

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.

DUSA PHARMACEUTICALS, INC.
Patent Owner

Case IPR2024-01312

U.S. Patent No. 11,697,028

PATENT OWNER'S SUR-REPLY TO PETITIONER'S REPLY

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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
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2017	https://www.levulanhcp.com/
2018	https://www.levulanhcp.com/how-to-use

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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/
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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> Investigation No. 337-TA-1411 (Sun Pharma’s Redacted Final Validity Contentions dated December 18, 2024)

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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 https://www.dermatologytimes.com/view/icymi-fda-approves-rhodoled-xl-lamp-red-light-source-for-use-in-actinic-keratosis-treatment

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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-releases/biofrontera-inc-reports-third-quarter-and-nine-month-2024-financial-results-and-provides-business-update , November 14, 2024

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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
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

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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)

I. Introduction

Petitioner's Reply fails to demonstrate that the proposed combination discloses each limitation. **First**, Petitioner has not identified any reference with hinges "on inner side surfaces of adjacent panels," or any evidence rebutting Dr. Jokerst's testimony that a POSITA would have been *discouraged* from placing hinges on those inner side surfaces. **Second**, Petitioner fails to show that the combination renders obvious the "uniformly illuminate" limitations, merely providing hindsight-driven and conclusory arguments about common knowledge. *Visa Inc. v. Cortex MCP, Inc.*, IPR2024-00488, Paper 31 (PTAB 2025), 43-46 (finding Petitioner's combination to be "influenced by impermissible hindsight" because Petitioner did not explain how the elements identified in each reference would work in the proposed combination); *TQ Delta, LLC v. CISCO Sys., Inc.*, 942 F.3d 1352, 1362 (Fed. Cir. 2019) (finding expert's conclusory testimony inadequate). Petitioner claims a POSITA would have known Larsen's LEDs would solve any uniformity problems, but that conflicts with its expert's admission that there are "lower irradiance regions," a contradiction Petitioner fails to ever address. EX2082, ¶151. **Third**, Petitioner cannot rely on Lundahl for the "higher intensity" limitation, at least because there is no disclosure of differing intensities for "each of the five panels." That is, the reference is silent on intensities outside the "active emitting area."

II. The Challenged Claims Are Patentable Over Lundahl And Larsen¹

A. Larsen Discloses Hinges On The Bottom Of Applicators, And Never Suggests Hinges On Inner Side Surfaces.

Petitioner argues Larsen’s disclosure of hinges “connecting one edge with the other” discloses the “hinges” limitation. Reply, 23-24. However, the edges of Larsen’s applicators are connected through hinges at the *bottom* of the applicators. POR, 48-53. Larsen’s express disclosure of “hinges 10” on the bottom of panels in Figure 1 directly contradicts Petitioner’s argument that Larsen’s hinges are on inner side surfaces of the panels. POR, 48-50.²

Petitioner continues to argue that “hinges 10” is a typo and Larsen’s hinges are instead element 20 (Reply, 23-24), 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.” EX2084, 143:18-144:15; POR, 50. Petitioner’s analysis of “hinges” in its Reply includes only attorney argument unsupported by the evidence of record: Dr. Grove does not address this limitation in his supplementary

¹ Petitioner dropped Ground 2. Reply, 2, fn2. Regardless, the Challenged Claims of the ’028 Patent are patentable over Lundahl, Larsen, and Bansal. POR, 65-72.

² Dr. Grove contradicted Petitioner’s identification, admitting that Larsen lacks any disclosure about the hinge structure and testifying that hinges are not visible in Larsen’s Figure 1. EX1031, 563:1-13.

declaration (EX1026). Reply, 23-26. Petitioner repeats its claim that the Examiner's statements endorse its read of Larsen (Reply, 24), but the Examiner's later statements corrected that mistake. POR, 51-52.

After failing to present any evidence of prior art with hinges on the panels' inner side surfaces, Petitioner presents in Reply new obviousness arguments. Petitioner now relies on a POSITA's alleged understanding that "the most logical location for hinges connecting panels" was between the panels and that "it would have been obvious for a POSITA to arrive at hinges located on inner side surfaces" because "the most common option is to put 'hinges between the two panels.'" Reply, 24-25. As an initial matter, these new obviousness arguments are without citation to expert analysis in this proceeding. Instead, Petitioner relies solely on conclusory testimony from another proceeding. Reply, 24-25 (citing EX1031, 592:2-8, 591:5-7, **not** EX1015 or EX1026); *see DSS Technology Management, Inc. v. Apple, Inc.* 885 F.3d 1367 (Fed. Cir. 2019) (conclusory statements cannot close the gaps in the prior art's disclosure); *Juniper Networks Inc. v. Swarm Technology LLC*, IPR2021-01445, Paper 62 (PTAB 2023), 28-29 (citing PTAB Consolidated Trial Practice Guide, 73) ("Petitioner may not submit new evidence or argument in reply that it could have presented earlier, *e.g.* to make out a prima facie case of

unpatentability.”).³ Petitioner’s injection of an obviousness theory allegedly supported by conclusory testimony from a different proceeding, nearly a year after the Petition, proves that its Petition never included this theory; Petitioner’s belated argument should be rejected. *In re Magnum Oil Tools Int’l, Ltd.*, 829 F.3d 1364, 1380–81 (Fed. Cir. 2016) (finding that the Board cannot consider unpatentability theories not raised in the Petition).

In any event, Dr. Jokerst opined, relying on statements from the inventors of the ’028 Patent and ***Petitioner’s own expert***, that a POSITA would have been ***discouraged*** from putting hinges on inner side surfaces of adjacent panels. EX2050, ¶175; EX1032, 765:3-25; EX2052, 88:15-89:1; EX2053, 101:16-102:4; EX2082, ¶151; POR, 55-56. And that testimony stands unrebutted, as Dr. Grove never responds to Dr. Jokerst’s testimony.

³ Moreover, Petitioner is limited to grounds that are “prior art consisting of patents or printed publications” (35 U.S.C. §311(b)), and the Petition “must specify where ***each element*** of the claim is found ***in the prior art patents or printed publications*** relied upon.” 37 C.F.R. §42.104(b)(4); *cf. Qualcomm Inc. v. Apple Inc.*, 134 F.4th 1355, 1365 (Fed. Cir. 2025) (Petitioner’s reliance on applicant-admitted prior art “to ‘supply a missing claim limitation’ to show ‘the general knowledge of a skilled artisan’” violated §311(b)).

Petitioner’s citation to *Teva* is inapplicable because, unlike in *Teva*, there is un rebutted expert testimony and evidence here that a POSITA would have been discouraged from placing hinges on the inner side surfaces of adjacent panels. *See 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); *In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Pat. Litig.*, 676 F.3d, 1072 (internal citation omitted) (“Evidence of obviousness, especially when that evidence is proffered in support of an ‘obvious-to-try’ theory, is insufficient unless it indicates ... *that skilled artisans would have had a reason to select the route that produced the claimed invention.*”).

Accordingly, Larsen does not disclose or render obvious the “hinges” limitation.

B. Modifying Lundahl To Use Larsen’s Panels And LEDs Would Not Have Provided The Required Degree Of Uniformity.

1. No Showing That Combination Achieves Uniformity.

Petitioner asserts that “Patent Owner [(“PO”)] does not dispute that Lundahl teaches uniform illumination” under the agreed-to construction of “uniformly

illuminate....”⁴ Reply at 2-3. However, Petitioner misses the point. Lundahl discloses achieving uniformity using a single-panel device with a precise combination of several components.⁵ Petitioner never shows **combining** Lundahl with Larsen to create a five-panel device that lacks nearly all Lundahl’s components required to achieve uniformity would render obvious the “uniformly illuminate” limitations. POR, 20-29.

“Obviousness requires **more** than a mere showing that the prior art includes separate references covering each separate limitation in a claim under examination”—a POSITA must have “selected and combined those prior art elements in the normal course of research and development **to yield the claimed invention.**” *Unigene Lab’ys, Inc. v. Apotex, Inc.*, 655 F.3d 1352, 1360 (Fed. Cir. 2011). Because Petitioner only addresses Lundahl and Larsen individually with no

⁴ Parties agreed that “uniformly illuminate a treatment surface” and “uniformly illuminating a treatment surface” 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.”” POR, 17-20; Reply, 6; EX2033, 15.

⁵ Though Dr. Grove now claims he “wouldn’t describe [Lundahl] as a single panel” (EX2087, 58:2–12), he previously testified “Lundahl discloses a single-panel fixed U-shaped device.” EX1031, 559:13-15.

analysis of the combination, and because that combination will not “yield the claimed invention” with the required uniformity, its argument fails. POR, 20-30; *see* Petition, 39-42.⁶

2. No “Primary Factor” For Uniformity.

Petitioner argues that Lundahl’s “spacing of light sources is the primary factor in uniformity” (Reply, 3), but Lundahl never discloses or suggests a “primary factor” for uniformity.

To the contrary, Lundahl emphasizes “[a] much higher degree of precision and *integration is required for the components* of the present invention. Output spectrum, irradiance, and *irradiance uniformity all must be controlled* to assure that the properties of the device are suitable to deliver light to the target lesions and drive the photodynamic reaction. To achieve this, *each functional block within the present invention comprises carefully selected and engineered components*” including (1) the U-shaped tubes, (2) the reflector, (3) the electrical control system, and (4) the cooling system. EX1014, 4:12-22; POR, 21-22; EX1031, 575:24-578:7. Indeed, Dr. Jokerst explained that Lundahl’s spacing with LEDs would create gaps at the treatment surface, thwarting uniformity. EX2050, ¶¶127-128; POR, 26;

⁶ PO disputes that Larsen discloses these limitations. POR, 29-30; EX1031, 574:16-20.

EX1032, 765:3-25. Thus, the record reflects that the combination of Lundahl's tube spacing with Larsen's LEDs would not provide the required "uniform illumination." POR, 26; EX2050, ¶¶127-128.

3. No Spacing That Achieves Uniformity.

Originally, Petitioner incorporated Lundahl's uneven spacing of light sources into its combination. Petition, 49; EX1015, ¶¶176-179 (Dr. Grove's original declaration, opining a POSITA would "incorporate the uneven spacing of light sources of Lundahl."); EX2036, 149:24-150:4 (Dr. Grove testifying he is relying on Lundahl's spacing, not Larsen's); POR, 24-26; EX1031, 570:15-19; EX2087, 38:18-40:10. In Reply, Petitioner presents a new obviousness theory, replacing Lundahl's spacing with a POSITA's supposed common knowledge: "a POSITA would have been well aware how to space LEDs ... to eliminate any gaps." Reply, 1, 6-13.⁷

First, Petitioner's belated attempt to substitute a new obviousness argument not articulated in its Petition, especially one that conflicts with its expert's testimony, should be rejected. *Magnum Oil*, 1380–81. **Second**, Lundahl *only* teaches a

⁷ However, in his most recent deposition, Dr. Grove backtracked and confirmed that his analysis relied on Lundahl's spacing. EX2087, 56:19-57:1 ("Q. And here you're discussing how to achieve the uniformity required by the '028 patent *using Lundahl's spacing* and Larsen's disclosure of LEDs; right? A. *Yes.*"), 38:18-41:3.

“*chosen*” spacing, in combination with all other disclosed elements, that achieves Lundahl’s desired uniformity. EX1014, 6:43-45, 8:60-67; EX2087, 39:10-40:4 (Dr. Grove admitting Lundahl provides “specific measurements ... between each of the tubes such as 7 centimeters, 5 centimeters,” etc.). Lundahl never teaches that changing those distances will maintain the uniformity achieved; as Dr. Grove agreed, Lundahl discloses only one set of dimensions for the lateral spacing of lights. EX2087, 39:4-40:10 (“...Q. There are not another set of distances in alternative embodiments in Lundahl that provide different dimensions for the lateral spacing of tubes; true? ... A. Not that I am aware of.”).

Petitioner’s new argument that positioning LEDs to achieve uniformity was within a POSITA’s knowledge is directly contradicted by Dr. Grove’s prior declaration, where he argued that achieving uniform illumination with LEDs would have required “undue experimentation.” POR, 32; EX2034, ¶186; EX1031, 575:3-23. Petitioner now claims Dr. Grove’s contrary position was limited to “the difficulty of providing uniform illumination ... to a patient’s extremities and torso,” not the face. Reply, 13. But that *post hoc* division is artificial: Petitioner’s expert admitted that Lundahl’s illuminator “provides a uniform distribution of visible light for treating the scalp, face, arms, and legs.” EX2087, 34:10-14, 31:20-32:15; EX1014, 1:10-16 (Lundahl is directed to “the scalp or facial areas of a patient” and “other areas of the patient (e.g., arms, legs, etc.).”). Moreover, Larsen is directed to

“large-area tissues such as the human back” and never even mentions the face. EX1004, [0027]. Even further, the ’028 Patent claims are not limited to any particular type of “treatment surface.” *See, e.g.*, EX1001, claim 1. Thus, Petitioner’s new position runs contrary to the evidentiary record.

4. No Uniformity By Chopping Up Single Panel.

Petitioner argues uniformity can be routinely achieved because “this same functionality [of the U-shaped fluorescent tubes] is achieved in a superior way using the adjustable hinged panels taught by Larsen.” Reply, 4. However, Larsen’s panels do not provide the “same functionality” as Lundahl’s continuous U-shaped tubes. When broken into five panels as Dr. Grove proposes, gaps are created between the panels that affect uniformity. POR, 24-25; EX2050, ¶¶126-129; EX2082, ¶151; EX2052, 88:8-89:1; EX1032, 765:3-25; EX2087, 59:20-62:15; EX2088, 199:12-200:14. Petitioner never addresses its own expert’s contradictory testimony, but instead misconstrues PO’s argument that incorporating panels would negatively impact the uniformity as a motivation to combine argument. Reply, 14-15.

Petitioner now contends its combination’s LED panels would not lead to gaps at the treatment surface, but such an argument directly contradicts the evidentiary record. Reply, 14-15; POR, 24-26, 29-30, 32-33. As an initial matter, Petitioner never raised in its Petition that a POSITA could account for gaps created by panels, and thus the new argument should be rejected. *Magnum Oil*, 1380–81. Even so,

Petitioner focuses its arguments only on how the combination could achieve *gap-free* illumination at the treatment surface, which entirely fails to address *uniform* illumination, namely “the measured irradiance at a treatment surface of the patient is at least within 60% of the measured maximum.” As shown in Fig. 7 of the '028 Patent, conventional illuminators achieved gap-free illumination (*i.e.*, no unlit spaces) but failed to achieve uniform illumination such that intensities measured were at least within 60% of the measured maximum.

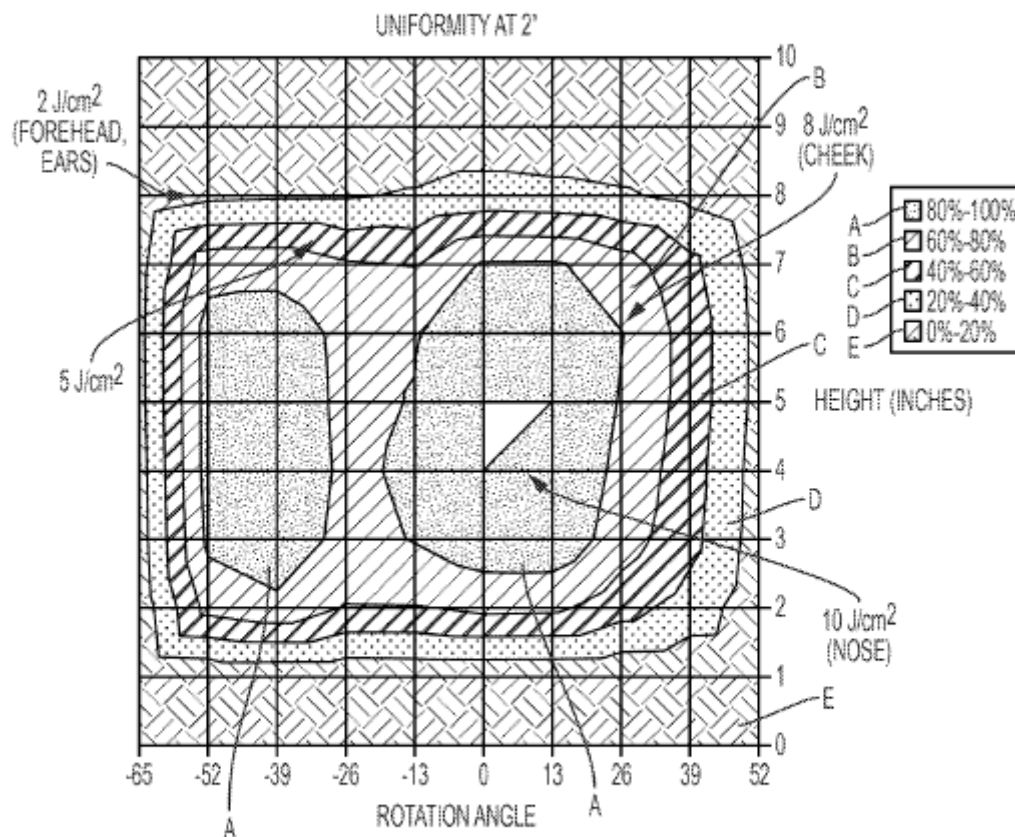


FIG. 7

EX1001, Fig. 7 (gap-free, non-uniform illumination). The inventors solved this exact problem with their claimed invention, shown in Fig. 8.

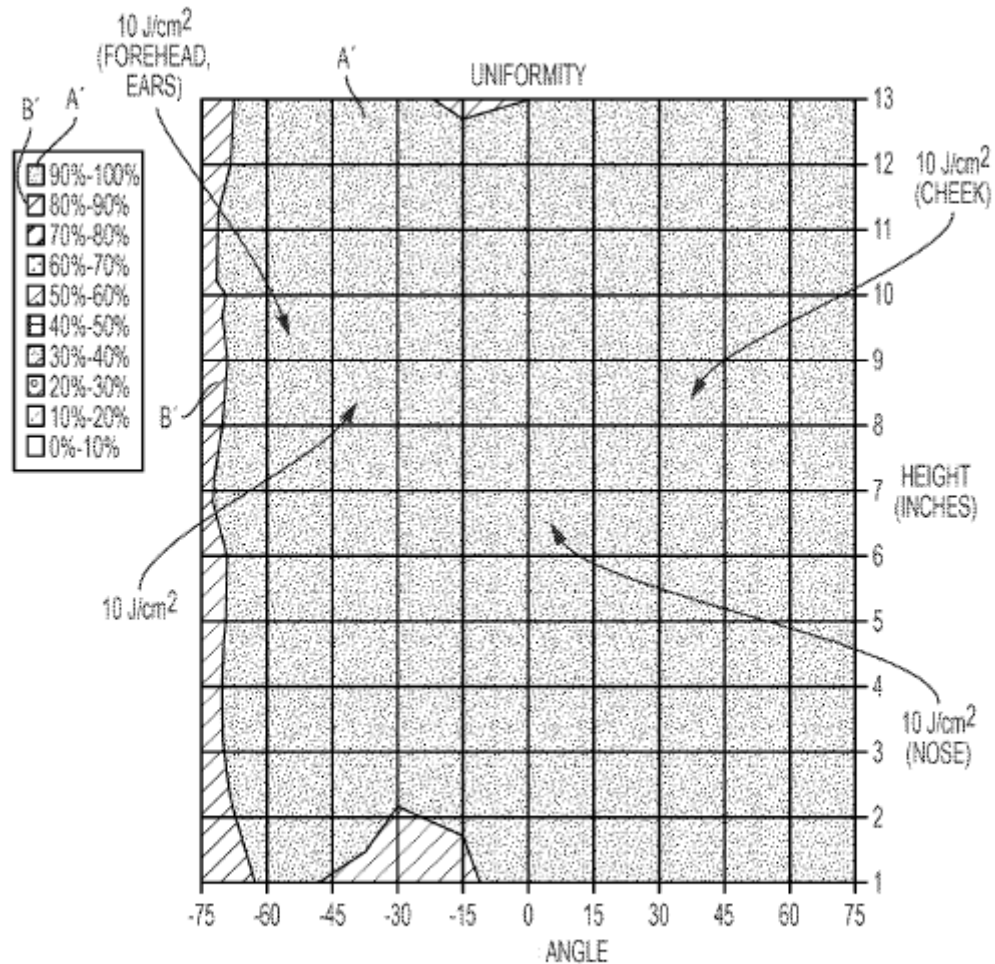
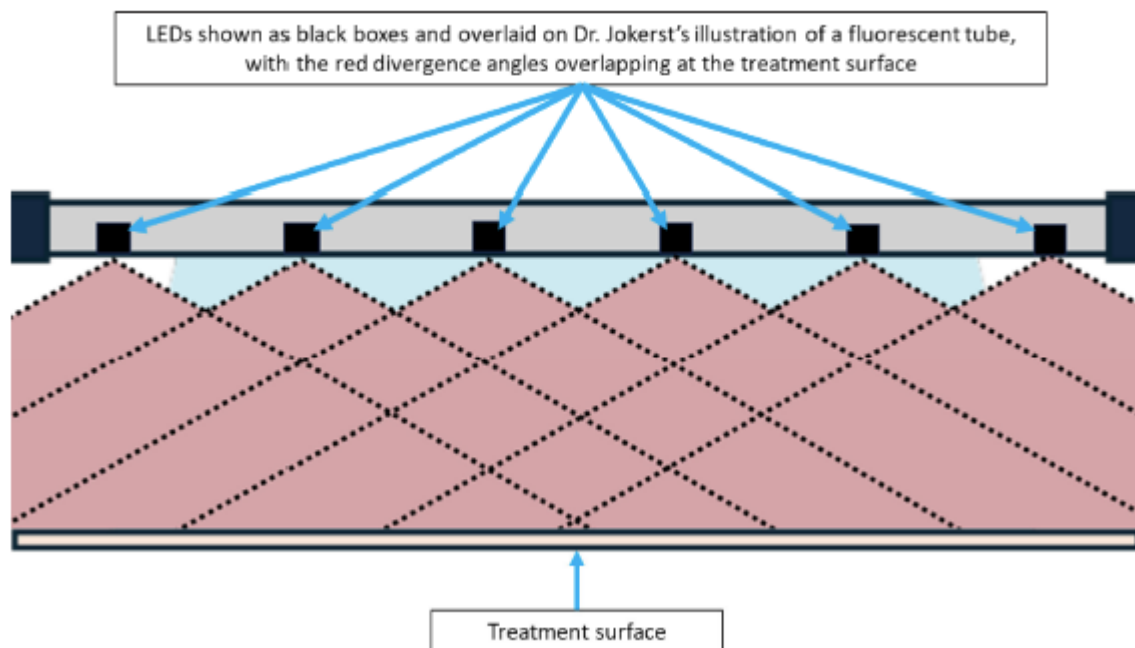


FIG. 8

EX1001, Fig. 8 (gap-free, uniform illumination). *See also* EX1001, 8:17-67; EX2052, 118:13-120:2; POR, 4-7; EX2050, ¶¶49-71.

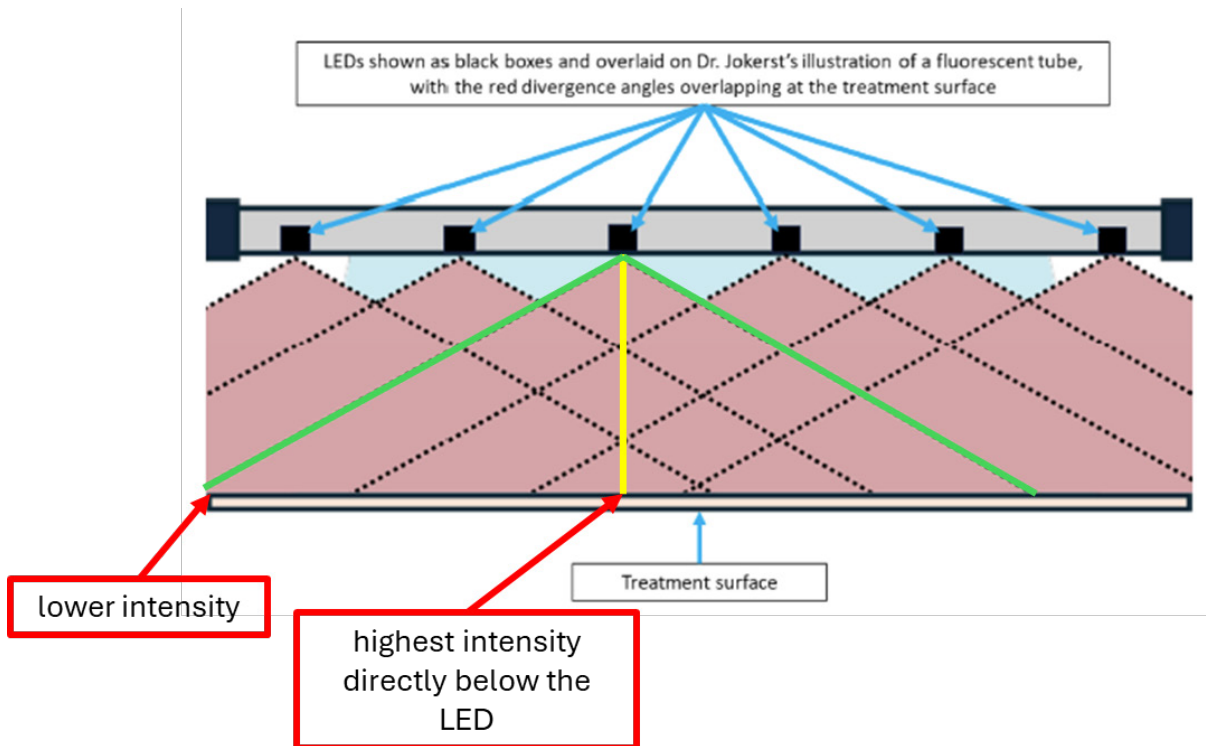
Without support from prior art references, Petitioner again tries to belatedly fill logical holes, arguing (for the first time) a “POSITA would know how to position

the LED light sources” to achieve uniformity and “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.” Reply, 6-13. Petitioner argues “[i]t 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,” as shown in Dr. Grove’s illustration below.



Reply, 10-11; EX1026, ¶¶15-16. However, even if all areas of the surface are illuminated, as Dr. Grove testified, the LED **output** at all angles is **not equal**: the highest intensity is “directly below ... the LED,” but the off-center locations experience decreases in intensity. EX2087, 29:1-30:8 (“...Q. ...The intensity of light can be different at each angle from the LED; right? A. Yes. ***It is, in fact,***

different at each angle with the highest intensity directly below, if you will, the LED. And then the intensity decreases as you move one side or the other, looking back toward the LED.”).



EX1026, ¶¶15-16 (annotated). Petitioner’s graphics—even if accepted—only show no gaps at the treatment surface; they fail to show a POSITA could have achieved the required **uniformity** “over the active emitting area”—even though Dr. Grove claims such an estimate could have been provided. EX2087, 52:22-53:21 (“Q. ...And you haven’t calculated the intensity of light received at the treatment surface in the example you’re providing in figure -- in paragraph 15; true? A. ***I have not calculated it mathematically***, but from the drawing it’s easy to estimate a degree of uniformity. Q. Okay. ***You have not provided an estimate of the degree of***

uniformity for the illustrations you’ve provided in your declaration; right? A. ***No, I have not.***”). Additionally, Dr. Grove only states that his illustrations show how the divergence angles of “LEDs to overlap and prevent any gaps in illumination” – ***not*** that the illustrations demonstrate uniform illumination at a treatment surface, as Petitioner asserts. *Compare* EX1026, ¶16 with Reply, 10-12. Petitioner and Dr. Grove never rebut Dr. Jokert’s analysis showing how the spacing between the rows of LEDs themselves would create gaps. POR, 24-26.

Moreover, those graphics depict a flat treatment surface. However, Dr. Grove agrees that it is more difficult to achieve uniformity when the treatment surface is not flat. EX2087, 55:4-20 (“Q. ...the drawing that you're providing your opinions on in your declaration, that drawing shows a flat treatment surface; right? A. Yes. Q. And in the PDT context, the treatment surface such as a face is often not a flat surface; right? A. True. Q. It’s your opinion that the amount of experimentation and testing necessary to achieve a specific design goal increases when the treatment surface is not flat; right? A. In general, that’s true, yes.”); EX2034, ¶191; EX2084, 66:1-67:14; POR, 19-33.

The evidentiary record here contradicts that a POSITA would have had a reasonable expectation of success. The ’028 Patent inventors testified that achieving uniformity was their biggest challenge when going from tubes to LEDs (POR 33; EX2050, 72-73, 83-85; EX2053, 87:3-89:12, 100:7-12, 100:22-101:15; EX2052,

73:20-74:14); Dr. Grove opined that achieving uniformity requires undue experimentation (POR 32; EX2034, ¶¶186, 191; EX2084, 66:1-67:14; EX2087, 55:8-20); and Dr. Jokerst opined that a POSITA would not have had a reasonable expectation of success in achieving uniform illumination (POR 31-33; EX2050, ¶¶137-140). Both experts agree the output profile of fluorescent tubes and LEDs are very different. POR, 31-33; EX2050, ¶¶137-140; EX1026, ¶¶9, 14, 15; EX2087, 46:21-47:1. Therefore, while LEDs may have certain benefits over fluorescent tubes, there is no evidence that LEDs automatically achieve the claimed uniformity when replacing single-panel fluorescent tubes in a multi-panel system. *See Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1367 (Fed. Cir. 2016) (“[t]he reasonable expectation of success requirement refers to the likelihood of success in combining references to *meet the limitations of the claimed invention.*”).

5. No Hypothetical Modifications Achieve Uniformity.

Petitioner proposes numerous modifications to the design of Lundahl’s system. POR, 22-28. Because Petitioner modifies or removes multiple “carefully selected and engineered components” without addressing the impact on uniformity, Petitioner cannot show the *combination* renders obvious the “uniform illumination” limitations. POR, 28-29.

Petitioner argues that 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.” Reply, 6. As explained above, Petitioner’s new position is inconsistent with its previous positions. For example, Dr. Grove previously conceded his combination uses reflectors (EX2034, ¶265; POR, 26-27) and LEDs require temperature control (EX1015, ¶121; POR, 28; EX1031, 595:16-19). Petitioner never shows how selectively removing components that Lundahl says are integrated to achieve uniformity would still achieve the required “uniform illumination.” POR, 19-33.

Yet Petitioner now argues “reflectors to re-direct the light going away from the intended illumination surface are unnecessary when using LEDs.” Reply, 4. Not only is Petitioner’s new position inconsistent with its previous position (Dr. Grove previously argued the combination would include five reflectors (EX2034, ¶265; POR, 26-27)), but Larsen also expressly teaches LEDs mounted with reflectors. Indeed, Dr. Grove argues Larsen’s LEDs—with reflectors—are used in Petitioner’s combination. EX1004, [0028], [0070], Figs. 2a-2d; POR, 26-27. A POSITA reading both Larsen and Lundahl would not understand that reflectors are “unnecessary.” EX2087, 34:19-38:17.

Petitioner does not contest that Lundahl’s electrical control and cooling systems contribute to the achieved uniformity. EX1031, 576:4-578:7. Nevertheless,

Petitioner argues that “a POSITA would have known that an LED device did not need to utilize Lundahl’s electrical control system” and “a POSITA would not have used Lundahl’s cooling system.” Reply, 5. However, Petitioner never addresses how departing from those systems that Lundahl credits with achieving its uniformity would impact that uniformity. Additionally, Dr. Grove admits that LED output requires temperature control because it is affected by temperature. EX1015, ¶121; POR, 28; EX1031, 595:16-19. LEDs introduce different design challenges than fluorescent tubes, require optimization, and require their own electrical and temperature control systems. EX2050, ¶¶126-128, 138; EX2053, 87:3-89:12, 100:7-12, 100:22-101:15; EX2052, 73:20-74:14; POR, 32-33. Therefore, Petitioner cannot show that the combined device meets the “uniformly illuminate” limitations.

Petitioner’s citation to *PGS* is inapplicable here. Reply, 5. In *PGS*, the dispute was over the motivation to combine references, but there was no dispute that combination taught “all of the limitations of the challenged claims.” *PGS Geophysical AS v. Iancu*, 891 F.3d 1354, 1359, 1363 (Fed. Cir. 2018). Here, however, the references alone and in combination do not teach this limitation. POR, 19-33.

Tyco is also inapplicable. Reply, 7. In *Tyco*, the court did not address reasonable expectation of success, but rather whether an aspect that “would not be ‘particularly useful’” would discourage a POSITA from combining pieces of prior

art. *Tyco Healthcare Grp. LP v. Ethicon Endo-Surgery, Inc.*, 774 F.3d 968, 978 (Fed. Cir. 2014). Here, however, Petitioner argues that the combination still teaches “uniform illumination,” despite removing or modifying every feature Lundahl teaches contributes to uniform illumination.⁸ EX1031, 580:13-581:19. Yet Petitioner did not do any analysis of the combination to support its argument that a POSITA would have had a reasonable expectation of success in achieving uniform illumination. Reply, 7; POR, 31-33. As explained above, Dr. Grove confirmed this lack of analysis. EX2087, 53:11-21.⁹

Accordingly, Lundahl in view of Larsen does not render obvious the “uniformly illuminate” limitations.

⁸ Petitioner claims that LEDs “provide better control of light output characteristics in comparison to earlier technologies like fluorescents.” Reply, 7 (citing EX1015, ¶129). However, in EX1015, ¶129, Dr. Grove never says LEDs have “better control of light output,” only that fluorescent tubes were known to have inconsistent output.

⁹ In *Acorda*, the only claimed result was “to improve walking.” *Acorda Therapeutics, Inc. v. Roxane Lab'ys, Inc.*, 903 F.3d 1310, 1329 (Fed. Cir. 2018). Here, the claims require a specific level of uniformity that Petitioner has not shown the combination achieves.

C. Lundahl Does Not Support Emission Outside Active Emitting Area.

Petitioner focuses on PO's invocation of "areas of lower output (known as Faraday dark spaces). POR, 33-38." Reply, 1. But that mischaracterizes PO's argument. Petitioner cannot show that its combination has higher intensity proximate the second shorter edges for *all* five panels because it has *no support* for the degree of intensity found for the panels *outside of Lundahl's active emitting area*. POR, 34-38; EX1014, 5:38-43, claim 15.

First, Petitioner mischaracterizes Lundahl, which never explicitly teaches "increased intensity at the edges corresponding to a patient's forehead and chin." Reply, 19. Dr. Grove admitted Lundahl does not use the terms forehead or chin. EX2087, 46:6-9.

Second, Petitioner apparently concedes that Lundahl only discloses higher intensity at the top and bottom within the "active emitting area." However, Petitioner argues that "Dr. Jokerst's description of the dark areas of the fluorescent tubes is exaggerated," arguing that "Lundahl describes the above dimensions as the 'minimum' active emitting area, meaning that the actual 'active emitting area' may be much larger." Reply, 16-18. But Lundahl teaches only one "active emitting area" that is approximately "30 cm high by 46 cm wide." EX1014, 5:38-46, claim 15, 6:10-30, 15:22-27; EX1032, 752:1-753:3. Lundahl never discloses a larger active

emitting area. EX2087, 43:2-46:5 (“...Q. Lundahl does not disclose any intermediate area between the maximum total emitting area and the minimum therapeutically active emitting area; true? A. Not that I’m aware of, no. ...”). And, in any event, Petitioner still hasn’t shown the **combination** of Lundahl and Larsen would have higher intensity on **each** of the five panels as the claims require. EX1032, 750:9-751:10, 753:4-756:1. Petitioner’s citation to *American* is inapplicable here. Reply, 17. In *American*, the prior art **taught** to vary size. *Am. Infra-Red Radiant Co. v. Lambert Indus., Inc.*, 360 F.2d 977, 987 (8th Cir. 1966). Here, Lundahl only teaches **one size** of the active emitting area.

Third, Petitioner’s argument regarding dermatologists’ use of BLU-U®’s arms is irrelevant and conflicts with Lundahl’s disclosure. Reply, 18-19. Petitioner did not—and cannot—rely on the BLU-U® **system** in its obviousness combination. Instead, Petitioner chose Lundahl, which expressly teaches that “[o]**nly** the more uniform center portion of the tube output is used for patient treatment.” EX1014, 6:21-22. Lundahl’s arms 10B (in Fig. 5B) are **outside** the active emission region by Lundahl’s dimensions and are expressly taught as **not** used for patient treatment. EX1014, FIGS. 4A, 5B, 5:44-46, 6:21-22; POR, 34-38.

Fourth, regarding the impact of Larsen’s scan engine on the combination, Petitioner attempts to isolate its reliance, claiming it “merely cited the scan engine for the proposition that Larsen also taught the benefits of uniform light

distribution....” Reply, 22. However, Petitioner explicitly relied on Larsen’s scan engine for the “uniform illumination” limitation (Petition, 41), found in every independent claim alongside the “higher intensity” limitation. Petitioner cannot include an element in its combination for one element of a claim and remove the element from its combination for another element of the same claim. *See Application of Wesslau*, 353 F.2d 238, 241 (C.C.P.A. 1965) (“It is impermissible within the framework of section 103 to pick and choose from any one reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art.”). Petitioner argues that Dr. Jokerst’s scan engine illustration and related arguments are “a construct that is unsupported by any evidence.” Reply, 22-23. However, Petitioner takes Dr. Jokerst’s testimony out of context and disregards the teachings of the references as a whole: Dr. Jokerst’s illustration represents **Petitioner’s** proposed combination of Lundahl and Larsen, and therefore follows Dr. Grove’s LED spacing. EX2050, ¶¶150-152 (“...In Dr. Grove’s alleged resulting device, which ‘maintain(s) the same light distribution pattern Lundahl utilized for the fluorescent bulbs,’ a POSITA reading Larsen would have understood that the scan engine moves the light sources up and down with linear movements Therefore, a POSITA would have understood that **the light sources in Dr. Grove’s alleged resulting device** are arranged such that a lower

intensity of light is emitted proximate the second shorter 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...”); EX1032, 757:16-760:13 (“....A. So *I did not use Larsen's regular row arrangement of LEDs and lasers, of emitters. I used Dr. Grove's sort of made-up array of -- or arrangement of light sources.* And so I'm showing the scan engine, how the scan engine would move that printed circuit board up and down inside the applicator as indicated by Larsen....”); *see* EX1015, ¶¶178-179. Larsen discloses that the scan engine moves the light sources up and down with “linear movements” when “in front of” the patient. EX1004, [0072]-[0073]; EX1032, 757:16-758:11. Lundahl and Larsen also both disclose that treatment occurs over time. EX1014, 1:39-59 (incorporating Kennedy by reference); EX1004, [0122] (“...irradiation takes place for 30 minutes.”).

Accordingly, Lundahl in view of Larsen does not render obvious the higher intensity limitation.

D. Larsen Never Discloses Adjusting Each Panel’s Output, As Required By The Individually Configurable Limitation.

Petitioner cites new disclosure from Larsen that was not in the Petition or Dr. Grove’s declaration. Reply, 26-27 (citing EX1004, claim 5). Petitioner additionally cites disclosure from a background reference, attempting to fill holes in its deficient

Petition. Reply, 27 (citing EX2011, 2). Petitioner's belated attempts to rely on Larsen's claim 5 and EX2011 should be rejected. *Magnum Oil*, 1380–81.

First, Dr. Jokerst's testimony refuting Larsen's disclosure is un rebutted: Dr. Grove's supplemental declaration, EX1026, does not address "individually configurable," and Petitioner makes only attorney arguments unsupported by expert testimony and the evidentiary record. *See DSS Technology Management*, 1367; 35 U.S.C. §311(b); 37 C.F.R. §42.104(b)(4); *cf. Qualcomm*, 1355, 1365.

Second, Petitioner's new argument conflicts with Larsen's disclosure, which only ever adjusts the device's output **as a whole**. POR, 59-63. Claim 5 states only that "light sources are individually selected—switched ON or OFF." EX1004, claim 5. As recited in claim 1, from which claim 5 depends, the applicators can have both "semiconductor diode[s] and/or ... laser diode[s]." EX1004, claim 1, [0079]. Larsen discloses a single switch-select system that activates either semiconductor diodes or laser diodes across all panels, **not** independently controlling individual panels. EX1004, [0074] ("With the help of the control mechanism 16, **the invented device is adjustable** ... so that the semiconductor diodes 17, 17a and 18, as well as laser 17 diodes with the same realisation as semiconductor diode 17, can be used as light sources. For that purpose the control mechanism is equipped with a **switch select system for operating different types of semiconductor diodes 17 and/or with laser diodes.**").

Petitioner argues “a POSITA would understand that a single controller can control multiple individual LEDs,” relying on a newly cited portion of a background reference. Reply, 27 (citing EX2011, 2). However, EX2011 does not relate to Larsen, does not teach controlling individual panel output, and contradicts Larsen’s express disclosure of adjusting “the invented device” as a whole. Petitioner’s expert never applied EX2011 to this limitation. See EX1015, ¶¶228-231, 262.

Accordingly, because Larsen never discloses individually controlling the LED output on a panel-by-panel basis (POR, 56-63), Larsen does not disclose or render obvious this limitation.

E. Larsen’s Gaps Between Applicators Do Not Disclose Or Suggest Continuous Illumination.

Petitioner improperly conflates “*continuous* illumination” with “*uniform* illumination.” Reply, 28. As explained in Section II.B, “gap-free” illumination does not imply uniformity.

Petitioner presents a new argument that could have been (but was not) presented in its Petition, now arguing that 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.” Reply, 28. Petitioner’s belated attempt to rely on another new obviousness argument not in its Petition should be rejected. See *Magnum Oil*, 1380–81.

Petitioner's new argument runs contrary to the evidentiary record. As explained in Sections II.B and II.A, multi-panel devices create gaps between the panels. EX2050, ¶¶175, 193-195; POR, 64-65; EX1032, 765:3-25; EX2082, ¶151; EX2052, 88:8-89:1; EX2053, 101:16-102:4; EX2087, 59:20-62:15; EX2088, 199:12-200:14; POR, 63-65.

Accordingly, Larsen does not disclose or render obvious the “continuous illumination” limitation.

III. Secondary Considerations Support Non-Obviousness

Petitioner does not provide any expert testimony to rebut Dr. Jokerst and Dr. Vander Veen's analyses of secondary considerations.¹⁰ Petitioner does not contest that the RhodoLED®-XL embodies the Challenged Claims, or that the RhodoLED®-XL has sold more units from launch as compared to the cheaper

¹⁰ Petitioner attacks Dr. Vander Veen's credibility because he himself did not determine whether the RhodoLED®-XL embodies the Challenged Claims and relied on information from Dr. Jokerst. Reply, 31. However, Dr. Vander Veen's economic analysis incorporated his discussion with Dr. Jokerst about her analysis of “what features of the product were enabled by the '028 patent.” EX1029, 24:14-25:1, 37:17-22, 16:15-17:1, 20:21-23:7, 52:18-53:7.

RhodoLED®. The RhodoLED®-XL embodies the Challenged Claims, including claims 1 and 16. POR, 72-73 (citing EX2050, Appendix B; EX1019).

There is nexus between the Challenged Claims and both commercial success and industry praise because each is undisputably tied to an illuminator including five panels, uniform illumination of the treatment surface, and an LED arrangement providing higher intensity of light emitted proximate the shorter edges. POR, 78.

Contrary to Petitioner's characterization, the record includes multiple instances of industry recognition specifically tied to the patented features, namely the enhanced illumination field, improved maneuverability, and flexible configuration. EX2054, 1; EX2045, 1-2; EX2042, 4; EX2046, 1 (dermatologist noting RhodoLED®-XL's "larger illumination area has significantly increased our patient throughput"). These are precisely the features that distinguish the claimed invention from the prior art and are absent from Lundahl and Larsen individually or in combination. RhodoLED®-XL was specifically developed to address limitations of the original RhodoLED®, which could not adequately treat larger surface areas. EX1033, 311:4-10; EX1030, 120 (citing testimony from Luebbert "admitting that '[i]n the 2015 to 2016 time frame...there was an unmet need for a PDT lamp with a larger treatment area in the market.'"). Because the RhodoLED®-XL is coextensive with the Challenged Claims, a presumption of nexus applies. *WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1329-30 (Fed. Cir. 2016). Petitioner's reliance on unclaimed

features (e.g., touch screens, casters, or distance sensors) ignores that the record demonstrates customer purchasing decisions were driven by the patented illumination and panel configuration, not incidental add-ons. EX1029, 38:15-39:14, 46:22-52:17; EX2048, ¶27. Moreover, some of these features, including casters and touch screens, are found in both the RhodoLED® XL and RhodoLED®, and would not motivate a customer to spend twice as much money on the RhodoLED® XL. EX1033, 295:20–297:24.

A. Commercial Success

Petitioner’s dismissal of commercial success because Biofrontera’s CFO described revenue as “flat” is both selective and misleading. Biofrontera’s financial disclosures show that RhodoLED®-XL surpassed 100 units placed by the end of 2024. EX2057, 3; EX1033, 310:10–310:19. RhodoLED®-XL sales, over \$1million to date, contributed to a 9.5% revenue increase and drove record quarterly revenues in late 2024 and early 2025. EX2047; EX2048, ¶30; EX2057, 3. That the device may not have met Biofrontera’s most ambitious internal projections is irrelevant. Courts have repeatedly rejected reliance on unmet projections to negate commercial success. *See Dey, L.P. v. Teva Parenteral Medicines, Inc.*, 6 F. Supp. 3d 651, 679 (N.D.W. Va. 2014); *Pfizer Inc. v. Mylan Pharms. Inc.*, 71 F. Supp. 3d 458, 476 (D. Del. 2014). Instead, the proper comparison is with other products in the PDT market. Despite selling at more than double the price of the prior RhodoLED®, the

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

B. Industry Praise

Petitioner claims PO only cites “elegant design” and “maneuverability” as unrelated to the '028 Patent, but ignores record evidence of industry recognition directly tied to patented features. Multiple dermatologists and providers specifically praise clinical benefits of the larger illumination field and flexible panel configuration of the RhodoLED®-XL, which are features enabled by the patented combination. EX2054, 1; EX2045, 1-2; EX2046, 1.

IV. Conclusion

For the foregoing reasons, the Challenged Claims are patentable.

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

Dated: September 24, 2025

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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 5,597 words as counted by Microsoft Word 365, the word-processing system used to prepare this paper.

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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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