0072]; EX2082, ¶154 (Petitioner’s expert acknowledging Larsen’s scan engine is “configured to only move the lights linearly in a single direction.”); IPR2024-00874, Paper 1, 18 (“scan engine is configured to only move the lights along a single axis”). Based on Larsen’s teaching, and as shown in Larsen’s figures, a POSITA would have understood the scan engine “move[s] the light sources with linear movements” up and down along the longer axis of each of the applicators:



EX1004, Figs. 2c-d, Fig. 3 (rotated 90° to be same orientation as Figs. 2a-d), [0072];
EX2050, ¶151.

A POSITA reading Larsen would have understood that in Petitioner’s alleged “resulting device” (EX1015, ¶¶178-179), the scan engine 66 would move the light sources linearly up and down, as shown below:



EX1015, ¶¶178-179; EX1004, [0072]; EX2050, ¶152. (illustrating light sources moving up and down over time, *e.g.*, from $t=0$ to $t=3$). As Petitioner’s expert explained, this linear movement “*would only decrease unradiated gaps on the portion of the treatment surface towards which the light sources are being moved.*”

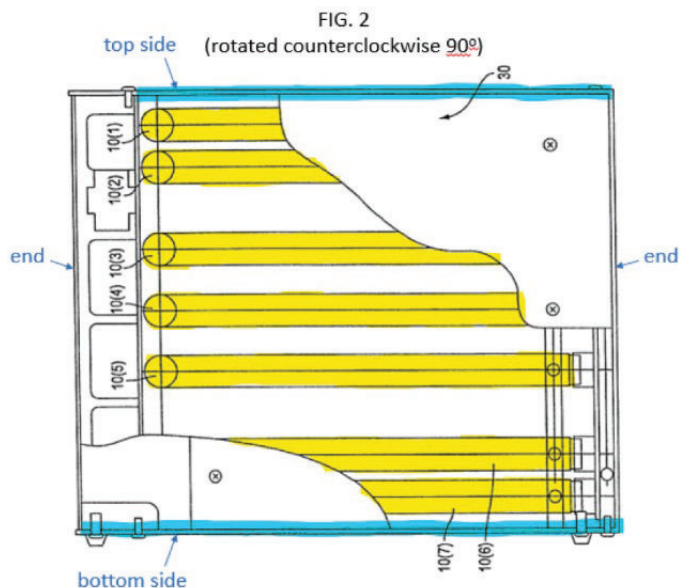
EX2082, ¶154, IPR2024-00874, Paper 1, 18. When taken as a time lapse, *e.g.*, from $t=0$ to $t=3$, *there would be more light sources in the center portion of each panel than near the shorter edges of each panel.* EX2050, ¶152. Therefore, a POSITA would have understood the light sources in the alleged “resulting device” applying Larsen’s teaching would not meet the higher intensity limitation because a *lower* intensity of light is emitted proximate the second edges compared to the intensity of light not proximate the second edges (*e.g.*, the center), when the teachings of Lundahl and Larsen are considered as a whole. EX2050, ¶¶150-152.

Third, the Board preliminarily found “Petitioner’s proposed modification *applies Lundahl’s disclosure* of providing greater light intensity at the top and bottom sides *to the top and bottom sides of Larsen*, which are the shorter edges in Larsen.” Institution Decision, 19. However, the Board applied the combination backwards—Petitioner did not argue to apply Lundahl’s disclosure to Larsen’s device. Rather, Petitioner argued a POSITA would have been motivated “to *incorporate Larsen’s solution* of disposing light sources, specifically LEDs, on the surface of the light applicators *to Lundahl’s device*.” Petition, 32 (citing EX1015, ¶130); IPR2025-00287, Petition, 31 (citing EX1015, ¶¶119 (“*incorporate* the hinged panel LED displays of *Larsen into the PDT device of Lundahl*”), 192 (“hinged panels and LEDs taught by *Larsen* are *incorporated into the device of Lundahl*”)).

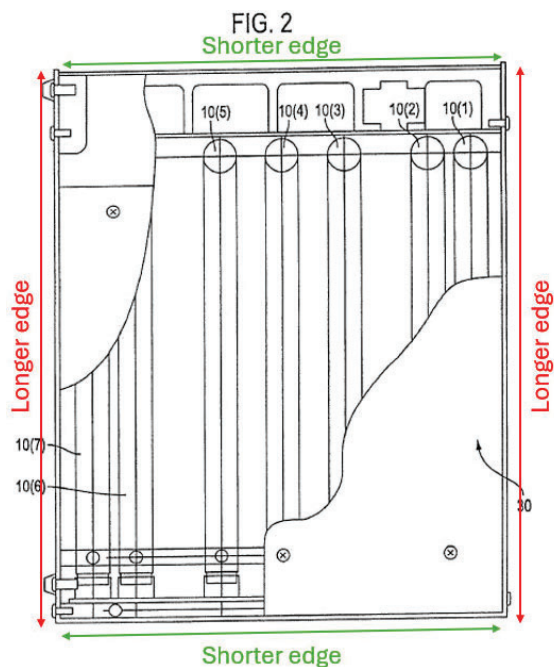
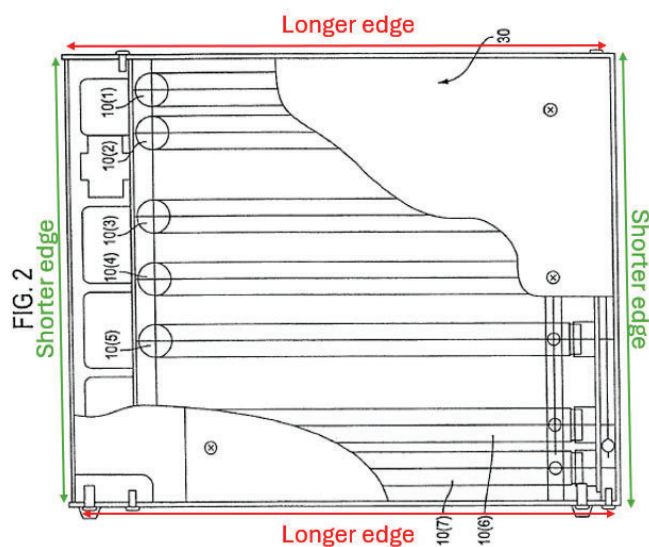
In any event, the combination of Lundahl and Larsen does not render obvious the higher intensity limitation because *neither of the references teaches or suggests that the light sources emit a higher intensity close to the shorter edges*. Lundahl’s more closely spaced fluorescent tubes are at the *longer edges* of Lundahl’s panel, not the *shorter edges*. As discussed below, a POSITA reading Lundahl’s and Larsen’s disclosures would have understood that *both Lundahl and Larsen* teach to have *lower* intensity near the shorter edges. EX2050, ¶¶153-154. Petitioner’s piecemeal reconstruction of the prior art in an attempt to manufacture the claimed invention should be rejected because *neither of the references teaches or suggests*

that the light sources emit a higher intensity close to the shorter edges. Application of *Wesslau*, 353 F.2d 238, 241 (CCPA 1965) (reversing the Board’s decision affirming the rejection of the claims because “*no one of the references suggests* such a substitution” and “[s]uch piecemeal reconstruction of the prior art patents ... is contrary to the requirements of 35 U.S.C. §103”); *Purdue Pharma L.P. v. Depomed, Inc.*, 643 F. App’x 960, 966 (Fed. Cir. 2016) (finding improper to use “hindsight in formulating the problem to be solved”); *In re Kotzab*, 217 F.3d 1365, 1371-1372 (Fed. Cir. 2000) (reversing and finding “the Board fell into the hindsight trap” where there “was no finding as to the specific understanding...that would have motivated one with no knowledge of Kotzab’s invention to make the combination in the manner claimed”).

Dr. Grove argues a “POSITA would have understood that the tubes of Lundahl are spaced to emit a higher intensity of light proximate the *top and bottom sides* compared to the intensity of light emitted not proximate the *top and bottom sides*.” EX1015, ¶176; Petition, 47-48. Dr. Grove rotates Fig. 2 and labels in blue a “top side” and “bottom side”:



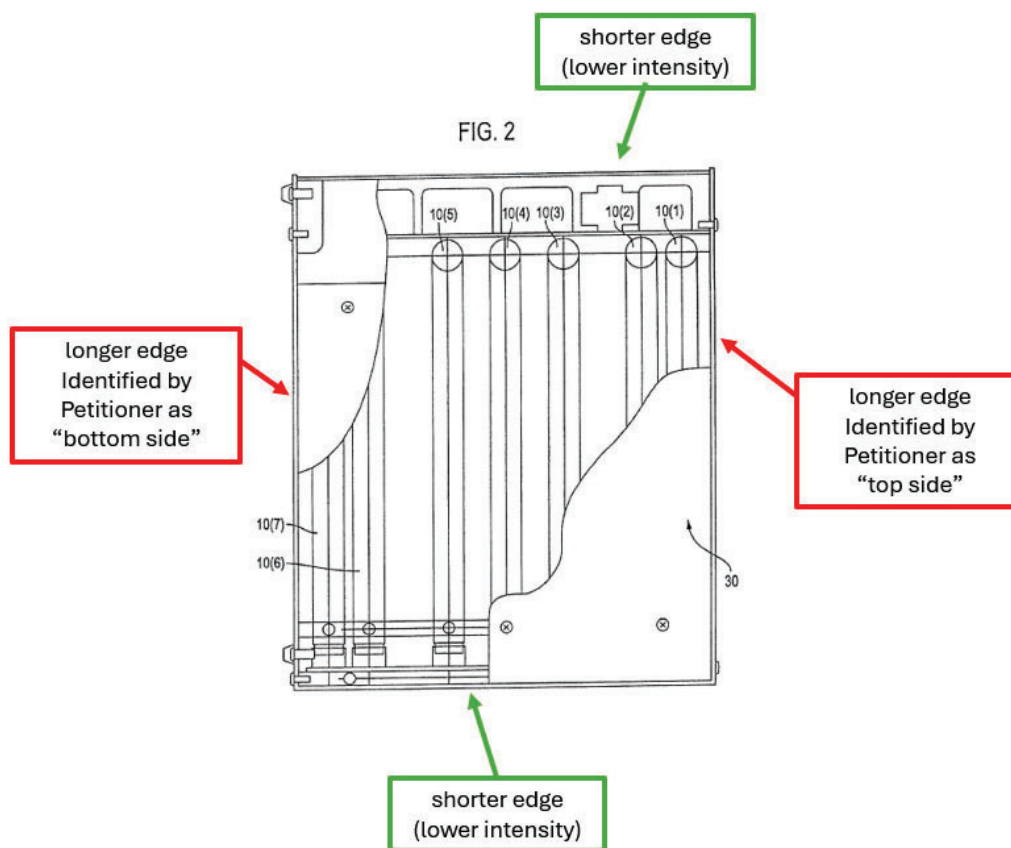
EX1015, ¶175; Petition, 47. However, Dr. Grove’s labels are misleading—a POSITA reading Lundahl would have understood that rotating and labeling Fig. 2 does not change that the “top side” and “bottom side” are the *still* the *longer* edge:



EX1014, FIG. 2; *see also* FIG. 1. EX2050, ¶¶155-156. Based on Lundahl’s express disclosure, the “seven 36” U-shaped F34T8 Ultra Blue fluorescent tubes 10(1)-10(7) provide a *maximum visible light-emitting area 36 cm high by [79] cm wide (approximately 2850 cm²)*, with a *minimum therapeutically active area 30 cm high by 46 cm wide (approximately 1350 cm²)*.” EX1014, 5:38-43; EX2037. Therefore, there can be no dispute the “*top side*” and “*bottom side*” identified by Dr. Grove are the *longer edges*, regardless of how he orients the figures. EX2050, ¶¶155-157.

Petitioner fails to consider the requirements of the “higher intensity” limitation as a whole and instead breaks the limitation into disjointed pieces. Petition, 45-49; EX1015, ¶¶173-181. When the entire claim limitation is read (“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*”), it is clear the claims distinguish between the *shorter second edges* and the longer first edges of the panels. In context, the plain language of the claims requires that the intensity of light emitted *proximate the shorter second edges* is higher than the intensity of light emitted *not proximate the shorter second edges*. EX2050, ¶158. Therefore, Dr. Grove’s “top side” and “bottom side” are the *longer edges*—not the *shorter second edges* required by the claims. *Id.*

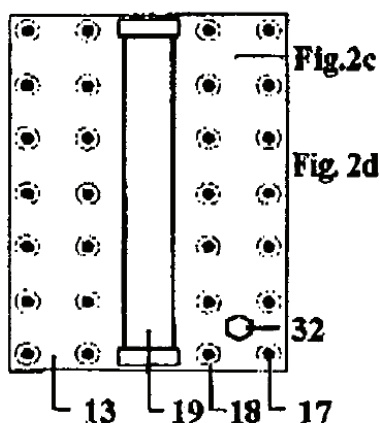
Additionally, as discussed above, Lundahl discloses its *shorter edges* are in “*area[s] of reduced emission*,” not areas of higher intensity, as illustrated below:



EX1014, Fig. 2; EX2050, ¶159. As Lundahl explains, “[t]he output measured in the immediate vicinity of the cathode is typically much lower than the output over the rest of the tube. ... This *area of reduced emission* is known as the Faraday dark space”; the “*low output area*” is “located outside the active emitting area (effectively behind the patient's ears)”. EX1014, 6:10-22. Based on Lundahl’s disclosure, a POSITA would have understood that maintaining Lundahl’s “light distribution” would place the “*area[s] of reduced emission*” on the panels proximate the *shorter*

edges such that the light emitted proximate the shorter edges would be of *lower intensity*, not “higher intensity” as required by the claims. EX2050, ¶159.

Further, Larsen’s disclosure would have discouraged a POSITA from having a higher intensity near the shorter edges. EX2050, ¶160. As shown in Fig. 2c, at least one of Larsen’s applicators contains a “light source 19 formed as a tube” that can emit “fluorescent light.” EX1004, [0071].



EX1004, Fig. 2c. The cathodes of the light source 19 are at the *shorter edges* of the applicator. Because fluorescent tubes have “area[s] of reduced emission” near the cathodes, a POSITA would have understood the intensity of light is *lower* proximate the *shorter edges* than not proximate the shorter edges of the applicator. EX2050, ¶¶160-161; EX1014, 6:10-16; EX2012, 1:31-45, 4:9-25; EX2080. Thus, a POSITA would have been discouraged from pursuing a higher intensity near the shorter edges. *Id.*; *Arctic Cat Inc. v. Bombardier Recreational Prods. Inc.*, 876 F.3d 1350, 1363 (Fed. Cir. 2017) (one must consider evidence that “suggests reasons that a

skilled artisan would be discouraged from pursuing such a combination,” even when not rising to the level of teaching away).

Accordingly, for each of the reasons set forth above, Lundahl in view of Larsen does not render obvious the “higher intensity” limitation. Petitioner has not met its burden for all Challenged Claims. EX2050, ¶¶141-162.²

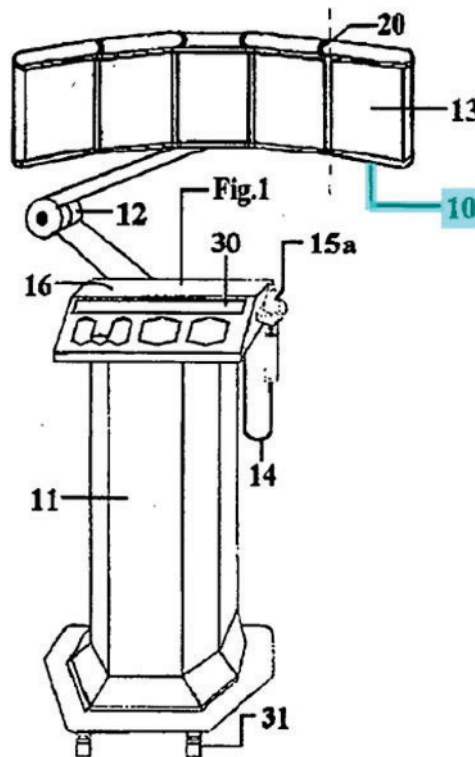
C. Larsen Does Not Disclose Or Render Obvious “Hinged Structures On Inner Side Surfaces Of Adjacent Panels” (Claims 1, 5, 20, 21)

Petitioner argues Larsen discloses or renders obvious an “illuminator comprising five panels connected by hinged structures on inner side surfaces of adjacent panels.” Petition, 35-38, 55, 69-71, 73, 77; EX1015, ¶¶152-156, 198-199, 246-248, 257, 266, 277. However, Larsen does not disclose or render obvious this limitation. EX2050, ¶¶163-164.

First, Larsen does not disclose “hinged structures on inner side surfaces of adjacent panels.” EX2050, ¶165. Larsen states “several applicators 13 are flexibly connected to each other through *hinges 10*.” EX1004, [0072]. As shown in Fig. 1

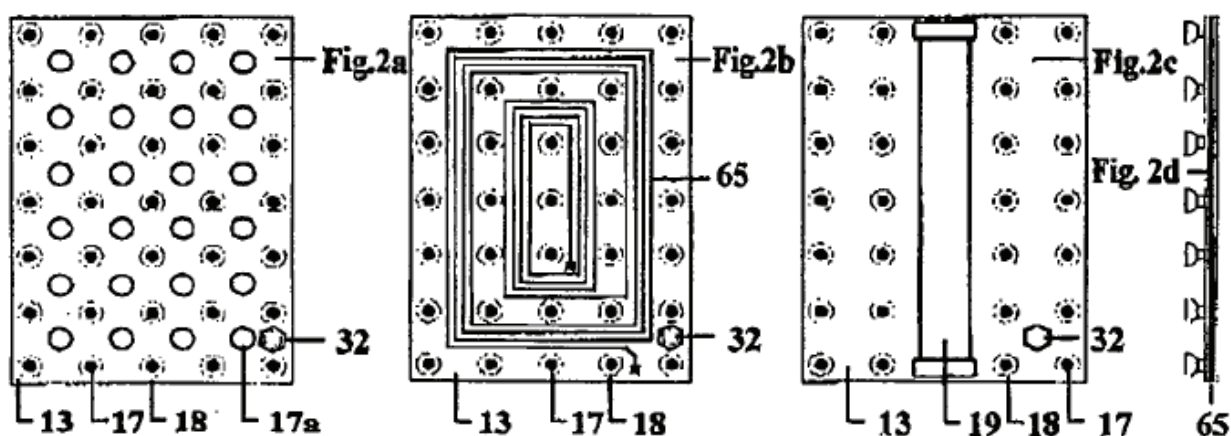
² The Board should reject any argument by Petitioner that the alleged combination of Lundahl and Larsen is “similar” to the RhodoLED XL; this is irrelevant and Petitioner has failed to disclose the details of such device.

below, element “10” points to the *bottom* of the applicator 13, not to the inner side surface of the adjacent panels.



EX1004, FIG. 1; EX2050, ¶165.

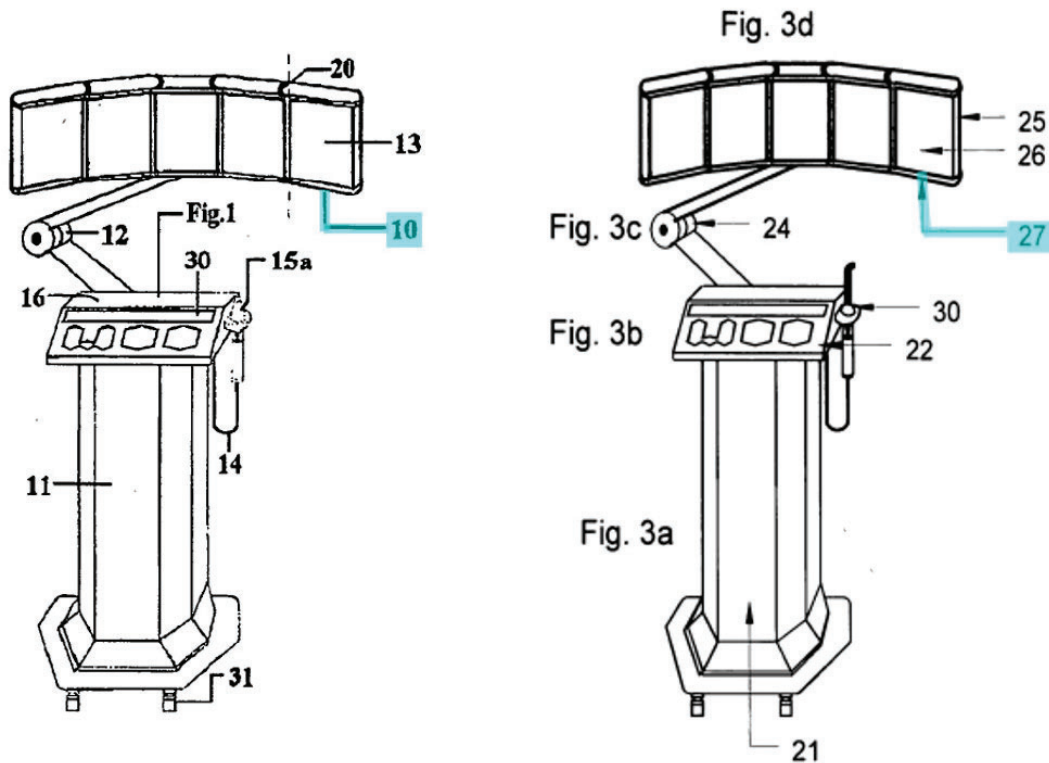
Petitioner argues that, despite Larsen’s clear labeling of “hinges” as “10,” the hinges are “shown as element 20 in Figure 1.” Petition, 36-37; EX1015, ¶153-154. However, Larsen identifies “20” as the regular row arrangements of light sources in the applicator 13, which are shown below, for example, in Figs. 2b and 2c: “According to FIGS. 2b and 2c *the light sources 17 are placed in regular row arrangements, i.e., 20* equidistant from each other.” EX1004, [0071].



EX1004, Figs. 2a-2d. Dr. Grove’s deposition testimony contradicts Petitioner’s argument that the hinges are shown as element 20 in Figure 1—when Dr. Grove was shown the disclosure in Larsen that “the light sources 17 are placed in *regular row arrangements, i.e., 20*” (EX1004, [0071]), he stated “it’s not clear to me what 20 is referring to, unless it’s simply referring to rows of light sources. In which case *if it’s referring to rows of light sources as is shown in, for example, Figure 2a, then I understand what 20 means.*” EX2084, 143:18-145:18. A POSITA reading Larsen’s disclosure would have understood that “hinges 10” refers to element 10 at the bottom of the applicator and not to element 20 in Fig. 1. EX2050, ¶166; EX0014, [0071]-[0072]). A POSITA would have further understood that element 20 refers to the light sources in regular row arrangements. *Id.*

That Larsen’s hinges 10 are on the bottom of the applicator (not the inner side surfaces) is confirmed by Fig. 3 of another Larsen publication (AU 2001/43869),

which like Fig. 1 of Larsen, points to hinges (27) on the *bottom* of the applicator (shown highlighted in blue below):



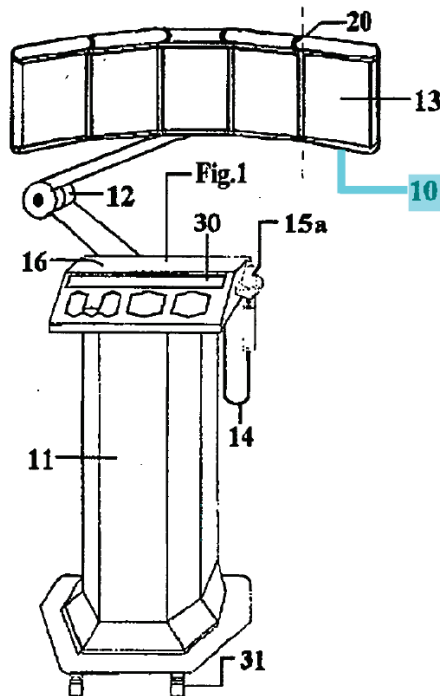
EX1004, Fig. 1; EX2004, Fig. 3; EX2050, ¶167. As shown, the claims of the Larsen publication recite “a flat applicator (25) consisting of a number of individual hinged (27) flat elements.” EX2004, claim 19. Like Larsen, the Larsen publication has no disclosure of “hinged structures on inner side surfaces of adjacent panels.” EX2050, ¶167.

Petitioner points to an Examiner statement during prosecution of the '871 patent application that Larsen taught “five panels connected by a plurality of hinges 20 ... on inner side surfaces of adjacent panels that connect panels together.”

Petition 37 (citing EX1009, ¶4 (citing EX1004, Figs. 1-3, [0069], [0072], lines 1-4); EX1015, ¶154). However, Petitioner fails to address the *later contradictory* statements by the *same Examiner*. For example, *after* the '871 Office Action, the *same Examiner* allowed the claims of the '512 Patent, stating “*the art of record* [including Larsen] *neither anticipates nor renders obvious ‘nested hinges on inner side surfaces of adjacent panels.’*” EX2061, 494, 559. And, during the *later prosecution* of the '028 Patent, the *same Examiner* identified the hinges as element 10 in reference to Figure 1: “*Larsen discloses ... the illuminator comprising: at least five panels 13 connected by hinged structures 10 (see Figure 1....*” EX1002, 328. In fact, Dr. Grove acknowledged the Examiner’s statement points to *Larsen’s Figure 1* when referencing Larsen’s “*hinged structures 10.*” EX2084, 190:12-22. EX2050, ¶¶168-170.

Moreover, there is no inherent disclosure in Larsen of “hinged structures on inner side surfaces of adjacent panels.” EX2050, ¶171. Petitioner asserts that because “the panels (13) are nearly flush with each other,” Larsen’s hinges are on inner side surfaces of adjacent panels. Petition, 36-37; EX1015, ¶154. However, a POSITA would have understood that Larsen’s hinges are *not necessarily* on inner side surfaces of adjacent panels. EX2050, ¶171 (citing EX1004, [0071], [0072], Fig. 1). As explained above, Larsen discloses its applicators **13** are connected to each

other by “hinges **10**.” EX1004, [0072]. Element **10** in Fig. 1 of Larsen (shown in blue) points to the *bottom* of the applicator **13**, not any inner side surfaces.



EX1004, Fig. 1. Larsen refers to element **20** as “light sources” “placed in regular row arrangements, i.e., **20**” and never references element **20** as hinges. EX1004, [0071]; EX2050, ¶171; *see also* EX2005, 2, 5, 10 (“BEAUTYLIGHT” illuminator showing hinges on the bottom and listing Mr. Eric Larsen as addressee).

Second, Larsen does not render obvious “hinged structures on inner side surfaces of adjacent panels.” EX2050, ¶172. Petitioner provides only unsupported, conclusory argument that a POSITA “would have found it obvious to try placing the hinges on the inner side surfaces of the panels.” Petition, 37-38; EX1015, ¶155. Petitioner *does not identify a single prior art reference* that discloses a “hinged

structure on inner side surfaces of adjacent panels.” Nor does Petitioner provide any evidence that the claimed hinge was known at the time of the invention or that it would work for its intended purpose in an illuminator to output uniform light for PDT. Indeed, Petitioner cites only a single paragraph of Dr. Grove’s declaration that merely regurgitates verbatim its unsupported assertions. Petition, 37-38 (citing EX1015, ¶155). EX2050, ¶172. Such conclusory opinion, unsupported by actual underlying evidence, is insufficient to support alleged obviousness. *See Xerox Corp. et. al. v. Bytemark, Inc.*, IPR2022-00624, Paper 9, 16-18 (Aug. 24, 2022) (finding Petitioner did not show the claims would have been obvious where the expert did not cite to any additional supporting evidence or provide and technical reasoning to support his statement); *Johns Manville Corp. v. Knauf Insulation, Inc.*, IPR2018-00827, Paper 9, 12-13, 19-20 (Oct. 16, 2018) (informative) (denying Petition and giving little weight to expert testimony unsupported by evidence); 37 C.F.R. §42.65(a) (“Expert testimony that does not disclose the underlying facts or data on which the opinion is based is entitled to little or no weight”).

Petitioner has not met its burden of showing obviousness because Larsen *already* had hinges 10 on the *bottom* of the applicators 13 that were “flexibly connected to each other.” *See* EX1004, [0072], Fig. 1; EX2004, Fig. 3; EX2050, ¶173. In addition, Dr. Grove alleges the panels of Figure 1 were *already* “nearly flush with each other” (EX1015, ¶154), so there would have been no motivation for

a POSITA to change Larsen's hinges from the bottom of the applicators to another undisclosed hinge type and orientation to allegedly achieve flush panels. EX2050, ¶173.

Dr. Grove argues “there were finite number of known, predictable solutions for Larsen's panels to be ‘flexibly connected to each other through hinges.’” Petition, 38; EX1015, ¶155. But, contrary to Dr. Grove's unsupported argument, a POSITA would have attached hinges on the *bottom* of the panels, as disclosed in Larsen, and would have understood there were *numerous* other designs that could have attached the hinges, for example, on the bottom, top, or back of the panels. EX2050, ¶174. For example, there are butt hinges that sit on top of the surfaces you are connecting; overlay hinges that are used on cabinet doors to help them sit flush; strap hinges that include a leaf and a strap; offset hinges that attach at an angle to increase the clearance; and knife hinges, also called pivot hinges, where the hinge rotates around a center point. *Id.* A POSITA would have understood that these hinges could be placed in numerous locations in various orientations. *Id.* Contrary to Dr. Grove's unsupported argument, a POSITA designing an illuminator to output uniform light for PDT would have been discouraged from placing the hinges on the front of the panels, which would have blocked light from reaching the patient, or between the panels, which can create gaps between the panels, interfere with the panels' wiring, and create issues with the use and alignment of the PDT panels—all

of those issues would frustrate the goal of providing uniform illumination. EX2050, ¶175. Additionally, for all these reasons, Petitioner does not show a POSITA would have had a reasonable expectation of success in combining the references to meet the claimed invention, as there were numerous design options for placing hinges on Larsen’s panels that would not reasonably lead to panels with Dr. Grove’s “nearly flush arrangement.” *Id.*; *Intelligent Bio-Sys.*, 821 F.3d at 1367.

Accordingly, Larsen does not disclose or render obvious an “illuminator comprising five panels connected by hinged structures on inner side surfaces of adjacent panels.” Petitioner has not met its burden for claims 1, 5, 20 and 21 (and their dependent claims). EX2050, ¶¶163-176.

D. Larsen Does Not Disclose “The Five Panels Are Individually Configurable To Control Illumination From Each Of The Five Panels” (Claims 16, 21)

Petitioner argues Larsen discloses “the five panels are individually configurable to control illumination from each of the five panels.” ’028 Patent Petition, 63-65, 71-72, 77; EX1015, ¶¶228-231, 262, 266, 277. However, Larsen does not teach or suggest this limitation. EX2050, ¶¶177-178.

As explained (Section V), the ALJ in the related ITC proceeding construed “the five panels are individually configurable to control illumination from each of the five panels” to mean “the power output and/or light intensity of each panel can be individually controlled.” EX2033, 35-40 (adopting Patent Owner’s

construction). The Board should apply this same construction because Petitioner “[f]or purposes of this IPR” took a “view of the scope of the claims consistent with Patent Owner’s infringement allegations.” Petition, 12, 63-65. Larsen does not teach or suggest this limitation for each of the reasons set forth below. EX2050, ¶179.

None of Larsen’s disclosures relied on by Petitioner teaches or suggests that Larsen’s “five panels are individually configurable to control illumination from each of the five panels.” *First*, Petitioner asserts Larsen discloses this limitation because Larsen teaches “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.’” Petition, 64 (citing EX1004, [0070]) (emphasis by Petitioner); EX1015, ¶229. However, Petitioner misreads Larsen’s disclosure. When properly read in context, Petitioner’s alleged support identifies the *printed circuit boards* as the subject, *not* “each of the applicators (13).” EX1004, [0070] (“The FIGS. 2a, 2b and 2c show plain surfaced *printed circuit boards* with light sources mounted in the applicators 13. *These* can be used in the working model according to FIG. 2a to 2c individually, side by side (in large numbers) or in combination with an applicator. *Furthermore the printed circuit boards....*”). EX2050, ¶180. When properly read in context, Larsen discloses only that the printed circuit boards can be used in the working model individually, side by side or in

combination with an applicator, **not** that “five panels are individually configurable to control illumination from each of the five panels.” *Id.*; *Phillips*, 415 F.3d at 1314 (“the context of the surrounding words of the claim also must be considered in determining the ordinary and customary meaning of those terms”).³ In fact, Petitioner acknowledged that [0070] of Larsen teaches “[t]hese circuit boards can be used ‘individually, side by side (in large numbers) or in combination with an applicator.’” IPR2024-00874, Paper 1, 20 (citing EX1004, [0070]). Under any of these three options—printed circuit boards used (i) individually, (ii) side by side, or (iii) in combination with an applicator—Larsen does not teach five panels individually configurable to control illumination from each of the panels, as claimed. That is, these 3 different use cases for the printed circuit boards do not teach each of Larsen’s applicators being individually configurable to control illumination from each applicator of a five-applicator device (*i.e.*, “the power output and/or light intensity of each panel can be individually controlled”). EX2050, ¶¶180-181.

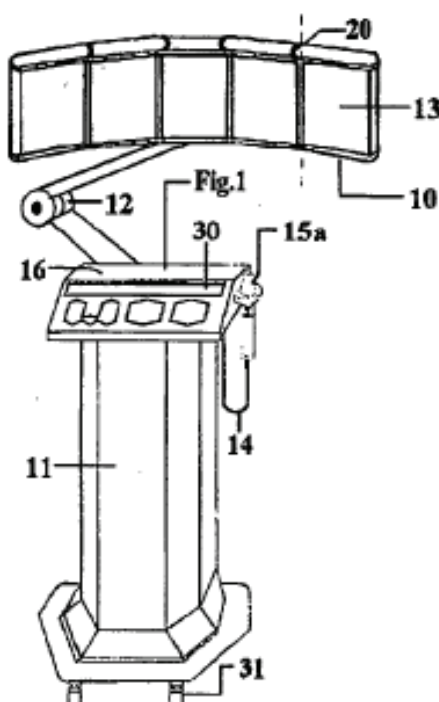
³ Petitioner’s reliance on an Examiner’s statement again fails. Petition, 64 (citing EX1002, ¶328. That the printed circuit boards “can be used in the working model according to FIG. 2a to 2c **individually**” provides no disclosure that “five panels are individually configurable to control illumination from each of the five panels.” EX2050, ¶182.

Second, Petitioner relies on Larsen’s disclosure that “[u]sing 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.’” Petition, 64 (citing EX1004, [0074]); EX1015, ¶229. However, this passage discloses only that “*the invented device* is adjustable,” **not** that each of the five applicators is individually configurable to control illumination from each of the five panels. EX2050, ¶183 (citing EX1004, [0074]); see also Petition, 69 (quoting adjustments to “the invented device”).

Third, Petitioner relies on Larsen’s disclosure that “[t]he 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.’” Petition, 64 (citing EX1004, [0074]); EX1015, ¶229. However, once again Larsen discloses that the control mechanism 16 is controlling the wavelengths of *the invented device*, **not** that the panels are individually configurable to control illumination from each of the five panels. EX2050, ¶184; EX1004, [0074] (“With the help of the control mechanism 16, *the invented device* is adjustable...**For that**

purpose the control mechanism is equipped with a switch select system for operating different types of semiconductor diodes 17 and/or with laser diodes.”). A POSITA would have understood that Larsen discloses that *the device* switches between the LEDs and/or laser diodes, *not* that “the five panels are individually configurable to control illumination from each of the five panels” (*i.e.*, “the power output and/or light intensity of each panel can be individually controlled”). EX2050, ¶184.

Fourth, Petitioner argues “[e]ach of the applicators is connected to a control mechanism 16.” Petition, 64 (citing EX1004, [0074], FIG. 1); EX1015, ¶229 (citing FIGS. 1 and 4). However, Larsen shows only *one* control mechanism 16 for the *entire device*, not one control mechanism 16 connected to each of the applicators 13. EX2050, ¶185.



EX1004, FIG. 1. In fact, Larsen consistently depicts and refers to only “*the* control mechanism 16” and not to multiple control mechanisms. See EX1004, FIG. 4, Abstract (“The stand is freely moveable on wheels and includes *a control mechanism...*”), [0027] (“The stand, freely moveable on wheels, consists of *a control mechanism...*”), [0030] (“At least one of the applicator elements is equipped with feedback sensors for controlling the patient's response to the therapy, and via an automatic regulation system in *the control mechanism* it is possible to optimise the therapy results.... *The control mechanism* is also connected with a hand applicator...”), see also [0043], [0069], [0073], [0074], [0079], FIG. 4. EX2050, ¶¶185-186. This is in contrast to the ’028 Patent, which discloses that “each panel may have a dedicated control unit to regulate power to the individual LED array on

a given panel,” and claimed “the five panels are ***individually configurable*** to control illumination from ***each*** of the five panels.” EX1001, 5:57-62, 11:57-58; EX2050, ¶186.

Fifth, Petitioner argues “each applicator is individually configurable, since each one can be adjusted by the controller based on feedback from its own sensors.” Petition, 65; EX1015, ¶230. To allegedly support its argument, Petitioner relies on Larsen’s disclosure that “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.’... 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.’” Petition, 65 (citing EX1004, [0079]-[0080], Figs. 2a-2c); EX1015, ¶230. However, Larsen does not teach or suggest that each applicator 13 is adjusted individually based on the feedback received at the sensors 32. Rather, Larsen discloses that “[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.***” EX1004,

[0079]. Larsen discloses changing the amount of energy emitted *by the device, not* by each applicator 13. EX2050, ¶187.

Sixth, Dr. Grove alleges Fig. 17b has light sources that are “individually controllable” (EX1015, ¶158, fn 5), but Larsen provides no basis to support this conclusory allegation and the Fig. 17b embodiment has only two panels. EX2050, ¶188.

Accordingly, Larsen does not teach or suggest that “the five panels are individually configurable to control illumination from each of the five panels.” Petitioner has not met its burden for claims 16 and 21 (and their dependent claims). EX2050, ¶¶177-189.

E. Larsen Does Not Disclose “Five Panels Connected By Hinged Structures To Allow Continuous Illumination Across The Five Panels” (Claim 16)

Petitioner argues “Larsen discloses five panels connected by hinged structures to allow continuous illumination across the five panels.” Petition, 63-65; EX1015, ¶¶228-231. However, Larsen does not disclose this limitation. EX2050, ¶¶190-191.

First, Petitioner references back to claim 1(a). But, Larsen does not disclose “hinged structures on inner side surfaces of adjacent panels” *See* Section VI.C, *supra*. Because Larsen lacks any such disclosure, Petitioner cannot show Larsen’s

“hinged structures...allow continuous illumination across the five panels.”
EX2050, ¶192.

Second, Petitioner cites Larsen [0027] and [0072] (Petition 64), but these paragraphs contain no teaching or suggestion that Larsen’s “hinged structures...allow continuous illumination across the five panels.” EX2050, ¶193. Indeed, Petitioner’s own expert, Dr. Bretschneider, admitted in the first IPR that Larsen does not provide continuous illumination across the five panels—he stated there are “lower irradiance regions at the junction of two of Larsen’s panels.” EX2082, ¶151. A POSITA would understand that with “lower irradiance regions at the junction” of Larsen’s panels, Larsen does not provide continuous illumination across its five panels. EX2050, ¶193.

Third, Petitioner cannot rely on Larsen’s scan engine for this limitation, because claim 16 requires “***hinged structures*** [to] allow continuous illumination,” not a scan engine. Larsen does not connect hinges 10 to scan engine 66. EX2050, ¶194. Regardless, Larsen’s scan engine does not allow for continuous illumination. *See* EX1004, [0072], Fig. 3; EX2050, ¶¶194-195. As Petitioner’s expert confirmed, Larsen’s “scan engine can only move lights linearly in one direction at a time, which ***would only decrease unradiated gaps on the portion of the treatment surface towards which the light sources are being moved.***” EX2082, ¶154, IPR2024-00874, Paper 1, 18. Larsen’s scan engine “move[s] the

light sources with linear movements” up and down along the longer axis of each of the applicators—the up and down movement on the panels does not affect the gap *between* the panels. EX1004, [0072], Fig. 3; EX2050, ¶¶194-195; *see* Section VI.B, *supra*.

Accordingly, Larsen does not teach or suggest “five panels connected by hinged structures to allow continuous illumination across the five panels.” Petitioner has not met its burden for claims 16 and 21 (and their dependent claims). EX2050, ¶¶190-196.

VII. Ground 2: The Challenged Claims Are Patentable Over Lundahl, Larsen And Bansal

A. Lundahl In View Of Larsen And Bansal Does Not Render Obvious The “Uniformly Illuminate” Limitations (All Claims)

Petitioner argues “Bansal’s teachings are in addition to what Lundahl and Larsen teach, as discussed in Ground 1.” Petition, 73-75; EX1015, ¶¶266-270. Patent Owner incorporates herein the entirety of its response regarding Lundahl and Larsen from Ground 1. *See* Section VI.A.1-3, *supra*. Additionally, for all the same reasons as in Ground 1, Petitioner’s reliance on Bansal’s *separate* reference to the output of light from *Bansal’s phototherapy system* does not inform the POSITA what the output would be for the *combination* of Lundahl, Larsen, and Bansal. *Unigene*, 655 F.3d at 1360; EX2050, ¶¶199-201.

Petitioner presents no supporting evidence or analysis to show the proposed **combination** of Lundahl, Larsen, and Bansal would “irradiat[e] light over the active emitting area such that the measured irradiance at a treatment surface of the patient is at least within 60% of the measured maximum.” Petitioner’s assertion that Bansal teaches the limitations is based on Dr. Grove’s declaration (EX1015, ¶¶266-270), *which contains neither supporting evidence nor analysis by comparison to a maximum “over the active emitting area”* for the proposed combination. Petition, 74-75. Dr. Grove addresses only the *individual* teachings of the references. For the proposed **combination**, Dr. Grove provides no comparison of outputs to the maximum output at the alleged operation distances of “2-4” of the entire treatment surface of the patient.” EX1015, ¶¶125-126. Dr. Grove does not identify what the measured maximum is for the **combination**, nor does he explain how a POSITA would have achieved the same results as Bansal after combining Bansal with Lundahl and Larsen. Petitioner fails to meet its burden of showing obviousness because Petitioner does not explain how the **combination** of prior art references is mapped to the claim limitations under the agreed-to construction or articulate its reasoning for why the subject matter of the claim would have been obvious. EX2050, ¶¶202-203, 119-136; *KSR*, 550 U.S. at 418.

Additionally, for the same reasons set forth above, Petitioner fails to show a POSITA would have had a reasonable expectation of success that the combination

of Lundahl, Larsen and Bansal would “irradiat[e] light over the active emitting area such that the measured irradiance at a treatment surface of the patient is at least within 60% of the measured maximum.” Petitioner has not met its burden for all Challenged Claims. *See* Section VI.A.3, *supra*; EX2050, ¶¶204-205, 137-140.

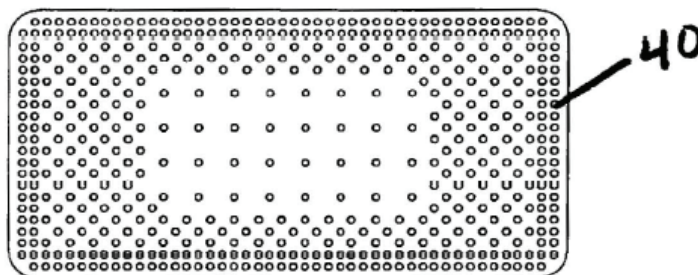
B. Lundahl In View Of Larsen And Bansal Does Not Render Obvious The “Higher Intensity” Limitation (All Claims)

Petitioner argues “Bansal’s teachings are in addition to what Lundahl and Larsen teach, as discussed in Ground 1.” Petition, 73-77; EX1015, ¶¶266, 271-275. Patent Owner incorporates herein the entirety of its response regarding Lundahl and Larsen from Ground 1. *See* Section VI.B, *supra*. Additionally, Petitioner has not shown that Bansal discloses or renders obvious this limitation in combination with Lundahl and Larsen. EX2050, ¶¶206-207. *The Board should find Ground 2 deficient for the same reasons it already determined Petitioner cannot prevail,* namely “Petitioner has not sufficiently shown for institution that Bansal teaches or suggests arranging light sources ‘such that a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges.’” IPR2024-00874, Paper 9, 12-13, 17-18; *see also* Institution Decision, 22.

Petitioner argues Bansal discloses 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” and that “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



Petition, 75-76 (citing EX1005 [0025], claim 10, Figs. 9a-9d); EX1015, ¶272. In addition, Petitioner argues Bansal discloses “*driving the light sources with a lower power in the center and a higher power on the outer edges.*” Petition, 77 (citing EX1005, [0025]-[0026]); EX1015, ¶273. However, none of Bansal’s disclosures teaches the “higher intensity” limitation. EX2050, ¶¶208-210.

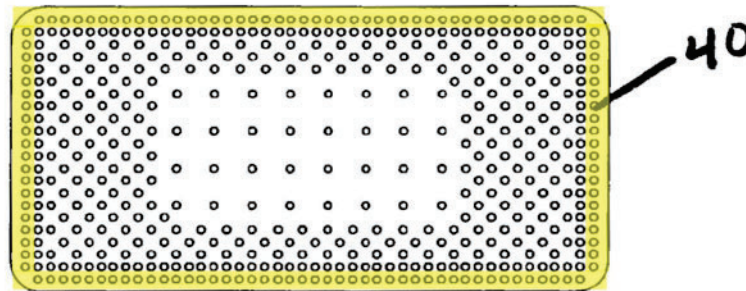
Petitioner fails to consider the requirements of the higher intensity limitation as a whole and instead breaks the limitation into disjointed pieces. Petition, 45-56, 75-77. When the entire claim limitation is read (“wherein each of the five panels has *two first edges and two second edges shorter than 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*”), it is clear the claims distinguish between the shorter second edges and the longer first edges of the panels. In context, the plain language of the claims

requires that the intensity of light emitted *proximate the second edges* be higher than the intensity of light emitted *not proximate the second edges, which includes at least light proximate the first edges*. EX2050, ¶¶210-214; *Phillips*, 415 F.3d at 1314 (“the context of the surrounding words of the claim also must be considered in determining the ordinary and customary meaning of those terms”).

Contrary to the claim requirements, Petitioner admitted “Bansal’s solution provides higher intensity (or density) of lights *around all edges of the panel*.” IPR2024-00874, Paper 1, 18 (citing EX2082, ¶154).⁴ Bansal discloses “*higher density in the periphery* and a lower density in the center” and “lower power in the center and a *higher power on the outer edges*.” Petition, 75-77; EX1015, ¶¶272-273 (citing EX1005, [0025]); EX2050, ¶¶211-212. As shown in Fig. 9b relied on by Petitioner, the intensity of light emitted proximate *both* the second edges *and* the first edges (*e.g.*, shown in yellow below) is higher than the intensity of light emitted in the center of the array. See Petition, 76-77; EX1015, ¶272 (citing EX1005, Fig. 9b).

⁴ Further, Dr. Grove admitted “if a POSA designed a rectangular lamp to be bright *near four edges*, such that the light had equal intensity around the four edges, *it would not meet the [higher intensity] claim limitation*.” EX2036, 123:21-124:13; *see also* EX2084, 63:17-65:2.

Fig. 9b



EX1005, Fig. 9b. Bansal distinguishes between higher intensity (or density) of lights “*around all edges of the panel*” and the center of the panel instead of between the intensity of light emitted proximate the second edges and *not proximate the second edges*, which includes at least light proximate the first edges. Bansal thus fails to disclose “a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges,” as required by the claims. EX2050, ¶¶211-212.

This distinction between the first and second edges is supported by the specification of the '028 Patent. For example, as shown in Fig. 5 below, the '028 Patent distinguishes between areas 1 and 2 (shown in red) proximate the shorter second edges and areas 3 and 4 (shown in yellow) proximate the longer first edges. “[A]reas 1 and 2 emit a higher intensity of light than areas 3 and 4.” EX1001, 6:33-38; EX2050, ¶213.

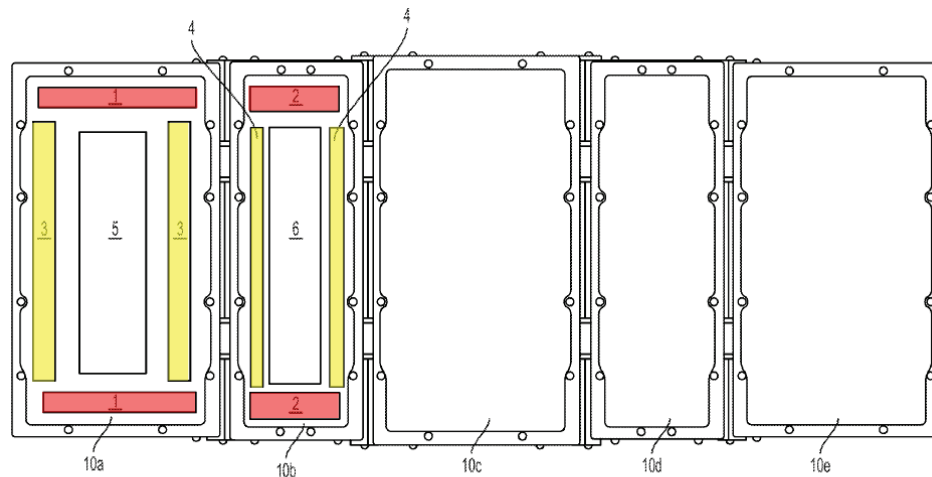


FIG. 5

EX1001, Fig. 5. This is in direct contrast to Bansal’s solution that discloses a higher intensity (or density) of lights “*around all edges of the panel.*” IPR2024-00874, Paper 1, 18; EX2082, ¶154. Petitioner’s reliance on Bansal’s disclosure of higher intensity *around all edges of the panel* is misplaced because both the specification and the claims consistently distinguish between areas proximate the shorter second edges that emit a higher intensity of light than areas proximate the longer first edges. EX2050, ¶¶213-214.

Accordingly, Lundahl in view of Larsen and further in view of Bansal does *not* render obvious the “higher intensity” limitation of the ’028 Patent. Petitioner has not met its burden for all Challenged Claims. EX2050, ¶¶206-215.

C. Lundahl In View Of Larsen And Bansal Does Not Disclose Or Render Obvious The Remaining Limitations

For the remaining limitations, Petitioner merely argues they “are taught for the same reasons provided in Ground 1.” Petition, 73, 77. However, the combination of Lundahl, Larsen, and Bansal does not disclose or render obvious the “hinges,” “individually configurable,” and “continuous illumination” limitations. Petitioner cannot prevail for the same reasons provided for Ground 1. *See* Section VI.C-E, *supra*; EX2050, ¶¶216-224, 163-196.

VIII. All Grounds: Secondary Considerations Support Non-Obviousness

Objective indicia of nonobviousness guard against hindsight reasoning in an obviousness analysis and are often “the most probative and cogent evidence in the record.” *WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1328 (Fed. Cir. 2016). Here, the patentability of the Challenged Claims is supported by strong secondary considerations of non-obviousness. The Petition is deficient for that reason alone. *WBIP*, 829 F.3d at 1328; 37 C.F.R. §42.104(b).

A. The '028 Patented Invention Has Achieved Commercial Success

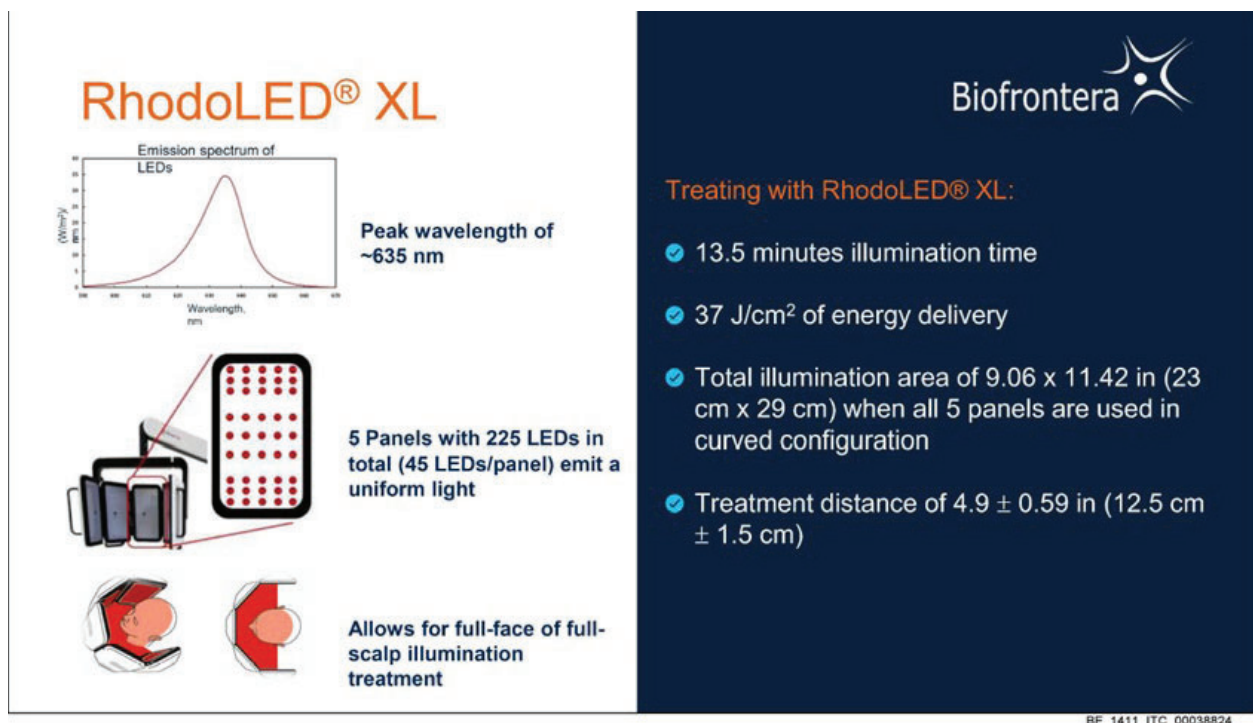
The increased sales of Biofrontera’s RhodoLED® XL and its rapid uptake in the US market compared to its predecessor, the RhodoLED®, demonstrate the commercial success of the claimed invention. EX2048 ¶¶19-33, 43. While the original RhodoLED® does not embody the claimed features of the '028 Patent, the

RhodoLED® XL embodies the claimed features and is coextensive with them. EX2050, ¶¶226-232, Appendix B; EX2038, 127-132; EX2043; EX2056, 2; EX2058, 1; EX2059; EX2060, 1; EX1019. Tellingly, in 2024, Biofrontera sold more RhodoLED® XL devices (marketed with the claimed features) than RhodoLED® devices in just half the time on the market. EX2048, ¶¶27-33; EX2045, 1; EX2046, 1; EX2047, 1; EX2057, 3; EX2064, 1; EX2066, 3, 8; EX2067, 3; EX2068, 2; EX2069, 1-2; EX2078, 1. This commercial success is a result of the combined features of the claimed invention and the benefits enabled by those features. EX2048, ¶¶27-36; EX2050, ¶¶225-226, 230-231, 233-246.

The RhodoLED® XL practices at least exemplary claim 1 of the '028 Patent. EX2050, ¶¶226-229, Appendix B; EX2043; EX2056, 2; EX2058, 1; EX2059; EX2060, 1. In its marketing materials, Biofrontera touts the claimed features of the '028 Patent, including (1) an adjustable five-panel design, (2) uniform illumination of the treatment surface of a patient, and (3) an LED arrangement, which provides for a higher intensity of light emitted proximate the shorter edges of the panels. EX2050, ¶¶228-245. For example, in marketing materials to customers, Biofrontera highlighted how the RhodoLED® XL outputs uniform light to photodynamically treat patients using ALA together with a five-panel illuminator in a curved configuration, where LEDs are arranged on each panel such that there is a higher intensity of light emitted proximate the shorter edges. EX2039, 33:2-16, 36:13-37:9,

37:13-46:21, 48:3-21; EX2040, 1, 5-7; EX2041, 5; EX2043, 7; EX2050, ¶¶233-238.

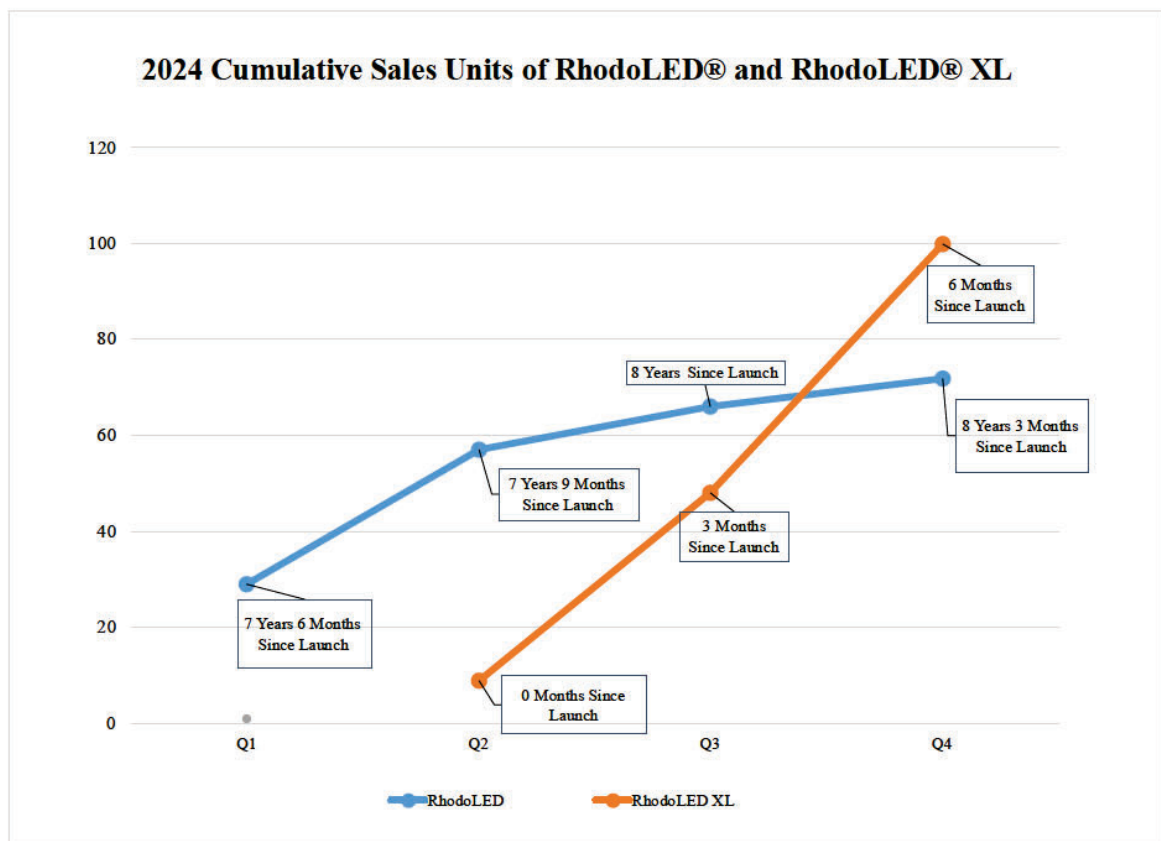
In the marketing presentation below, Biofrontera showcased that the RhodoLED® XL includes “**5 Panels** with 225 LEDs in total” which emits “*a uniform light*,” and includes a graphic that has *all five panels illuminated*, next to the text “[a]llows for full-face o[r] full-scalp illumination treatment.” EX2040, 7; EX2039, 44:18-46:21.



Mark Baldyga, Biofrontera Inc.’s Vice President of Sales and Marketing, confirmed that, in reference to the above presentation, “another one of the features that was advertised with the customer was that the *RhodoLED XL includes five panels with this particular LED arrangement* that we see here.” EX2039, 44:9-45:11. Mr. Baldyga testified that the *purpose of the presentation was to encourage customers to purchase the RhodoLED® XL*. *Id.*, 40:6-11.

Biofrontera also promotes the benefits enabled by the claimed features. According to Mr. Baldyga, the five panels of the RhodoLED® XL are different from the original RhodoLED device and allow for a larger illumination area and healthcare providers appreciate that benefit. EX2039, 46:2-5, 58:15-59:6. In press releases, in marketing materials, and on earnings calls, Biofrontera has touted the enabled benefit of illumination over a larger treatment area. EX2039, 37:13-45:15; EX2040, 7; EX2043, 7, 17; EX2044, 1 (“The new PDT lamp *enables the illumination of larger areas.*”); EX2045, 1 (“[T]he RhodoLED XL offers a *larger illumination area with five panels compared to one*”); EX2046, 1 (“The main difference between the company’s existing BF-RhodoLED lamp and the new RhodoLED XL is the *number of LED panels which allows a larger surface area to be illuminated,*” and touting that customers were impressed by “the *lamp’s robust yet elegant design,*” “*adjustability,*” and a “*larger illumination area*”); EX2057, 3; (“[the RhodoLED XL] provides clinicians with the *ability to illuminate a larger treatment area*”); EX2050, ¶¶233-238, 240-245; EX2048, ¶¶37-45.

Since its launch in June 2024, Biofrontera “has seen rapid uptake in the US market” for the RhodoLED® XL. EX2046, 1; EX2045, 1. Biofrontera sold far more RhodoLED® XL devices (embodying the patented invention) in six months than the original RhodoLED® sold (not embodying the patented invention) in all of 2024.



EX2048, ¶¶27-33; EX2045, 1; EX2046, 1; EX2047, 1; EX2057, 3; EX2064, 1; EX2066, 3, 8; EX2067, 3; EX2068, 2; EX2069, 1-2; EX2070-EX2077. Biofrontera also saw nearly 10% revenue increase in 2024, which Biofrontera stated “was *primarily driven by...the successful launch of our RhodoLED® XL.*” EX2047, 1; EX2055, 6, 51; EX2078, 1; EX2048, ¶30; EX2050, ¶245. Additionally, the 2.5X price premium of the RhodoLED® XL over the RhodoLED® further underscores the commercial success of the RhodoLED® XL as a result of the patented invention. EX2048, ¶¶34-36; EX2050, ¶239; EX2015, ¶¶40-42; EX2049, 10-12; EX2039, 56:19-57:4, 91:2-10, 114:20-22; EX2047, 1; EX2055, 6, 51; EX2078, 1.

Accordingly, the evidence demonstrates commercial success of the claimed invention. EX2048, ¶¶27-46; EX2050, ¶¶226-246.

B. The '028 Patented Invention Has Received Industry Praise

Petitioner's RhodoLED XL has received industry praise as a result of the combined patented features of the claimed invention and the benefits enabled by those features. EX2050, ¶¶247-252. The RhodoLED® XL has been called an "innovative device," "state-of-the-art," and a "considerable upgrade" with "advanced features." EX2045, 1; EX2054, 1; EX2050, ¶¶248-251. In addition to the above, customers have proclaimed, "[w]e were thoroughly impressed by the *lamp's robust yet elegant design*, as well as its exceptional maneuverability and *adjustability*, which made it ideal for Photodynamic Therapy (PDT) treatments in our offices. . . The *larger illumination area* has significantly increased our patient throughput while also enhancing the overall quality of care and patient experience" (EX2046, 1; EX2039, 44:9–45:11, 58:15–59:6), and that "[t]he RhodoLED® XL should be the lamp of choice for PDT" (EX2042, 4).

Additionally, Patent Owner's BLU-U® 4170E, which embodies the '028 Patent, has been praised by the dermatology industry as "a step forward in photodynamic therapy." EX2014; EX2085, 3; EX2079; EX2050, ¶252.

C. Nexus Between The '028 Patent Claimed Invention And The Objective Evidence Of Non-Obviousness

Finally, there is a nexus between the '028 Patent claimed invention and the objective evidence of non-obviousness. EX2050, ¶253; EX2048, ¶¶27-46. The evidence discussed above is the direct result of the combination of features claimed in the claims of the '028 Patent. Biofrontera prominently showcased and received praise for the RhodoLED® XL, which it touted “offers a larger illumination area with five panels compared to one,” “a uniform light,” and “five panels with [the] particular LED arrangement.” It is the claimed combination of features and the benefits enabled by those features that have driven commercial success and garnered praise in the industry. EX2050, ¶¶225-254; EX2048, ¶¶26-46.

IX. Conclusion

For the foregoing reasons, the Challenged Claims are patentable.

Dated: May 21, 2025

Respectfully submitted,

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CERTIFICATION UNDER 37 C.F.R. § 42.24(d)

I hereby certify that this paper, excluding the portions exempted under 37 C.F.R. § 42.24(a), has 13,957 words as counted by Microsoft Word 365, the word-processing system used to prepare this paper.

Dated: May 21, 2025

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CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6(e), the undersigned certifies that on May 21, 2025, a complete copy of the foregoing was served on counsel of record for Petitioner by filing this document through P-TACTS and by sending this document via electronic mail to the following addresses:

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I, Antoine R. Bland, hereby certify that on March 23, 2026, copies of the foregoing were served upon the following as indicated:

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