

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 REQUEST FOR DIRECTOR REVIEW
UNDER 37 C.F.R. § 42.75

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Patent Trial and Appeal Board
U.S. Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

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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

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2017	https://www.levulanhcp.com/
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
2091	Patent Owner’s Demonstratives
2092	Notice Of A Commission Determination Requesting Additional Briefing From The Parties; Extension Of The Target Date, dated March 5, 2026 filed in ITC Investigation No. 337-TA1411
2093	Complainant Sun Pharmaceutical Industries, Inc.’s Submission In Response To Commission’s Notice Requesting Additional Briefing, dated March 12, 2026 and Complainant’s responsive briefing on this issue filed on March 19, 2026, filed in ITC Investigation No. 337-TA1411
2094	Respondent Biofrontera Inc., Biofrontera Pharma GmbH, Biofrontera Bioscience GmbH, and Biofrontera AG’s Response To The Commission’s Request For Additional Briefing, dated March 12, 2026 and Respondent’s responsive briefing on this issue filed on March 19, 2026, filed in ITC Investigation No. 337-TA1411
2095	Respondent Biofrontera Inc., Biofrontera Pharma GmbH, Biofrontera Bioscience GmbH, and Biofrontera AG’s Petition For Review Of The Initial Determination Finding Violation Of Section 337, dated November 17, 2025, filed in ITC Investigation No. 337-TA1411
2096	Respondent Biofrontera AG, Biofrontera Bioscience GmbH, Biofrontera Pharma GmbH, and Biofrontera Inc.’s Pre-Hearing Brief, dated May 23, 2025, filed in ITC Investigation No. 337-TA1411

EX #	DESCRIPTION
2097	Respondent Biofrontera AG, Biofrontera Bioscience GmbH, Biofrontera Pharma GmbH, and Biofrontera Inc.'s Post-Hearing Brief, dated July 21, 2025, filed in ITC Investigation No. 337-TA1411
2098	Respondent Biofrontera AG, Biofrontera Bioscience GmbH, Biofrontera Pharma GmbH, and Biofrontera Inc. Responsive Post-Hearing Brief, dated August 4, 2025, filed in ITC Investigation No. 337-TA1411

I. Introduction

Patent Owner Sun Pharmaceutical Industries, Inc. (“Sun” or “Patent Owner”) respectfully requests Director Review of the Board’s Final Written Decision (Paper 53) (“FWD”) in IPR2024-01312. The Board’s FWD finding claims 1, 2, 4-6, 16, 17, and 19-21 (the “Challenged Claims”) of U.S. Patent No. 11,697,028 (the “’028 Patent”) unpatentable as obvious implicates (a) erroneous conclusions of law, (b) erroneous findings of material fact, and (c) important issues of law or policy that warrant Director Review. 37 C.F.R. § 42.75(a); Director Review Process § 2(B)(ii).

II. The Board Deviated From The Agreed-Upon Construction And Improperly Broadened The Construction Of “Uniformly Illuminate” In Three Separate Ways

The FWD did not expressly construe any claim term, and asserted that the FWD is “not inconsistent with the claim constructions set forth in the ID.” FWD, 13, fn. 7. That is incorrect. The FWD improperly included three key implicit constructions of the “uniformly illuminate a treatment surface” / “uniformly illuminating a treatment surface” claim terms (the “‘uniformly illuminate’ terms”) that critically and improperly broadened the scope away from the agreed-upon 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.” Paper 14 (“POR”), 17-19; EX2033, 15; EX2090, 26.

First, the Board held that “the recited ‘treatment area’ is unspecified, and therefore *includes very small and/or flat areas of a patient’s body.*” FWD, 27. But this is a construction-of-a-construction that neither the parties—nor the ITC—ever considered. “Uniformly illuminate” requires uniformity when *all five panels* are used. *See, e.g.,* EX1001, claim 1 (“an *illuminator comprising five panels... the illuminator* being configured to uniformly illuminate a treatment surface”). Nonetheless, the Board improperly found that the limitation can be met “for a small, flat treatment area covered *by a single panel (which is all the claim requires).*” FWD, 28. Not only is the Board’s understanding inconsistent with the claim language itself, it is inconsistent with the stated purpose of the patent itself. *See* EX1001, 2:7-64 (contrasting conventional illuminators being limited to treatment of “acne” in which “uniformity of light across the target area during a given treatment is less of a concern” against the claimed illuminator that eliminates “optical dead space that can occur at or near the hinges of conventional adjustable illuminators” to “deliver a uniformity of light across various areas of a patient’s body, such as a patient’s extremities (e.g., arms and legs) or torso, in addition to a patient’s face and scalp”).

Indeed, Biofrontera premised its non-infringement arguments at the ITC on the understanding that the agreed-upon construction must be satisfied when *all five panels* are used. *See, e.g.,* EX2097, 29 (“Consistent with the plain and ordinary

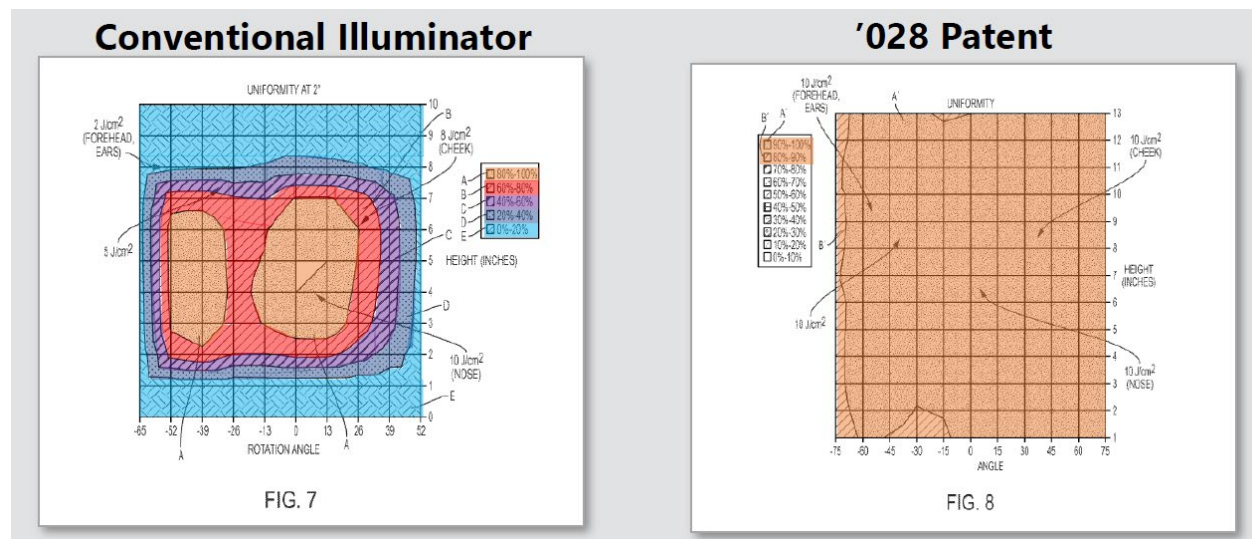
meaning of this phrase, light sources disposed on all of ‘the at least five panels’ must be used to ‘uniformly illuminate a treatment surface.’ The use of fewer than five panels to uniformly illuminate a patient does not infringe.”) (citations omitted); EX2095, 99 (asserting that Biofrontera’s recommendation to use only three panels to treat a patient “does not infringe”). “The Board’s claim construction rules are designed to ensure that the Board correctly construes claim terms and to *minimize inconsistency in claim construction between forums*. ... To that end, the rules *discourage petitioners from seeking broader constructions at the Board to support a patentability challenge while seeking narrower constructions in litigation to avoid infringement liability*.” *Revvo Techs., Inc. v. Cerebrum Sensor Techs., Inc.*, IPR2025-00632, Paper 20 (Dir. Rev. Nov. 3, 2025) (precedential), 4 (internal citations omitted). But ironically, the Board’s FWD allows such gamesmanship to play out here between the two proceedings by adopting a construction that is even broader than the one advanced by the Petitioner at the ITC and making it easier to find unpatentability.

Second, the Board held the “uniformly illuminate” terms to be a “functional limitation” requiring that “the combination [of Lundahl and Larsen] is [merely] ‘capable of’ uniformly illuminating a treatment area.” FWD, 27. When a claim term is interpreted as a functional limitation, it is often viewed as a broad claim term because the claim may encompass all means or methods of meeting the required

“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.” *Application of Swinehart*, 439 F.2d 210, 213 (Cust. Ct. 1971) (“‘Functional’ terminology may render a claim quite broad. By its own literal terms a claim employing such language covers any and all embodiments which perform the recited function.”). Yet, the Board provided no explanation whatsoever why this claim term—which had an agreed-upon construction by the parties—suddenly warranted treatment as a functional limitation, a position neither party advanced. This is yet another clear error by the Board. *See, e.g., Kohler Co. v. Delta Faucet Co.*, IPR2024-00700, Paper 35 (Dir. Rev. Jan. 16, 2026), 3-4 (vacating-in-part the FWD and remanding to the Board because “although the Board did not expressly construe the disputed limitation..., it appears that the Board implicitly determined that the claim requires a ‘meaningful’ amount of light to be emitted in the required direction and applied that implicit construction...,” that the Board’s “construction was erroneous,” and that the Board “credited an argument that [the parties] did not make.”).

Third, the FWD conflates “uniform” illumination with “gap-free” illumination. Under the parties’ agreed-upon construction, “uniform” illumination requires “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.***” *See, e.g., POR*, 18. This is distinct from a “gap-free” illumination that

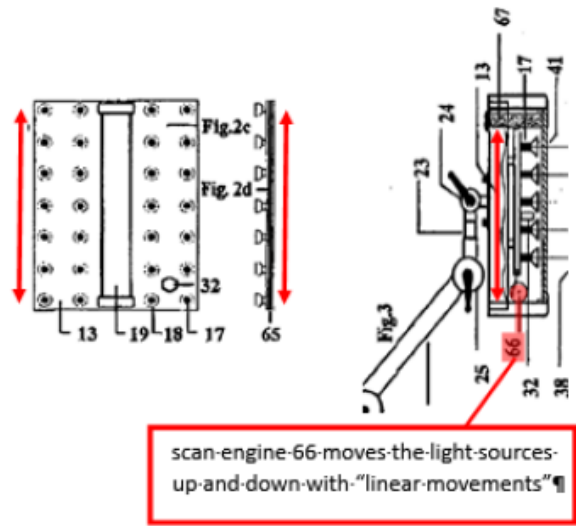
merely requires some light to reach the treatment surface without any gaps. And this different concept is readily illustrated by Figures 7 and 8 of the '028 Patent, reproduced below. Conventional illuminators achieved “gap-free” illumination (*i.e.*, no unlit spaces including purple and blue colored regions on the left) but were not able to achieve “uniform” illumination (*i.e.*, orange and red colored regions on the left and right) throughout the entirety of the treatment surface.



EX1001, Figures 7 and 8; *see also* EX2091, 26.

But the Board conflated the two because the Board held that not only Lundahl, but ***Larsen also independently*** meets “uniform” illumination. FWD, 27 (“We also find that Larsen is configured to provide uniform illumination.”). The Board cites to EX2018, ¶¶151, 154 and EX1004, [0072] as alleged support for why Larsen meets the “uniform” illumination limitation. *See* FWD, 27. But both citations demonstrate the Board’s error. First, EX2018 is not even remotely related to Larsen nor does it

even have ¶¶151, 154. Second, as for EX2004, [0072], as illustrated below, it merely discusses Larsen’s scan engine, which moves the LEDs up and down such that it provides radiation “without leaving any *unradiated gaps*” in the region illuminated by that particular panel. EX1004, [0072].



EX1004, Figures 2c-d, 3; POR, 38-40. While that vertical movement of the scan engine may demonstrate that the particular region illuminated by that single panel may achieve “gap-free” illumination (e.g., with 30% of the measured maximum), there is nothing in Larsen or in any of Petitioner’s analysis that demonstrate “the measured irradiance at a treatment surface of the patient is *at least within 60% of the measured maximum*” is achieved by “the illuminator” “comprising five panels,” as the claim requires. See, e.g., EX1001, claim 1.

The Board’s improper implicit broadening of the scope of the “uniformly illuminate” terms in these three key manners facilitated the finding of unpatentability

over that of the construction agreed upon by the parties. That was legal error and a due process violation and—at a minimum—warrants the FWD be vacated and remanded to the Board.

III. The Board Improperly Credited Arguments That Were Presented After Institution As If Those Arguments Were Presented In The Petition

The Board found that “Petitioner contends that the *combined teachings* of Lundahl and Larsen disclose illuminators with light sources on panels ‘configured to uniformly illuminate a treatment surface.’” FWD, 26 (citing Pet., 39-42). But that is incorrect for two reasons.

First, the Petition only discussed *Lundahl and Larsen individually*. See Pet., 39-42 (“Lundahl teaches ... Larsen teaches... Thus, Lundahl and Larsen teaches the limitations of claim 1(c).”). But “[o]bviousness requires more than a mere showing that the prior art includes separate references covering each separate limitation in a claim under examination.” *Unigene Lab’ys, Inc. v. Apotex, Inc.*, 655 F.3d 1352, 1360 (Fed. Cir. 2011); *see also KSR International Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (“A patent composed of several elements is not proved obvious by merely demonstrating that each of its elements was, independently, known in the prior art.”). The Petition never explains how *the proposed combination*—by (1) replacing the fluorescent tubes of Lundahl with the LEDs of Larsen *and* (2) breaking up Lundahl’s single panel into *five* separate panels that have gaps and hinges between them—

would have achieved the required “measured irradiance at a treatment surface of the patient [] ***at least within 60% of the measured maximum***” under the agreed-upon construction. *See, e.g.*, POR, 19-33; Paper 35 (“Sur-Reply”), 5-19; Paper 42, 1-5. That omission alone renders the Petition deficient. *See ActiveVideo Networks, Inc. v. Verizon Commc'ns, Inc.*, 694 F.3d 1312, 1327 (Fed. Cir. 2012) (finding the claims to be valid because the challenger “failed to explain how specific references could be combined, which combination(s) of elements in specific references would yield a predictable result, or how any specific combination would operate or read on the asserted claims.”).

Second, the Petition never attempted to demonstrate ***how the combined system of Lundahl and Larsen meets the agreed-upon construction*** of “uniformly illuminate”—namely how the “measured irradiance at a treatment surface of the patient is ***at least within 60% of the measured maximum.***” As such, Patent Owner highlighted the Petitioner’s failure to address the agreed-upon construction from the ITC in the Petition. Patent Owner did not stop there. Patent Owner additionally explained that Petitioner’s proposed combination of Lundahl and Larsen would (1) create “gaps” between the panels, (2) create “gaps” between the LEDs, (3) require “undue experimentation,” and (4) relies on hindsight reconstruction. POR, 22-24, 31-33. Petitioner only ***then—after*** Patent Owner pointed out the Petition’s deficiencies—attempted to address the “measured irradiance at a treatment surface

of the patient is at least within 60% of the measured maximum” requirement. *See* Reply, 6-13. The Board then improperly credited Petitioner’s Reply arguments as if those arguments were present in the Petition itself. FWD, 27-29. But those reply arguments cannot cure the deficiencies of the Petition itself. *See Wasica Fin. GmbH v. Cont'l Auto. Sys., Inc.*, 853 F.3d 1272, 1286–87 (Fed. Cir. 2017) (“Rather than explaining how its original petition was correct, Continental's subsequent arguments amount to an entirely new theory of *prima facie* obviousness absent from the petition. Shifting arguments in this fashion is foreclosed by statute, our precedent, and Board guidelines.”). The Board’s adoption of those belated arguments was an abuse of discretion by the Board and warrants vacatur because, even if remanded, the Petitioner would not be able to demonstrate that this limitation was met by the *proposed combination of Lundahl and Larsen*.

IV. Earlier Finding of Validity At the ITC And Petitioner’s Inconsistent Claim Construction Positions Warrant De-Institution

The FWD also implicates important issues of law or policy. When the same arguments were presented in the ITC and every single one of the factual determinations were found in Patent Owner’s favor, the same outcome (*i.e.*, validity of all challenged claims) is justified in the PTAB even under the lower preponderance of the evidence standard. The FWD attempts to justify the contradicting outcomes between the ITC and the FWD (1) based on the assertion

that the Board was able to consider new arguments in the IPR that the ALJ was never able to consider at the ITC and (2) because the two forums have differing burdens of proof. Both assertions lack merit.

A. The Board Substantively Considered The Same Arguments That The ALJ Considered

The FWD asserts that “the record before us includes critical declaration and deposition testimony not before the ITC (*see, e.g.*, Tr. 10:11-14:2; Exs. 1026-1027).” FWD, 4. But the Board’s discussion at FWD, 4 is merely a generic statement, not tied to any specific arguments. Indeed, the Board identifies only ¶¶17-20 and ¶¶22-26 of EX1026 as testimony that was not considered by the ITC in the FWD’s limitation-by-limitation analysis. *See* FWD, 25, fn. 9 and 31, fn. 13. Notably, neither citation provides any critical evidence or arguments that the ITC did not already hear.

First, beginning with EX1026, ¶¶22-26, the table below compares the key arguments presented in EX1026, ¶¶22-26 with the corresponding arguments made by Biofrontera in its pre-hearing brief (EX2096) at the ITC. As shown, the near verbatim arguments were presented to and considered by the ITC.

EX1026, ¶¶22-26	EX2096, 173, fn. 25
“[T]he illustration provided by Dr. Jokerst shows an area of reduced emission that is next to and even in front	“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."	of the ears. ... However, this is not what Lundahl discloses, as Lundahl states that the reduced emission is behind the ears. ... Consequently, Dr. Jokerst's positions on the areas of reduced emission mischaracterize the teachings of Lundahl."
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See also EX2097, 64.

Second, EX1026, ¶¶17-20 does not contain any new evidence that “directly refut[es] Dr. Jokerst’s testimony.” FWD, 25. Indeed, the Petitioner itself admits that this testimony is commensurate with the testimony already heard by the Board and the ALJ. Petitioner argued to the ITC’s Commission that “[a]lthough 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 ..., 74:2-14, 88:15-89:8) regarding parameters they adjusted to reach uniformity... This testimony is before the Commission and should lead to the same conclusion.” See EX2094, 20-21.

In fact, EX1026, ¶¶17-20 itself demonstrates why Biofrontera’s argument has no teeth: EX1026, ¶¶17-20 argues that this “gap” problem is “easily addressed” by pointing to *the ’028 Patent itself as purported evidence of this “common understanding”* of the purported solution. See EX1026, ¶¶18-19. Relying on the patent itself as evidence of obviousness is improper and the Board should never have

credited that testimony. *Univ. of Strathclyde v. Clear-Vu Lighting LLC*, 17 F.4th 155, 167 (Fed. Cir. 2021) (rejecting reliance on “the ’706 patent itself” to support obviousness because “[t]he inventor’s own path itself never leads to a conclusion of obviousness; that is hindsight” (quoting *Otsuka Pharm. Co. v. Sandoz, Inc.*, 678 F.3d 1280, 1296 (Fed. Cir. 2012))).

In other words, contrary to the Board’s assertions, no new “critical” arguments or evidence were presented in the IPR that the ALJ did not hear in the ITC proceeding. Accordingly, the Board’s assertion that the record materially differed from the ITC is unsupported.

B. Director Has De-Instituted IPR Proceedings After ITC’s Initial Determination Despite The Different Burdens Of Proof

The Board’s reliance on the different burdens of proof between the ITC and the PTAB has little teeth given the fact that not only did the ALJ hear substantively identical arguments, but the ALJ also had the benefit of live testimony, which courts have repeatedly found to be significantly more reliable than evidence “from the sterile nature of a proceeding that is limited to documentary and declaration or deposition evidence.” *Streck, Inc. v. Research & Diagnostic Sys., Inc.*, 659 F.3d 1186 (Fed. Cir. 2011). Indeed, the ALJ’s findings should be given great deference “because the district court [or ITC] may observe witnesses under examination and cross-examination, [so] it can have a ‘powerful advantage’ over the Board which

can never receive testimony in such a manner.” *Winner Int’l Royalty Corp. v. Wang*, 202 F.3d 1340, 1347 (Fed. Cir. 2000); *see also Burlington Indus., Inc. v. Quigg*, 822 F.2d 1581, 1582 (Fed. Cir. 1987).

Indeed, Paper 42 identified the factual determinations made by the ALJ that were based on the identical evidence and arguments presented in both this instant IPR and the ITC. *See generally* Paper 42. When every disputed factual issue was resolved in Patent Owner’s favor in the ITC (*i.e.*, a forum that had the advantage of live testimony), the Board should have given deference to those factual determinations, and there is no justification for the Board’s finding of unpatentability even under the lower preponderance of the evidence standard.

The Director, in similar situations, has previously *sua sponte* de-instituted an IPR proceeding when the ITC’s ID involving the same patent, same prior art, and same asserted grounds found that the claims are not invalid. *See, e.g., Sinclair Pharma Ltd. et al. v. Hydrafacial, LLC*, IPR2025-00145, Paper 41. Indeed, the Director has *sua sponte* vacated a FWD and terminated the proceeding altogether because the “Board improperly ignored prior decisions.” *See Verizon Connect Inc., v. Omega Patents, LLC*, IPR2023-01162, Paper 35, 1. Patent Owner requests the same here as well.

C. Director Has De-Instituted IPR Proceedings Because Petitioner Took Inconsistent Claim Construction Positions

The request for de-institution is further warranted because Petitioner took different claim construction positions in the IPR relative to the ITC—without any explanation as to why it is taking inconsistent positions. *First*, in the Petition, Petitioner merely “has taken a view of the scope of the claims consistent with Patent Owner’s infringement allegations,” (Pet., 12), and never addressed how the agreed-upon construction of “uniformly illuminate” was met ***in the Petition itself by the proposed combination*** of Lundahl and Larsen. *Second*, Petitioner contended that the following claim terms are indefinite in the ITC: (1) “a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges,” (2) “photodynamically diagnosing or treating a patient,” (3) “the five panels are individually configurable to control illumination from each of the five panels,” and (4) “within approximately four inches of the treatment surface.” *Compare* EX2033, 16, 26, 37, 43 *with* Petition, 12-13. In other words, Petitioner is engaging in gamesmanship by arguing that the same claim terms have different meaning at the ITC than in the instant proceeding.

Again, the Director, in similar situations, has de-instituted IPR proceedings. *See Revvo Techs.*, Paper 20 (vacating institution by holding that a Petitioner must explain why it takes different claim construction positions in the Petition and in district court; merely adopting a Patent Owner’s district court claim construction is not sufficient); *Tesla, Inc. v. Intellectual Ventures II LLC*, IPR2025-00340, Paper 18

(Dir. Rev. Nov. 15, 2025) (informative) (vacating institution by holding that a Petitioner’s explanation that it could not argue indefiniteness in an IPR is insufficient to show why different claim construction positions are warranted in district court and at the Board). Patent Owner submits that de-institution is also warranted here to ensure no further expenditure of the Board’s resources.

V. CONCLUSION

For the foregoing reasons, Patent Owner respectfully requests that the Director reverse the Board’s Final Written Decision because *the Petition itself* never demonstrated how the *proposed combination of Lundahl and Larsen* meets the agreed-upon construction of the “uniformly illuminate” terms—the Petition merely treated Lundahl and Larsen’s teaching *individually*. At a minimum, Patent Owner requests that the Director vacate the Board’s Final Written Decision and remand the proceeding back to the Board so that the proper and agreed-upon construction of the “uniformly illuminate” terms can be correctly applied.

Finally, for policy reasons, Patent Owner respectfully request the Director to vacate the Institution Decision and terminate the proceeding such that consistency between the ITC and the Board can be maintained and/or because the Petitioner chose to pursue inconsistent claim construction positions across the two different proceedings—precisely the behavior the Director has previously found to warrant de-institution.

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

Dated: March 25, 2026

Respectfully submitted,

/Yung-Hoon Ha/

Yung-Hoon Ha

Reg. No. 56,368

yha@desmaraisllp.com

DESMARAIS LLP

230 Park Avenue

New York, NY 10169

Telephone: 212-351-3400

Facsimile: 212-351-3401

*Lead Counsel for Patent Owner
Sun Pharmaceutical Industries, Inc.*

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 the documents through P-TACTS and by sending via electronic mail to the following addresses:

Lead Counsel	Back-up Counsel
James P. Murphy, Reg. No. 55,474 Polsinelli PC 1000 Louisiana Street, Suite 6400 Houston, Texas 77002 jpmurphy@polsinelli.com	Corey Casey, Reg. No. 66,950 Polsinelli PC 900 West 48th Place, Suite 900 Kansas City, Missouri 64112 ccasey@polsinelli.com Megan Hart, Reg. No. 79,202 Polsinelli PC 7676 Forsyth Blvd., Suite 800 St. Louis, Missouri 63105 mkhart@polsinelli.com Brian Larivee (<i>pro hac vice</i>) Polsinelli PC 100 Oliver Street, Suite 3900 Boston, MA 02110 blarivee@polsinelli.com Kendall Gurule, Reg. No. 77,605 Chad Landmon (<i>pro hac vice</i>) Polsinelli PC 1401 I St NW, Suite 800 Washington, DC 20005 kgurule@polsinelli.com clandmon@polsinelli.com

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Respectfully submitted,

/Yung-Hoon Ha/
Yung-Hoon Ha
Reg. No. 56,368
yha@desmaraisllp.com
DESMARAIS LLP
230 Park Avenue
New York, NY 10169
Telephone: 212-351-3400
Facsimile: 212-351-3401

*Lead Counsel for Patent Owner
Sun Pharmaceutical Industries, Inc.*