

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

v.

SUN PHARMACEUTICAL INDUSTRIES, INC.
Patent Owner.

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

REPLY TO PATENT OWNER'S RESPONSE

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PETITIONER’S EXHIBITS

Exhibit No.	Description
1001	U.S. Patent No. 11,697,028 by Thomas Boyajian et al. entitled “Adjustable Illuminator for Photodynamic Therapy and Diagnosis” (“’028 Patent”)
1002	File History for U.S. Patent No. 11,697,028 provided in Application No. 17/942,353
1003	Reserved
1004	U.S. Patent Publication No. 2005/0075703 by Eric Larsen entitled “Photodynamic Stimulation Device and Methods” (“Larsen”)
1005	U.S. Patent Publication No. 2004/0068305 by Vineet Bansal et al. entitled “Phototherapy System and Device” (“Bansal”)
1006	Reserved
1007	Reserved
1008	U.S. Patent No. 7,033,381 (“Lundahl ’381”)
1009	Office Action dated March 23, 2021, from file history of Application No. 17/009,871
1010	Office Action dated October 25, 2021, from file history of Application No. 16/791,004
1011	WO 99/56827 by Scott Lundahl et al. entitled “Illuminator for Photodynamic Therapy”
1012	Reserved
1013	U.S. Patent No. 11,179,574 by Thomas Boyajian et al. entitled “Method of administering 5-aminolevulinic acid (ALA) to a patient”
1014	U.S. Patent No. 6,223,071 (“Lundahl”)
1015	Declaration of Dr. Robert Grove
1016	Declaration of Dr. Michael Ehrenreich
1017	U.S. Pat. No. 5,079,262 (“Kennedy”)
1018	Complaint filed in <i>Sun Pharmaceutical Industries, Inc. v. Biofrontera Bioscience GmbH, Biofrontera Pharma GmbH, Biofrontera AG, and Biofrontera Inc.</i> , Civil Action No. 1:24-cv-11637 (D. Mass) (filed on June 25, 2024)
1019	Plaintiff’s Infringement Contentions submitted as Exhibit 4 attached to complaint filed in <i>Sun Pharmaceutical Industries, Inc. v. Biofrontera Bioscience GmbH, Biofrontera Pharma GmbH,</i>

Exhibit No.	Description
	<i>Biofrontera AG, and Biofrontera Inc.</i> , Civil Action No. 1:24-cv-11637 (D. Mass) (filed on June 25, 2024)
1020	<i>In Re Certain Photodynamic Therapy Systems, Components Thereof, And Pharmaceutical Products Used In Combination With The Same</i> , Investigation No. 337-TA-1411 (complaint filed on June 25, 2024)
1021	Agostinis et. al., <i>Photodynamic Therapy of Cancer: An Update</i> , <i>CA Cancer J Clin.</i> Author manuscript; available in PMC 2012 July 1 (also published in final edited form at <i>CA Cancer J Clin.</i> 2011 ; 61(4): 250–281)
1022	Levulan® Kerastick® (aminolevulinic acid HCl) for Topical Solution, 20% Initial U.S. Approval: 1999, Revised 3/2010
1023	Michael H. Gold, <i>Therapeutic and Aesthetic Uses of Photodynamic Therapy, Part Two of a Five-Part Series, Lasers and Light Treatments for Acne Vulgaris, Promising Therapies</i> , <i>Journal of Clinical and Aesthetic Dermatology</i> , Vol. 1(3), pp. 28-34 (September 2008)
1024	Declaration of Brian Larivee in Support of Pro Hac Vice Motion
1025	Declaration of Chad Landmon in Support of Pro Hac Vice Motion
1026	Supplemental Declaration of Dr. Robert Grove
1027	Deposition Transcript of Nan Marie Jokerst, Ph.D., taken July 22, 2025
1028	Deposition Transcript of Heather J. Roberts, M.D., FAAD, taken July 25, 2025
1029	Deposition Transcript of Thomas D. Vander Veen, Ph.D., taken July 29, 2025
1030	Complainant’s Post-Hearing Brief (Public Version) filed in <i>In Re Certain Photodynamic Therapy Systems, Components Thereof, And Pharmaceutical Products Used In Combination With The Same</i> , Investigation No. 337-TA-1411 ¹

¹ All exhibits provided from the related ITC proceeding are publicly accessible redacted versions of those filings.

Exhibit No.	Description
1031	Trial Transcript Day 3 (Open Sessions) for <i>In Re Certain Photodynamic Therapy Systems, Components Thereof, And Pharmaceutical Products Used In Combination With The Same</i> , Investigation No. 337-TA-1411
1032	Trial Transcript Day 4 (Open Sessions) for <i>In Re Certain Photodynamic Therapy Systems, Components Thereof, And Pharmaceutical Products Used In Combination With The Same</i> , Investigation No. 337-TA-1411
1033	Trial Transcript Day 2 (Open Sessions) for <i>In Re Certain Photodynamic Therapy Systems, Components Thereof, And Pharmaceutical Products Used In Combination With The Same</i> , Investigation No. 337-TA-1411

I. INTRODUCTION

In its Patent Owner’s Response (POR), Patent Owner relies on a shotgun approach that raises many arguments but fails to provide persuasive evidence supporting these arguments. Most of Patent Owner’s arguments rely on the legally impermissible theory that a POSITA is an automaton incapable of applying ordinary creativity. *KSR Intern. Co. v. Teleflex Inc.*, 550 U.S. 398, 420-21 (2007) (“A person of ordinary skill is also a person of ordinary creativity, not an automaton.”).

For example, Patent Owner argues that the prior art fails to render obvious the “uniform illumination” limitation because Petitioner fails to account for the various “engineered components” discussed in Lundahl that are specific to fluorescent tubes. POR, 21-28. However, a POSITA would not incorporate components for fluorescent tubes into a device using LEDs as in Petitioner’s proposed combination. In addition, Patent Owner argues that using discrete LEDs would result in “gaps” compared to fluorescent tubes (POR, 24), but this overlooks that a POSITA would have been well aware how to space LEDs so that their light output overlaps to eliminate any gaps at the treatment surface.

Likewise, Patent Owner argues that the prior art fails to render obvious the “higher intensity” limitation because the fluorescent tubes of Lundahl have areas of lower output (known as Faraday dark spaces). POR, 33-38. Again, Patent Owner

ignores that eliminating these dark spaces (which are not present in LEDs) was part of the motivation to move away from fluorescent tubes to LEDs.

Moreover, Patent Owner alleges the prior art fails to teach “hinged structures on inner side surfaces of adjacent panels,” based on labeling inconsistencies in Larsen (POR, 48-52), but fails to acknowledge there are only three places that a hinge can be located: between panels, on the top/bottom of panels, and behind the panels, and a POSITA would know that the most common option is to put “hinges between the two panels.” EX1031, 591:5-7, 592:2-8.

These arguments, as well as others raised by Patent Owner in its response, are addressed below.

II. REPLY ON GROUND 1²

A. Lundahl in View of Larsen Renders Obvious the “Uniform Illumination Limitation” of All Challenged Claims

1. A POSITA would not need to use the fluorescent specific components of Lundahl for an LED device.

Patent Owner does not dispute that Lundahl teaches uniform illumination where “the measured output over the active emitting area is within 70% of the

² Petitioner no longer intends to pursue Ground 2 in view of the Board’s findings in IPR2024-00874.

measured maximum” at distances of 2” and 4”, which is greater uniformity than required under the ITC’s claim construction. EX1014, 15:22-27; EX1030, 97; *see* EX2033, 15 (ITC construction). Rather, Patent Owner argues that Lundahl is only able to achieve this uniformity via integration of at least four components specific to fluorescent tubes including: U-shaped fluorescent tubes, fluorescent tube reflectors, a fluorescent tube electrical system, and a fluorescent tube cooling system. POR, 10. This is factually incorrect but also legally irrelevant given that the proposed combination relies on LED light sources rather than fluorescent tubes.

First, Patent Owner’s attempt to elevate the importance of these features to achieve uniformity is contradicted by Lundahl itself, which teaches the spacing of light sources is the primary factor in uniformity. As noted in the Petition, Lundahl explains that “uniformity can also be adjusted by varying the lateral spacing of the tubes.” EX1014, 6:22-30, 6:43-57(“[t]he number of tubes used and the spacing between them were chosen to achieve desired uniformity and power output specifications” with greater density of lighting near the top and bottom edges); EX1015, ¶¶160-162.

Second, the features Patent Owner cites as contributing to uniformity are only needed to solve uniformity issues specific to fluorescent tubes, meaning that they would be rendered unnecessary once fluorescent tubes are replaced by panels with

LEDs as set out for the proposed combination. Each feature is addressed in turn below.

With regards to the U-shaped fluorescent tubes, this same functionality is achieved in a superior way using the adjustable hinged panels taught by Larsen. As explained by Dr. Grove, the combination would utilize Larsen's hinged panels instead of the U-shape fluorescent tubes because the panels can be "individually adjusted to account for variations" in anatomy while "provid[ing] the desired irradiance and irradiance uniformity to all target areas during PDT." EX1015, ¶¶126-127; EX1004, [0072]; EX1027, 35:14-36:5. Consequently, the device formed by combining the design principles of Larsen related to hinged panels and LED lights with the PDT device and light distribution of Lundahl, can provide a U-shape around a patient's face and scalp, contributing to the desired uniformity of illumination. EX1015, ¶¶126-127; EX1027, 31:5-18, 35:3-36:5.

Next, Lundahl provides a reflector positioned behind "the rear surface of the tubes" (EX1014, 8:65-67) because "fluorescent tubes put out light 360 degrees around the circumference of the tube." EX1031, 593:9-22. However, a POSITA would have appreciated that "LEDs put out light in basically one direction." *Id*; EX2050, ¶46; EX1027, 59:12-60:9. Consequently, reflectors to re-direct the light going away from the intended illumination surface are unnecessary when using LEDs.

Similarly, Lundahl discloses an electrical control system tailored to address flaws in fluorescents. EX1014, 7:11-8:59. This electrical system is necessary in Lunahl because “[f]luorescent tubes, being gas discharge devices, are particularly sensitive to the electrical voltages and currents used to drive them.” EX1014, 7:14-31. In contrast, as Dr. Jokerst admits, a POSITA would have been aware that LEDs “do not face the same [electrical] challenges as fluorescent tubes.” EX1027, 37:17-39:2, 47:12-21. Accordingly, a POSITA would have known that an LED device did not need to utilize Lundahl’s electrical control system. As Dr. Jokerst further admits, a POSITA would have known how to construct an electrical system appropriate for operating LEDs. EX1027, 40:12-42:3, 45:17-48:6.

Lastly, Lundahl explains that “[s]ince cathode and tube wall temperatures strongly affect the output distribution, a cooling system is provided to ensure proper bulb operation” particularly due to variations in “phosphor coating thickness caused by the bending process” of the tube. EX1014, 9:13-15 and 9:39-54. LEDs do not utilize tubes with walls having variable phosphor coating thickness. EX1027, 47:12-21. Accordingly, a POSITA would not have used Lundahl’s cooling system for fluorescent tubes for the combination that relies on LEDs. EX1031, 594:17-595:6.

In sum, a POSITA would not incorporate design strategies intended to address the shortcomings of fluorescent tubes into a device that used LEDs. *PGS Geophysical AS v. Iancu*, 891 F.3d 1354, 1366 (Fed. Cir. 2018) (“[Plaintiff’s]

argument relies on the presumption that one of ordinary skill would blindly incorporate [secondary reference's] exact methodology into [primary reference]. But the Board **properly** did not view [defendant's] proposed combination to be so limited.")³. Instead, a POSITA would use their knowledge to retain only those teachings that still provide utility in the combination – in this case, Lundahl's light source distribution (via LEDs on adjustable panels instead of U-shaped fluorescent tubes) to achieve uniformity where "the measured output over the active emitting area is within 70% of the measured maximum." EX1014, 15:22-27, 6:16-30.

2. A POSITA would know how to position the LED light sources so that the "measured irradiance at a treatment surface...is at least within 60% of the measured maximum."

Contrary to Patent Owner's unsupported allegations, ample evidence and analysis shows that the combination of Lundahl and Larsen would meet the ITC construction of "uniformly illuminate a treatment surface" including the requirement that the "measured irradiance at a treatment surface...is at least within 60% of the measured maximum." See EX2033, 15.

Lundahl reports that "the measured output over the active emitting area is within 70% of the measured maximum" on a treatment surface 2-4 inches away,

³ Emphasis always added unless otherwise noted.

meaning that a higher degree of uniformity than that required by the '028 Patent was achieved with the fluorescent tubes of the Lundahl device. EX1014, 15:22-27. This is despite the fact that “fluorescents tubes are known to have inconsistent light output within the tube itself.” EX1015, ¶129; EX1027, 36:14-37:4 (Dr. Jokerst admitting that “achieving satisfactory performance from a fluorescent tube...includes many challenges.”). LEDs, on the other hand, provide better control of light output characteristics in comparison to earlier technologies like fluorescents. EX1015, ¶129. Here, a POSITA would have reasonably expected to achieve at least the same uniformity using LEDs than had already been achieved by Lundahl using fluorescent tubes. *Tyco Healthcare Group LP v. Ethicon Endo-Surgery, Inc.*, 774 F.3d 968, 978 (Fed. Cir. 2014) (“One of ordinary skill knows how to combine familiar prior art elements to achieve the same functions.”).

While Patent Owner argues that a reasonable expectation of success has not been adequately shown because Dr. Grove did not conduct uniformity measurements for his combination (POR, 20-21), there is no “law-required minimum for what can support a ‘reasonable’ expectation of success,” and the Federal Circuit has stated that testing is not required. *Acorda Therapeutics, Inc. v. Roxane Labs, Inc.*, 903 F.3d 1310, 1333 (Fed. Cir. 2018). That is particularly true here, where the combination of Lundahl and Larsen substitutes the more predictable light output from LEDs for “output from a fluorescent tube [which is] not inherently uniform.” EX1014, 6:9-11.

Furthermore, Patent Owner argues that Larsen *on its own* does not teach the required uniformity, but this is legally irrelevant. EX2050, ¶134; POR, 29; *Bradium Techs. LLC v. Iancu*, 923 F.3d 1032, 1050 (Fed. Cir. 2019) (cannot overcome obviousness of a combination “by attacking references individually”). Petitioner has not relied on Larsen (or Lundahl) *separately* to achieve uniformity. Petition, 39-40. Rather Petitioner’s argument relies on combining the teachings of Lundahl and Larsen to produce a device with adjustable LED panels that achieves at least the same level of uniformity that Lundahl’s fluorescent tube device did. EX1014, 15:22-27; EX1015, ¶160.

What is more, Patent Owner’s argument that LED’s have narrow divergence angles that would not be able to meet the claimed uniformity requirement contradicts the evidence. As acknowledged by Dr. Jokerst, LEDs “are discrete, point source, directional illuminators *with a Lambertian output characteristic*”. EX2050, ¶46; EX1026, ¶9. Figure 6 of EX2013, a 2015 article relied on by Dr. Jokerst to describe LED light emission (EX2050, ¶44), illustrates a *Lambertian* emission profile as shown below. EX2013, 8; EX1026, ¶11.

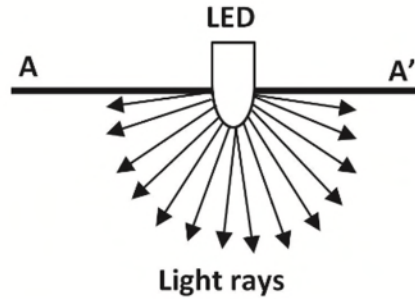
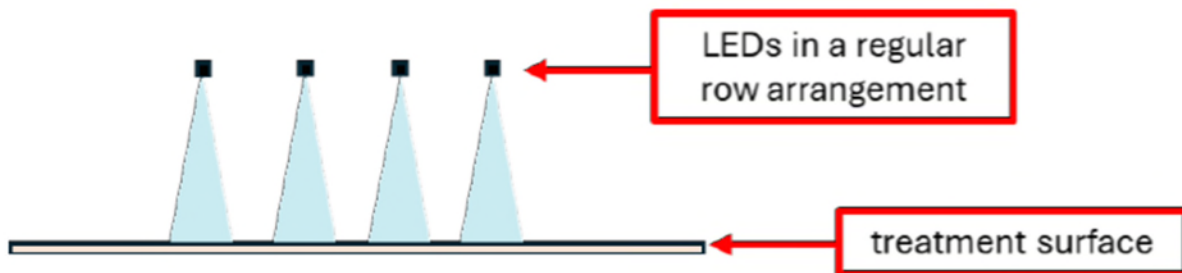


Figure 6: Scattering of the light from LEDs (Lambertian distribution); ($A - A'$) represents the Lambertian surface in the profile view

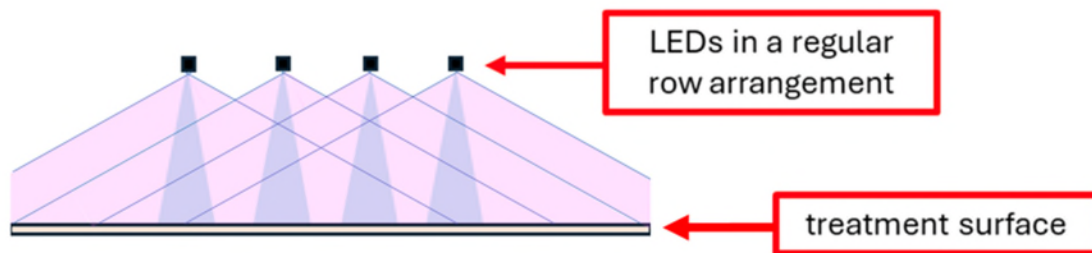
EX2013, 8.

This evidence directly contradicts the below drawing provided by Dr. Jokerst that inaccurately portrays narrow cones of light (shown as light blue) emitted from each LED instead of the actual Lambertian output of an LED. EX2050, ¶46; EX1026, ¶9-11.



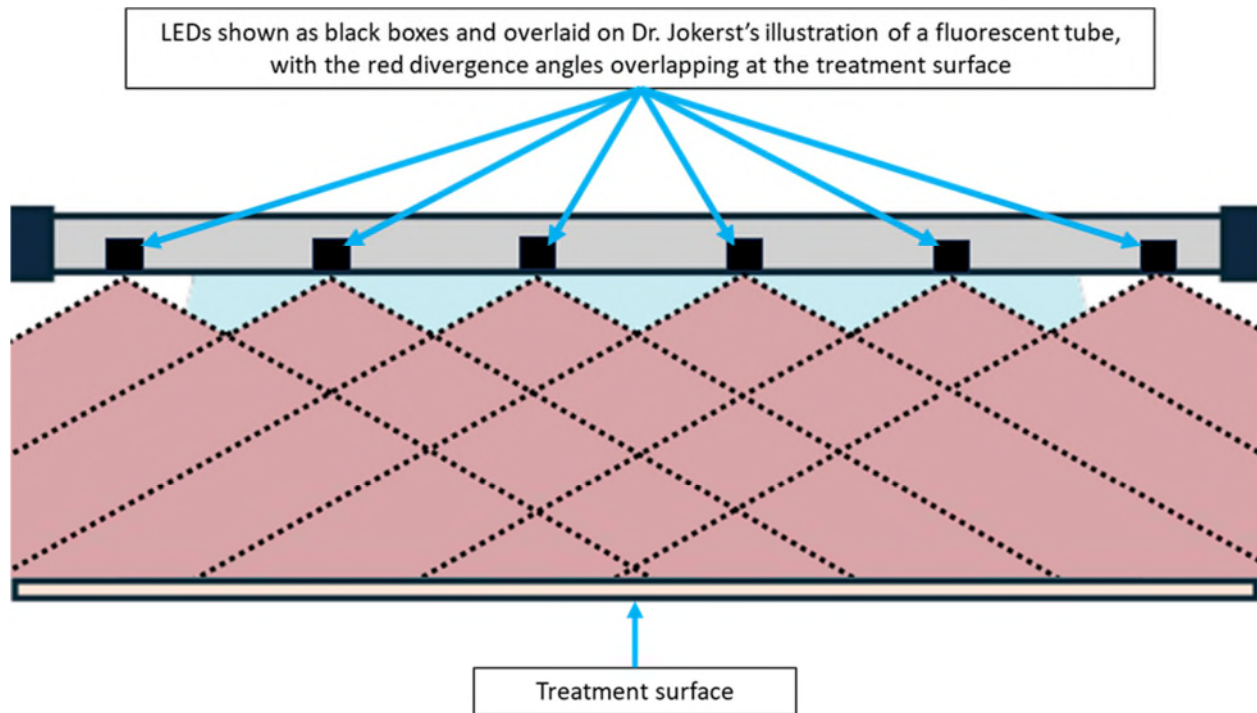
EX2050, ¶46. The only support for this drawing that Dr. Jokerst cites to is a statement in the Bourget article that “LED light is of a noncoherent, narrow band.” EX2050, ¶46; EX2011, 1; EX1026, ¶10. However, this statement refers to the *wavelength* of the emission from an LED light (i.e., color), not the light emission. EX2011, 1; EX1026, ¶10.

A revised drawing showing a more accurate divergence angle for each LED, where the rays shown represent $I = I_0/2$ as required by a Lambertian distribution, is below. EX1026, ¶12.



EX1026, ¶12. As shown in the drawing above, a POSITA would understand that while LEDs may have gaps between where the light is **emitted** from each LED, the row of LEDs can still uniformly **illuminate** a treatment surface of a patient some distance away, where the divergence angles of the LEDs overlap. EX1026, ¶13-17. More specifically, achieving a desired uniformity of *illumination* with LEDs is based on (a) spacing between individual LEDs, (b) spacing between rows of individual LEDs, and (c) spacing between the LEDs and the treatment surface. EX1026, ¶14. Lundahl provides guidance as to (b), teaching that distance between light source rows can be manipulated to increase uniformity (EX1014, 6:43-57), and as to (c), teaching illumination of a treatment surface 2-4” away (EX1014, 15:22-28). EX1026, ¶14. Accordingly, only (a) spacing between individual LEDs need be addressed. EX1026, ¶14. It would have been straightforward for a POSITA to space

adjacent LEDs in a manner that allows the divergence angles to overlap to prevent gaps in illumination. EX1026, ¶14-15.



EX1026, ¶15. Tellingly, the '028 Patent does not discuss how to arrange LEDs to achieve the claimed uniformity or identify any problem in spacing LEDs to do so. EX1026, ¶19. This is further evidence that appropriate LED spacing to achieve uniform illumination was well known to a POSITA at the time of the invention. *McRO, Inc. v. Bandai Namco Games America Inc.*, 959 F.3d 1091, 1102 (Fed. Cir. 2020) (“[A] patent need not teach, and preferably omits, what is well known in the art.”); *see also In re Buchner*, 929 F.2d 660, 661 (Fed. Cir. 1991) (“Sec. 112 requires that, unless the information is well known in the art, the application itself must contain this information”). Specifically, the '028 Patent reports that “Fig.

8...illustrates the light uniformity produced by an embodiment of the present invention....” EX1001, 8:43-44.

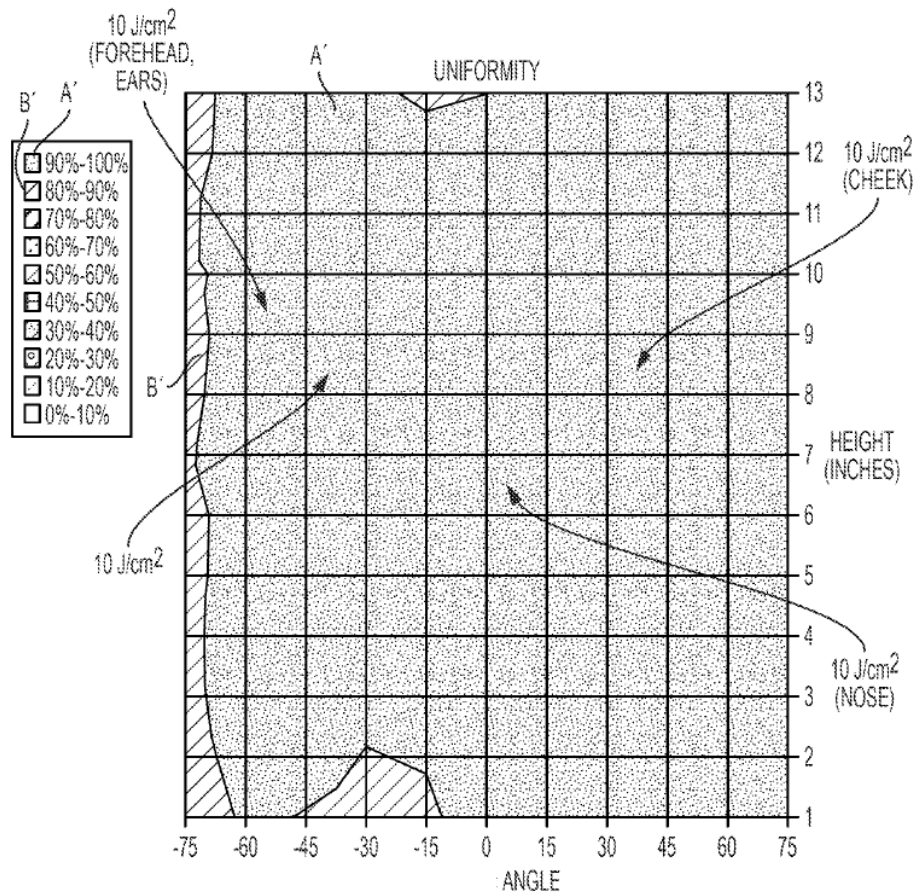


FIG. 8

EX1001, Fig. 8. As shown in Fig. 8, the '028 Patent reports that uniformity of 90-100% was achieved over the vast majority of the illuminated surface – uniformity values significantly higher than the 60% standard claimed. EX1026, ¶18-19. Yet, despite these high uniformity values, not once does the '028 Patent describe the specific spacing between the LEDs of the illuminator tested in Fig. 8. The '028 Patent references “addressable strings” included in areas 1, 3, and 5, and 2, 4, and 6

(see EX1001, Fig. 5, 6:24-37), but, again, the '028 Patent includes no disclosure as to the specific spacing of LEDs within each of these areas. EX1026, ¶19. This is because a POSITA would consider the determination of LED spacing a straightforward task in light of the understanding in the art of divergence angles and Lambertian distribution, and Lundahl's teachings regarding manipulation of lateral spacing to account for illumination drop off at the forehead and chin. EX1026, ¶19.

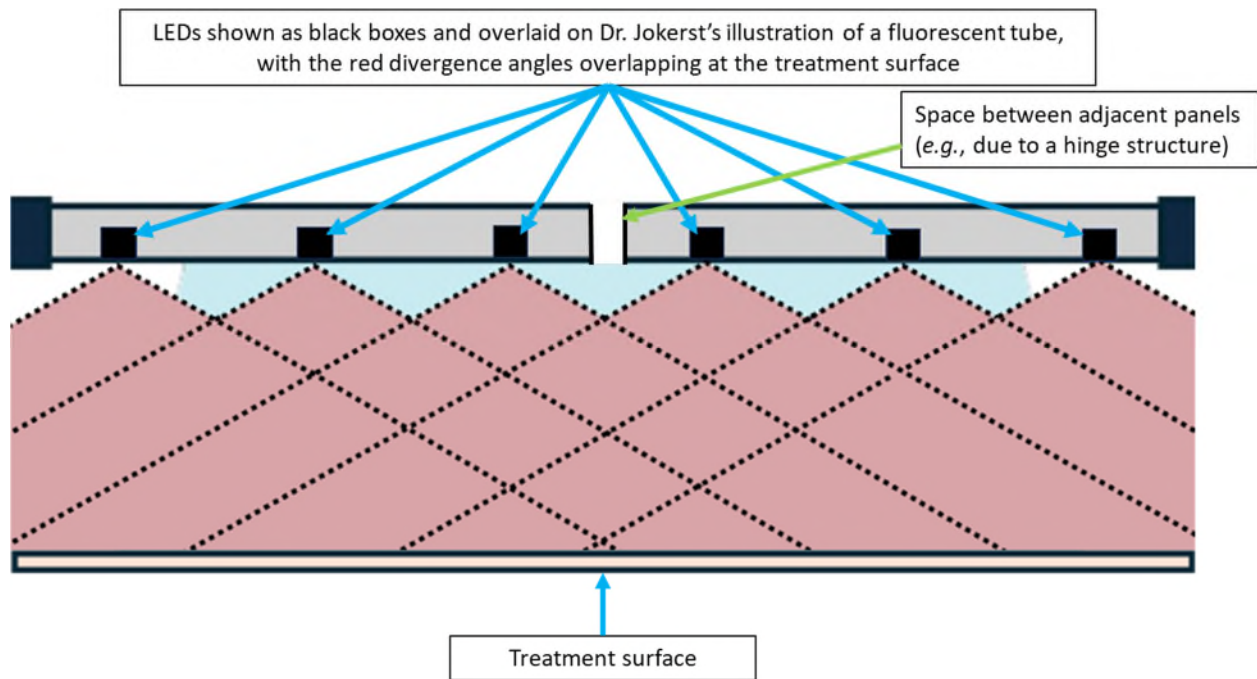
Lastly, Patent Owner argues that Dr. Grove himself admitted that achieving uniform illumination was not routine, citing a statement that a "POSA would be required to perform undue experimentation to make and use an illuminator that provides 'uniform illumination.'" POR, 32 (citing EX2034, ¶186). But this quote is taken out of context. Dr. Grove's statement was in relation to the difficulty of providing uniform illumination to the far reaches of the claim scope – *e.g.*, providing uniform illumination to a patient's extremities and torso. EX1031, 587:4-588:21. This statement was not made in relation to providing uniform illumination of, *e.g.*, the face, which is both within the claim scope and disclosed in Lundahl. EX2034, ¶186; EX1014, 2:35-40, 2:60-67, 3:29-38.

Accordingly, a POSITA would know how to position the LED light sources to achieve the desired illumination uniformity. EX1026, ¶13-21.

3. A POSITA would understand that modifying Lundahl's U-shaped tubes to incorporate panels would not affect the illumination uniformity.

While Patent Owner argues that a POSITA would not have been motivated to modify Lundahl's U-shape with panels because such modification "would create gaps between the panels," (POR, 24) this argument does not comport with the law, which states that "[t]he fact that the motivating benefit comes at the expense of another benefit, however, should not nullify its use as a basis to modify." *Medichem, S.A. v. Rolabo, S.L.*, 437 F.3d 1157, 1165 (Fed. Cir. 2006); *In re Fulton*, 391 F.3d 1195, 1200 (Fed. Cir. 2004).

Further, at the time of invention, it was feasible to create a paneled device that provided uniform illumination, notwithstanding gaps between panels. As discussed above, gaps in light emission do not require gaps in the illumination of a treatment surface. *Supra*, Section II(A)(2). Rather, as with gaps between individual LEDs on a panel, gaps in emission between adjacent panels are easily addressed by accounting for the overlap of divergence angles as Dr. Grove illustrates below. EX1026, ¶17.



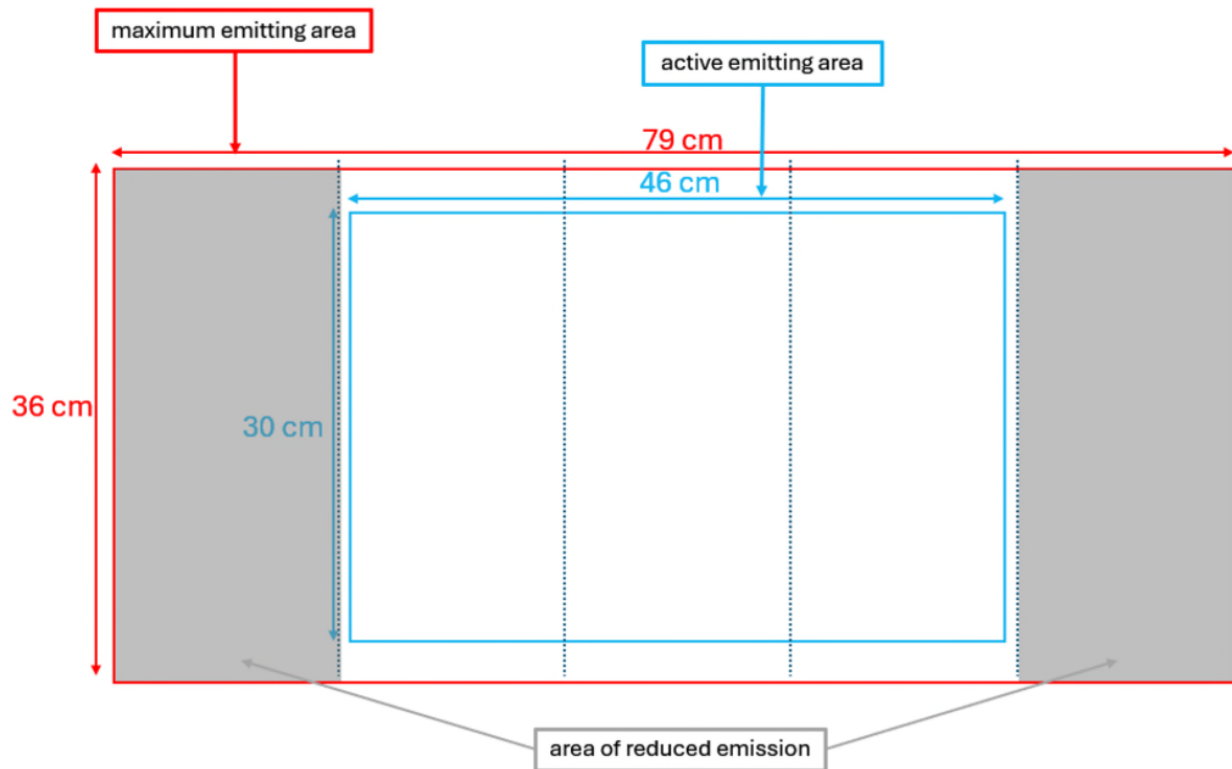
EX1026, ¶17.

B. Lundahl in View of Larsen Renders Obvious the “Higher Intensity Limitation” of All Challenged Claims

Patent Owner’s argument that the “higher intensity close to the second shorter edges” limitation is not obvious rests on two main assertions: (1) a POSITA would replicate Lundahl’s low output areas in a combination with Larsen; and (2) Lundahl would lead a POSITA to increase intensity near the *longer* edges. POR, 33-47. These assertions rest on the false assumption that a POSITA is an automaton, lacking capacity for normal creativity and logical interpretation of the teachings in the art. *KSR*, 550 U.S. at 420-21. A POSITA would not blindly follow every teaching of the prior art, especially when doing so makes no sense in the context of the proposed combination.

With respect to the first point, Patent Owner points out that Lundahl's light sources have "low output area[s]" or "areas of reduced emission." POR, 34-37. Patent Owner is correct on this point – Lundahl discloses that its fluorescent tubes have what are known as "Faraday dark space[s]" near their cathodes. EX1014, 6:9-22. Patent Owner is not correct, however, that a POSITA would incorporate these dark spaces into a combination using LEDs. It was well-known that Faraday dark spaces were a problem specific to fluorescents. *Id.*; EX1032, 732:7-10. LEDs did not have such dark spaces, and, as Dr. Jokerst noted, a POSITA "wouldn't typically incorporate the shortcomings of a prior device when developing a new device." EX1032, 768:10-13.

Further, Dr. Jokerst's description of the dark areas of the fluorescent tubes is exaggerated. Specifically, Dr. Jokerst asserts that Lundahl's "active emitting area" does not include the "low output area[s]," which, according Dr. Jokerst's illustration provided below, constitute a significant portion of the length of the tubes:



EX2050, ¶146. However, Dr. Jokerst omits that Lundahl describes the above dimensions as the “minimum” active emitting area, meaning that the actual “active emitting area” may be much larger. EX1032, 737:19-738:12. In any case, variations in size (i.e., of the emitting area) are not a basis for patentability absent unexpected results. *American Infra-Red Radiant Co. v. Lambert Indus.*, 360 F.2d 977, 987 (Fed. Cir. 1966) .

Moreover, Dr. Jokerst’s description of the dark areas of the fluorescent tubes is inconsistent with the testimony of Patent Owner’s other expert, Dr. Heather Roberts. Dr. Jokerst argued that only the curved central portion of Lundahl’s device is appropriate for patient treatment, while the straight portions underneath the dotted

line in FIG. 4A are not (i.e., because they are areas of reduced emission). EX1027, 91:3-92:17, 100:15-101:13.

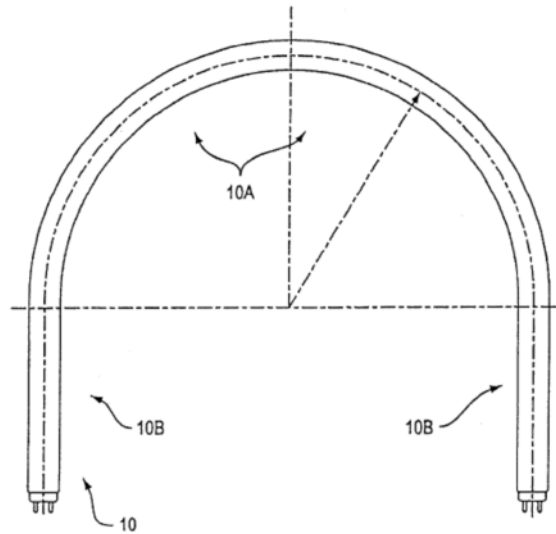


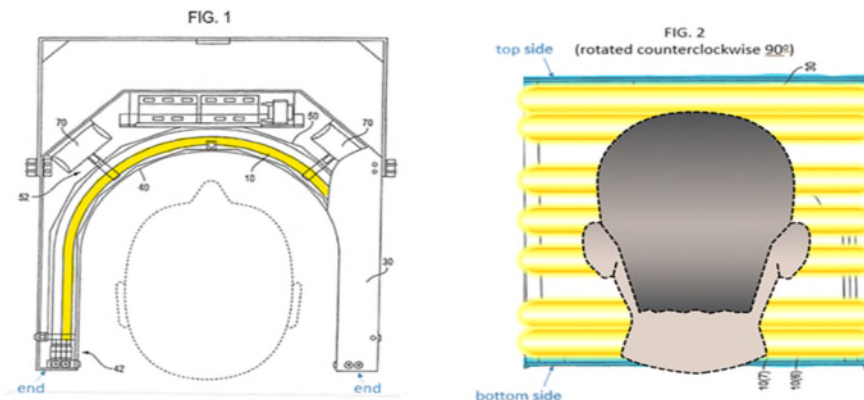
FIG. 4A

EX1014, FIG. 4A. However, Dr. Roberts testified that she treats patients' chest and backs with the BLU-U 4170D⁴, by having "the patient turn to the right so the 'U' of the device wraps halfway around their chest and back. Then, I have turned them to the left so the 'U' of the device wraps around the other half of their chest and back." EX2015, ¶36. Consequently, Dr. Roberts makes clear that the straight portions of the "U" shape, which correspond to the "low output areas," emit light and are used

⁴ Dr. Jokerst has admitted that the BLU-U 4170D device is an embodiment of Lundahl. EX1032, 731:24-732:3.

to illuminate a treatment surface, thereby undercutting the factual foundation of Dr. Jokerst's opinion.

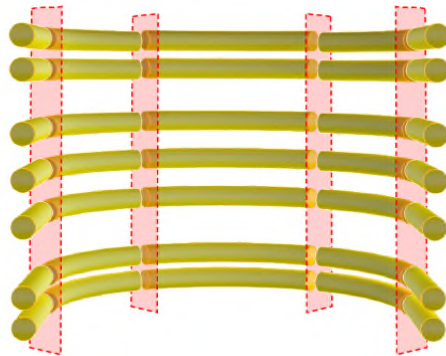
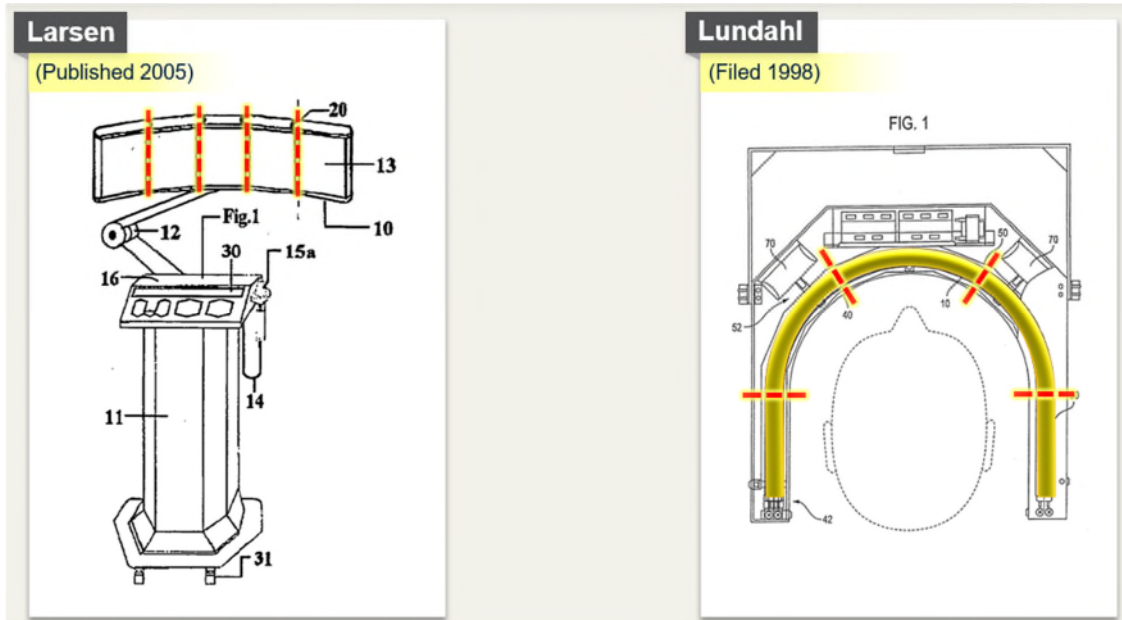
Patent Owner's second point, i.e., that Lundahl would lead a POSITA to increase intensity near the *longer* edges, is also incorrect. As fully explained in the Petition (Petition, 17-20, 39-41), Lundahl teaches that the uniformity benefits provided by its light distribution are realized by providing increased intensity at the edges corresponding to a patient's forehead and chin, when the device is used as shown in Figure 1. EX1014, 6:25-30; EX1015, ¶¶77-78, 83-84. Dr. Jokerst similarly admits that Lundahl teaches a light source distribution that increases intensity near the forehead and chin, when the device is used as shown in Figure 1. EX1032, 740:25-741:5, 748:10-21; EX1014, Fig. 1.

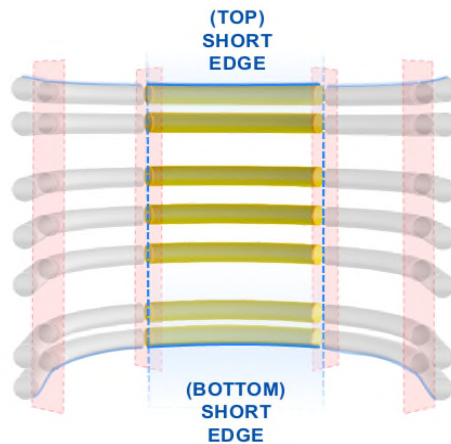


EX1014, Figs. 1-2 (annotated).

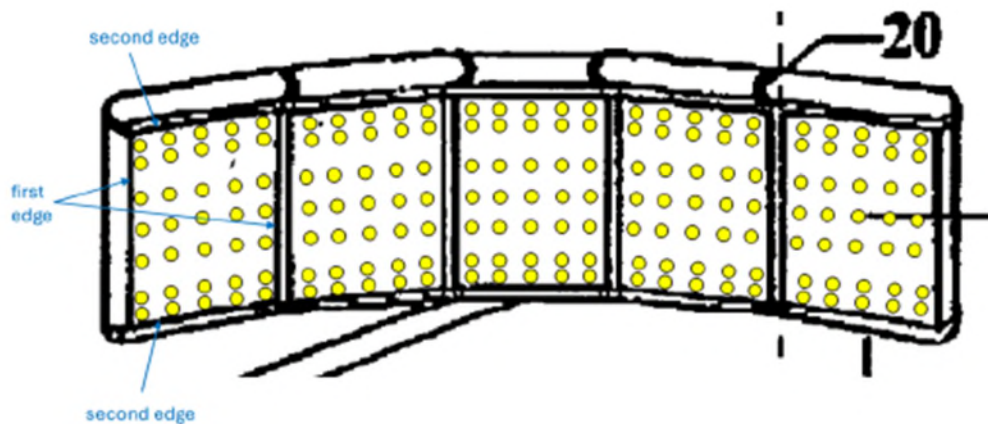
A POSITA would be able to understand this and apply this principle in combining Larsen with Lundahl. As Dr. Jokerst admits, if Lundahl's device were

divided into five panels, the edges near the patient's forehead and chin would be the shorter edges (EX1032, 748:22-749:7), which is further illustrated below:





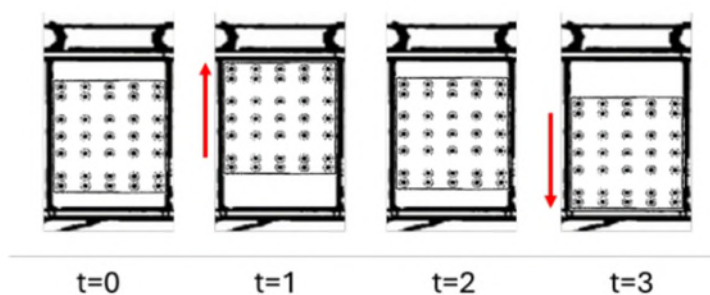
Accordingly, a POSITA applying ordinary creativity would arrive at a combination providing higher intensity (via increased density of LEDs) along these shorter edges corresponding to the forehead and chin as shown in Dr. Grove's illustration below. EX1015, ¶178-179.



Finally, Patent Owner's argument that "Petitioner relies on Larsen's disclosure of a scan engine in its combination...[that] would move the light sources linearly up and down" is unsupported. POR, 38-41. First, Petitioner has never argued

that Larsen's scan engine *must* be incorporated into the combination to achieve uniformity since the Petition relies on Lundahl's teaching of light source spacing for that aspect. *See* EX1015, 172. Rather, Petitioner merely cited the scan engine for the proposition that Larsen also taught the benefits of uniform light distribution which further supported the reason to combine Larsen's LED panels with Lundahl's positioning of light sources. Petition, 40-44.

Second, while Dr. Jokerst imagines hypothetical movements of a scan engine that would supposedly cause "the light sources [to] move up and down from $t=0$ to $t=3$, as shown below," she admitted that none of these imaginings is actually disclosed in Larsen.

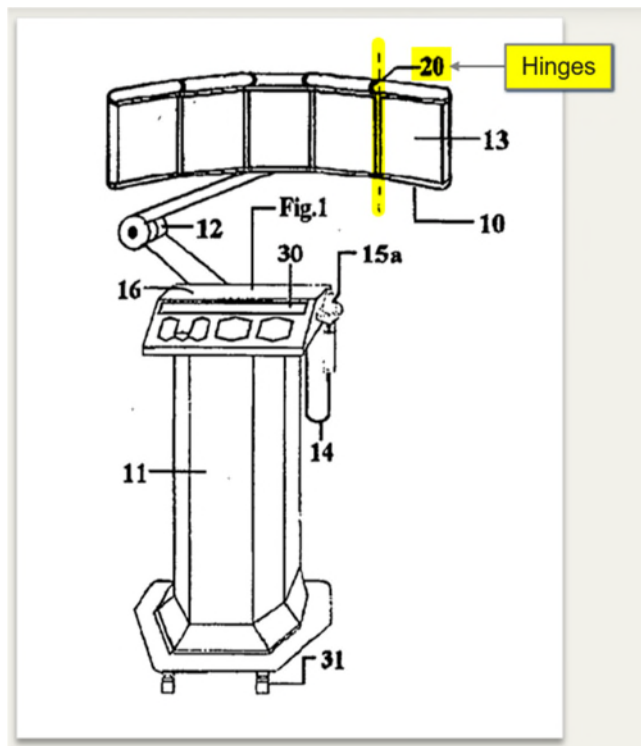


EX2050, ¶152. For example, Dr. Jokerst admitted that Larsen fails to disclose whether the scan engine causes movement up or down or side to side, any pattern of movement for the scan engine, any range of movement for the scan engine, any rate of movement for the scan engine, or any specific time points. EX1032, 741:22-

743:5. As a result, Patent Owner’s argument regarding the scan engine is a construct that is unsupported by any evidence. Petition, 40-44; EX1015, 172.

C. Larsen Discloses and Renders Obvious the “Hinges Limitation” of Claims 1, 5, 20, and 21

Although Patent Owner notes that Larsen teaches “several applicators 13 are flexibly connected to each other through *hinges 10*...on the bottom of the applicator 13,” (POR, 48-49), Larsen also identifies element number 10 as corresponding to “the *invented device 10*.” EX1004, [0069]; EX1032, 743:14-21. Accordingly, it is clear that one of these passages must contain a typographical error.



The specification taken as a whole indicates that the most reasonable understanding is that the reference to “hinges 10” was the typographical error, as the

hinges are properly indicated by element number 20. EX1015, ¶154. For instance, Larsen notes that its panels “are flexibly connected to each other through hinges... **connecting one edge with the other.**” EX1004, [0027]. The description of hinges as **connecting edges** of adjacent panels indicates that the hinge is located between the inner side surfaces – which is exactly where element number 20 is illustrated in Figure 1. EX1015, ¶154. Indeed, this sentence alone is sufficient to establish obviousness even if it were somehow a mistake (which it is not). *Beckman Instruments, Inc. v. LKB Produkter AB*, 892 F.2d 1547, 1551 (Fed. Cir. 1989) (reference used for obviousness “is prior art for all that it teaches”).

The examiner of the '028 Patent concurred with this conclusion. During prosecution of the parent of the '028 Patent, the examiner explicitly noted that Larsen's hinges had been erroneously labeled as element number 10 in the specification while being correctly shown as element number 20 in the Figures. EX1009, 3 (“**hinges 20** (indicated as 10 in the specification, but shown as element 20 in the Figures)...”); EX1032, 744:6-15; EX1015, ¶154. Further, as Dr. Grove testified, a POSITA would understand that the most logical location for hinges connecting panels would be between the panels in the location identified by number element 20. EX1015, ¶155; EX1031, 592:2-5.

Moreover, even if Figure 1 does not explicitly teach hinges 20, it would have been obvious for a POSITA to arrive at hinges located on inner side surfaces.

EX1015, ¶155. There are only three reasonable options for placing hinges to connect adjacent panels – (1) between adjacent panels; (2) on the top or bottom of the panels; or (3) on the rear surface of the panels. EX1031, 591:5-7 (“Yeah, in general, there are three locations to connect adjacent panels.”). Among these three, the most common option is to put “hinges between the two panels.” EX1031, 592:2-8. People have been doing this for generations prior to 2015. *Id.* This would be especially obvious where Larsen teaches “hinges... **connecting one [panel] edge with the other.**” EX1004, [0027]. The choice of whether to place hinges between panels, on the top or bottom, or on the back is not an act of invention. EX1015, ¶155; *see Teva Pharms. U.S.A., Inc. v. Sandoz, Inc.*, 906 F.3d 1013, 1025 (Fed. Cir. 2018) (finding claims obvious where “a POSITA had only a limited number of permutations...to explore”).

Patent Owner’s additional arguments do not change this conclusion. Although Patent Owner argues that Larsen’s element number 20 identifies regular row arrangements in Figs. 2a-d (as opposed to hinges between panels) (POR, 49-50), Dr. Jokerst admitted that Figs. 2a-d do not list the element number 20. EX1032, 746:6-19; EX1004, Figs. 2a-d. Further, element number 20 indicates a location between panels, which does not make sense as a location for “regular row arrangements” of light sources – which would necessarily be on the front of the panels.

Patent Owner's reliance on Fig. 3 of EX2004 similarly fails to move the needle. POR, 50-51. EX2004 is a different patent, with a different disclosure, from a different family, in a different jurisdiction than Larsen and therefore of dubious relevance. Further, although Patent Owner points out that the parent of the '028 Patent was allowed over Larsen, such allowance was not based solely on the absence of hinges in the prior art. EX2061, 1731. In fact, earlier in prosecution, the examiner cited Larsen as anticipatory to claims including the term "nested hinges" - which, Patent Owner has asserted in the related ITC investigation mean hinges "on inner side surfaces of adjacent panels." EX2061, 555; EX2033, 29-34.

D. Larsen Discloses the "Individually Configurable Limitation" of Claims 16 and 21

Larsen teaches that "the invented device is adjustable within a relatively large range with reference to duration, amplitude and frequency of surge of current...." EX1004, [0074]. While Patent Owner argues that this refers to the device as a whole rather than to each of the five panels "being individually configurable to control illumination from each of the five panels" (POR, 59), this argument ignores Larsen's disclosure as a whole.

Larsen discloses applicators (*i.e.*, panels), with each panel containing multiple light sources. EX1004, [0070]-[0072]; EX1015, ¶157-158. Claim 5 of Larsen recites "wherein the light sources are *individually selected*—switched *ON* or *OFF*."

EX1004, claim 5 (emphasis added). Thus, Larsen teaches illuminating or darkening individual light sources within a panel, which necessarily alters or configures the power output and/or light intensity of the panel – i.e., by allowing for brightening or dimming of the panel. Accordingly, a POSITA reading Larsen’s disclosure that “the invented device is adjustable” would understand that to include adjustability of light output from each individual panel. EX1004, [0074].

Although Patent Owner argues that Larsen allegedly discloses only a single controller for the device (POR, 60-61), this argument ignores the basic functionality of a controller. It was known as early as 2008 that “LED control systems allow the user to set various parameters of system operation including **brightness**, time on or off, photo periods, **light quality**...Controls are usually interfaced to the driver circuitry to **allow the brightness of the individual LEDs to be set.**” EX2011, 2. Accordingly, a POSITA would understand that a single controller can control multiple individual LEDs.

E. Larsen Discloses the “Continuous Illumination Limitation” of Claim 16

Initially, Patent Owner argues that the combination of Lundahl and Larsen does not render obvious “continuous illumination across the five panels” because Larsen allegedly does not teach “hinged structures on inner side surfaces of adjacent

panels.” POR, 63. However, Larsen does teach and render obvious hinged structures on inner side surfaces as discussed above. Supra, Section II(C).

Patent Owner further argues that Larsen does not teach continuous illumination because “there are lower irradiance regions at the junction of two of Larsen’s panels.” POR, 64. To the extent that Patent Owner is suggesting that the “continuous illumination” requirement would not be rendered obvious for the same reason as the “uniform illumination” requirement, this is incorrect for all the reasons discussed above. Supra, Section II(A). A POSITA was aware of the divergence angles and Lambertian distribution of LEDs, and would have positioned the LEDs in a manner to provide continuous illumination across panels. EX1026, ¶¶9-17. To the extent Patent Owner is suggesting that a five-panel device *cannot* provide “continuous illumination” because of the junctions of the adjacent panels, this position is entirely contrary to the positions set forth in Dr. Jokerst’s declaration, where she asserts that the RhodoLED[®]XL (a five-panel LED device) meets this claim limitation. EX2050, 178-182. Further, this is contrary to the ’028 Patent itself, which claims both a paneled device and uniform illumination. *See e.g.*, EX1001, claim 1.

III. SECONDARY CONSIDERATIONS SUPPORT OBVIOUSNESS GROUNDS OF REJECTION

A. Lack of Nexus Between the '028 Patent Claimed Invention and the Objective Evidence of Non-Obviousness

Patent Owner devotes a single paragraph to its argument for allegedly establishing nexus. POR at 78.⁵ This single paragraph fails to satisfy Patent Owner's burden to establish nexus to any claim of the '028 Patent, let alone for all challenged claims. *See Fox Factory, Inc. v. SRAM, LLC*, 944 F.3d 1366, 1373 (Fed. Cir. 2019) (“[t]he patentee bears the burden of showing that a nexus exists”).

Even if the Board looked outside this single paragraph, it would find only conclusory and contradictory statements about nexus. For example, on commercial success, Patent Owner provides conclusory statements that “RhodoLED® XL practices at least exemplary claim 1 of the '028 Patent” and that RhodoLED®XL is “coextensive” with all claims. But, Patent Owner provides no explanation, merely citing various exhibits, including Dr. Jokerst's declaration. POR, 73. Dr. Jokerst's declaration does not address claim 1, but instead addresses “exemplary claim 16”, which notably does not recite “hinged structures on inner side surfaces of adjacent

⁵ Patent Owner improperly incorporates by reference fifty paragraphs of expert declaration citations without analysis of the expert declarations into a single paragraph of its response and should not be considered. 37 CFR § 42.6(a)(3).

panels” as the other independent claims do. EX2050, ¶229 and Appendix B. Additionally, Dr. Jokerst’s conclusory chart for claim 16 merely identifies various excerpts of marketing material discussing the RhodoLED®XL without providing analysis for how claim 16 reads on those marketing excerpts. EX2050, Appendix B. Patent Owner wrongly assumes RhodoLED®XL infringes the claims of the ’028 Patent, but provides no analysis or evidence for why that is true.

Finally, Patent Owner relies on a RhodoLED®XL press release, but Patent Owner cites features indisputably known in the art, as both Lundahl and Larsen taught uniform light and Larsen taught using five panels with LEDs. Patent Owner willfully ignores unclaimed features touted by Petitioner about RhodoLED®XL in the same press release, including a “robust but sleek construction,” “intuitive user interface,” “simple to maneuver,” “able to accommodate various patient treatment positions,” and “positioning sensors.” EX2045, 1. Patent Owner has not shown how the limited features it self-selected (even when considered together) establish a nexus to the claims of the ’028 Patent.

B. The ’028 Patented Invention Has Not Achieved Commercial Success

Patent Owner fails to show that the sales volume of the RhodoLED®XL is significant enough to meet the standard of commercial success. *See J.T. Eaton & Co. v. Atl. Paste & Glue Co.*, 106 F.3d 1563, 1571 (Fed. Cir. 1997). Patent Owner

merely states that Biofrontera sold more RhodoLED®XL lamps than its older RhodoLED® over the same time period. POR, 77. This one data point merely establishes that RhodoLED®XL generated more revenue than RhodoLED®, but that is a far cry from establishing commercial success. Additionally, Biofrontera's CFO found the increase in revenue from the RhodoLED®XL unremarkable, describing Biofrontera's revenue as "flat." EX1033, 410:3-8. As such, the owner of the RhodoLED®XL did not find it a commercial success, contrary to Patent Owner's assertions.

Finally, Dr. Vander Veen, who Patent Owner relies on for commercial success of the RhodoLED®XL, testified that he compared the alleged evidence of commercial success to the "features of the product" provided to him by Dr. Jokerst, rather than compare the evidence to the '028 Patent claims. EX1029, 9:18-21, 31:20-32:4; EX2050, ¶230; EX2048, 16. Dr. Vander Veen also testified he was unable to "assess[] or opin[e] on the extent to which claims are or are not practiced by" the RhodoLED®XL, giving his testimony on this issue no weight. EX1029, 33:9-14.

C. The '028 Patented Invention Has Not Received Industry Praise

Patent Owner cites statements about the RhodoLED®XL's "elegant design," "maneuverability," "adjustability," and its "advanced features. POR, 77. Yet, these are not claimed features of the '028 Patent. For instance, the "elegant design" of the RhodoLED®XL includes aspects such as material choice, color, touch pad design,

and the design of the maneuverable arm holding the LED panels, which are not within the scope of the '028 Patent. Indeed, the reticulating arm holding the LED panels and wheels added to the base of the RhodoLED®XL would make the lamp highly maneuverable and adjustable for clinical use and are not claimed by the '028 Patent. *See* EX2041, 6.

With regards to Patent Owner's BLU-U 4170E device, Patent Owner does not even attempt to explain its single conclusory sentence on how this device "embodies the 028 Patent" or why the quoted statement about being a "step forward" has a nexus to the claimed invention. POR, 77.

IV. CONCLUSION

Patent Owner fails to overcome the strong showing of obviousness presented in the Petition and the Board should find claims 1, 2, 4-6, 16, 17, and 19-21 obvious over the prior art.

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Petition for Inter Partes Review of
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CERTIFICATION OF WORD COUNT

Petitioner certifies that the word count in this Reply, including all footnotes, is 5,583 words as counted by the word-processing program (Microsoft Word for Office 365) used to generate this Reply, where such word count excludes the table of contents, mandatory notices, certificate of service, list of exhibits, and this certificate of word count. This Petition is in compliance with the 5,600 word limit set forth in 37 C.F.R. § 42.24(c)(1).

CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of the foregoing Petitioner's Reply to Patent Owner's Response, is being served on August 13, 2025, via email directed to the following counsel of record for the Patent Owner:

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