

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 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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	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	"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
2053	Excerpted Deposition Transcript of Thomas Boyajian in ITC Inv. No. 337-TA-1411, taken December 10, 2024
2054	"FDA Approves RhodoLED XL Lamp Red Light Source for Use in Actinic Keratosis Treatment," Dermatology Times, dated July 2, 2024

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	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-

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	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]

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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,</i> affecting uniformity.” 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.

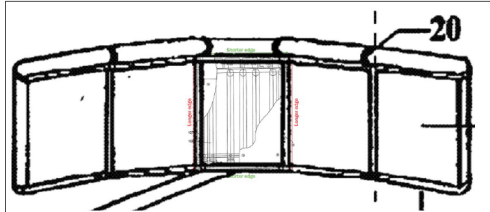
	“Biofrontera acknowledges hinged panels would introduce gaps ... Moreover, <i>introducing gaps would destroy Lundahl’s goal of uniform illumination</i>, undermining any motivation for flexibility....” ID, 120.
“<i>[R]eplacing</i> Lundahl’s diffuse <i>fluorescent tube</i> illuminators <i>with</i> discrete, point-source <i>LEDs would also create gaps</i> between the LEDs, impacting the uniformity.” POR, 24.	“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.
“<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.	“<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.

“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.	“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.
“Dr. Grove argued a ‘<i>POSA would be required to perform <u>undue experimentation</u> to make and use an illuminator that provides “uniform illumination.”</i>’” POR, 32.	“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.
“<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.	“<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.
“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.	“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

	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.
“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 would be more light sources in the center portion of each panel than near the shorter edges of each panel.” POR, 40-41.	“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.
“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	“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. “...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.

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.	“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. “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.
“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.

<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.	‘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.
“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	“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.
<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. <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>	<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.

<i>the panels’ wiring, and create issues with the use and alignment of the PDT panels</i> —all of those issues would frustrate the goal of providing uniform illumination.” 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.	“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, <i>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,

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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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