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 IPR2025-00287

U.S. Patent No. 11,446,512

DECLARATION OF NAN MARIE JOKERST, PH.D.

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I, Nan Marie Jokerst, declare under penalty of perjury as follows:

I. INTRODUCTION

1. I have been retained as an expert in this *Inter Partes* Review by counsel for Patent Owner Sun Pharmaceutical Industries, Inc. ("Sun Pharma") to provide my opinions in connection with U.S. Patent No. 11,446,512 (the "'512 Patent"). I submit this declaration to provide my opinions regarding Biofrontera Inc., Biofrontera Pharma GMBH, Biofrontera Bioscience GMBH, and Biofrontera AG's (collectively "Biofrontera" or "Petitioner") allegations of invalidity of the '512 Patent. Biofrontera has challenged claims 1, 3, 5, 8, 17, 18 and 20 of the '512 Patent in this IPR. *See* Ex. 1015 (Grove Declaration), ¶¶152-155 (the "Challenged Claims").

2. I am being compensated at a rate of $650 per hour for the time I spend on this matter. I do not have any financial or other interest in either party in this investigation, in this proceeding itself, or in any other proceeding involving the '512 Patent or any related patents. My compensation is not dependent on the outcome of this matter. Unless otherwise noted, the statements made herein are based on my personal knowledge, experience, and education. If called to testify about this declaration, I could and would do so competently and truthfully.

II. BASES FOR OPINIONS

3. I have considered the documents and other materials listed below in Section III in light of my specialized knowledge provided by my education, training, research, and experience, as summarized in Section IV and described in detail in my CV, which is provided as Exhibit 2051. My analysis of those materials, combined with the specialized knowledge that I have obtained over the course of my education and career, form the bases for my opinions in this declaration.

III. MATERIALS CONSIDERED

4. I have reviewed and considered the documents and other materials listed below in light of my specialized knowledge provided by my education, training, research, and experience, as summarized in Section IV and described in detail in my CV, which is provided as Exhibit 2051. My analysis of those materials, combined with the specialized knowledge in the fields of optoelectronics and electrical engineering that I have obtained over the course of my education and career, forms the bases for my opinions in this declaration.

- U.S. Patent No. 11,446,512 (Ex. 1001);
- U.S. Patent No. 11,697,028;
- the prosecution history of U.S. Patent No. 11,446,512 (Ex. 1035);
- the prosecution history of U.S. Patent No. 11,697,028 (Ex. 1002);
- Biofrontera's Petition for *Inter Partes* Review IPR2025-00287 of U.S.

Patent No. 11,446,512 (the "287 Petition") and all materials cited therein;

- the Declaration of Robert E. Grove, Ph.D. (Ex. 1015);
- the Declaration of Michael Ehrenreich, M.D. (Ex. 1016);
- the Declaration of Heather J. Roberts, M.D., FAAD (Ex. 2015);
- the Declaration of Thomas D. Vander Veen, Ph.D. (Ex. 2048);
- Papers and exhibits in *Inter Partes Review* proceeding IPR2024-00874;
- Papers and exhibits in *Inter Partes Review* proceeding IPR2024-01312; and
- all other exhibits cited herein.

IV. EDUCATION AND EXPERIENCE

5. I am qualified to serve as a technical expert in this proceeding based upon my educational, knowledge, and work experience. I have over thirty years of experience in optoelectronics, including the design and function of light-emitting diodes (LEDs).

6. A summary of my educational background, career history, areas of professional focus, and other relevant qualifications is provided herein. My curriculum vitae is attached as Ex. 2051, and includes relevant industry experience, publications, presentations, and a list of cases in which I have given testimony at trial or in deposition.

7. I have worked extensively in the field of optoelectronics, including LEDs, for use in a diverse array of applications, including diffuse reflectance spectroscopy of human breast and epithelial tissues, for which I have published multiple journal and conference papers and have one patent application. These studies have been supported by the National Institutes of Health under a Bioengineering Research Partnership. My research in the area of LED interactions with human tissue includes my collaborations with medical research colleagues at Duke in the areas of breast cancer, gastroenterology, anesthesiology, and pathology. My research includes the study of how multiple wavelengths of LED light interact with human tissue and tissue phantoms using both diffuse reflectance spectroscopy and spatially resolved diffuse reflectance spectroscopy. My work is highly experimental with a theoretical foundation, and my research group has fabricated and tested multiple systems in which LED light is transmitted through an optical fiber to human tissue or human tissue phantoms, and the reflected LED light is analyzed to determine if the illuminated tissue is normal, pre-cancerous, or cancerous. I have studied photonics since approximately 1983. Further, I have over thirty years of research experience in electrical engineering.

8. I received a B.S. in Physics from Creighton University in 1982. I received an M.S. and a Ph.D. in Electrical Engineering from the University of Southern California in 1984 and 1989, respectively. My Ph.D. thesis was titled

"Nonlinear Optical Absorption in Single Heterostructure Schottky Barrier Structures."

9. From 1989 to 2003, I was a Professor of Electrical Engineering, including two years as the Joseph M. Pettit Professor of Optoelectronics, at the Georgia Institute of Technology. During this time, I received numerous patents related to the manufacture, design, and system implementation of optoelectronic devices, including LEDs.

10. Since 2003, I have been a Professor of Electrical and Computer Engineering at Duke University, including as the J.A. Jones Professor of Electrical and Computer Engineering since 2004. From 2005 to 2025, I was the Executive Director of the Shared Materials Instrumentation Facility at Duke University. From 2017 to 2023, I was also an Associate Dean in Duke University's Pratt School of Engineering.

11. I am a Fellow of the Institute of Electrical and Electronics Engineers ("IEEE"), a Fellow of Optica (formerly known as the Optical Society of America ("OSA")), and I received an IEEE Third Millennium Medal in 2000.

12. I served on the U.S. National Academies Board on Global Science and Technology from 2010 to 2014, and I have served the IEEE Photonics Society as the Vice President for Technical Affairs, the Vice President for Conferences, and as an elected member of the Board of Directors. I also served the Atlanta IEEE Section

as the Chair, Vice Chair, Treasurer, and Secretary over a four-year timespan. I was a member of the Editorial Board of IEEE Proceedings from 2016 to 2018. I served the OSA as the Chair of the Engineering Council, and I was an Associate Editor of Optica from 2018 to 2024. I was awarded a National Science Foundation Presidential Young Investigator Award in l990, a DuPont Young Professor Award in 1989, a Newport Research Award in 1986, and a Hewlett Packard Fellowship in 1983. I received the University of Southern California Alumni in Academia award from the Viterbi School of Engineering in their 100th anniversary year, 2006. From 2015 through 2017, I served as the Chair of the Duke University Academic Council, which is the Duke University faculty senate.

13. During my 14 years on the Electrical and Computer Engineering faculty at the Georgia Institute of Technology, where my ultimate rank was that of the Joseph Pettit Chaired Distinguished Professor of Electrical and Computer Engineering, a significant amount of my effort involved leadership and research in the National Science Foundation ("NSF") funded Engineering Research Center at Georgia Tech: the Packaging Research Center. This Center was funded for 11 years by NSF for $35M and involved over 30 faculty researchers and their research groups. I served as the co-Leader of the Optoelectronics and High Speed Electronics Thrust Area of the Packaging Research Center. In that role, I supervised multiple faculty researchers and led significant efforts in the integration and advanced packaging of

optoelectronic devices, with support from companies that included Intel, Panasonic-Matsushita, Broadcom, National Semiconductor, Hitachi Chemical, Kyocera, and Sony. For two years of my nine years, I served as the Research Director of the entire Packaging Research Center. When I joined the Duke faculty in 2003, I supervised the design and upfit of Duke's new Shared Materials Instrumentation Facility ("SMIF")—a shared facility that is used by Duke, as well as local, regional, and international users. SMIF is part of the Research Triangle Nanotechnology Network ("RTNN"), a partnership that I developed with North Carolina State University and the University of North Carolina at Chapel Hill—and is also one of 16 sites funded by the NSF to serve as national resources for research, education, workforce development, and outreach in nanotechnology.

14. Since 2000, I have technically consulted at numerous businesses and organizations, including the American Society for the Advancement of Science, the National Institute of Health, and the Army Research Office. I have also been active in the Institute of Electrical and Electronics Engineers ("IEEE") where I have served various positions over the course of three decades, including in the IEEE Photonics Society (previously the IEEE Lasers and Electro-Optics Society).

15. In addition to my research awards, I have also been recognized for my teaching accomplishments, which include the award for Best Teacher in Electrical Engineering at Georgia Tech in 1990, and the IEEE Education Society/Hewlett

Packard Harriet B. Rigas Medal in 2002. I am a co-author of the three-volume book set "Microelectronics Packaging Handbook," and I am an internationally recognized expert and speaker in optics, photonics, and integration/packaging. I have served on and Chaired review panels for organizations that include the Army Research Office in 2017 and the Scientific Foundation of Ireland in 2015 and 2017, as well as serving as a plenary speaker initiating the new Indian Institute of Technology Nanotechnology Center in Mandi, India, in 2018. My undergraduate and graduate classes focus on optics and photonics, optoelectronic devices, and optical systems, as well as First Year Design and Senior Capstone Design courses. These classes contain both theoretical groundwork as well as practical, hands-on design/build/operate content. I also created and originated the massively online Coursera course "Nanotechnology: A Maker's Course," which has had over 60,000 learners since its release.

16. As a researcher, teacher, and consultant in the area of optoelectronic devices and integration/packaging, I am intimately familiar with the hardware technology associated with LEDs. I have personally led the design, fabrication, testing, and publication of original research in the area of optoelectronic devices that include LEDs, lasers, and photodetectors for applications such as transceivers, optical interconnections, and medical instruments. I am a named inventor of four

optoelectronics-related patents and an author of over 280 journal and conference technical research publications.

V. LEGAL STANDARDS

17. I am not an attorney or a legal expert, and I offer no opinions on the law. Sun Pharma's counsel, however, has explained to me certain legal concepts, which I understand are relevant to my analysis and opinions below. Below I provide those relevant standards as explained to me by counsel for Sun Pharma and as I understand them.

A. Obviousness

18. I understand that a claim is invalid for obviousness if the differences between the invention and the prior art are such that the subject matter of that claim as a whole would have been obvious to a POSITA at the time the invention was made. A claim may be invalid for obviousness if two or more prior art references in combination disclose, expressly or inherently, every claim limitation so as to render the claim, as a whole, obvious to a POSITA at the time of the invention.

19. Patent Owner's attorneys have informed me that determining obviousness includes considering the following factors: (1) the scope and content of the prior art; (2) the differences between the prior art and the claimed invention as a whole; (3) the level of ordinary skill in the art at the time the invention was made; and (4) objective secondary considerations that reflect the contemporaneous

response to the invention at the time the invention was made, as discussed further below.

20. I further understand that a reference qualifies as prior art for an obviousness determination only when that reference is analogous to the claimed invention, meaning that it is in the field of the inventors' endeavor or if a POSITA would reasonably have consulted the reference and applied its teachings in seeking a solution to the problem that the inventor was attempting to solve.

21. I understand that, for the purpose of obviousness, a single prior art reference can be combined with one or more other prior art references and the knowledge of one of skill in the art. I further understand that a POSITA would have needed a motivation to combine multiple obviousness references together and have needed a reasonable likelihood of success in the combination.

22. I understand that the obviousness determination considers the analysis to occur at the time of the patented invention. Therefore, the analysis must not use hindsight. It is improper to use the patented invention as a plan or template for hindsight reconstruction of bits and pieces of the prior art to form the patented invention. For example, the inventive contribution of a patent may lie in defining a problem in a new way. Therefore, the obviousness determination must show that a POSITA at the time of the invention would have recognized the specific problem recognized by the inventors and found it obvious to use the inventors' methods to

solve that problem. It would be improper to merely present a POSITA with the identical problem and tell them to make the patented invention as part of the analysis.

23. I understand that when a patent claim is composed of several elements, that the claim is not proved obvious by demonstrating that each of its elements was, independently, known in the art at the time of the invention. The patent challenger has the burden to show that a person of ordinary skill in the relevant field had a reason to combine the elements in the manner claimed when asserting obviousness in view of a combination of references.

24. A POSITA must have an apparent reason why it would have been obvious to modify the prior art to arrive at the claimed invention.

25. I also understand from counsel that conclusory statements are insufficient to support the legal conclusion of obviousness. Instead, I understand that the patent challenger must articulate a basis on which it concludes that it would have been obvious to make the claimed invention.

26. I also understand that when the prior art "teaches away" from combining prior art references or certain known elements, discovery of a successful means of combining them is more likely to be non-obvious. I further understand that a reference may be said to teach away when a POSITA, when reading the reference, would be discouraged from following the path set out in the patented invention, or would be led in a direction divergent from the path that was taken by

the inventors. I also understand that a reference may teach away from a use when that use would render the result inoperable.

27. I further understand that when a modification proposed by the patent challenger would render the prior art invention unsatisfactory for its intended purpose, then there is no suggestion or motivation to make that modification to the reference. I also understand that a patent challenger cannot rely on a combination of references that would require a substantial reconstruction and redesign of the elements shown in the primary reference as well as a change in the basic principle under which the primary reference was designed to operate.

B. Objective Secondary Considerations Of Non-Obviousness

28. I understand that, even if a patent claim is deemed obvious on its face, a patentee may point to objective indicia of non-obviousness, also known as secondary indicia of non-obviousness, to rebut a case of prima facie obviousness. Therefore, I understand that I must consider any secondary indicia before reaching a conclusion of whether an invention is obvious. I understand that evidence can include:

a. **Commercial success**. It is my understanding that when a product embodying the claimed invention enjoys commercial success, that can be considered evidence of non-obviousness when there is a nexus (i.e., a sufficient connection) between the claimed inventions of the asserted

patent and the commercial success. It is my understanding that the success must be because of the claimed invention, though the invention does not need to be the only reason for the commercial success.

b. **Copying**. It is my understanding that when a competitor copies a product that embodies the patent or inventions, as opposed to a prior art device, evidence of said copying can be an indication of non-obviousness.

c. **Long-standing problem or need**. I understand that a persistent problem or unfulfilled requirement in the field of endeavor that is resolved by the alleged invention can be an indication of non-obviousness.

d. **Skepticism**. Evidence that those of skill in the art either taught away from or were skeptical towards the alleged invention are indications of non-obviousness.

e. **Industry Praise**. I understand that evidence of praise for the invention by others skilled in the art is an indication of non-obviousness.

f. **Unexpected results**. It is also my understanding that if the claimed invention exhibits some superior property or advantage that a POSITA would have found surprising or unexpected, then that can be an indication of non-obviousness.

29. I understand that in applying considerations of secondary indicia of non-obviousness that there needs to be some nexus between the secondary indicia and the claimed subject matter. I understand Sun Pharma is entitled to a rebuttable presumption of nexus when the product in question embodies the claimed features and is coextensive with them.

VI. LEVEL OF ORDINARY SKILL IN THE ART

30. I have been advised that a POSITA is a hypothetical person to which the claimed subject matter pertains with the capability of understanding the scientific and engineering principles applicable to the pertinent art. I understand that the following factors may be considered in determining the level of ordinary skill: 1) the type of problems encountered in the art, 2) prior art solutions to those problems, 3) the speed with which innovations are made, 4) the sophistication of the technology, and 5) the educational level of active workers in the field. I also understand that not every factor may be present and that one or more factors may predominate.

31. Sun Pharma's attorneys have informed me that the filing date of the provisional application to which the '512 Patent claims priority is October 15, 2015. Petitioner and Dr. Grove have referenced this date as the "time of invention" for the Challenged Claims of the '512 Patent. Ex. 1015 (Grove Declaration), ¶¶54-55.

32. Based on these criteria, it is my opinion that a POSITA, with respect to the '512 Patent and at the time of the invention of the '512 Patent, would have had

a M.D. and/or a Ph.D. in an electrical engineering, optoelectronics, physics, optical sciences, optical engineering, or a related scientific or engineering field, and at least one to two years of work or research experience in optical engineering, optics, optoelectronics, phototherapy ("PT"), photodynamic therapy ("PDT"), or a related field. Alternatively, a POSITA could have a Bachelor's degree in one of the foregoing areas and at least three to four years of work or research experience in optical engineering, optics, optoelectronics, phototherapy, photodynamic therapy, or a related field.

33. I met and exceeded the definition of a POSITA as of at least October 15, 2015 (and thereafter), and consider myself to be a person with at least ordinary skill in the art of the '512 Patent. My experience working with undergraduate students, graduate students, postdoctoral fellows, industry professionals, and others in the relevant field provides me with significant insight on the knowledge of a POSITA.

34. I understand that Dr. Grove's and my opinions differ as to the level of a POSITA. Dr. Grove opined in his declaration for this IPR2025-00287 that:

> 24. In my opinion, a person of ordinary skill in the art ("POSITA") at the time of the earliest effective filing date of the '512 Patent would have been an individual or member of a multi-disciplinary team with education of (1) at least a Bachelor of Science degree in one or more fields of electrical engineering, physics, biomedical engineering, computer engineering, chemical

> engineering or material science, in fields relating to optics, optoelectronics, radiometry, photometry, photodynamic diagnosis (PD), photodynamic therapy (PDT), phototherapy (PT), and related technologies; and (2) a medical degree in fields relating to the diagnosis and treatment of skin conditions and related disease states. Alternatively, a POSITA individually or members of the multi-disciplinary team would have had at least four years of experience in one or more fields of optics, optoelectronics, radiometry, photometry, photodynamic diagnosis (PD), photodynamic therapy (PDT), or phototherapy (PT), and at least four years of experience in one or more fields of medical treatment of skin conditions and related disease states. A POSITA would have easily

See Ex. 1015 (Grove Declaration), ¶24. I disagree with Dr. Grove's proposed level of skill in the art, which would require that the POSITA (individual or team) have a B.S. degree in engineering **and** a medical degree, or alternatively four years of experience in one or more fields of optics **and** medical treatment of skin conditions and related disease states. Ex. 1015 (Grove Declaration), ¶24.

35. Dr. Grove's opinion contradicts the opinion of Petitioner's expert, Dr. Bretschneider, regarding the level of skill of the POSITA in IPR2024-00874 concerning the related '028 Patent. Dr. Bretschneider opined that:

> 37. In my opinion, a person of ordinary skill in the art ("POSITA") at the time of the earliest effective filing date of the '028 Patent would have had at least a Bachelor of Science in electrical engineering, physics, biomedical engineering, computer engineering, chemical engineering, material science, or a related scientific or engineering field, and at least one year of work or research experience in optics, optoelectronics, radiometry, photometry, photodynamic diagnosis (PD), photodynamic therapy (PDT), phototherapy (PT), or a related field. Alternatively, POSITA in the relevant time frame would have been someone with at least four years of industry or academic experience in optics, optoelectronics, radiometry, photometry, PD, PDT, PT, or a related field.

See IPR2024-00874, Ex. 1003 (Bretschneider Declaration), ¶37. Contrary to Dr. Grove's definition, I note that Dr. Bretschneider's definition does not require that the POSITA would have been a medical doctor or have four years of experience in medical treatment of skin conditions and related disease states. In addition, Dr. Grove's definition of the POSITA does not encompass the level of skill of the inventors themselves at the time of invention of the '512 Patent, as I understand none of the '512 Patent's inventors were medical doctors or had four years of medical experience. *See* Exs. 2007-2009 (LinkedIn profiles of Tom Boyajian, Mark Carota, and Brian Mazejka).

36. I understand that for the purposes of the institution decision in IPR2024-01312, the Board adopted Patent Owner's proposed definition of a

POSITA. *See* IPR2024-01312, Paper 9 (Institution Decision), at 10. My definition of a POSITA in this IPR is the same as the definition of a POSITA in IPR2024-01312. *See* IPR2024-01312, Ex. 2001 (Sasian Declaration), ¶¶27-32. Nevertheless, my opinions set forth in this Declaration would not change if Dr. Grove's proposed level of ordinary skill were adopted.

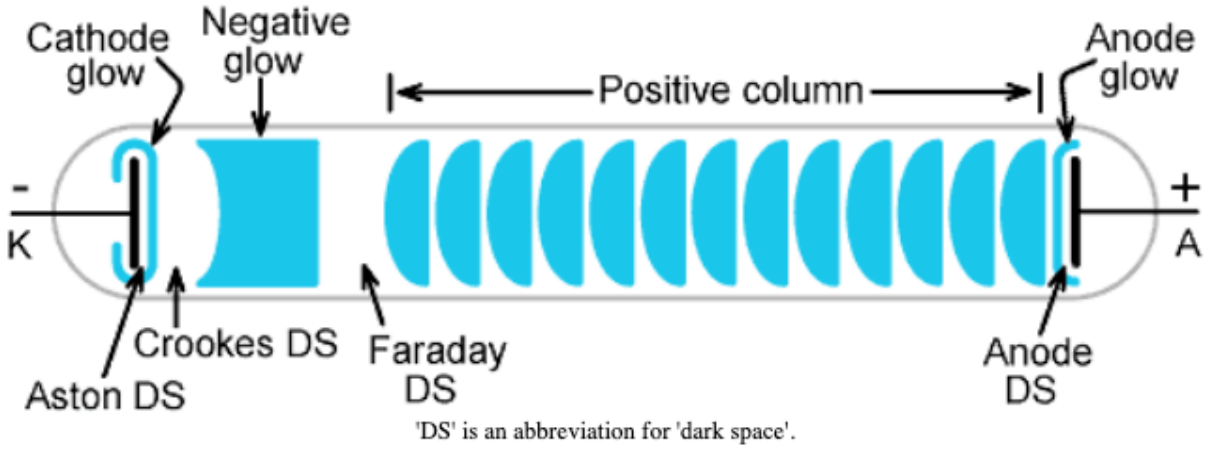
VII. TECHNOLOGY BACKGROUND

37. Fluorescent tubes were used for photodynamic therapy prior to the time of the '512 Patent's invention. *See, e.g.*, Ex. 1014 (Lundahl), 2:33-34, 5:38-46; Ex. 1001 ('512 Patent), 1:51-55 (incorporating Lundahl by reference); Ex. 1011 (WO 99/56827), 3:32-4:2, 9:34-10:8; Ex. 1004 (Larsen), [0029] [0071], [0102], [0105]-[0106], Figs. 2c, 17b.

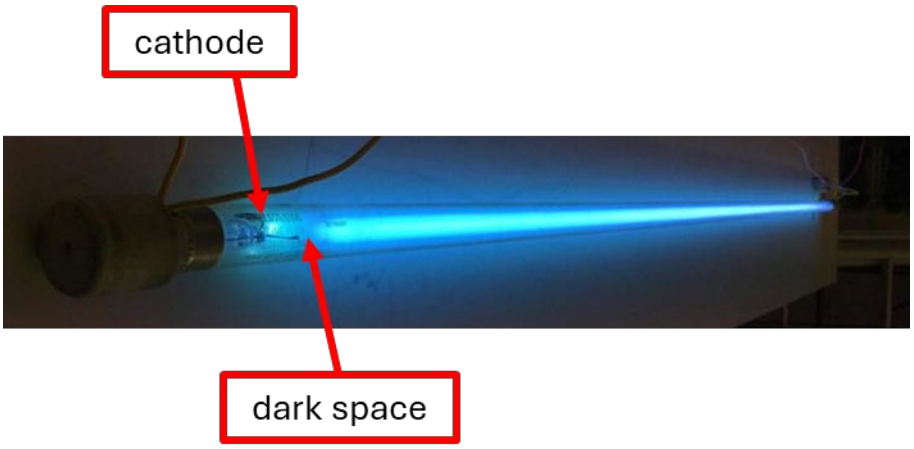
38. Fluorescent tubes are gas discharge lamps that emit light by using "an electric discharge through a low pressure gas to create a plasma which interacts with a fluorescing phosphor." Ex. 1014 (Lundahl), 5:47-50. A fluorescent tube is a "sealed glass tube with electrodes, or cathodes, at both ends" that is "internally coated with a uniform luminescent inorganic crystalline phosphor" and "filled with a low pressure inert gas, usually argon, to which a small amount of liquid mercury is added prior to sealing." Ex. 1014 (Lundahl), 5:50-56. Some of the liquid mercury evaporates to create an argon/mercury atmosphere in the tube because of the low pressure in the tube. Ex. 1014 (Lundahl), 5:56-58.

39. When a "sufficiently high voltage potential" is applied, the cathodes emit electrons that "diffuse along the length of the tube and ionize the argon/mercury vapor." The electric current flows through the ionized gas atmosphere and excites the mercury atoms. Ex. 1014 (Lundahl), 5:58-64. The excited mercury atoms "emit ultraviolet (UV) radiation" as they "return to a lower energy state." The phosphor coating the fluorescent tube wall absorbs the UV radiation and fluoresces, "converting the energy of the principle resonant line of mercury to a longer wavelength." Ex. 1014 (Lundahl), 5:66-6:4.

40. Fluorescent tubes do not emit "inherently uniform" light. Ex. 1014 (Lundahl), 6:10-11; Ex. 1015 (Grove Declaration), ¶¶122-123, 130. In a fluorescent tube, "[t]here are several dark spaces adjacent to the cathode," including Ason, Crookes, and Faraday dark spaces. Ex. 2012 (US 6,979,101), 1:31-45, 4:9-25. Faraday dark spaces are areas of "reduced emission" near the cathode of the tube. Ex. 1014 (Lundahl), 6:10-16; *see also* Ex. 2012 (US 6,979,101), 1:31-45 ("Accordingly, the illumination intensity or brightness along the length of a fluorescent tube gas discharge lamp is not uniform."). For example, as shown in the fluorescent tube below, there is a Faraday dark space – an area of lower intensity – near the cathode of the tube.



See, e.g., Ex. 2080 (Gas Discharge Tubes – Introduction) (https://www.g3ynh.info/disch_tube/intro.html.)



See, e.g., Ex. 2010 (https://www.lighting-gallery.net/gallery/displayimage.php?album=1601&pos=188&pid=211863) (rotated and annotated).

41. The fluorescent tubes emit diffuse light radially from the exterior of the tube. Thus, to efficiently utilize light which is not incident toward the illuminated surface, this light can be redirected. To "utilize visible light emitted from the back

of the tubes," a reflector is placed behind the tubes. Ex. 1014 (Lundahl), 8:62-67, 4:3-11, 5:29-31, Fig. 1, Fig. 5b.

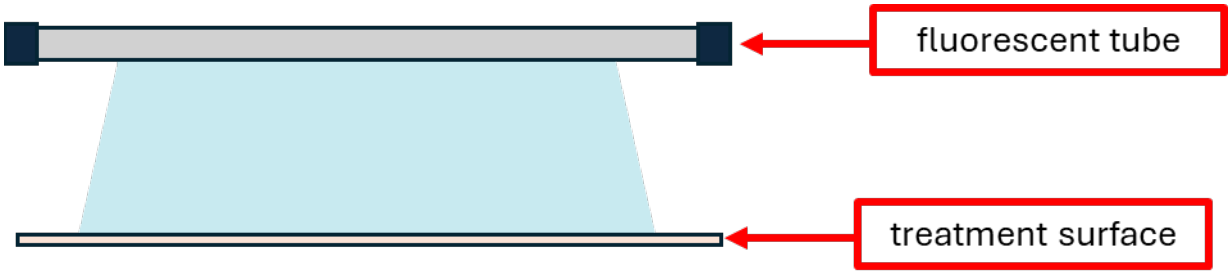
42. The wavelengths of light emitted by a fluorescent tube are determined by the "chemistry of the phosphor material," which can be used "to tune the wavelength output of the light source to suit the requirements of the application." Ex. 1014 (Lundahl), 6:4-9.

43. The light output of a fluorescent tube is controlled by the "magnitude of the tube current" and the tubes are "particularly sensitive to the electrical voltages and currents used to drive them." Ex. 1014 (Lundahl), 5:64-66, 7:11-17. Increasing the current "result[s] in higher cathode temperatures" and decreasing the current "can result in low tube wall temperatures that may cause condensation of the mercury vapor, adversely affecting the lamp output." Ex. 1014 (Lundahl), 7:16-25. Additionally, the cathode needs to be heated. Ex. 1014 (Lundahl), 7:25-27. Fluorescent tube voltage, current, and heating are controlled by ballasts that regulate the current and voltage flowing to the electrodes. Ex. 1014 (Lundahl), 7:27-34.

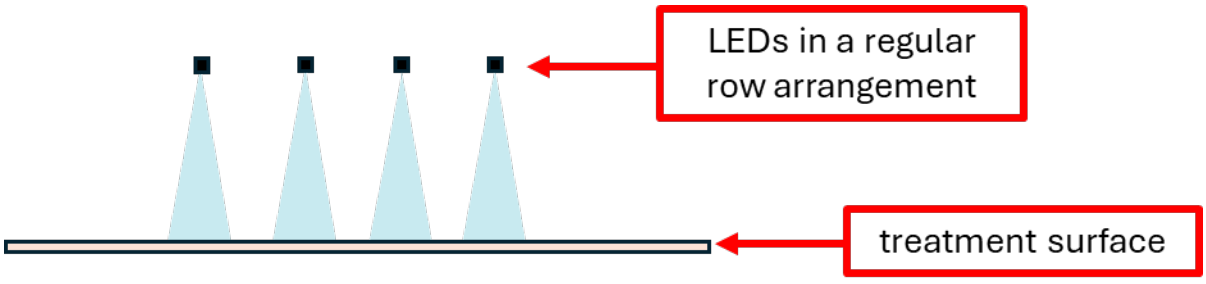
44. Fluorescent tubes were understood to operate differently and have very different characteristics than light emitting diodes (LEDs). In contrast to fluorescent tubes, LEDs are semiconductors that emit light by luminescence. When current is applied to an LED, electrons are excited and move from the *n*-type layer to

recombine with holes in the *p*-type layer. When the electron returns to its lower energy state, it releases light. Ex. 2011 (Bourget), 1944; Ex. 2013 (Ndjiongue), 15.

45. Fluorescent tubes are continuous, broad area, diffuse illuminators that illuminate over a treatment area that is continuous with the continuity of the tube, as illustrated below.



46. LEDs, unlike fluorescent tubes, are discrete, point source, directional illuminators with a Lambertian output characteristic. LEDs were available in a variety of sizes and packages in 2015. LEDs emit light in a specific direction in a "noncoherent, narrow band." Ex. 2011 (Bourget), 1944. As illustrated below, LEDs placed in a regular row arrangement are ***not*** a continuous light source.



Since LEDs are discrete, directional point sources, the distance between LEDs affects the ability of the LEDs to illuminate a light source. To uniformly illuminate

a surface, careful design and engineering of the LEDs is critical, including factors such as LED divergence angle, LED Lambertian output (intensity output as a function of divergence angle), LED drive current, number of and positioning of LEDs, and heat dissipation.

47. Unlike fluorescent tubes, LEDs are driven and controlled by current sources at low voltage to prevent damage. Ex. 2011 (Bourget), 1944 ("The de facto standard for a modern, high-power LED is a 1-W device with a nominal forward current of 350 mA at 3 V."), 1945 ("if the LED is connected directly to a power source of a voltage greater than the LED's specified value" it "can potentially damage or destroy the LED"). Notably, LEDs can also be damaged by excessive heat. Thus, heat dissipation methods are typically used to protect LEDs from heat damage. Ex. 2011 (Bourget), 1944 ("LEDs do not radiate heat directly, but do produce heat that must be removed to ensure maximum performance and lifetime."), 1945 ("It is a common misconception that LEDs do not create any heat. … Consideration must be taken when designing the fixture to properly conduct the heat away from the LED, or the device's lifetime could be shortened considerably.").

48. Dr. Grove states in the background of his declaration that "[t]he design of the light source plays an important role in achieving an irradiance that is as uniform as possible." Ex. 1015, ¶51. I agree with this statement. Uniformity of the light source is affected by various factors, including the type of light source (*e.g.*,

fluorescent tube or LED), size of the light source, distance between the light sources, electrical voltage and currents used to drive the light sources, temperature, and reflectors used, as discussed above.

VIII. THE '512 PATENT

49. The '512 Patent is entitled "ADJUSTABLE ILLUMINATOR FOR PHOTODYNAMIC THERAPY AND DIAGNOSIS." The inventors of this patent are Thomas Boyajian, Mark Carota, and Brian Mazejka.

50. The '512 Patent pertains to an adjustable illuminator suitable for use in photodynamic therapy (PDT) and photodynamic diagnosis (PD) as well as methods which use a combination of the illuminator and a photoactivatable agent or precursor to selectively treat and/or diagnose diseases such as acne, warts, psoriasis, photo-damaged skin, and cancer. Ex. 1001 ('512 Patent), 1:17-33. The '512 Patent specifies that "PDT or PD may be used for treatment or diagnosis of actinic keratosis of the scalp or facial areas of a patient." Ex. 1001 ('512 Patent), 1:27–29. Actinic keratosis is a skin condition that, in some cases, may evolve into skin cancer.

51. In typical PDT and PD, "a patient is first administered a photoactivatable agent or a precursor of a photoactivatable agent that accumulates in the tissue to be treated or diagnosed." Ex. 1001 ('512 Patent), 1:34–37. The '512 Patent refer to 5-aminolevulinic acid ("ALA") as one example of a precursor of a photoactivatable agent used in PDT of actinic keratosis. Ex. 1001 ('512 Patent),

1:43–45. The ’512 Patent notes that “As they are used here, the terms ALA or 5-aminolevulinic acid refer to ALA itself, precursors thereof and pharmaceutically acceptable salts of the same.” Ex. 1001 (’512 Patent), 1:45–47.

52. An illuminator irradiates the tissues, causing “chemical and/or biological” changes to the agent. Ex. 1001 (’512 Patent), 1:37–39. The illumination affects only the tissues containing the agent, allowing the agent to “selectively locate, destroy, or alter the target tissue.” Ex. 1001 (’512 Patent), 1:39–41. Other tissues in the treatment area suffer only “mild and reversible damage.” Ex. 1001 (’512 Patent), 1:41–43; *see also generally* Ex. 2035 (U.S. Patent No. 8,216,289), (describing illuminators and their function). The ’289 Patent is “incorporated by reference in [its entirety] for the techniques, methods, compositions, and devices related to PDT and PD.” Ex. 1001 (’512 Patent), 1:50–54.

53. The ’512 Patent describes adjustable illuminators used in PDT or PD. In general, these illuminators improve the uniformity of light on the patient’s treatment area, increasing the effectiveness of diagnosis and treatment. The abstract states:

> An adjustable illuminator for photodynamically diagnosing or treating a surface includes a plurality of first panels and at least one second panel. The plurality of first panels have wider widths and the at least one second panel has a narrower width. The narrower width is less than the wider widths. The illuminator further includes a plurality of light sources, each mounted to one of the plurality of first panels or the at least one second panel and configured to irradiate the surface with substantially uniform intensity visible

> light. The plurality of first panels and the at least one second panel are rotatably connected. The at least one second panel is connected on each side to one of the plurality of first panels. The second panel acts as a "lighted hinge" to reduce or eliminate optical dead spaces between adjacent panels when the illuminator is bent into a certain configuration.

Ex. 1001 ('512 Patent), Abstract.

54. Conventional adjustable illuminators suffered from drawbacks that prevented sufficient light uniformity. Ex. 1001 ('512 Patent), 2:5-20. Insufficient illumination uniformity caused the patient's treatment to suffer. Ex. 1001 ('512 Patent), 2:21-49. The '512 Patent explains that sufficient illumination uniformity is required for certain forms of PDT, including treating actinic keratosis:

> [S]ome forms of treatment involving PDT, such as the use of ALA to treat actinic keratosis, require specific and highly uniform intensity and color of light to achieve effectiveness. In these instances, successful PDT relies on the targeted delivery of both the correct quantity of the photoactivatable agent and the correct quantity (i.e., power and wavelength) of light to produce the desired photochemical reactions in the target cells. Thus, to achieve this, the light source must provide illumination to the target area and this illumination must be uniform with respect to both wavelength and power.

Ex. 1001 ('512 Patent), 2:29–38.

55. The '512 Patent describes how uniformity can be "measured using a cosine response detector, which mimics the response of a patient's skin to the incident of [sic] light." Ex. 1001 ('512 Patent), 8:14–18. The '512 Patent explains how, under Lambert's cosine law, the light intensity at a given point is directly proportional to the cosine of the angle between the incoming ray of light and the

normal to the surface, such that a ray of light normally incident on the front of a curved surface (like the head of a patient) arrives in a substantially perpendicular manner to that area, with 100% absorbance. However, if the ray of light is obliquely incident on the side of a curved surface, it will arrive in a substantially parallel manner. The absorption of light at the side edges will approach zero, which lowers the effectiveness of treatment at the edges of curved surfaces. A fall-off effect for intensity also increases as the distance between the light source and the point on the surface increases. Ex. 1001 ('512 Patent), 5:60–6:8.

56. The '512 Patent provides in Figure 7, reproduced below, an example of the light uniformity produced by a conventional illuminator. Ex. 1001 ('512 Patent), Figure 7. The Figure 7 graph shows total light dose (J/cm²) measured based on emitted irradiance (W/cm²) over time (sec). Ex. 1001 ('512 Patent), 8:18-19. With conventional illuminators, higher light doses are found at the center of the face, near the patient's nose, and the light dose drops off in the areas further away from the center of the face, such as the patient's cheeks, forehead, and ears. Ex. 1001 ('512 Patent), 8:22–33. The '512 Patent notes how "due to the various contours of a patient's body, the uniformity of light delivered by these conventional illuminators may vary substantially depending on the treatment area of the patient." Ex. 1001 ('512 Patent), 2:46–49. The '512 Patent concludes that conventional illuminators "produce a varying field of light uniformity, making it undesirable and ineffective

for those treatments requiring highly specific light uniformity." Ex. 1001 ('512 Patent), 8:33–38.

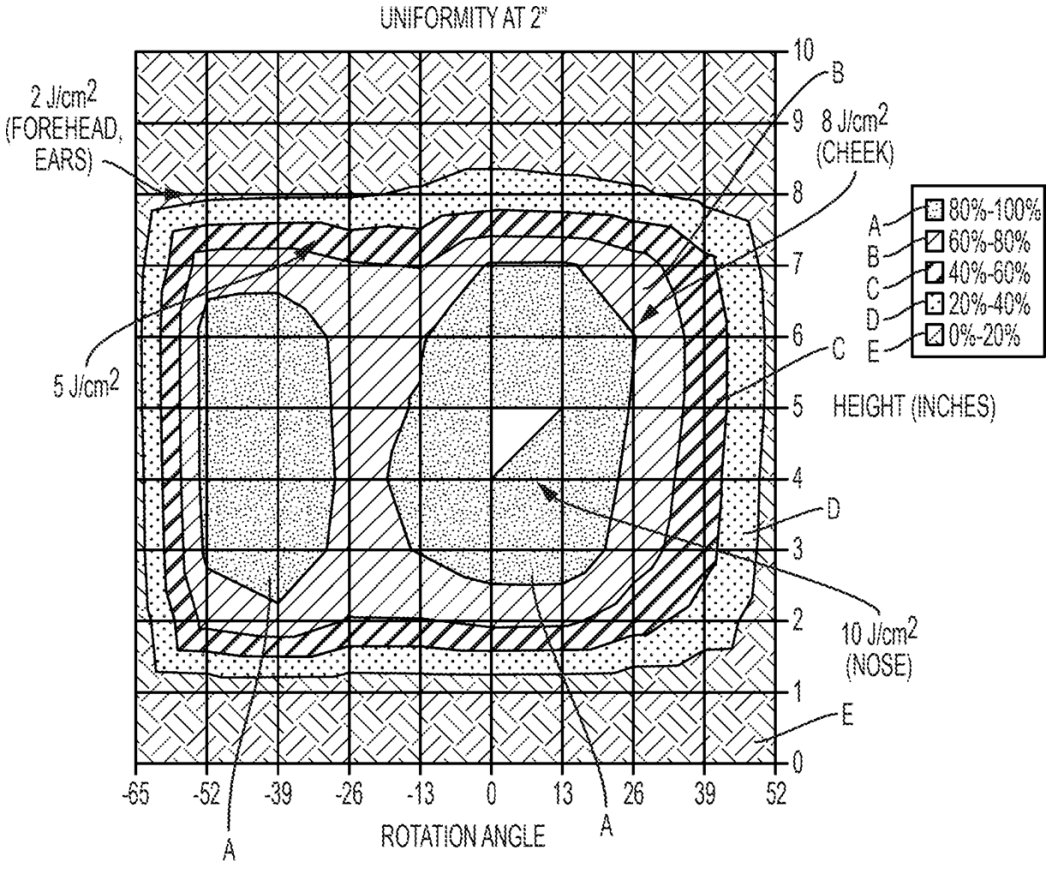


FIG. 7

Ex. 1001 ('512 Patent), FIG. 7.

57. The devices disclosed in the '512 Patent have novel features that are designed to improve illumination uniformity on the patient's treatment surface, resulting in improved treatment and diagnosis. Ex. 1001 ('512 Patent), 2:50-3:19. The '512 Patent further describes how those features allow for the effective delivery of 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." Ex. 1001 ('512 Patent), 2:54–59. "Thus, a uniform light may be delivered to a targeted treatment area regardless of the shape and location of the contoured surface of the patient's body." Ex. 1001 ('512 Patent), 2:59–62. Some of those exemplary features are discussed below.

58. For example, the '512 Patent discloses an illuminator with five panels, with an array of light emitting diodes (LEDs) on each panel, as seen in Figure 2B, reproduced below.

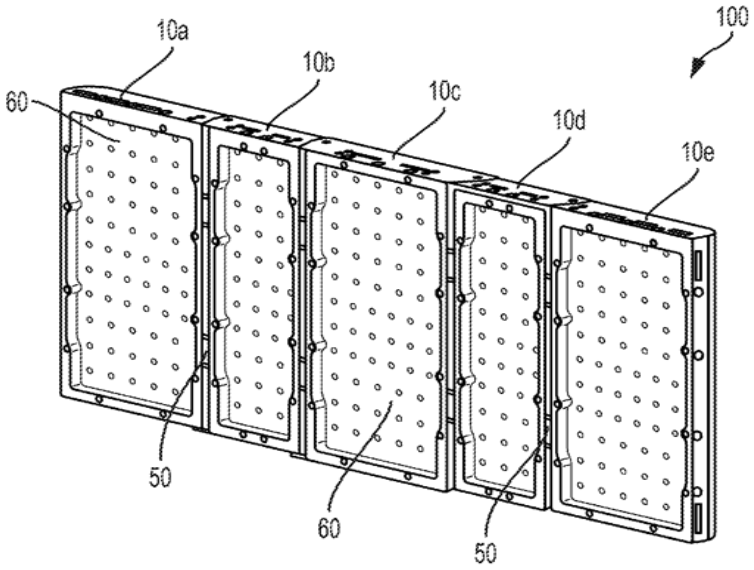


FIG. 2B

Ex. 1001 ('512 Patent), Figure 2B.

59. As shown in Figure 4, reproduced below, the illuminator can be mounted to a stand, which includes a base and a vertical pillar. Ex. 1001 ('512 Patent), Figure 4. The base can include four wheels on the bottom, to aid in moving

the illuminator to the appropriate position near the patient. The top of the pillar includes an arm that connects to the illuminator. That arm can include a hinge point which allows the illuminator's position to be further adjusted. The pillar can further include a controller and a power supply to direct power to the panels. The panels can also include fans as a cooling system for the LEDs on the panels. Ex. 1001 ('512 Patent), 5:13–49.

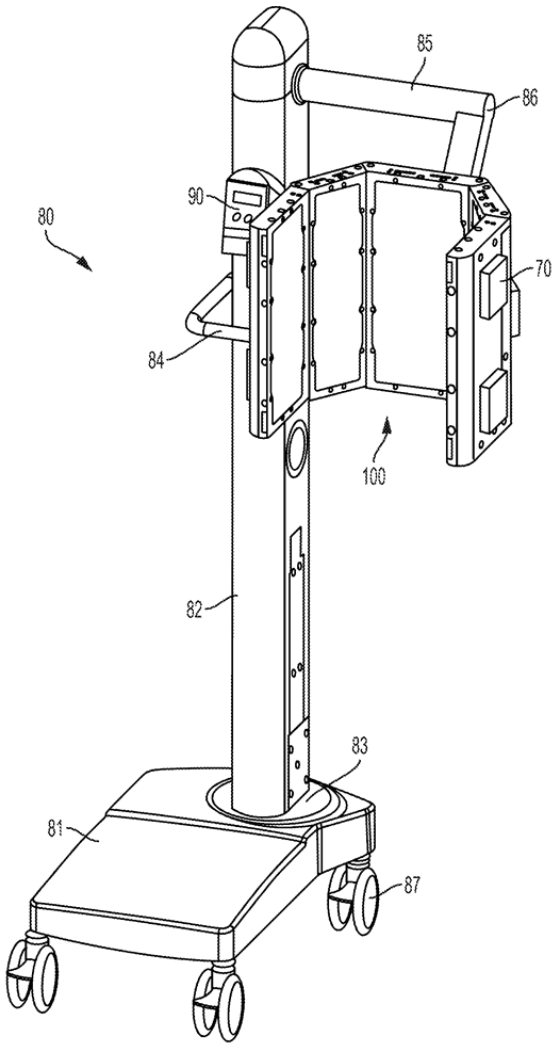


FIG. 4

Ex. 1001 (’512 Patent), FIG. 4.

60. The ’512 Patent describes how the panels can be connected by nested hinges that fit between the illuminator’s panels. Ex. 1001 (’512 Patent), 4:63–66. In an embodiment of the invention, the “nested hinges 50” are “mounted to the inner side surfaces of adjacent panels (e.g. **10*a*, 10*b***) to allow for rotation of the panels.” Ex. 1001 (’512 Patent), 4:64-5:12, Fig. 3A. The nested hinges reduce the space between panels thereby reducing or eliminating optical “dead space.” Ex. 1001 (’512 Patent), 4:46-48, 5:6–10. The reduction or elimination of “dead space” improves the uniformity of illumination on the patient’s treatment area.

61. For example, Figures 3A and Figures 3B display “detailed views of the nested hinges of the main body of the illuminator of FIGS. 1A-1B,” reproduced below. Ex. 1001 (’512 Patent), 3:31-32, 4:63-64, Figs. 3A–3B.

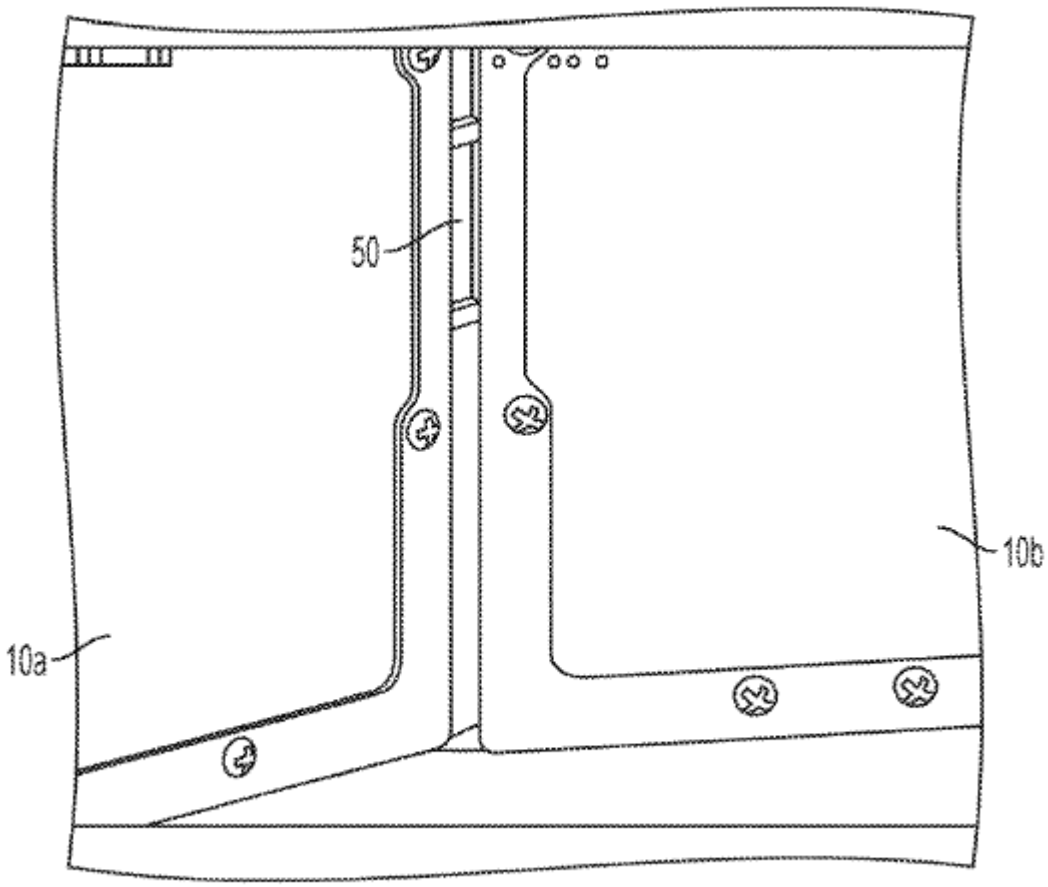


FIG. 3A

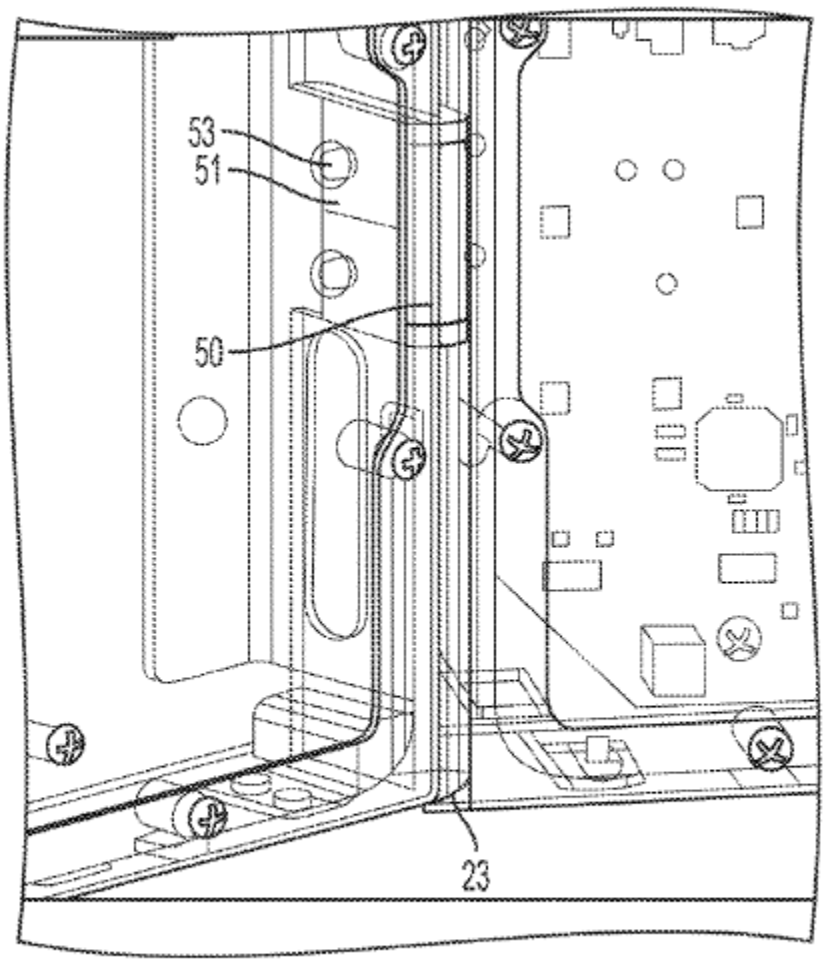


FIG. 3B

Ex. 1001 (’512 Patent), FIGS. 3A, 3B.

62. Furthermore, the specification explains that in one embodiment the nested hinges “are mounted to the inner side surfaces of adjacent panels (e.g., **10***a*, **10***b*) to allow for rotation of the panels.” Ex. 1001 (’512 Patent), 4:64–66. The hinges may in one embodiment contain a “flange,” “mounted to the inner side surface of a panel.” Ex. 1001 (’512 Patent), 4:66–67.

63. The specification further explains that "[t]he inner side surface of a panel may include a recess in which the flange **51** may be placed. The inner side surface of the panel may also include an additional recess to accommodate the joint of the hinge **50** such that the joint of the hinge 50 becomes substantially flush with an outer front surface of the panel. Such configurations may allow for the outside vertical edges of adjoining panels to be positioned closer to one another. By spacing the vertical edges of adjoining panels closer, optical dead spaces may be further reduced or eliminated. In addition, the hinges **50** together with the tabs **23** may reduce the number of pinch points present in the system." Ex. 1001 ('512 Patent), 5:1–12.

64. As another example, the '512 Patent discloses the ability to configure the illuminator's panels in a U-shape. Ex. 1001 ('512 Patent), 6:9–12. As noted in the '512 Patent, "a 'fall off' of light exposure tends to occur at the edges of a curved surface" (for example, the head of a patient). Ex. 1001 ('512 Patent), 6:5–6. Because the illuminator's panels can be configured in a U-shape to wrap around the curved surface (for example, a head of a patient) this effect is reduced, increasing overall uniformity. Ex. 1001 ('512 Patent), 6:9–12.

65. Also, for example, the '512 Patent discloses increasing the light intensity at the shorter edges of the illuminator's panels. The illuminator has panels that include light sources (such as LEDs) and each panel has two long edges and two

short edges. Ex. 1001 ('512 Patent), Figure 5. In some disclosed embodiments, there are more LEDs present, or at higher density, at the short edges than the long edges or the center of the panel, resulting in a greater density of emitted light at those short edges. *See* Ex. 1001 ('512 Patent), 6:49-51, 7:1–4. In other embodiments, the LEDs at the panel's short edges can be controlled to emit light at a greater intensity than at the diodes at the panel's long edges or at the center of the panel. Ex. 1001 ('512 Patent), 6:30–36. Thus, the higher light intensity emitted at the short edges results in a more uniform illumination on the patient's treatment area, enhancing the treatment and diagnosis. Ex. 1001 ('512 Patent), 6:36-38.

66. Figure 5 of the '512 Patent shows that each of the panels of the adjustable illuminator has two longer edges and two shorter edges:

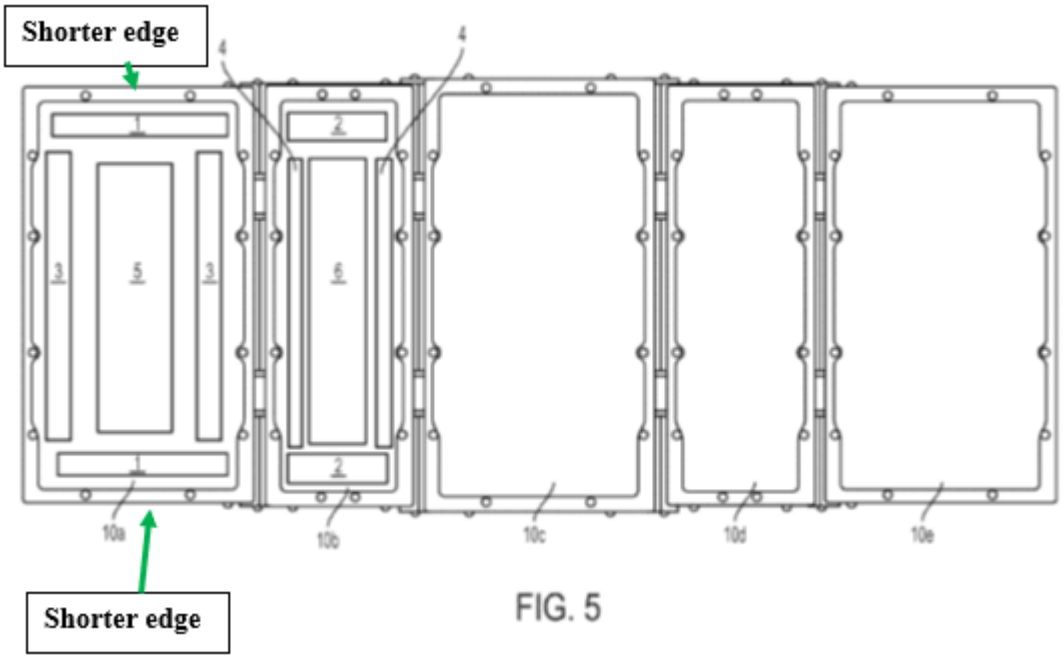


FIG. 5

Ex. 1001 (’512 Patent), Figure 5 (annotated).

67. The ’512 Patent further discloses that the LED arrays can be “individually configured” to increase the intensity of the light emitted to compensate for the fall-off effect. Ex. 1001 (’512 Patent), 6:16–23. Each panel can have a dedicated control unit on the panel to regulate power provided to the individual LED array on the panel. Ex. 1001 (’512 Patent), 5:55–57. The LED arrays of the panels can be “divided into three general areas, which may be described as ‘addressable strings.’ Areas 1, 3, and 5 correspond to an addressable string configuration that may be included in the wider panels **10***a*, **10***c*, and **10***e*, while areas 2, 4, and 6 correspond to an addressable string configuration that may be included in the narrower panels **10***b* and **10***d*.” Ex. 1001 (’512 Patent), 6:24–29. The ’512 Patent goes on to state that: “[t]he current to each area is adjusted in order to adjust the intensity of light emitting from each of the areas. For example, a higher current may be supplied to areas 1 and 2 than the current supplied to areas 3 and 4 such that areas 1 and 2 emit a higher intensity of light than areas 3 and 4. Similarly, a higher current may be supplied to areas 3 and 4 than the current supplied to areas 5 and 6.” Ex. 1001 (’512 Patent), 6:30–36.

68. In addition to increasing the current to a particular area of the array to increase the intensity of light, the ’512 Patent also discloses that the intensity of light from an area of the array can alternatively be increased by increasing the density of

LED diodes. Specifically, the '512 Patent discloses that "[t]he addressable strings of the LED arrays **60** may also include varying amounts of individual diodes mounted within the particular area." Ex. 1001 ('512 Patent), 6:49–51. For example, the '512 Patent discloses that "12 diodes may be mounted in each of areas 1, while 9 diodes may be mounted in each of areas 3." Ex. 1001 ('512 Patent), 6:52–53. The '512 Patent further discloses that "[b]y varying the arrangement of the diodes within each of the addressable strings of the LED arrays **60**, power output and/or the intensity of light emitted from a given array may be better controlled and fine-tuned." Ex. 1001 ('512 Patent), 7:1–4. The '512 Patent notes that "the number and arrangement of diodes included within each of the LED arrays **60** is not particularly limited." Ex. 1001 ('512 Patent), 6:61–63.

69. By adjusting the current to particular areas or by varying the arrangement of diodes in particular areas, "fall-off" may be minimized. As the '512 Patent states, by adjusting current to particular areas "a higher intensity of light is emitted overall from the edges, which may allow for a reduction in any fall-off effect." Ex. 1001 ('512 Patent), 6:36–38. Additionally, by varying the arrangement of diodes in particular areas "power output and/or the emitted light intensity may be increased close to the edges of the array that are closest to the nested hinges to compensate for the lack of light emitting from the meeting point of panels." Ex. 1001 ('512 Patent), 7:8–11.

70. The ’512 Patent displays in Figure 8, reproduced below, another light uniformity graph that corresponds to the uniformity of light produced by an embodiment of the inventions of the Patent. Ex. 1001 (’512 Patent), Figure 8. The light uniformity is substantially improved compared to the uniformity provided by conventional illuminators shown in Figure 7, as there is little to no deviation in the light intensity measured at various areas of the patient’s face (e.g., the nose, cheek, forehead, ears), with minimal drop-off at the extreme boundaries of the patient’s face. Ex. 1001 (’512 Patent), 8:39–46. The ’512 Patent describes that, “[I]n one embodiment, the measured output over the active emitting area (over the entire active emitting area) is within 60% of the measured maximum (over the entire active emitting area) measured with a cosine response detector over all operation distances.” Ex. 1001 (’512 Patent), 8:54–58.

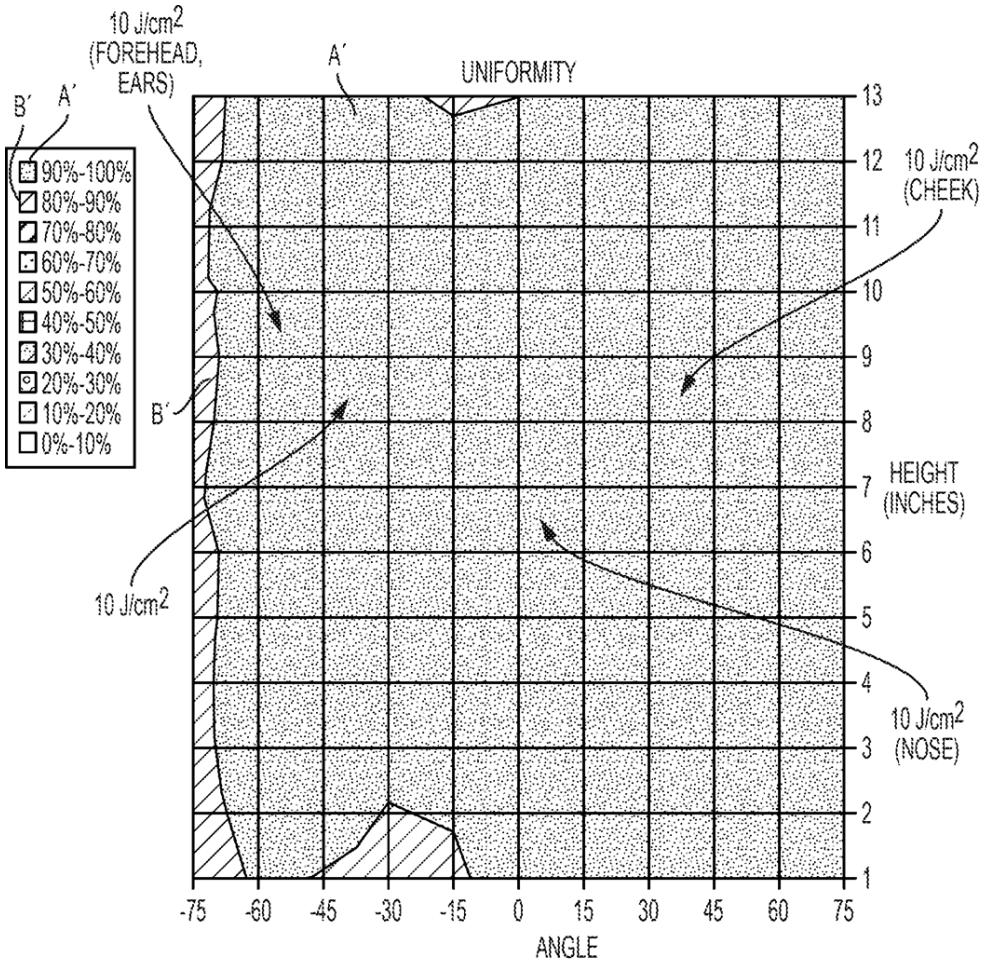


FIG. 8

Ex. 1001 ('512 Patent), FIG. 8.

71. The full text of the challenged claims appears in Appendix A to my declaration.

IX. PROSECUTION HISTORY OF THE '512 PATENT

72. United States Patent No. 11,446,512 issued from U.S. Application 16/791,004 ("the '004 Application"). Ex. 1035 ('512 File History), 763. The '004 Application was filed as a divisional application on February 14, 2020, claiming

priority to U.S. Application 15/292,731. Ex. 1035 ('512 File History), 12, 3, 1. Application 15/292,731 claimed priority from U.S. Provisional Application 62/241,902 filed on October 15, 2015. Ex. 1035 ('512 File History), 12.

73. The '004 Application listed three inventors: Thomas Boyajian, Mark Carota, and Brian Mazejka. Ex. 1035 ('512 File History), 4. The '004 Application was titled "ADJUSTABLE ILLUMINATOR FOR PHOTODYNAMIC THERAPY AND DIAGNOSIS." Ex. 1035 ('512 File History), 1.

74. On October 25, 2021, the Examiner sent a non-final rejection stating that "[c]laims 1-20 are rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor . . . regards as the invention." Ex. 1035 ('512 File History), 245-249. Specifically, the Examiner stated that "Claim 1 recites the limitation 'nested hinges configured to reduce optical dead space' in lines 2-3. The metes and bounds of the claim are unclear as it is not known what the optical dead space is compared to in order to known [sic] that it has been 'reduced'." Ex. 1035 ('512 File History), 248. The Examiner also rejected various other claims under 35 U.S.C. 102 (anticipation) and 35 U.S.C. 103 (obviousness), for example: *See* Ex. 1035 ('512 File History), 249-256.

> Claims 1, 2, 6, 7, 13, 18, and 19 are rejected under 35 U.S.C. 102(a)(1) as being anticipated by Tobin . . .

> Claims 1, 2, 5-7 and 18 are rejected under 35 U.S.C. 102(a)(1) as being anticipated by Larsen . . .
>
> Claims 3-5 are rejected under 35 U.S.C. 103 as being unpatentable over Tobin . . . in view of Harth . . .
>
> Claims 11, 12, and 14-17 are rejected under 35 U.S.C. 103 as being unpatentable over Tobin . . . in view of Tapper . . .
>
> Claims 3 and 4 are rejected under 35 U.S.C. 103 as being unpatentable over Larsen . . . in view of Harth . . .
>
> Claims 11, 12, and 14-17 are rejected under 35 U.S.C. 103 as being unpatentable over Larsen . . . in view of Tapper . . .
>
> Claim 20 is rejected under 35 U.S.C. 103 as being unpatentable over Larsen.

75. On January 24, 2022, the Applicant and the Examiner conducted a telephonic interview to discuss the Examiner's rejections. Ex. 1035 ('512 File History), 379. To overcome the Examiner's indefiniteness rejection, the Applicant proposed to clarify the meaning of "nested hinges" by amending the claims to recite "nested hinges on inner side surfaces of adjacent panels": Ex. 1035 ('512 File History), 380 (annotated).

> an illuminator comprising at least five panels connected by nested hinges on inner side surfaces of adjacent panels, the nested hinges being configured so as to allow illumination between the at least five panels ~~to reduce optical dead space~~,

76. To overcome the Examiner's anticipation and obviousness rejections, the Applicant proposed to amend the claims by adding the following limitation to claim 1: "wherein each of the at least five panels has two long edges and two short edges, and the light sources are arranged such that a higher intensity of light is

emitted proximate the short edges compared to the intensity of light emitted not proximate the short edges": Ex. 1035 ('512 File History), 380 (annotated).

1. (Currently Amended) A system for photodynamically diagnosing or treating a patient, comprising:

an illuminator comprising at least five panels connected by nested hinges on inner side surfaces of adjacent panels, the nested hinges being configured so as to allow illumination between the at least five panels ~~to reduce optical dead space~~,

light sources disposed on surfaces of the at least five panels ~~a surface of the illuminator~~, the illuminator being configured to uniformly illuminate a treatment surface of the patient via the light sources,

one of the at least five panels positioned as a center panel configured to face the treatment surface, and two or more of the at least five panels being configured to be angled relative to the center panel,

wherein each of the at least five panels has two long edges and two short edges, and the light sources are arranged such that a higher intensity of light is emitted proximate the short edges compared to the intensity of light emitted not proximate the short edges.

77. On February 25, 2022, the Applicant submitted the proposed amendments to Claim 1 to the USPTO. Ex. 1035 ('512 File History), 459-468.

78. On May 16, 2022, the Examiner allowed the claims. Ex. 1035 ('512 File History), 489. In the Notice of Allowability, the Examiner stated that "[i]t is in the opinion of the examiner that the art of record neither anticipates nor renders obvious 'nested hinges on inner side surfaces of adjacent panels' and 'wherein each of the at least five panels has two first edges and two second edges shorter than the two first edges, and the light sources are arranged such that a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not

proximate the second edges' in combination with the rest of the claimed limitations set forth in the independent claim": Ex. 1035 ('512 File History), 494 (annotated).

Allowable Subject Matter

3. Claims 1-6 and 11-24 are allowed.

4. The following is an examiner's statement of reasons for allowance: It is in the opinion of the examiner that the art of record neither anticipates nor renders obvious "nested hinges on inner side surfaces of adjacent panels" and "wherein each of the at least five panels has two first edges and two second edges shorter than the two first edges, and the light sources are arranged such that a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges" in combination with the rest of the claimed limitations set forth in the independent claim.

79. The Corrected Notice of Allowability issued on May 20, 2022 reiterated the allowed subject matter. Ex. 1035 ('512 File History), 557-560 (annotated).

Allowable Subject Matter

3. Claims 1-6 and 11-24 are allowed.

4. The following is an examiner's statement of reasons for allowance: It is in the opinion of the examiner that the art of record neither anticipates nor renders obvious "nested hinges on inner side surfaces of adjacent panels" and "wherein each of the at least five panels has two first edges and two second edges shorter than the two first edges, and the light sources are arranged such that a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges" in combination with the rest of the claimed limitations set forth in the independent claim.

80. The Corrected Notice of Allowability issued on August 24, 2022 allowed the same claims. Ex. 1035 ('512 File History), 705-706.

81. On September 20, 2022, the United States Patent and Trademark Office sent an Issue Notification to the Applicant informing them that the ’512 Patent issued from the ’004 Application. Ex. 1035 (’512 File History), 763.

82. On December 27, 2024, Biofrontera Inc., Biofrontera Bioscience GmbH, Biofrontera Pharma GmbH, and Biofrontera AG filed an *Inter Partes* Review Petition against the ’512 Patent. IPR2025-00287, Petition. As of the date of my declaration, the Patent Trial and Appeal Board has not yet entered any decision on Biofrontera’s petition.

X. CLAIM CONSTRUCTION

83. I understand that the parties agreed on the following construction for “uniformly illuminate a treatment surface” / “uniformly illuminating a treatment surface,” which has been adopted by the Administrative Law Judge in the related ITC proceeding, and which I have applied in my analysis:

Claim Term	Agreed Upon Construction
“uniformly illuminate a treatment surface” / “uniformly illuminating a treatment surface”	“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”

Ex. 2033 (ITC Claim Construction Order), 13; Petition, 43.

84. In addition to the agreed-to construction above, I understand that the Administrative Law Judge in the related ITC proceeding has construed the following claim terms:

Claim Term	Construction in ITC Proceeding
"a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges"	"a higher intensity of light is emitted close to the second shorter edges compared to the intensity of light emitted not close to the second shorter edges"
"photodynamically diagnosing or treating a patient"	Preamble is limiting
"nested hinges on inner side surfaces of adjacent panels"	"hinges that fit on inner side surfaces of adjacent panels"
"recess"	"indentation, small hollow, or cleft"

Ex. 2033 (ITC Claim Construction Order), 14-35, 46-47.

85. I have applied these constructions in my analysis. I understand that terms not construed are given their ordinary and customary meaning within the context of the '512 Patent—that is, the meaning to a POSITA at the time of the invention. I have applied this ordinary and customary meaning for claim terms that have not been construed. I reserve the right to advance additional claim constructions to the extent it is raised later in this proceeding, in later *inter partes* review proceedings, or in court proceedings.

XI. BIOFRONTERA'S ASSERTED PRIOR ART

A. Lundahl (Ex. 1014)

86. U.S. Patent No. 6,223,071 to Lundahl et al. ("Lundahl") is entitled "Illuminator for Photodynamic Therapy and Diagnosis Which Produces Substantially Uniform Intensity Visible Light." Ex. 1014 (Lundahl), Cover.

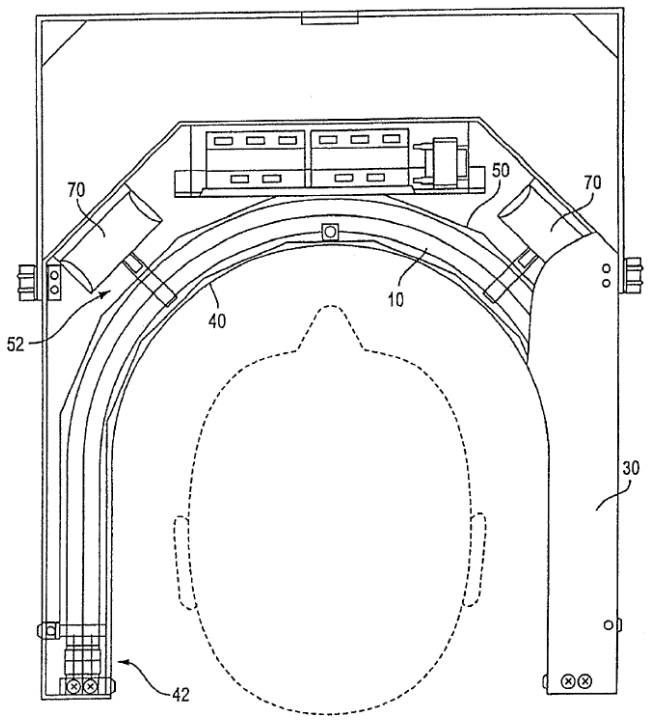
87. Lundahl discloses an illuminator for photodynamic therapy that "produces visible light of consistent uniformity in terms of both spectral characteristics and intensity over a diversely contoured surface." Ex. 1014 (Lundahl), 2:35–40. Lundahl discloses that "***[a] much higher degree of precision and integration is required for the components of the present invention***" than in "conventional light sources because of biological requirements imposed on a PDT light source." Ex. 1014 (Lundahl), 4:12-16. Lundahl emphasizes that ***uniformity "must be controlled to assure that the properties of the device are suitable to deliver light to the target lesions and drive the photodynamic reaction."*** Ex. 1014 (Lundahl), 4:16-18. To achieve this uniformity, Lundahl teaches "each functional block within the present invention comprises carefully selected and engineered components." Ex. 1014 (Lundahl), 4:19-21. As explained below, Lundahl's "functional blocks" that "comprise carefully selected and engineered components" include: (1) ***U-shaped tubes*** (Ex. 1014 (Lundahl), 4:27-38, 6:31-59, Abstract, 2:62-67, 3:62-67, claim 1, FIG. 1, FIG. 4a), (2) ***reflector*** (Ex. 1014 (Lundahl), 8:62-67,

5:30-32, Abstract, FIG. 5B); (3) ***electrical system*** (Ex. 1014 (Lundahl), Abstract, claims 23, 26, 7:10-35, 8:10-59, FIGS. 3, 7, 8, 9A); and (4) ***cooling system*** (Ex. 1014 (Lundahl), 4:39-44, Abstract, 2:46-48, 3:22-28, 9:14-53, claims 5, 6, 7, 8, FIGS. 1, 3).

88. Lundahl discloses an illuminator with "seven U-shaped fluorescent tubes **10(1)-10(7)**" that "are driven by three electronic ballasts **20**. Adjusting the ballast voltage controls the output power of the tubes. The tubes **10(1)-10(7)** are supported by a housing **30** and are covered by a polycarbonate shield **40** which directs cooling airflow within the unit and prevents glass-patient contact in the event of tube breakage. ***An aluminum reflector 50 located behind the tubes increases both the output irradiance and the uniformity of the output distribution***." Ex. 1014 (Lundahl), 5:22–35.

89. FIG. 1 of Lundahl shows "a partial cross-section, front elevation view of an illuminator according to the present invention."

FIG. 1



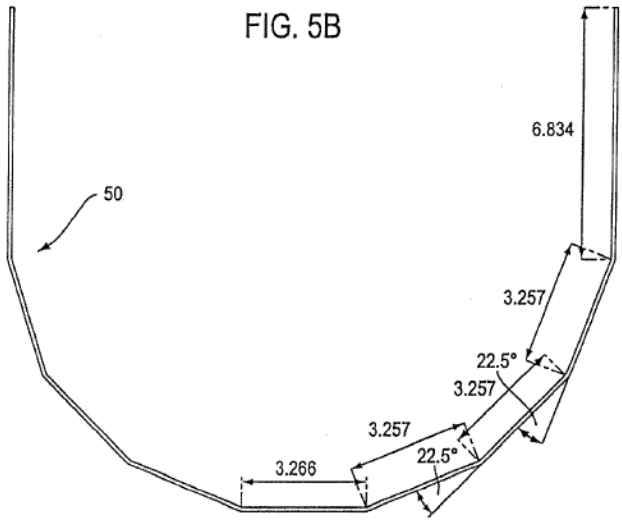
Ex. 1014 (Lundahl), FIG. 1, 4:60–61.

90. Lundahl discloses that ***the U-shape of the illuminator "minimizes the variations in distance between the emitter and the target, providing a uniform visible light distribution*** to the face or scalp of the patient" and "***provides the desired irradiance and irradiance uniformity*** for scalp and facial irradiation, and thus ensures that the proper visible light dosage is applied to all target areas during PDT." Ex. 1014 (Lundahl), 6:31–42. The U-shape design "ameliorate[s]" the "problem" of "flat emitting surface[s that] would not deliver a uniform light dose to all contours of the face simultaneously." Ex. 1014 (Lundahl), 4:28-37. Lundahl discloses that

"[t]he present invention is also directed to . . . other areas of the patient (e.g., arms, legs, etc.)." Ex. 1014 (Lundahl), 1:14–17.

91. Lundahl discloses that "[i]n order to utilize the visible light emitted from the back of the tubes, ***and to increase the uniformity of the output distribution, a reflector 50*** is positioned approximately 10 mm from the rear surface of the tubes." Ex. 1014 (Lundahl), 8:62–65. The reflector **50** is "made of polished aluminum sheet" and "is bent to approximately conform to the configuration of the tubes," as shown below in FIG. 5B. Ex. 1014 (Lundahl), 8:65–67, FIG. 5B.

FIG. 5B



92. FIG. 4A is "a detail view of the fluorescent tube light source shown in FIG. **1**." Ex. 1014 (Lundahl), 4:66–67. As shown below in FIG. 4A, "the tubes have a generally arcuate central region **10**A and arms **10**B extending from respective ends of the central region." Ex. 1014 (Lundahl), 5:43–46, FIG. 4A (annotated).

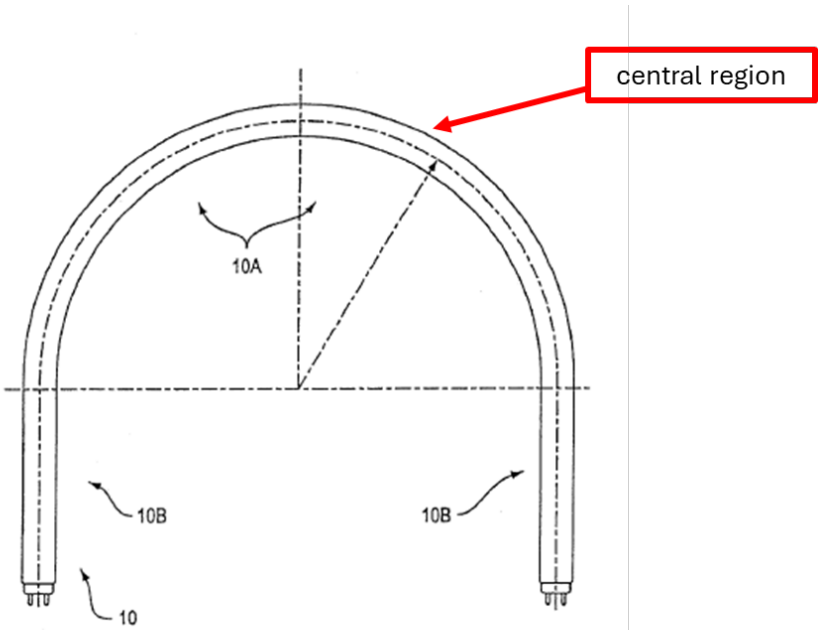


FIG. 4A

93. Lundahl discloses that "[s]ince the output irradiance for this tube increases (to a point) with tube wall temperature, the hotter central region of the tube produces higher output irradiances than the rest of the tube." Ex. 1014 (Lundahl), 9:42–53. Because "temperature distribution also plays a key role in irradiance uniformity" and "the tube output may vary over its length, modulation of the temperature distribution may be used to control irradiance uniformity of the illuminator." Ex. 1014 (Lundahl), 4:39-44.

94. Further, as shown below in FIG. 4A, the "fluorescent tube consists of a sealed glass tube with electrodes, or cathodes, at both ends." Ex. 1014 (Lundahl), at 5:50–52; FIG. 4A (annotated).

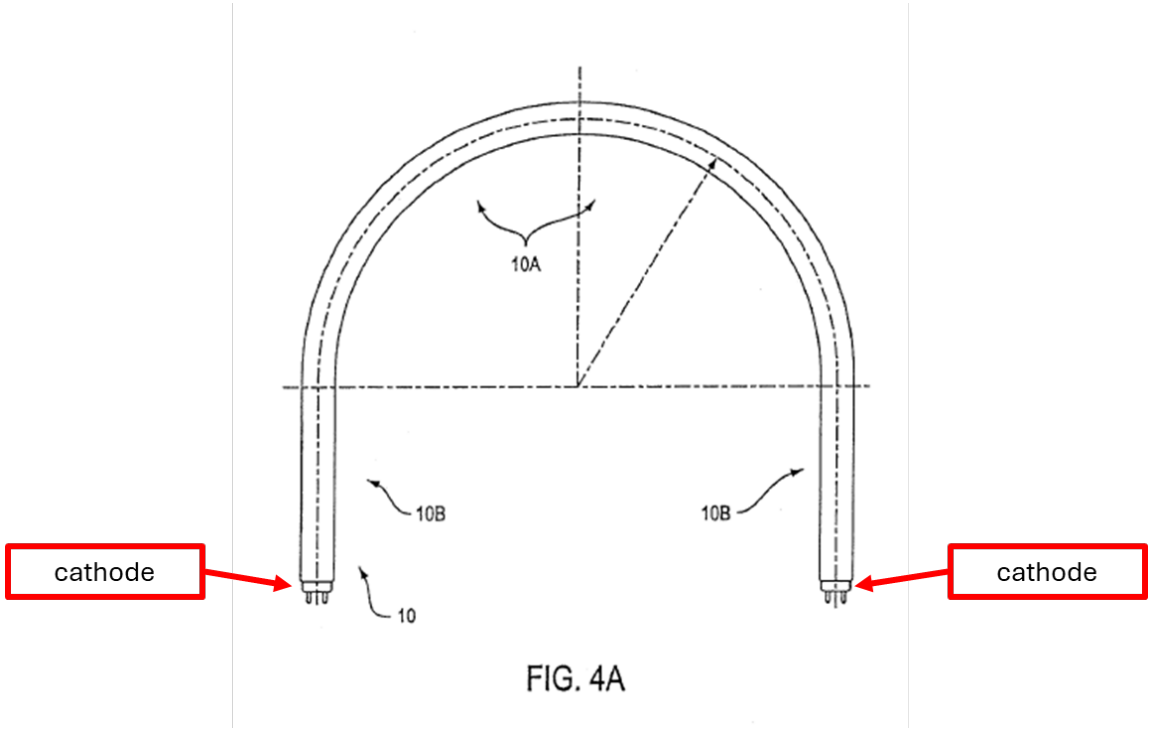


FIG. 4A

95. Lundahl discloses that "[t]he output from a fluorescent tube is not inherently uniform" and "[t]he output measured in the immediate vicinity of the cathode is typically much lower than the output over the rest of the tube." The "area of reduced emission [shown below] is known as the Faraday dark space." Ex. 1014 (Lundahl), 6:10–16, FIG. 4A (annotated).

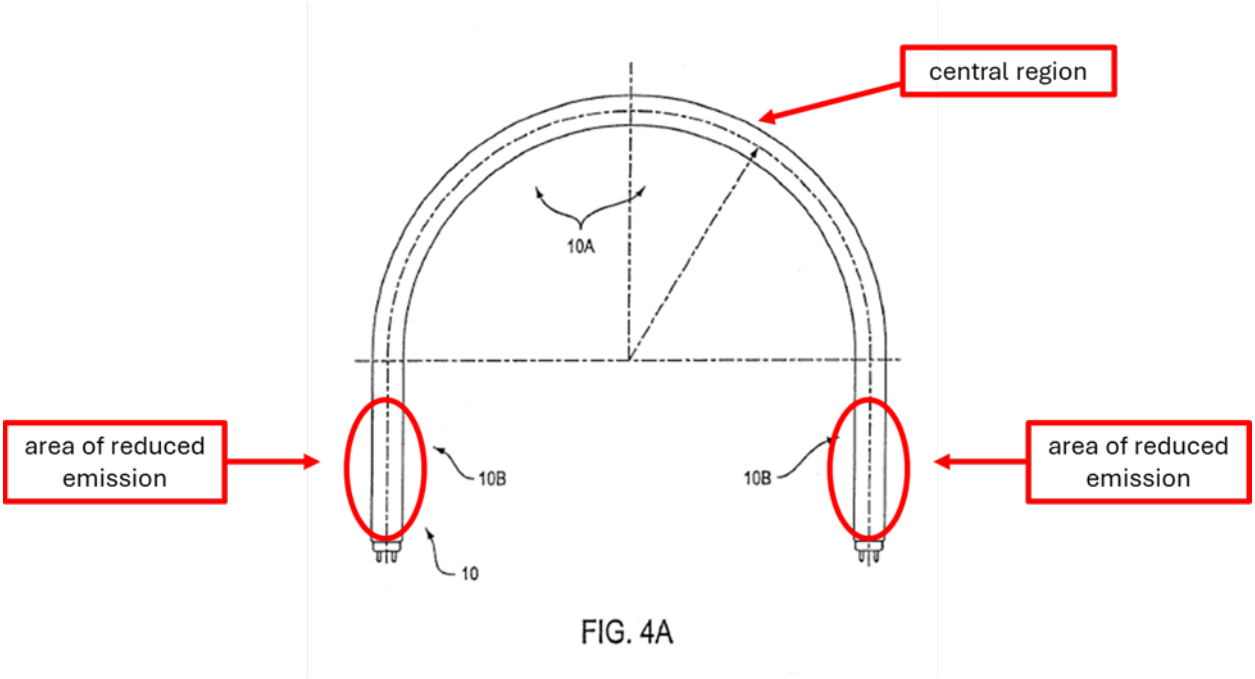
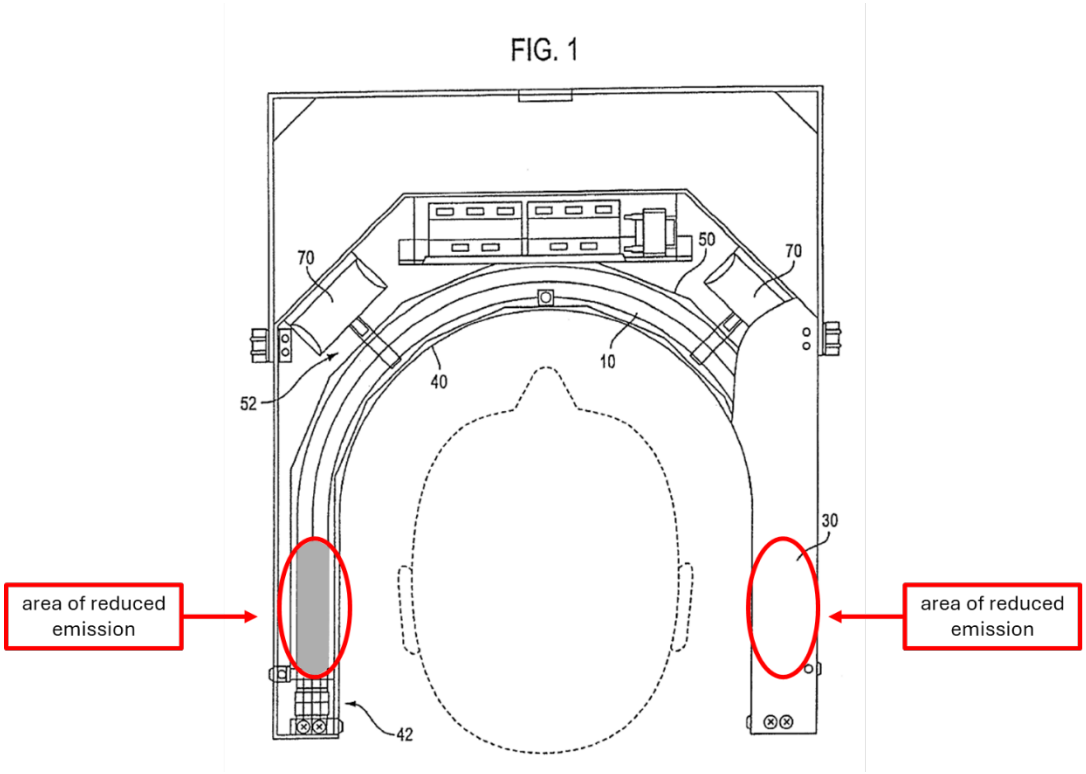


FIG. 4A

96. Lundahl discloses that "[t]o avoid uniformity problems, one embodiment, of the present invention utilizes a plurality of U-shaped tubes **10(1)-10(7)**. This arrangement allows the cathodes and their ***low output area to be located outside the active emitting area (effectively behind the patient's ears). Only the more uniform center portion of the tube output is used for patient treatment***." Ex. 1014 (Lundahl), 6:16–22.

97. Lundahl discloses that the "area of reduced emission" is "located outside the active emitting area (effectively behind the patient's ears)," as illustrated in Fig. 1 below. Ex. 1014 (Lundahl), 6:10–22, FIG. 1 (annotated).

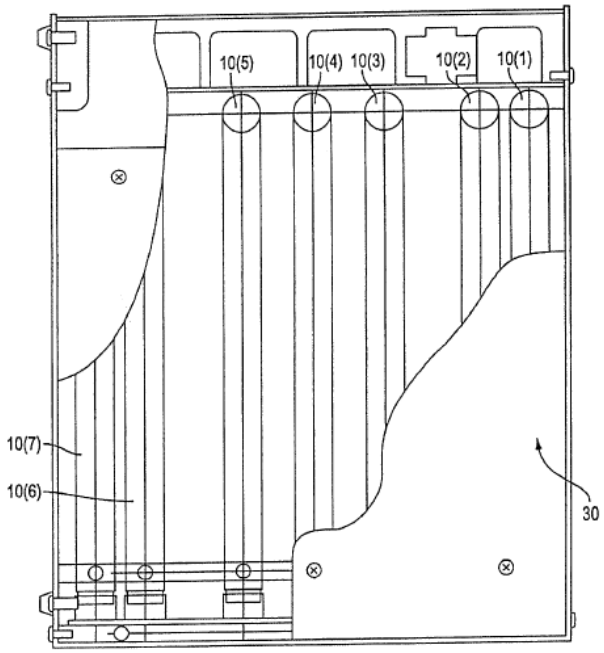


98. Lundahl discloses optical specifications for the "maximum visible light-emitting area" and the "minimum therapeutically active emitting area" (also referred to as the "active emitting area"). Ex. 1014 (Lundahl), 5:38–43, 6:10–22. Specifically, Lundahl states that the "fluorescent tubes **10(1)-10(7)** provide a maximum visible light-emitting area 36 cm high by 46 [sic] cm wide (approximately 2850 cm^2), with a minimum therapeutically active area 30 cm high by 46 cm wide (approximately 1350 cm^2)."[1] Ex. 1014 (Lundahl), 5:38–43.

[1] The "46 cm wide" should read "*79* cm wide." This is a clear typo because the formula for area is: $Area = Height\ x\ Width$. Lundahl states the "maximum

99. FIG. 2 is "a partial cross-section, side elevation view of the illuminator shown in FIG. 1." Ex. 1014 (Lundahl), 4:62–63. Lundahl discloses that the "number of tubes used and the spacing between them were chosen to achieve desired uniformity and power output." Ex. 1014 (Lundahl), 6:43–45, FIG. 2.

FIG. 2



visible light-emitting area" is "approximately 2850 cm^2" and the height is "36 cm." Therefore, the width of the maximum light-emitting area is 79 cm (*i.e.*, dividing 2850 cm^2 by 36 cm: (2850 cm2 / 36 cm) = 79.16 cm). It is also consistent with the DUSA BLU-U® Optical Specification, which states that the "Total Emitting Area" is "36 cm H X ***79 cm W***." Ex. 2037 (BLU-U Optical Specification).

Specifically, Lundahl discloses that ***the plurality of light sources are adapted for "irradiating substantially uniform intensity light from said emitting area***." Ex. 1014 (Lundahl), 3:35–36.

100. Lundahl discloses that operation of the illuminator requires "application of a voltage to the tube cathodes to initiate tube conduction and subsequently control the tube current. Fluorescent tubes, being gas discharge devices, are particularly sensitive to the electrical voltages and currents used to drive them. Higher tube currents will increase the electron yield causing the output irradiance to increase. But higher currents result in higher cathode temperatures, potentially increasing the erosion of the cathode emitting material and contamination of the tube atmosphere by material removed from the cathodes; this ultimately results in decreased tube life. Tube currents that are too low can result in low tube wall temperatures that may cause condensation of the mercury vapor, adversely affecting the uniformity of the lamp output. Furthermore, for most tube designs it is necessary to heat the cathodes to achieve proper tube starting." Ex. 1014 (Lundahl), 7:12-28.

101. Lundahl further discloses that "[c]ontrol of the voltage and/or tube current characteristics, as well as heating of the cathodes is accomplished with external electronic circuitry which is usually engineered and packaged into a single device commonly referred to as a 'ballast'." Ex. 1014 (Lundahl), 7:28-32, 8:46–51,

11:6–18, FIGS. 7, 8, and 9A. The ballasts "convert 120 VAC line voltage available from a standard wall outlet into a high frequency (~25 kHz) sinusoidal current suitable for driving the fluorescent tubes." Ex. 1014 (Lundahl), 8:51–54. Lundahl's electrical system ***"correct[s] output of said light from said plurality of light sources so as to maintain substantially uniform intensity***." Ex. 1014 (Lundahl), claim 26.

B. Larsen (Ex. 1004)

102. U.S. Patent Publication No. 2005/0075703 to Larsen ("Larsen") is entitled "Photodynamic Stimulation Device and Methods." Ex. 1004 (Larsen), Cover.

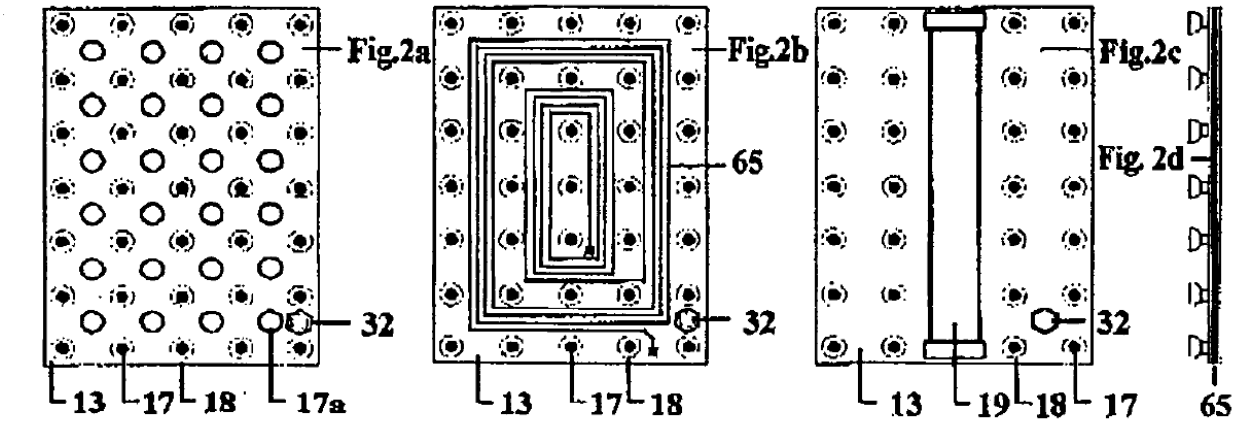
103. Larsen discloses that "the present invention provides a device with changeable applicators using a light and/or laser radiation of several wavelength ranges suited for the photodynamic stimulation of the cell energy in living cells, in particular human cells of both surface and underlying tissue." Ex. 1004 (Larsen), [0026].

104. Larsen discloses that "[t]he applicators contain printed circuit boards mounted with semiconductor diodes and/or laser diodes (in large numbers), and the diodes are mounted with reflectors, which collect the radiation and bundle them in front of the applicator. The applicators also contain one or more transmitter coils for the emission of pulse-shaped electromagnetic radiation. The applicators are also equipped with an adjustable scan system, which permits an even and gap-free

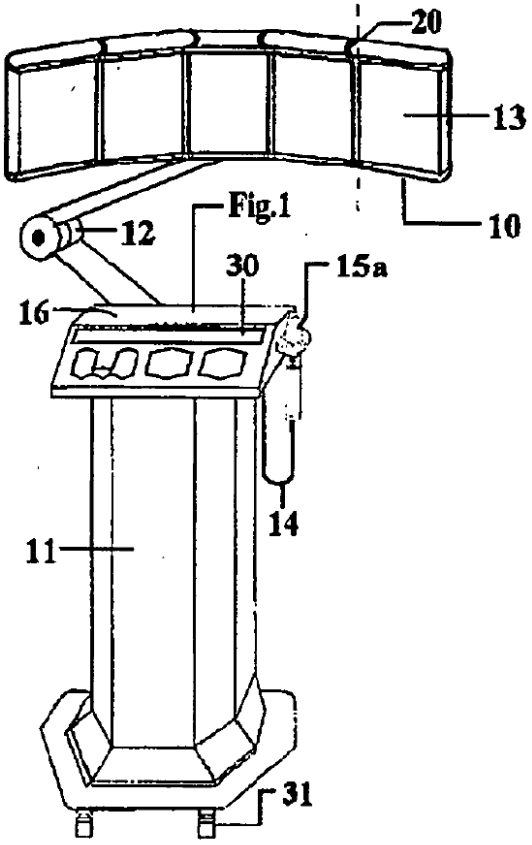
radiation of the surface with the multiple wavelengths of light." Ex. 1004 (Larsen), [0028], FIG. 3. Larsen further discloses that "[a]t least one of the applicator elements is equipped with feedback sensors for controlling the patient's response to the therapy, and via an automatic regulation system in the control mechanism it is possible to optimise the therapy results." Ex. 1004 (Larsen), [0030].

105. Larsen discloses that Figs. **2**a, **2**b, **2**c, and **2**d "illustrate details of the machine applicator of the invented device." Ex. 1004 (Larsen), [0041]. "The **FIGS**. **2***a*, **2***b* and **2***c* show plain surfaced printed circuit boards with light sources mounted in the applicators **13**." Ex. 1004 (Larsen), [0070]. The printed circuit boards "can be used in the working model according to **FIG**. **2***a* to **2***c* individually, side by side (in large numbers) or in combination with an applicator." Ex. 1004 (Larsen), [0070].

106. As shown in Figs. 2b and 2c below, "the ***light sources 17 are placed in regular row arrangements, i.e., 20 equidistant from each other***." Ex. 1004 (Larsen), [0071], FIGS. 2a-2d.

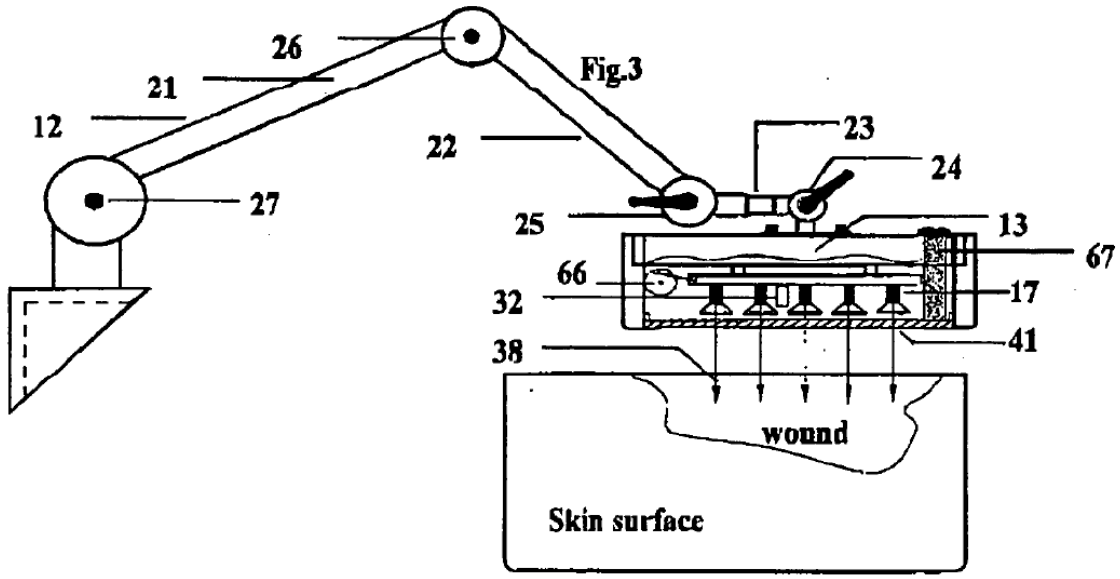


107. Larsen further discloses that Fig. 1 is "a perspective drawing of the invented device." Ex. 1004 (Larsen), [0040]. As shown below in Fig. 1, the device "consists of a stand **11**, with which machine applicators **13** (in the following just called applicators **13**) are connected through a jointed arm **12**. … The stand **11**, freely movable on wheels, includes control mechanism **16** (described in **FIG. 4**), whereby the function of the control mechanism **16** can be adjusted and switched ON/OFF at a control panel **30** (also called description equipment **30**)." Ex. 1004 (Larsen), [0069], FIG. 1.



108. Larsen discloses that "[f]or the treatment of large-area tissues ***according to FIG. 1, several applicators 13 are flexibly connected to each other through hinges 10,*** respectively connecting one edge with the other, whereby the applicators are suitable for the treatment of for example, the backs of humans and so become adjustable for an equidistant positioning of the applicators **13** above the skin." Ex. 1004 (Larsen), [0072], [0027].

109. Larsen discloses that "[i]n each applicator the printed circuit board carrying the light sources is connected to a small electrical ***scan engine 66, which can move the light sources with linear movements***." Ex. 1004 (Larsen), [0072].



Ex. 1004 (Larsen), FIG. 3.

110. Larsen discloses that "[t]he applicators **13**, according to **FIGS. 2***a*, **2***b* and **2***c* are equipped with sensors **32** arranged between the semiconductor and/or

laser diodes **17**." Ex. 1004 (Larsen), [0079]. The "[s]ensors **32** measure the amount of energy radiated away from the skin surface, which is indicative of the total energy penetrating into the tissue. Taking into account individual variations from patient to patient, the exposure can be determined according to the measurements taken by the sensors **32** so that the correct amount of therapeutic energy (Joule/cm2) reaches the tissue. An increase of the registered amount of energy can be achieved by the invented device by increasing the operating potential (and thereby the pulse amplitude) or the pulse frequency and/or prolonging the duration of the treatment time through an adjustment of the control mechanism **16**." Ex. 1004 (Larsen), [0079].

111. Larsen further discloses that "[w]ith the help of the control mechanism **16**, the ***invented device is adjustable*** within a relatively large range with reference to duration, amplitude and frequency of surge of current, so that the semiconductor diodes **17**, **17*a*** and **18**, as well as laser **17** diodes with the same realisation as semiconductor diode **17**, can be used as light sources." Ex. 1004 (Larsen), [0074].

C. Hente (Ex. 1026)

112. U.S. Patent Publication No. 2010/0118522 to Hente ("Hente"), is titled "Light Emitting Device Using OLED Panels In Folded Or Deployed Configuration." Ex. 1026, Cover.

113. Hente describes a "light emitting device which combines the ability to illuminate large and point-like limited areas." Ex. 1026, [0005]. Specifically, Hente describes the application of the light emitting device to "do-it-yourself-work" for which "a large area lamp is needed to illuminate a workbench or a lathe" and needing "illumination devices for small, limited areas." Ex. 1026, [0002].

114. Hente explains that "[t]he leading idea of the invention is that the artificial ***light***, generated within the organic light emitting layer ***is able to leave the light emitting device*** through the bottom side—for large area illumination—as well as ***through the side surfaces***—for illuminating a small area. To achieve this aim the light emitting device is distributed into at least two sections wherein each section comprises a stack of layers, forming an OLED." Ex. 1026, [0008], *see also* [0007]. Hente also explains that "artificial ***light may also leave the stack of layers through*** one for [sic] ***the rims***." Ex. 1026, [0010], *see also* [0020] ("***artificial light leaving the sections through the rims***").

115. FIG. 1 shows an embodiment of the invention with two sections having a "basic layer **40**, being a glass or a polymer substrate," with a "first electrode layer **41**," and "[a]bove this first electrode layer **41** an organic light emitting layer **43** and a second electrode layer **42** … the organic light emitting layer **43** emits an artificial light **45**." Ex. 1026, [0033], FIG. 1.

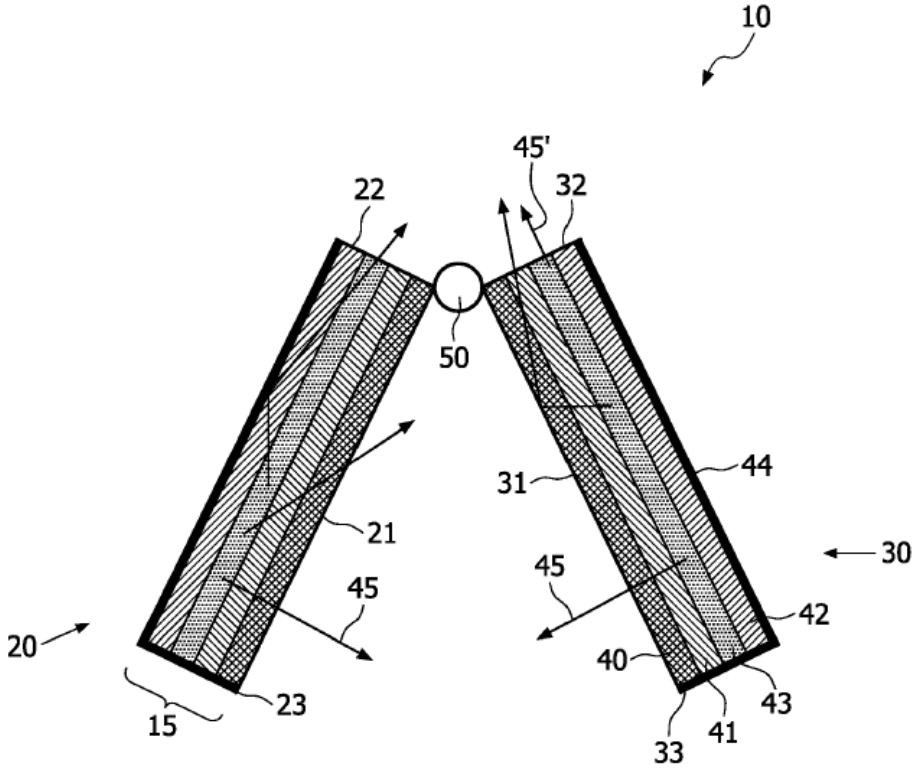


FIG. 1

116. As shown in Fig. 1, Hente discloses a "connection mean [**50**], connecting the first section [**20**] and the second section [**30**]." Ex. 1026, [0012]-[0013], [0015] [0033]-[0037]. The "***connection mean (50) is "a hinge[], a stamping, a cutting or a foil***." Ex. 1026, claim 3, [0015]. Hente further identifies "side surfaces" [**22, 32**] and rims [**23, 33**], and explains that "the term 'side surface' describes the edgewise plane of the stack of layers, through which the artificial light is emitted in the compact position. The remaining edgewise planes of the stack of layers are labeled 'rim.' Although artificial light may leave the stack of layers

through one for [sic] the rims, it is not used for illumination as the artificial light leaving the light emitting device through the side surface." Ex. 1026, [0010], [0033]-[0038].

117. "As shown in FIG. **3** the ***connection mean may be a hinge[s], being located at the outer ends of each section 20, 30***." Ex. 1026, [0037], FIG. 3. Hente discloses that the hinges are "positioned at the outer rims of the light emitting device respectively sections." Ex. 1026, [0015].

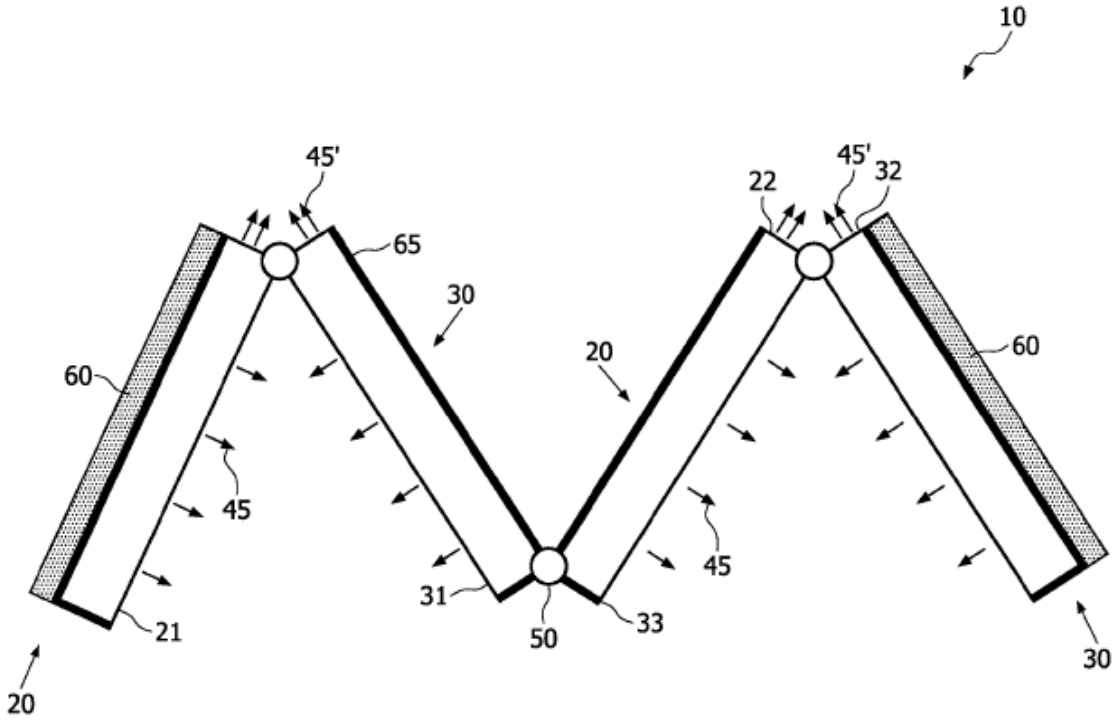


FIG. 3

Hente discloses that "in FIG. **3** the sections are arranged in a zigzag form, enabling artificial ***light 45, 45' to leave the light emitting device 10*** through the bottom sides **21**, **31** as well as ***through the side surfaces 22, 32***." Ex. 1026, [0037], FIG. 3.

118. Hente further discloses "[t]he compact position **110** is shown in FIG. **4**." Ex. 1026, [0038]. "To achieve the aim of the invention the artificial light **45′** leaving the side surfaces **22**, **32** of the sections **20**, **30** will form a point like light source, illuminating just a small dedicated area. In the shown embodiment a frame mean **65** boarders [sic] each section **20**, **30** and works as a mounting for the stack of layers **15**. The mounting means **65** of the sections **20**, **30** are interconnected by the connection mean **50**." Ex. 1026, [0038]. In the compact position, "the artificial ***light [45'] is primarily emitted through the side surfaces [22, 32]***," as shown below in Fig. 4. Ex. 1026, [0007], FIG. 4.

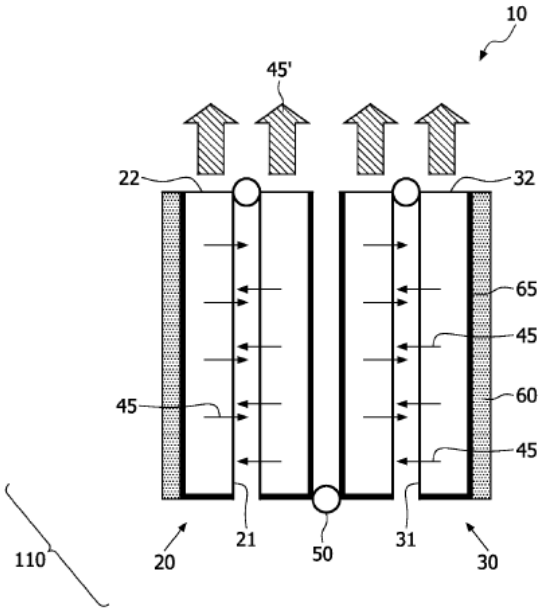


FIG. 4

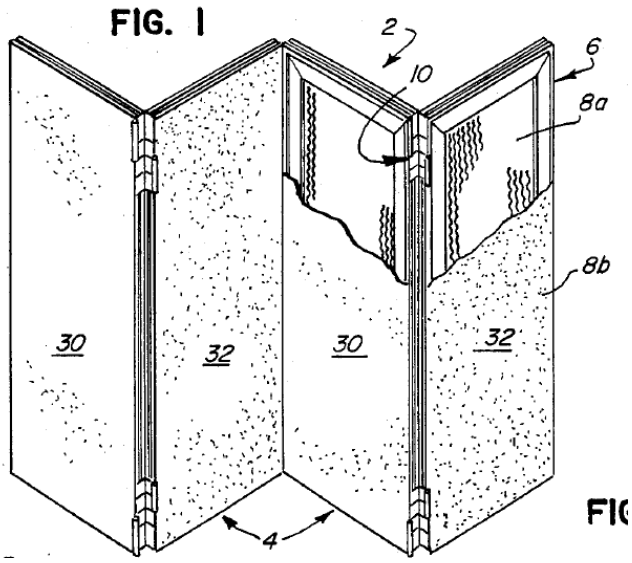
119. I disagree with Dr. Grove that Hente is directed to the same field of endeavor as the ’512 Patent. Ex. 1015 (Grove Declaration), ¶142. Hente does not disclose an illuminator suitable for use in photodynamic therapy (PDT). Ex. 1001 (’512 Patent), 1:17-33. Rather, Hente is directed to an OLED lighting system for “do-it-yourself-work,” such as a “workbench or a lathe.” Ex. 1026 (Hente), [0002], [0007]. The specifications of Hente’s device utilizing OLEDs are significantly different from the PDT device utilizing LEDs of the ’512 Patent. For example, Hente explains that each of its sections are comprised of “***thin***” layers—the “organic light emitting diodes consists of at least one thin layer, with a layer ***thickness of approximately 5 to 500 nm*** of organic substances. The OLED is regularly covered

with a layer of metal, like aluminum, forming the second electrode layer, whereas the metal layer features a ***thickness of approximately 100 nm*** and thus a thickness like the ITO-layer." Ex. 1026 (Hente), [0009], [0033]. The hinges described in Hente connect individual, ***sheet-like*** OLEDs rather than panels containing multiple LEDs in a rigid panel. Hente's OLEDs consist of one single OLED per section that have two broad area contacts (one contact on the top and one on the bottom of the OLED)—meaning each OLED section (**20**, **30**) is a longish single stretched, sheet like light source. For example, Hente discloses that an "OLED…is a homogenous light source" and Hente's OLEDs "form a ***longish stretched sheet like light emitting device***." Ex. 1026 (Hente), [0003], [0036]. Additionally, Hente does not disclose hinges on inner side surfaces of adjacent panels. Instead, Hente teaches that light is emitted through the side surfaces and rims, as discussed above. Hente does not purport to solve the problem of "uniform illumination" and never discloses uniformly illuminating any surface, and especially not a treatment surface of a patient.

D. Perutz (Ex. 1027)

120. U.S. Patent No. 4,823,858, issued on April 25, 1989, to Perutz ("Perutz") is titled "Portable Display Panel and Hinge System." Ex. 1027 (Perutz), Cover.

121. Perutz describes "display panel systems utilized for exhibiting at trade shows, promotional events and the like." Ex. 1027 (Perutz), 1:7-9. Perutz's display panel system is shown in FIG. 1. Ex. 1027 (Perutz), FIG. 1.



122. Perutz discloses that "several panel assemblies may be arranged in side by side relation and adjacent edges thereof interconnected so as to enable the system to be readily assembled and disassembled," as shown in FIG. 1. Ex. 1027 (Perutz), 3:59–63. Perutz discloses that the hinges **10** "includes a first hinge segment **12** and a second hinge segment **14**." Ex. 1027 (Perutz), 4:11–14.

123. Dr. Grove does not argue that Perutz is directed to the same field as the invention of the '512 Patent. This is not surprising as Perutz is not directed to an "an adjustable illuminator that provides a uniform distribution of visible light in a number of configurations and is suitable for use in photodynamic therapy and diagnosis." Ex. 1001 ('512 Patent), 1:17–20. Rather, Perutz is directed to a "display

panel system utilized for exhibiting at trade shows, promotional events and the like." Ex. 1027 (Perutz), 1:7–9. Perutz does not disclose an illuminator and contains no description of light sources.

XII. THE COMBINATIONS OF PRIOR ART DO NOT RENDER OBVIOUS "UNIFORMLY ILLUMINATE A TREATMENT SURFACE" / "UNIFORMLY ILLUMINATING A TREATMENT SURFACE"

A. Ground 1: Claims 1, 3, 5, 8, And 20 Are Not Obvious Over Lundahl In View Of Larsen

124. Independent Claims 1 and 20 of the '512 Patent require that the system for photodynamically diagnosing or treating a patient comprises "*light sources disposed on surfaces of the at least five panels, the illuminator being configured to uniformly illuminate a treatment surface of the patient via the light sources*." Independent Claim 8 of the '512 Patent requires that the method of photodynamically diagnosing or treating a patient comprises "*uniformly illuminating a treatment surface of the patient with light sources disposed on the at least five panels of the illuminator*."

125. Petitioner and Dr. Grove argue that Lundahl and Larsen teach these claim limitations. Ex. 1015 (Grove Declaration), ¶¶173-179, 217, 229; Petition, 41-45, 60, 64. However, Petitioner and Dr. Grove do not meet their burden to show that Lundahl in view of Larsen renders obvious these limitations because they only address the teachings of Lundahl and Larsen individually. Petitioner and Dr. Grove

fail to show that the ***combination*** of Lundahl and Larsen renders obvious "*uniformly illuminate a treatment surface*" and "*uniformly illuminating a treatment surface*."

126. As discussed above, the Administrative Law Judge adopted the parties' agreed-upon construction of "*uniformly illuminate a treatment surface*" and "*uniformly illuminating a treatment surface*" in the ITC proceeding, construing these claim limitations as "irradiating light over the active emitting area such that the measured irradiance at a treatment surface of the patient is at least within 60% of the measured maximum." Ex. 2033 (ITC Claim Construction Order), 13. Petitioner argued in the Petition that Lundahl discloses these claim limitations under the agreed-upon construction. Petition, 43-44; Ex. 1015 (Grove Declaration), ¶176; Ex. 2033 (ITC Claim Construction Order), 13. However, Petitioner and Dr. Grove fail to show that Lundahl and Larsen, as ***combined together,*** render obvious these limitations, for at least the following reasons.

1. Petitioner and Dr. Grove's reliance on Lundahl's disclosure does not show that the combination of Lundahl and Larsen renders obvious the "uniformly illuminate" limitations

127. Petitioner and Dr. Grove argue that Lundahl discloses these limitations under the agreed-upon claim construction, relying on Lundahl's disclosure that "[i]t has been found that, according to a preferred embodiment of the present invention, the measured output over the active emitting area is within 70% of the measured maximum when measured with a cosine response detector at distances of 4″ and 2″,

and within 60% of the measured maximum over all operation distances." Ex. 1015 (Grove Declaration), ¶176 (citing Ex. 1014 (Lundahl), 15:22-26); Petition, 43-44. However, Lundahl's ***individual reference*** to the measured output of ***Lundahl's preferred embodiment*** does not inform a POSITA what the ***measured output*** would be for the ***combination*** of Lundahl and Larsen.

128. Dr. Grove's declaration ***does not contain any supporting evidence or analysis by comparison to a maximum "over an active emitting area"*** for his proposed combination. *See* Ex. 1015 (Grove Declaration), ¶¶173-179. Dr. Grove provides no supporting evidence or analysis showing that the proposed ***combination*** of Lundahl and Larsen "irradiat[es] 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," only addressing the ***individual*** teachings of Lundahl and Larsen. Ex. 1015 (Grove Declaration), ¶¶173-176 (Lundahl), ¶¶177-178 (Larsen). Dr. Grove does not provide any comparison of outputs to the maximum output at the alleged varying operation distances of "2-4" of the entire treatment surface of the patient" for the proposed ***combination***. Ex. 1015 (Grove Declaration), ¶¶126-127. Nor does Dr. Grove identify the measured maximum for the ***combination*** of Lundahl and Larsen, or explain how a POSITA would have achieved the ***same*** measured results as Lundahl after ***combining*** Lundahl with Larsen and "chang[ing] the design of the system of Lundahl." Ex. 1015 (Grove Declaration), ¶¶127, 130. Because

Petitioner and Dr. Grove do not explain how the ***combination*** of Lundahl and Larsen maps to the claim limitations under the agreed-to construction or articulate their reasoning for why the claim limitations would have been obvious over the ***combination*** of Lundahl and Larsen, Petitioner and Dr. Grove fail to meet their burden.

129. Petitioner and Dr. Grove argue that a POSITA would replace the fluorescent bulbs of Lundahl with LEDs. Ex. 1015 (Grove Declaration), ¶¶130, 191; Petition, 50-51. However, Petitioner and Dr. Grove fail to show that the proposed ***combination*** of Lundahl and Larsen "irradiat[es] light over the active emitting area such that the measured irradiance at a treatment surface of the patient is at least within 60% of the measured maximum." Petitioner provides only a single, conclusory sentence stating "the combination of Lundahl and Larsen maintains Lundahl's light distribution pattern using LEDs instead of fluorescent tubes and thus maintains a highly uniform output irradiance." Petition, 43 (citing Ex. 1014 (Lundahl) 6:43-57, "[t]he number of tubes used and the spacing between them"). Dr. Grove's declaration does not provide any support for Petitioner's conclusory assertion. Dr. Grove's alleged resulting combination ***cannot*** "maintain[] Lundahl's light distribution pattern using LEDs instead of fluorescent tubes." As I explained in Section VII, fluorescent tubes are continuous, diffuse illuminators. By replacing the continuous, diffuse light of the fluorescent tubes with discrete, directional point-

source LEDs with Lambertian outputs, Dr. Grove is creating gaps (between the LEDs) that were not in Lundahl's light distribution. By changing the light source, Dr. Grove is not maintaining Lundahl's light distribution. Further, creating a uniform light distribution as demanded by PD and PDT using LEDs is an engineering challenge, as discussed herein.

130. Additionally, Dr. Grove proposes to "replace the fluorescent bulbs of Lundahl with LEDs" and "incorporate the uneven spacing of light sources of Lundahl." Ex. 1015, ¶¶191-195, 173-175. However, Dr. Grove fails to show that using Lundahl's spacing, after replacing the tubes with rows of LEDs, would result in an illuminator that "irradiat[es] 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* Ex. 1014 (Lundahl) 6:45-57 ("seven tubes **10(1)-10(7)** are placed in the chassis in a symmetric pattern with respect to opposite edges of the unit with the following lateral spacing: 7 cm between the center tube **10(4)** and each of the two tubes **10(3), 10(5)** adjacent to the center tube **10(4)**; 5 cm between the tubes **10(3)**, **10(2)** and **10(5)**,**10(6)**"…; and "3.5 cm between tubes **10(2)**, **10(1)** and **10(6)**, **10(7)**"). Dr. Grove fails to address the impact that these distances between LEDs would have on the uniformity, in view of the numerous differences between LEDs and fluorescent tubes, as discussed in Section VII.

131. Furthermore, only maintaining the spacing of Lundahl's fluorescent tubes does not show that the proposed combination of Lundahl and Larsen would "irradiat[e] light over the active emitting area such that the measured irradiance at a treatment surface of the patient is at least within 60% of the measured maximum." Petitioner and Dr. Grove fail to read Lundahl's disclosure as a whole, which discusses ***multiple "carefully selected and engineered components" that affect irradiance uniformity*** (Ex. 1014 (Lundahl), 4:16-21), including (1) the U-shaped tubes, (2) the reflector, (3) the electrical control system, and (4) the cooling system. Ex. 1014 (Lundahl), 4:39-44, Abstract, 2:46-48, 3:22-28, 9:14-53, claim 34, FIGS. 1, 3.

132. For example, Lundahl discloses that (1) "the 'U' shape ***provides the desired irradiance and irradiance uniformity***" (Ex. 1014 (Lundahl), 6:39-42); (2) the reflector "***increases*** both the output irradiance and the ***uniformity of the output distribution***" (Ex. 1014 (Lundahl), Abstract); (3) the electrical control system corrects the output of light from the light sources "so as to ***maintain said substantially uniform intensity***" (Ex. 1014 (Lundahl), claim 26); and (4) the cooling system "modulat[es]" the "temperature distribution…to ***control irradiance uniformity***" (Ex. 1014 (Lundahl), 4:39-44). Lundahl explains that these components require a "***much higher degree of precision and integration***" to control the "[o]utput spectrum, irradiance, and ***irradiance uniformity***" and "to assure that the properties

of the device are suitable to deliver light to the target lesions and drive the photodynamic reaction." Ex. 1014 (Lundahl), 4:12-19. Therefore, simply maintaining the spacing of Lundahl's fluorescent tubes does not show that the proposed combination of Lundahl and Larsen would "irradiat[e] light over the active emitting area such that the measured irradiance at a treatment surface of the patient is at least within 60% of the measured maximum." In fact, Dr. Grove acknowledges that "[t]he design of the light source plays an important role in achieving an irradiance that is as uniform as possible." Ex. 1015 (Grove Declaration), ¶51.

133. Petitioner and Dr. Grove fail to show that the ***combination*** of Lundahl and Larsen meets the "uniformly illuminate" limitations because they ***never*** address Petitioner's many proposed ***changes*** to Lundahl's fluorescent tube PDT device that would impact uniformity. Petitioner and Dr. Grove propose numerous modifications to Lundahl's system. Ex. 1015 (Grove Declaration), ¶127 ("…a POSITA would have been motivated to ***change the design of the system of Lundahl*** to allow for adjustment of the light surface to ensure a 2-4" distance from the face and from other varying anatomies. A POSITA would have understood that ***the easiest way to modify the fixed, curved U-shape of Lundahl would be to incorporate hinged panels***…"), ¶130 ("A POSITA was also motivated to ***modify Lundahl to incorporate LEDs*** as taught by Larsen, rather than the fluorescent tubes"), ¶191 ("a motivation existed to combine the teachings of Lundahl and Larsen to: (1) ***incorporate the hinged panels***

of Larsen into the PDT device of Lundahl to increase the adaptability of the device; and (2) ***replace the fluorescent bulbs of Lundahl with LEDs***."); Petition, 29, 30, 50-51; Ex. 2034 (Grove ITC Expert Report), ¶268 ("…***the electrical needs and design of Lundahl's system*** for operating fluorescent tubes ***would need to be changed*** to accommodate the electrical needs and design of Larsen's LED panels…"). However, neither Petitioner nor Dr. Grove presents any supporting evidence or analysis to show that the device resulting from the numerous modifications would "irradiat[e] light over the active emitting area such that the measured irradiance at a treatment surface of the patient is at least within 60% of the measured maximum." Petitioner and Dr. Grove do not identify what the measured maximum is for the resulting device, nor do they explain how a POSITA would have achieved the same measured results as Lundahl after changing the U-shaped fluorescent tubes, changing the reflector, changing the electrical system, and changing the cooling system. Because they fail to address the numerous modifications that impact uniformity, Petitioner and Dr. Grove have not shown that the ***combination*** of Lundahl and Larsen renders obvious "uniformly illuminate a treatment surface" and "uniformly illuminating a treatment surface."

134. First, Petitioner and Dr. Grove argue that "***a POSITA would have been motivated to change the design of the system of Lundahl***" and that "[a] POSITA would have understood that the easiest way to ***modify the fixed, curved U-shape of***

Lundahl would be to incorporate hinged panels." Ex. 1015 (Grove Declaration), ¶127; Petition, 29. Modifying Lundahl's "U-shape" to "incorporate hinged panels" would create gaps between the panels, affecting the uniformity. *See* IPR2024-00874, Ex. 1003 (Bretschneider Declaration), ¶151 (Petitioner's expert, Dr. Bretschneider, acknowledging "***lower irradiance regions at the junction of two of Larsen's panels***"); Ex. 2053 (Boyajian ITC Deposition Transcript), 100:22-101:15 ("Q. Right. So ***what's the challenges with having multiple panels***? A. ***So if you have something like a fluorescent, it's just – it's non-moving. There's no gaps***. There's no – it is a very uniform light output because it is a uniform light. ***With LEDs you have points of light and panels geometrically to give an area that you can't have light. So – and as well as, you know, different areas, as you started testing, would be more intense and less intense than other areas.*** And you just had to keep constantly adjusting. And sometimes you try to figure out why, and sometimes you don't bother figuring out why. Just trial and error, let's fix it."); Ex. 2052 (Carota ITC Deposition Transcript), 88:8-89:1 ("Q. -- was it the general consensus that you wanted to create an indentation on an inner side surface of the panel to accommodate the hinge? A. I would have to dig into the drawings to tell you that. Okay? But it's reasonable to assume that. Q. And then if we look -- A. ***The most difficult way to get uniformity is at the hinges so, that's where the challenges are.*** Where some of the challenges are. I shouldn't say "everything," but

that's one of them. ***Q. And is that difficulty because of the gap between the lights at the place where there is a hinge? A. Yes.***"). Petitioner and Dr. Grove argue that a POSITA would "replace the fluorescent bulbs of Lundahl with LEDs." Ex. 1015 (Grove Declaration), ¶¶191, 130; Petition, 50-51. However, replacing the fluorescent tubes with LEDs would affect the uniformity. As explained in Section VII, fluorescent tubes are continuous, broad-area, diffuse illuminators and LEDs are discrete, point-source, directional illuminators with Lambertian output intensity. Replacing the fluorescent tubes with LEDs would create gaps between the LEDs, impacting the uniformity. And, even reducing the gaps between the LEDs would not ensure uniformity, as each LED's output is nonuniform as a function of divergence angle (Lambertian). By changing Lundahl's U-shaped tubes that "provide[] the desired irradiance and uniformity" to discrete, point-source LEDs, and failing to address the impact this substitution has on the uniformity, Petitioner and Dr. Grove have not shown that the ***combination*** of Lundahl and Larsen "uniformly illuminates a treatment surface" under the parties' agreed-to construction.

135. Second, Dr. Grove argued that "a POSA ***would not seek to replicate the design of the reflector of Lundahl with nine sections conforming to the shape of the U-shaped fluorescent tubes***" and if a "POSA sought to include reflectors in the resulting device, he or she would ***simply include five reflectors***, ***matching the***

number of panels disclosed by Larsen." Ex. 2034 (Grove ITC Expert Report), ¶265. Dr. Grove ignores Lundahl's disclosure that the nine-section reflector "***increase[s] the uniformity*** of the output distribution" by "conform[ing] to the [U-shaped] configuration of the tubes" and contains vents "so that cooling air flows primarily over the straight section and the end portions of the curved section." Ex. 1014 (Lundahl), 8:62-67, 9:43-46, FIG. 5B. Because Dr. Grove changes Lundahl's reflector and fails to address the impact that would have on uniformity, Petitioner and Dr. Grove have not shown that the ***resulting device*** "uniformly illuminates a treatment surface" under the parties' agreed-to construction.

136. Third, Dr. Grove argued that "***the electrical needs and design of Lundahl's system for operating fluorescent tubes would need to be changed*** to accommodate the electrical needs and design of Larsen's LED panels." Ex. 2034 (Grove ITC Expert Report), ¶268. Petitioner and Dr. Grove ignore that Lundahl's electrical control system "correct[s] output of said light from said plurality of light sources so as to ***maintain said substantially uniform intensity***." Ex. 1014 (Lundahl), Abstract, claim 26. Changing Lundahl's electrical control system to drive LEDs at a lower voltage would necessarily impact the uniformity. For example, Lundahl's control system supplies voltage to the ballasts that drive the fluorescent tubes at a "sufficiently ***high voltage*** potential across the cathodes," while LEDs require a ***low voltage***. Ex. 1014 (Lundahl), 5:58-61, 8:46-54 ("120 VAC line

voltage"); Ex. 2011 (Bourget), 1944 ("The de facto standard for a modern, ***high-power LED*** is a 1-W device with a nominal forward current of 350 mA at ***3 V***."). Because they changed Lundahl's electrical control system and fail to address the resulting impact on uniformity, Petitioner and Dr. Grove have not shown that the ***resulting device*** "uniformly illuminates a treatment surface" under the parties' agreed-to construction.

137. Fourth, Petitioner and Dr. Grove fail to address Lundahl's cooling system that "control[s] irradiance uniformity," despite acknowledging that Lundahl's uniformity is "affected by heat and the ability to cool the Lundahl device." Ex. 1014 (Lundahl), 4:39-44; Ex. 1015 (Grove Declaration), ¶122; Petition, 25; Ex. 1016 (Ehrenreich Declaration), ¶¶68-69. Notably, some LED systems need thermal control to avoid LED damage, and thus, heat dissipation techniques must be assessed and addressed for LED systems. Ex. 2011 (Bourget), 1944 ("LEDs do not radiate heat directly, but do produce heat that must be removed to ensure maximum performance and lifetime."), 1945 ("Consideration must be taken when designing the fixture to properly conduct the heat away from the LED, or the device's lifetime could be shortened considerably."). Because they fail to address the effect that Lundahl's cooling system has on the alleged resulting device that replaces fluorescent tubes with LEDs, and do not discuss control of LED heat dissipation, Petitioner and Dr. Grove have not shown that the ***combination*** of Lundahl and

Larsen "uniformly illuminates a treatment surface" under the parties' agreed-to construction.

138. Accordingly, because Petitioner and Dr. Grove modified and/or replaced ***multiple carefully selected and engineered components*** that Lundahl teaches ***must work together in concert*** to achieve uniformity, and have replaced the diffuse fluorescent tube light sources with point source, Lambertian-output LEDs, Petitioner and Dr. Grove have not shown that the combination of Lundahl and Larsen renders obvious "uniformly illuminate a treatment surface" / "uniformly illuminating a treatment surface."

2. Petitioner and Dr. Grove's reliance on Larsen's disclosure does not show that the combination of Lundahl and Larsen renders obvious the "uniformly illuminate" limitations

139. Petitioner and Dr. Grove argue that Larsen's disclosure of a scan engine discloses "uniformly illuminate a treatment surface." Ex. 1015 (Grove Declaration), ¶¶177-178, 217 (citing Ex. 1004 (Larsen), [0072]); Petition, 44-45, 60. However, Petitioner and Dr. Grove rely on Larsen's ***individual*** disclosure and fail to show that the ***combination*** of Lundahl and Larsen renders obvious "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."

140. Larsen does not disclose ***any*** measurements that indicate that it "irradiat[es] 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." In fact, Dr. Grove testified that "***Larsen doesn't disclose how to achieve uniformity meeting the requirements of 60 percent of the measured maximum at all points***." Ex. 2036 (Grove ITC Deposition Transcript), 139:9-17. Additionally, Petitioner's expert, Dr. Bretschneider, confirmed that Larsen does not achieve uniform illumination, explaining that there are "lower irradiance regions at the junction of two of Larsen's panels." IPR2024-00874, Ex. 1003 (Bretschneider Declaration), ¶151. Dr. Bretschneider also explained that Larsen's "scan engine would have been a less effective way to achieve more uniform illumination" because "the scan engine can only move lights linearly in one direction at a time, which would only decrease unradiated gaps on the portion of the treatment surface towards which the light sources are being moved." IPR2024-00874, Ex. 1003 (Bretschneider Declaration), ¶154. And, Mark Carota testified that Larsen only "says that there weren't any gaps in the radiation. It doesn't say it's uniform." Ex. 2052 (Carota ITC Deposition Transcript), 118:10-119:17 ("Q. Sure. So at the bottom, it's 152531, and it's paragraph 72. A. Yep. Q. And that first sentence, it says: For the treatment of large tissue areas according to figure 1, several applicators are flexibly connected to each other through hinges. Do you see that? A. Yes. Q. And if you read all of paragraph 72, it ends by saying that the panels can be positioned so that the radiated surface -- sorry -- the adjusted scan length and frequency gives the radiated surface a total

radiation of the necessary wavelength without leaving any un-radiated gaps. Do you see that? A Yeah. ***Q. So that's providing a uniformity of light, right? A. Not necessarily.*** Q. Why not? A. It's saying it has un-radiated ***-- it says that there weren't any gaps in the radiation. It doesn't say it's uniform. So the gaps in the radiation at the gap lines, they could have barely anything. And in the center of those panels, there could be, you know, ten times that amount***. I don't know. Uniformity means uniformity of the skin.").

141. Petitioner and Dr. Grove also argue that "[a] POSITA would have understood that Larsen's applicator is configured to uniformly illuminate a treatment surface of the patient" because "Larsen also describes measurements taken by sensors 32." Ex. 1015 (Grove Declaration), ¶178; Petition, 45. However, Larsen's sensors 32 that "measure the amount of energy radiated away from the skin surface, which is ***indicative of the total energy*** penetrating into the tissue" do not teach or suggest "irradiating light over the active emitting area such that the measured irradiance at a treatment surface of the patient is at least within 60% of the measured maximum." A POSITA would have understood that the amount of energy radiated away from the skin surface (measured in Joules) measured by Larsen's sensors is ***not*** equivalent to the ***measured irradiance*** (measured in W/cm^2) at the treatment surface. Larsen ***does not*** teach or suggest "irradiating light over the active emitting area such that the ***measured irradiance*** at a treatment surface of the patient is at least

within ***60% of the measured maximum***," as required under the parties' agreed-to claim construction of the "uniformly illuminate" limitations.

142. Accordingly, Petitioner and Dr. Grove have not shown that Larsen ***individually*** discloses "uniformly illuminate a treatment surface" and "uniformly illuminating a treatment surface." Petitioner and Dr. Grove fail to show that the ***combination*** of Lundahl and Larsen, ***which includes Larsen's scan engine***, renders obvious these claim limitations.

3. Petitioner and Dr. Grove have not shown that a POSITA would have had a reasonable expectation of success that the combination of Lundahl and Larsen would uniformly illuminate a treatment surface

143. Petitioner and Dr. Grove fail to show that a POSITA would have had a reasonable expectation of success that the combination of Lundahl in view of Larsen would "irradiat[e] light over the active emitting area such that the measured irradiance at a treatment surface of the patient is at least within 60% of the measured maximum." Petitioner and Dr. Grove argue that "[a] POSITA would have had a reasonable expectation of success in combining Lundahl with Larsen, because both references describe similar illuminators for using light to treat conditions on a patient's skin" and "both references describe similar illuminators and the conversion from fluorescent tubes to LEDs was a routine practice prior to 2015." Ex. 1015 (Grove Declaration), ¶¶129, 132; Petition, 30-31. However, these statements do not

support that a POSITA would have had a reasonable expectation that the combination of Lundahl and Larsen would have "irradiat[ed] 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" under the parties' agreed-to construction of the claim limitations. As I explained above, Dr. Grove has proposed numerous and extensive modifications to Lundahl's PDT device that would have impacted the uniformity.

144. Additionally, the evidence contradicts Petitioner and Dr. Grove's assertion that achieving uniform illumination using LEDs was routine. I understand that the inventors of the '512 Patent testified that achieving uniform illumination using LEDs was "one of the more difficult challenges that we had." Ex. 2052 (Carota ITC Deposition Transcript), 73:20-74:14 ("Q. Did he ever tell you what he thought were patentable features of the device? A. Yes, I'm sure he did. Q. Do you recall which features? A I don't specifically. ***I know that uniformity was a big one because that was -- that's the more difficult. It was one of the more difficult challenges that we had.*** It was also challenges in just achieving the wavelength with LEDs because they weren't readily available at the target that we wanted. Q. So how did you solve the uniformity problem? A. A multitude of ways. It was done -- and this is just my recollection -- through sizing, spacing, electronic feedback, and the actual mechanical design."). The inventors had to conduct multiple tests and create

many prototypes to achieve uniform illumination because "LEDs don't act like fluorescent lightbulbs." Ex. 2053 (Boyajian ITC Deposition Transcript), 87:3-89:12 ("Q. I would like to understand how you came up with -- you and your team came up with the so-called invention set forth in the patents. A. So for this invention ***we wanted to utilize LEDs in place of fluorescent***. We wanted to have movable panels. There were a number of other things we were trying to achieve. Not all of them do I recollect perfectly, but we also had to hit power and uniformity. ***The technology is much different, and, therefore, those were the challenges***. Q. And what did do you to come up with the design? A. Lots of trial and error, figuring out different ways of achieving uniformity, figuring out different configurations of geometry to create the output required. ***Learning how LEDs react and are much different than fluorescent, learning the differences from and to and how we could get to achieve what we needed to achieve but with what I would consider a drastically different technology and an ever-changing technology***. Q. And how did you learn about the differences in LEDs between LEDs and fluorescents? A. Trial and error. Q. Did you read any literature about it? A. When you say "literature," like manufacturing literature from the LED manufacturers? Q. Anything written down whether it was online, in paper. A. The specifications for the LEDs we used, we would always read the specification so we knew what we were – its compelling. You had to know what you were using. Aside from that, there wasn't much help. ***What we were doing was***

so different than what had been done in the past. Q. Which way was it different? A. Again, ***LEDs don't act like fluorescent lightbulbs. Their directional output is different. Their power requirements are different. Their point density is different. And there's probably 20 other differences*** I can't remember. But learning through that and making prototypes is how we got through that. Q. How many prototypes did you make? A. No idea. No idea. And I wouldn't even know how to count them. You know, one is just a tweak of another. ***We created a lot of prototypes***."), 100:7-12 ("Q. What were some of the challenges? A. That is a pretty broad question. As I mentioned before***, LEDs don't act like fluorescents***. ***Having separate panels is not easy. Not easy. Uniformity is a big challenge***."), 100:22-101:15 ("Q. Right. So what's the challenges with having multiple panels? A. So if you have something like a fluorescent, it's just – it's non-moving. There's no gaps. There's no – it is a very uniform light output because it is a uniform light. ***With LEDs you have points of light and panels geometrically to give an area that you can't have light***. ***So – and as well as, you know, different areas, as you started testing, would be more intense and less intense than other areas. And you just had to keep constantly adjusting. And sometimes you try to figure out why, and sometimes you don't bother figuring out why. Just trial and error, let's fix it***.").

145. Further, Dr. Grove opined that a "***POSA would be required to perform undue experimentation to make and use an illuminator that provides 'uniform***

illumination."' Ex. 2034 (Grove ITC Expert Report), ¶¶183-186, 456. Dr. Grove further opined that "[i]t is well-known that the field of optics and illumination is complex, and in some cases requires extensive measurement and experimentation. A POSA will expect that the amount of experimentation and testing necessary to achieve a specific design goal increases where the treatment surface is not flat, a challenge further compounded by the fact that the shape of the illuminator does not follow the contours of a face or other treatment area. Moreover, there is a range of distances between the illuminator and the treatment surface, and this variation can dramatically affect irradiance of the skin. And, finally, much of the targeted skin area is not in the same plane as the emitting source; the irradiance falls off rapidly if the treatment surface is not orthogonal to the light emitted from the illuminator." Ex. 2034 (Grove ITC Expert Report), ¶191. Dr. Grove's opinion in the parallel ITC proceeding contradicts his arguments here that a POSITA would have been motivated to combine Lundahl and Larsen to allow treatment of varying anatomies with a reasonable expectation of success in achieving uniform illumination at a treatment surface. For at least these reasons, the evidence demonstrates that a POSITA would have had no reasonable expectation of success that the combination of Lundahl in view of Larsen would "irradiat[e] light over the active emitting area such that the measured irradiance at a treatment surface of the patient is at least within 60% of the measured maximum."

146. Accordingly, for at least the reasons explained above, Petitioner and Dr. Grove fail to meet their burden to show that Lundahl in view of Larsen renders obvious "uniformly illuminate a treatment surface" / "uniformly illuminating a treatment surface."

B. Ground 2: Claims 1, 3, 5, 8, 17, 18 and 20 Are Not Obvious Over Lundahl In View Of Larsen And Further In View Of Hente

147. Independent Claims 1 and 20 of the '512 Patent require that the system for photodynamically diagnosing or treating a patient comprises "*light sources disposed on surfaces of the at least five panels, the illuminator being configured to uniformly illuminate a treatment surface of the patient via the light sources*." Independent Claim 8 of the '512 Patent requires that the method of photodynamically diagnosing or treating a patient comprises "*uniformly illuminating a treatment surface of the patient with light sources disposed on the at least five panels of the illuminator*."

148. For Ground 2, Petitioner and Dr. Grove merely rely on their "previous analysis provided in Ground 1," arguing that Lundahl in view of Larsen renders obvious these limitations. Ex. 1015 (Grove Declaration), ¶234; Petition, 65, 78. Petitioner and Dr. Grove's repeated argument for the combination of Lundahl, Larsen, and Hente again fails. Petitioner and Dr. Grove do not provide any analysis to show that Lundahl in view of Larsen ***and further in view of Hente*** renders obvious

these limitations. Petitioner and Dr. Grove add Hente to the combination of Lundahl and Larsen, but do not explain how adding ***the hinge system of Hente*** allegedly renders obvious these limitations under the parties' agreed to construction. *See* Ex. 1015 (Grove Declaration), ¶233; Petition, 65, 78.

149. As explained in Section XII.A, Lundahl in view of Larsen does not render obvious the "uniformly illuminate" claim limitations. Petitioner and Dr. Grove do not explain how or why the combination of Lundahl, Larsen ***and further with Hente*** "irradiat[es] 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." Accordingly, Petitioner and Dr. Grove have not shown that the ***combination*** of Lundahl, Larsen, and Hente renders obvious the claims under Ground 2.

150. Additionally, Petitioner and Dr. Grove fail to show that a POSITA would have had a reasonable expectation of success that the combination of Lundahl, Larsen, and Hente would "irradiat[e] light over the active emitting area such that the measured irradiance at a treatment surface of the patient is at least within 60% of the measured maximum." Petitioner and Dr. Grove argue that a "POSITA would have been motivated with a reasonable expectation of success to place Hente's hinges in a location that fits on the inner side surfaces of the adjacent sections." Petition, 68, 73; Ex. 1015 (Grove Declaration), ¶239. However, Petitioner provides no evidence

or analysis to support that a POSITA would have had a reasonable expectation of success regarding the measured irradiance at a treatment surface by comparison to a measured maximum over an active emitting area for the ***combination*** of Lundahl in view of Larsen, and ***further in view of Hente***. On this basis alone, Petitioner cannot meet its burden with respect to the ***combination*** of Lundahl, Larsen, and Hente.

151. Accordingly, Petitioner and Dr. Grove have not shown that the ***combination*** of Lundahl, Larsen and Hente renders obvious the claims under Ground 2.

C. Ground 3: Claims 17 And 18 Are Not Obvious Over Lundahl In View Of Larsen, Hente And Further In View Of Perutz

152. Independent Claims 1 and 20 of the '512 Patent require that the system for photodynamically diagnosing or treating a patient comprises *"light sources disposed on surfaces of the at least five panels, the illuminator being configured to uniformly illuminate a treatment surface of the patient via the light sources."* Independent Claim 8 of the '512 Patent requires that the method of photodynamically diagnosing or treating a patient comprises "*uniformly illuminating a treatment surface of the patient with light sources disposed on the at least five panels of the illuminator*."

153. For Ground 3, Petitioner and Dr. Grove add Perutz's hinge system to the combination of Lundahl, Larsen, and Hente, but do not address the impact of

adding a third hinge system to the resulting device on the uniformity under the parties' agreed-to claim construction. Ex. 1015 (Grove Declaration), ¶¶234, 254; Petition, 78. Petitioner and Dr. Grove merely rely on their analysis "discussed previously for Grounds 1 and Ground 2." Petition, 81, 84; Ex. 1015 (Grove Declaration), ¶¶243, 260. As explained in Section XII.A, Lundahl in view of Larsen does not render obvious the "uniformly illuminate" claim limitations. Neither Petitioner nor Dr. Grove explains how or why the combination of Lundahl, Larsen, Hente, ***and further with Perutz*** "irradiat[es] 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." Accordingly, Petitioner and Dr. Grove have not shown that the ***combination*** of Lundahl, Larsen, Hente, and Perutz renders obvious the claims under Ground 3.

154. Additionally, Petitioner and Dr. Grove fail to show that a POSITA would have had a reasonable expectation of success that the combination of Lundahl, Larsen, Hente, and Perutz would "irradiat[e] light over the active emitting area such that the measured irradiance at a treatment surface of the patient is at least within 60% of the measured maximum." Petitioner and Dr. Grove merely provide a conclusory statement that "a "POSITA would have been motivated to combine the hinge system of Perutz with the panels of Larsen, and would have a reasonable expectation of success that the hinges of Perutz could be successfully utilized in the

device rendered obvious by Lundahl and Larsen." Petition, 81 (citing Ex. 1015, ¶151). However, Petitioner and Dr. Grove provides no evidence or analysis to support that a POSITA would have had a reasonable expectation of success regarding the measured irradiance at a treatment surface by comparison to a measured maximum over an active emitting area for the ***combination*** of Lundahl Larsen, Hente and ***further in view of Perutz***. On this basis alone, Petitioner cannot meet its burden with respect to the ***combination*** of Lundahl, Larsen, Hente, and Perutz.

XIII. THE COMBINATIONS OF PRIOR ART DO NOT RENDER OBVIOUS "WHEREIN EACH OF THE AT LEAST FIVE PANELS HAS TWO FIRST EDGES AND TWO SECOND EDGES SHORTER THAN THE TWO FIRST EDGES, AND THE LIGHT SOURCES ARE ARRANGED SUCH THAT A HIGHER INTENSITY OF LIGHT IS EMITTED PROXIMATE THE SECOND EDGES COMPARED TO THE INTENSITY OF LIGHT EMITTED NOT PROXIMATE THE SECOND EDGES"

A. Ground 1: Claims 1, 3, 5, 8, And 20 Are Not Obvious Over Lundahl In View Of Larsen

155. Independent claims 1, 8, and 20 of the '512 Patent require "*wherein each of the at least five panels has two first edges and two second edges shorter than the two first edges, and the light sources are arranged such that a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges*."

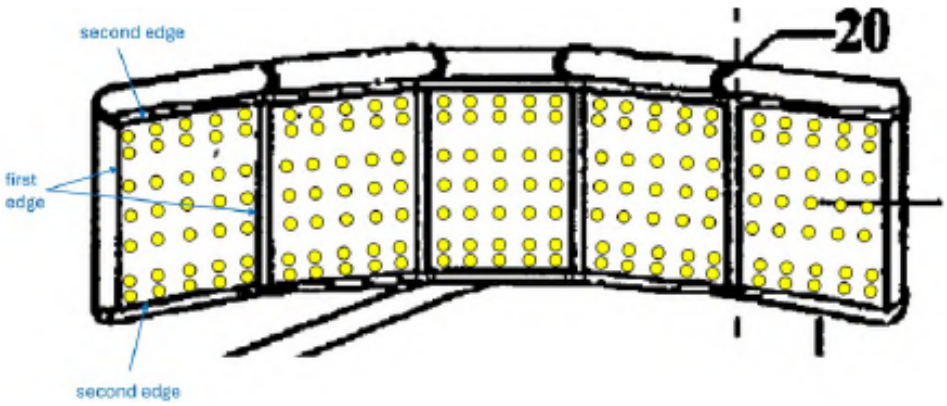
156. Petitioner and Dr. Grove argue that Lundahl in view of Larsen renders obvious "the light sources are arranged such that a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges." Ex. 1015 (Grove Declaration), ¶¶183-197, 219-221, 231-233; Petition, 48-53, 64-65. However, the combination Lundahl in view of Larsen does not render obvious this limitation for the reasons set forth below.

157. ***First***, Petitioner and Dr. Grove have not shown that the combination of Lundahl's device with Larsen's panels and LEDs would render obvious "the light sources are arranged such that a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges." Dr. Grove argues that combining "the PDT device and light distribution of Lundahl" with "the design principles of Larsen related to hinged panels and LED lights" renders obvious this limitation. Ex. 1015 (Grove Declaration), ¶¶191-192; Petition, 51. However, Dr. Grove has not shown that the alleged resulting device would meet the claim limitation because he relies on Lundahl's "light distribution" while ignoring the references' teachings as a whole.

158. Dr. Grove does not read the claim limitation as a whole, which requires that "***each*** of the at least five panels" has light sources arranged such that "a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges." *See*, *e.g.*, Ex. 1001 ('512 Patent),

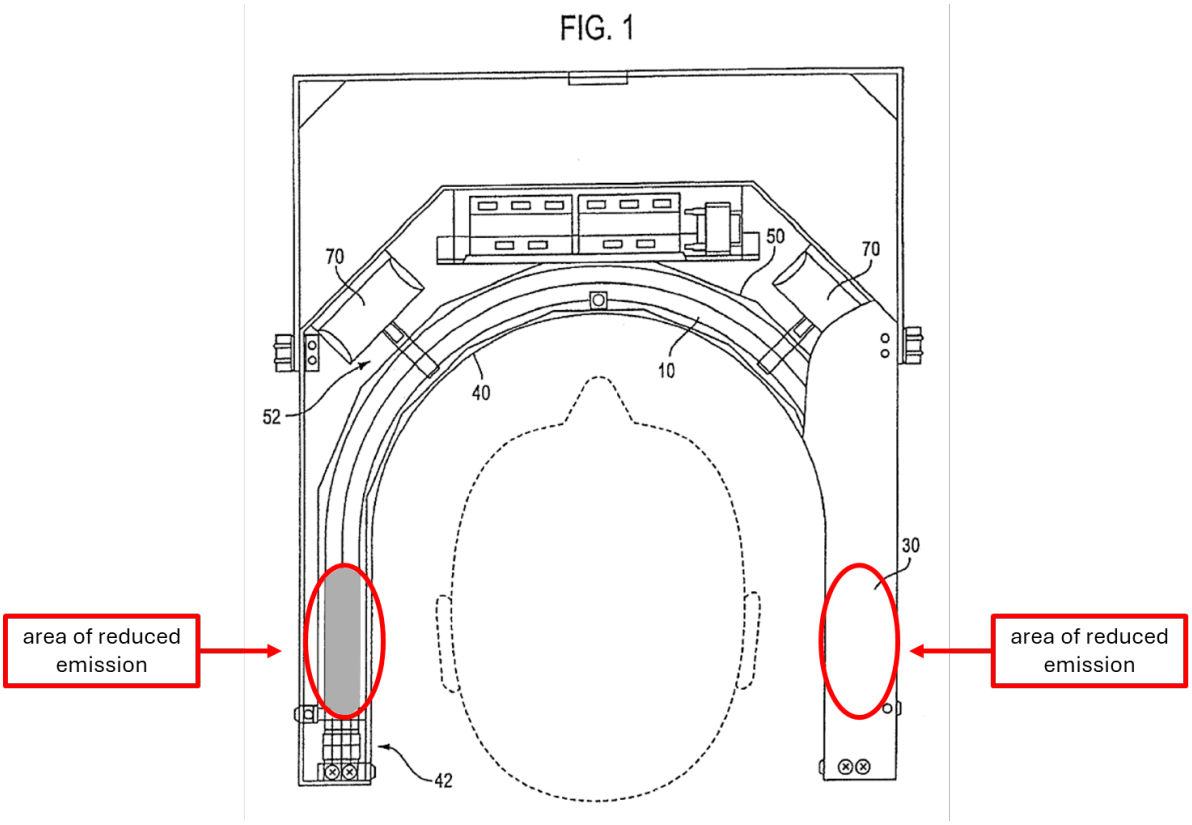
10:35-40 ("wherein ***each*** of the at least five panels has two first edges and two second edges shorter than the two first edges, and the light sources are arranged such that a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges"). Dr. Grove's depiction of the alleged "resulting device" contradicts Lundahl's teaching that the "arrangement" of light sources has "low output area[s]" and "area[s] of reduced emission." Ex. 1015 (Grove Declaration), ¶191; Ex. 1014 (Lundahl), 6:10-22. Dr. Grove argues that the alleged "resulting device," "maintaining the same light distribution pattern Lundahl utilized for the fluorescent bulbs," would "increase the intensity of light emitted from the second edges (e.g., extending along the top and bottom sides of the panel arrangement) of the panels of Larsen compared to regions not proximate to the second edges." Ex. 1015 (Grove Declaration), ¶¶191-192, 195. However, a POSITA applying Lundahl's teachings of "light distribution" would have understood that the output is "***not inherently uniform***" and that there are "***area[s] of reduced emission***." Ex. 1014 (Lundahl), 6:10-22. A POSITA would have understood that "***each*** of the least five panels" would ***not*** have "a higher intensity of light [] emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges," because of the "***low output area*** [] located ***outside the active emitting area***" on at least the outer panels (Ex. 1014, 6:16-22), as I discuss in detail below.

159. Dr. Grove alleges that "a POSITA would expect the resulting device to have a design similar to the below (yellow circles representing LEDs)." Ex. 1015 (Grove Declaration), ¶191; Petition, 51.

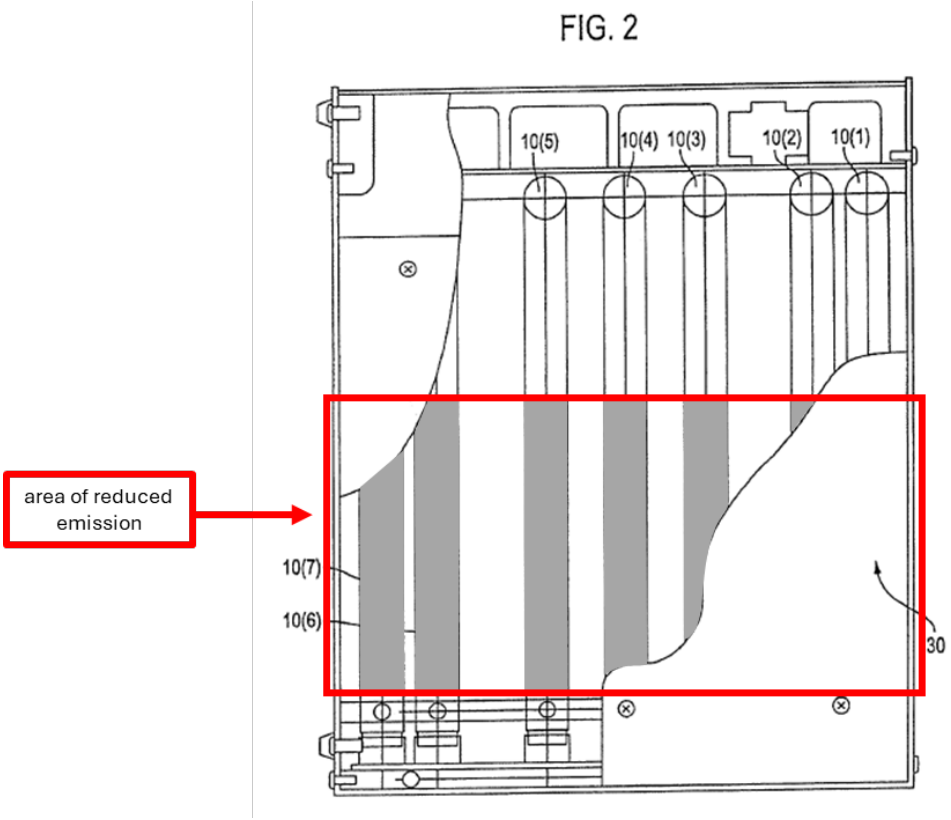


Dr. Grove's depiction that allegedly results by combining Lundahl's "PDT device and light distribution" with Larsen's "hinged panels and LED lights" (Ex. 1015, ¶191) directly contradicts Lundahl's teaching that ***"[t]he output from a fluorescent tube is not inherently uniform***." Ex. 1014 (Lundahl), 6:10-11. For example, Lundahl discloses that "[t]he output measured in the immediate vicinity of the cathode is typically much lower than the output over the rest of the tube. … This ***area of reduced emission*** is known as the Faraday dark space." Ex. 1014 (Lundahl), 6:10-16. Lundahl explains that "[t]o avoid uniformity problems, one embodiment of the present invention utilizes a plurality of U-shaped tubes **10**(**1**)-**10**(**7**). This arrangement allows the cathodes and their ***low output area to be located outside the active emitting area (effectively behind the patient's ears). Only the more uniform center portion of the tube output is used for patient treatment.***" Ex. 1014

(Lundahl), 6:16-22. Dr. Grove ignores Lundahl's express teaching of "area[s] of reduced emission," as illustrated below in red:



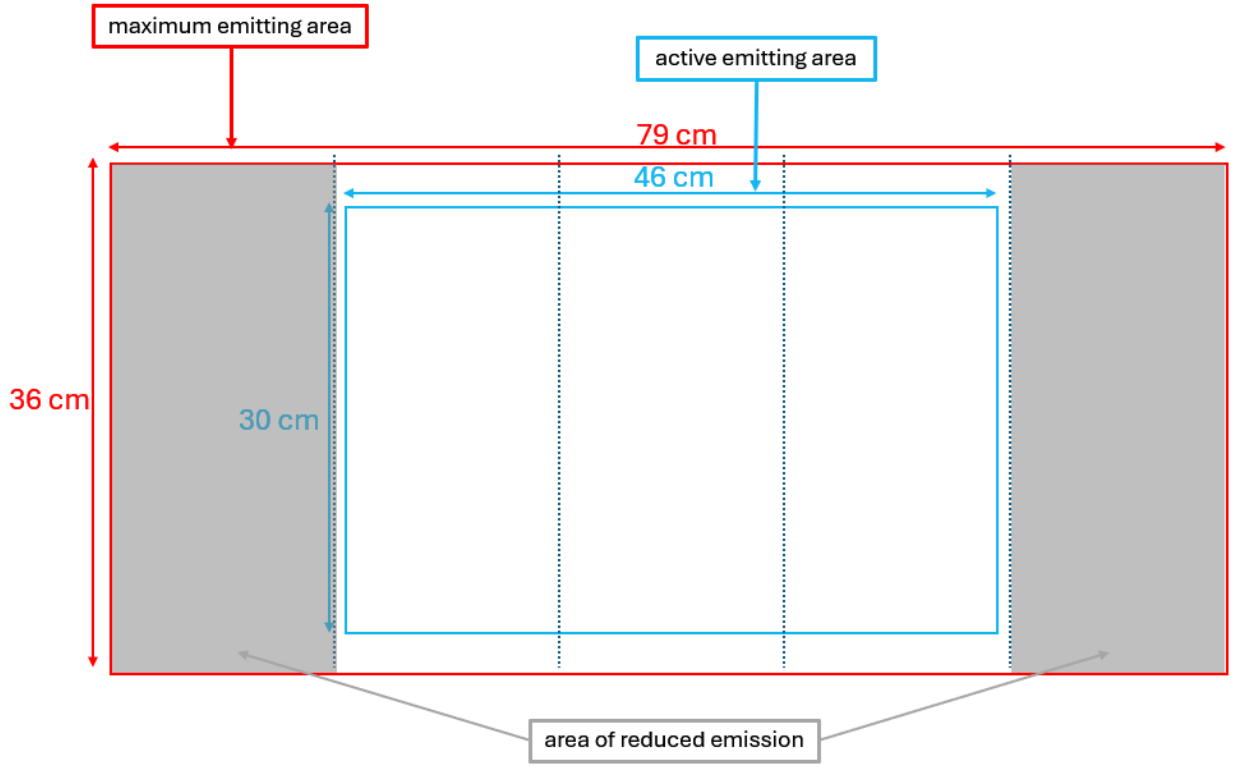
Ex. 1014 (Lundahl), FIG. 1 (annotated).



Ex. 1014 (Lundahl), FIG. 2 (annotated). In fact, Dr. Grove acknowledges that "fluorescent tubes are known to have inconsistent light output within the tube itself," citing to Lundahl's disclosure that "tube output may vary over its length' (4:41-42)." Ex. 1015 (Grove Declaration), ¶130; Petition, 30. A POSITA applying Lundahl's express teachings of "light distribution" would have understood that the alleged "resulting device" (Ex. 1015 (Grove Declaration), ¶191) would have had "***area[s] of reduced emission***" as shown in FIGS. 1 and 2 above.

160. In fact, a POSITA would have understood that if Larsen's five panels were incorporated into Lundahl's PDT device, as proposed by Dr. Grove ("maintain[] the same light distribution pattern Lundahl utilized for the fluorescent

bulbs"), the ***combination would <u>not</u> result*** in Dr. Grove's alleged design above. Ex. 1015 (Grove Declaration), ¶191. Instead, the light emitted proximate the second edges of ***<u>each</u>*** panel of the resulting device would ***<u>not</u>*** be a higher intensity than the light emitted not proximate the second edges, because of the "***low output area***" (*i.e.*, "area of reduced emission") that is "located ***outside the active emitting area***" on at least the outer panels, as shown below.



Ex. 1014 (Lundahl), 6:10-22. Lundahl discloses that the "therapeutically active emitting area" (shown in blue) is "30 cm high by 46 cm wide," and the "maximum visible light-emitting area" (shown in red) is "36 cm high by [79] cm wide." Ex. 1014 (Lundahl), 5:38-43; Ex. 2037 (BLU-U Optical Specification) (confirming

"Total Emitting Area" is "36 cm H X 79 cm W"). Therefore, if Larsen's panels were incorporated into Lundahl, a POSITA would have understood that the resulting device that "maintains Lundahl's light distribution" would have an active emitting area of ***only*** 60% (three panels of equal width) of the width of the maximum light-emitting area (five panels of equal width) as illustrated above. As discussed, Lundahl's "arrangement allows the cathodes and their ***low output area*** to be ***located outside the active emitting area (effectively behind the patient's ears)***. ***Only the more uniform center portion of the tube output is used for patient treatment***." Ex. 1014 (Lundahl), 6:18-22. Therefore, the light emitted proximate the second edges of ***each of the at least five panels*** would ***not*** be a higher intensity than the light emitted not proximate the second edges because there would be ***"area[s] of reduced emission"*** "located ***outside the active emitting area***" (Ex. 1014, 6:13-22) on at least the outer panels (shown in gray above).

161. The above illustration showing the active emitting area (three panels of equal width in blue) and the low output areas outside the active emitting area (outer panels in gray) is also consistent with Lundahl's disclosure of FIG. 4A—the "***active emitting area***" ("***center portion***") corresponds to FIG. 4A's ***central region 10A***, and the "***low output area[s]***" ("***outside the active emitting area***") correspond to FIG. 4A's "***arms 10B*** extending from respective ends of the central region," as shown below:

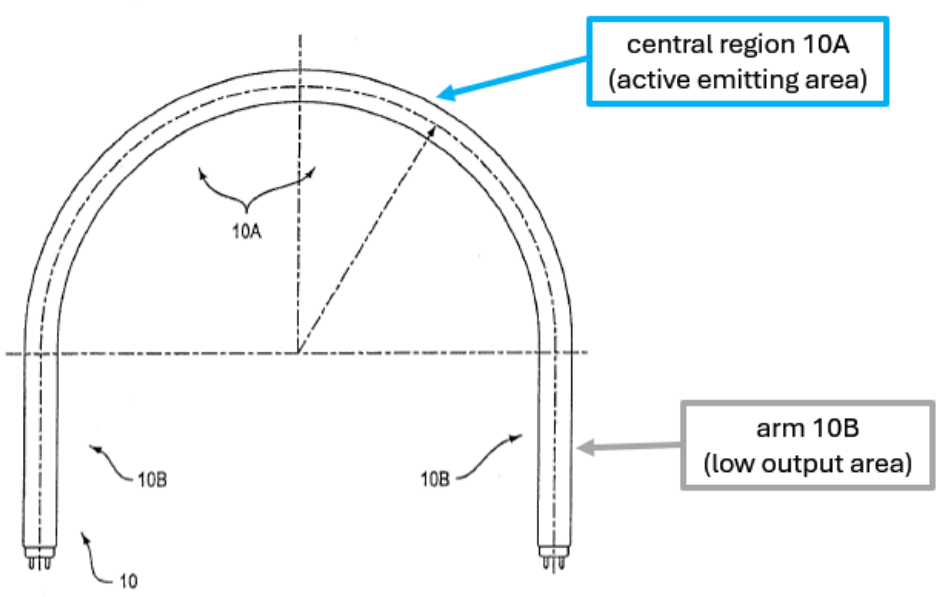


FIG. 4A

Ex. 1014 (Lundahl), FIG. 4A (annotated), 5:43–46 ("the tubes have a generally arcuate central region **10A** and arms **10B** extending from respective ends of the central region."). It is important to note that Lundahl teaches that "only the more uniform center portion of the tube output is used for patient treatment." Ex. 1014 (Lundahl), 6:18-22. The low output areas, corresponding to the arms 10B, are not used. Ex. 1014 (Lundahl), 6:18-22.; FIG. 4A.

162. A POSITA seeking to "maintain[] the ***same light distribution pattern Lundahl utilized for the fluorescent bulbs***," as Dr. Grove proposes (Ex. 1015, ¶192), would apply Lundahl's teaching as a whole—the POSITA would not cherry-pick Lundahl's teaching of tube spacing and reject Lundahl's teaching of low output areas located outside the active emitting area, unless they were using improper hindsight. Also, to the extent Dr. Grove is suggesting he would apply Larsen's

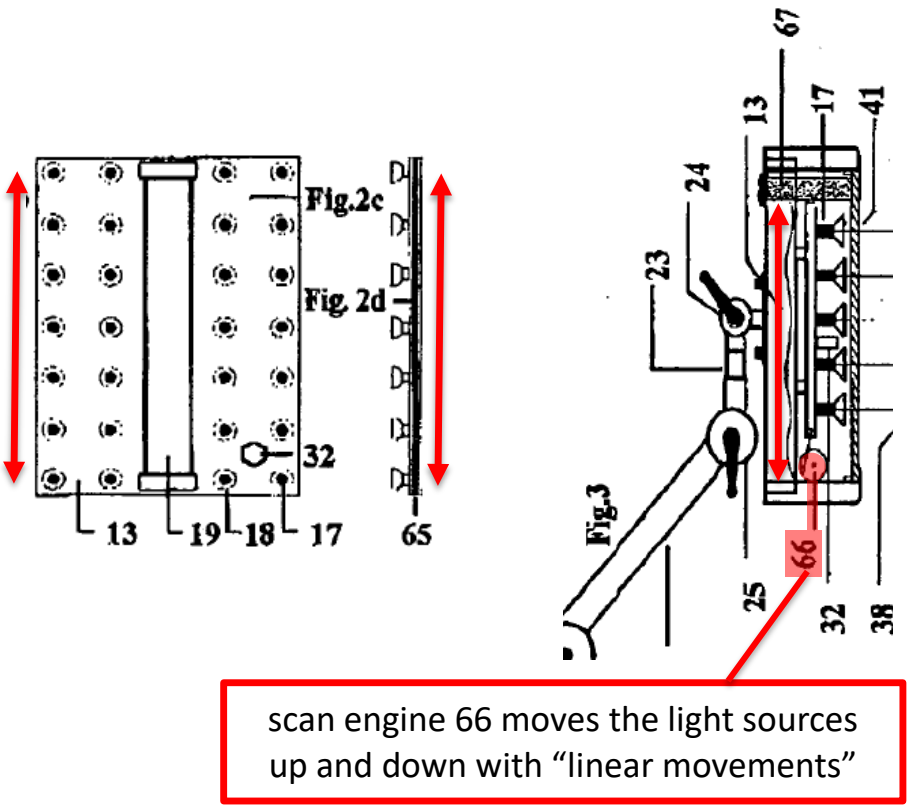
solution regarding LEDs (Ex. 1015 (Grove Declaration), ¶131), that does not fix the problem or meet the "higher intensity" limitation because Larsen's "regular row arrangements" of LEDs do ***not*** have a higher intensity proximate the shorter edges. Ex. 1004 (Larsen), [0071], FIGS. 2a-2d. In fact, Petitioner acknowledged that "Larsen does not expressly teach that the light sources on its applicators are arranged such that the higher intensity of light is emitted proximate the second edges." *See* IPR2024-00874, Paper 1 (Petition), at 36. [2]

163. Accordingly, when the claim language and references are read as a whole, Lundahl in view of Larsen does not render obvious "wherein ***each*** of the at least five panels has two first edges and two second edges shorter than the two first edges, and the light sources are arranged such that a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges."

[2] Further, Dr. Grove provides no basis to support that the light distribution of his alleged "resulting device" based on the combination of Lundahl and Larsen would be "nearly identical to the light distribution in BF-RhodoLED XL." Ex. 1015, ¶193-195; Petition, 51-53.

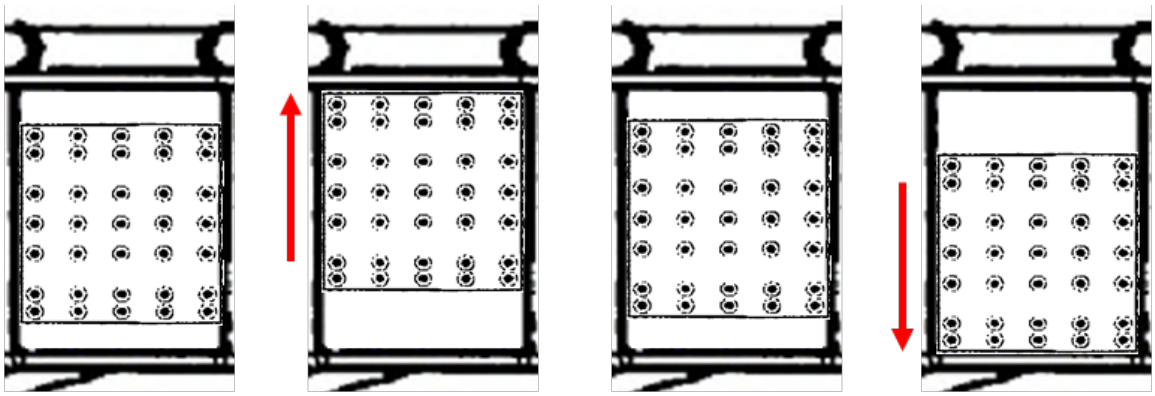
164. ***Second***, Petitioner and Dr. Grove argue that the alleged resulting device utilizes Larsen's "electrical scan engine 66, which can move the light sources with linear movements." Ex. 1015 (Grove Declaration), ¶¶177-178, 226 (citing Ex. 1004 (Larsen), [0072]); Petition, 44-45, 63-64. A POSITA would have understood that the alleged resulting device incorporating Larsen's scan engine that "***move[s] the light sources with linear movements***" would ***not*** result in a device that would render obvious "*the light sources are arranged such that a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges*."

165. As explained by Petitioner's expert Dr. Bretschneider, a POSITA would have understood that Larsen's scan engine is "configured to only move the lights linearly in a single direction." IPR2024-00874, Ex. 1003 (Bretschneider Declaration), ¶154; IPR2024-00874, Petition, 18 ("Larsen's scan engine is configured to only move the lights along a single axis"). Larsen discloses that "[i]n each applicator, the printed circuit board carrying the light sources is connected to a small electrical scan engine **66**, which can ***move the light sources with linear movements***." Ex. 1004 (Larsen), [0072]. A POSITA reading Larsen would have understood that Larsen's scan engine "move[s] the light sources with linear movements" up and down along the longer axis of the applicators, as shown below.



Ex. 1004 (Larsen), Fig. 2c-d, Fig. 3 (rotated 90°), [0072].

166. Dr. Grove relies on Larsen's "electrical scan engine **66**" in his proposed combination of Lundahl in view of Larsen. Ex. 1015 (Grove Declaration), ¶¶177-179, 226 (citing Ex. 1004 (Larsen), [0072]). In Dr. Grove's alleged resulting device, which "maintain(s) the same light distribution pattern Lundahl utilized for the fluorescent bulbs," a POSITA reading Larsen would have understood that the scan engine moves the light sources up and down with linear movements. For example, the light sources would move up and down from t=0 to t=3, as shown below.



Ex. 1015 (Grove Declaration), ¶¶191, 192; Ex. 1004 (Larsen), [0072]. As further explained by Dr. Bretschneider, this linear movement "***would only decrease unradiated gaps on the portion of the treatment surface towards which the light sources are being moved***." IPR2024-00874, Ex. 1003 (Bretschneider Declaration), ¶154; IPR2024-00874, Petition, 18. As seen in the time lapse from t=0 to t=3, ***there would be more light sources in the center portion of each panel than at the shorter edges of each panel***. Therefore, a POSITA would have understood that the light sources in Dr. Grove's alleged resulting device are arranged such that a ***lower*** intensity of light is emitted proximate the second shorter edges compared to the intensity of light not proximate the second edges (*e.g.*, the center), when the teachings of Lundahl and Larsen are considered as a whole. A POSITA would have understood that the alleged resulting device would ***not*** result in a device that would render obvious "*the light sources are arranged such that a higher intensity of light*

is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges."

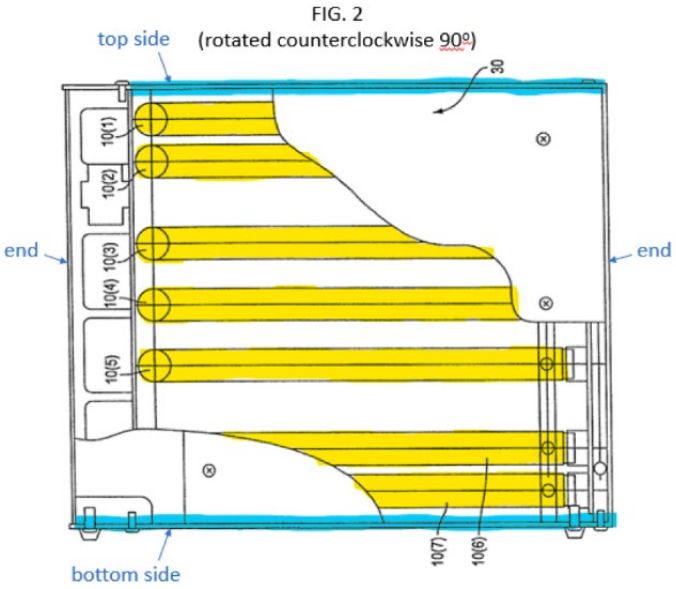
167. ***Third***, in IPR2024-01312, I understand that the Board preliminarily found that "Petitioner's proposed modification applies Lundahl's disclosure of providing greater light intensity at the top and bottom sides to the top and bottom sides of Larsen, which are the shorter edges in Larsen." IPR2024-01312, Paper 9 (Institution Decision), at 19. However, as an initial matter, the Board applied the combination ***backwards***. Petitioner and Dr. Grove argued in both proceedings that a POSITA would have been motivated "to ***incorporate Larsen's solution*** of disposing light sources, specifically LEDs, on the surface of the light applicators ***to Lundahl's device***." IPR2024-01312, Paper 3 (Petition), at 32 (citing Ex. 1015 (Grove Declaration), ¶130); Petition, 24, 50-51 (citing Ex. 1015 (Grove Declaration), ¶¶119, 191 ("***incorporate*** the hinged panel LED displays of ***Larsen into the PDT device of Lundahl***"), 192 ("hinged panels and LEDs taught by ***Larsen*** are ***incorporated into the device of Lundahl***")). Petitioner and Dr. Grove did ***not*** argue to apply Lundahl's disclosure to Larsen's device.

168. Regardless, the Board, Petitioner, and Dr. Grove overlooked Lundahl's teaching that Lundahl's more closely spaced fluorescent tubes are at the ***longer edges*** of Lundahl's panel, ***not*** the ***shorter edges***. A POSITA reading the references' express disclosures would have understood that ***both Lundahl and Larsen*** teach to

have a ***lower*** intensity near the shorter edges, and ***neither reference teaches or suggests that the light sources emit a higher intensity near the shorter edges***.

169. Dr. Grove argues that a "POSITA would have understood that the tubes of Lundahl are spaced to emit a higher intensity of light proximate the top and bottom sides compared to the intensity of light emitted not proximate the top and bottom sides." Ex. 1015 (Grove Declaration), ¶189; Petition, 49. To make this argument, Dr. Grove rotates FIG. 2 of Lundahl on its side and labels in blue a "top side," a "bottom side," and two "ends":[3]

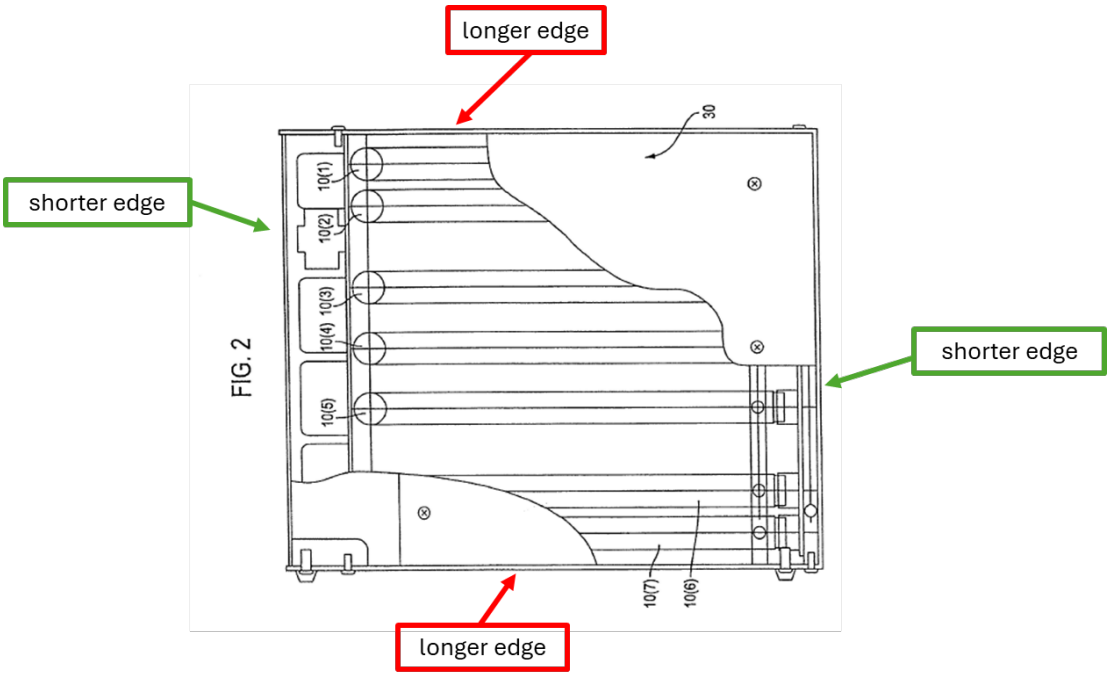
[3] The label "end" on the left-hand side of FIG. 2 that Dr. Grove indicated is misleading, as it is not an "end" of the fluorescent tube, but rather, only a portion of the fluorescent tube is shown on the left-hand side of the figure. The cathode shown on the right-hand side of the figure is one "end" of the fluorescent tube, as indicated by the presence of a cathode. The fluorescent tube extends to a cathode on the other end (not shown).



Ex. 1015 (Grove Declaration), ¶173; Petition, 48 (Fig. 2 as annotated by Dr. Grove).

170. However, a POSITA reading Lundahl would have understood that the "edges" of Lundahl's device labeled "top side" and "bottom side" are the ***longer*** edges, and that the edges labeled "end" are the ***shorter*** edges as illustrated below.[4]

[4] I note that the left-hand side of the figure is a partial cross-section and the fluorescent tubes extend to cathodes (not shown).



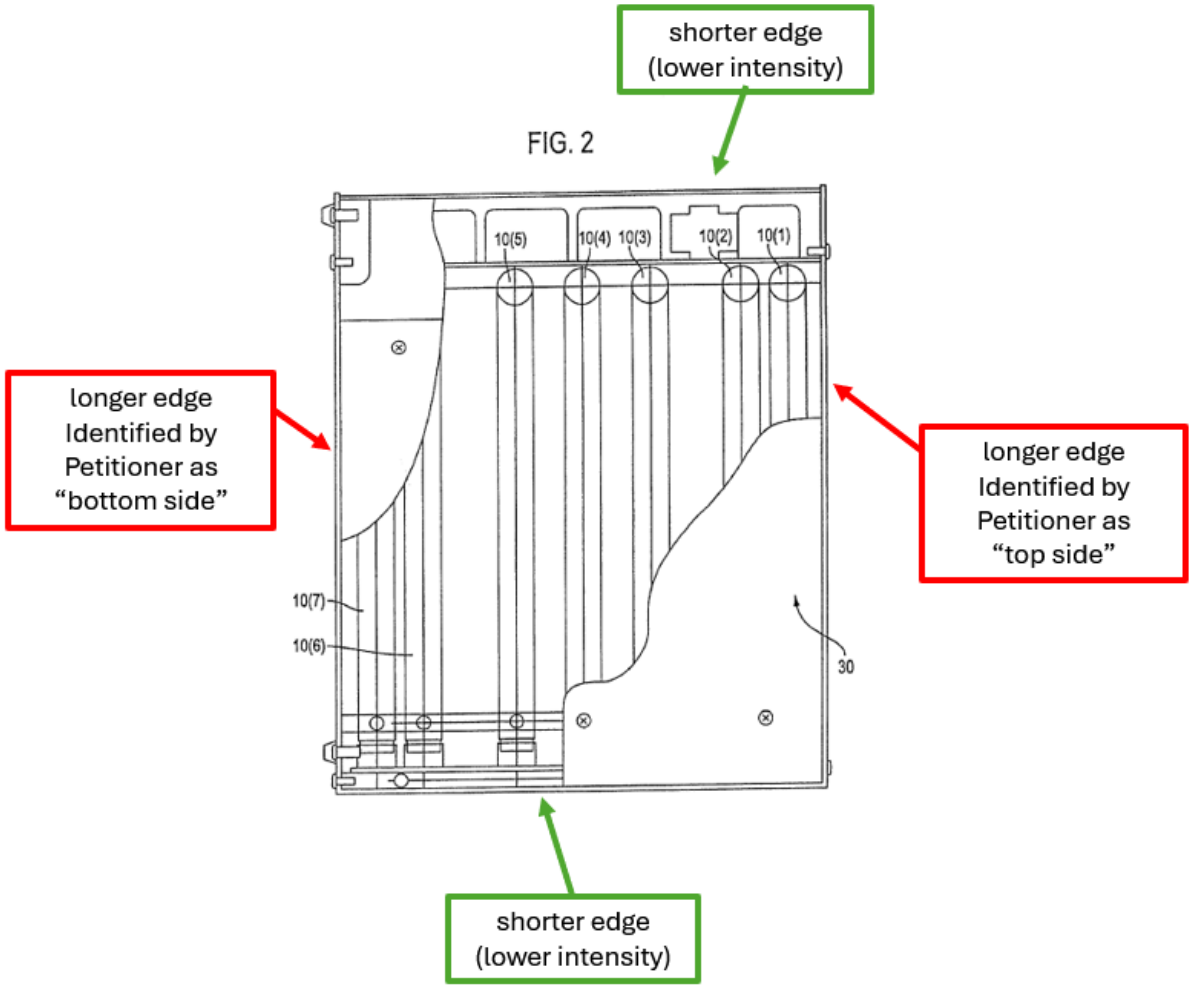
Ex. 1014 (Lundahl), FIG. 2 (annotated); *see also* FIG. 1.

171. Lundahl discloses that the "seven 36″ U-shaped F34T8 Ultra Blue fluorescent tubes **10(1)-10(7)** provide a ***maximum visible light-emitting area 36 cm high by [79] cm wide (approximately 2850 cm^2)***, with a ***minimum therapeutically active area 30 cm high by 46 cm wide (approximately 1350 cm^2)***." Ex. 1014 (Lundahl), 5:38-43; Ex. 2037 (BLU-U Optical Specification). Therefore, the "***top and bottom sides***" identified by Dr. Grove are the ***longer edges*** and the ***left and right sides*** are the ***shorter edges***.

172. Dr. Grove fails to consider the requirements of the "higher intensity" claim limitation as a whole and instead breaks the limitation into disjointed pieces. Ex. 1015 (Grove Declaration), ¶¶183-197; Petition, 47-53. When the entire claim

limitation is read ("wherein each of the at least five panels has *two first edges and two second edges shorter than the two first edges*, and the light sources are arranged such that a higher intensity of light is emitted *proximate the second edges* compared to the intensity of light emitted *not proximate the second edges*"), it is clear that the claims distinguish between the shorter second edges and the longer first edges of the panels. In context, the plain language of the claims requires that the intensity of light emitted ***proximate the shorter second edges*** is higher than the intensity of light emitted ***not proximate the shorter second edges***. Therefore, the "top and bottom sides" of Lundahl do not meet the claim requirements because the "top and bottom sides" that Dr. Grove alleges emit a higher intensity of light are the ***longer edges***, ***not*** the ***shorter second edges*** required by the claims.

173. Dr. Grove's attempt to equate Lundahl and Larsen by changing the orientation of the figures and labeling the "top side" and "bottom side" (Ex. 1015 (Grove Declaration), ¶173; Petition, 48) is incorrect and misleading, because Lundahl's "top side" and "bottom side" are the ***longer edges***, whereas Larsen's "top side" and "bottom side" are the ***shorter edges***. Dr. Grove's hindsight driven argument, which purports to modify Larsen's "regular row arrangements" of light sources to emit higher intensity of light near the shorter edges is not taught by Lundahl, which discloses that the ***shorter edges*** are in an "***area of reduced emission***," ***not*** an area of higher intensity as shown below.

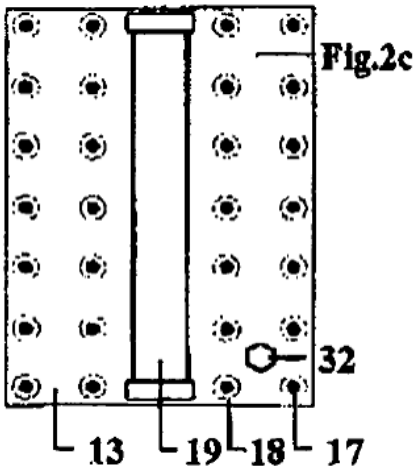


Ex. 1014 (Lundahl), Fig. 2 (annotated)[5]; *see also* Fig. 1, 6:10-22 (explaining that "[t]he output measured in the immediate vicinity of the cathode is typically much lower than the output over the rest of the tube. … This ***area of reduced emission*** is known as the Faraday dark space" and "[t]o avoid uniformity problems, one embodiment of the present invention utilizes a plurality of U-shaped tubes **10**(**1**)-**10**(**7**). This arrangement allows the cathodes and their ***low output area*** to be located

[5] I note that the fluorescent tubes extend to cathodes at each of the second edges.

outside the active emitting area (effectively behind the patient's ears"). A POSITA reading Lundahl's disclosure would have understood that "maintain[ing] Lundahl's light distribution" would place the "area[s] of reduced emission" in the alleged resulting device on the panels proximate the ***shorter edges*** such that the light emitted proximate the shorter edges would be of ***lower intensity***, ***not*** "higher intensity" as required by the claims.

174. Larsen's disclosure would have discouraged a POSITA from having a higher intensity near the second shorter edges. As shown in Fig. 2c, at least one of Larsen's applicators contains a "light source **19** formed as a tube" that can emit "fluorescent light." Ex. 1004 (Larsen), [0071].



Ex. 1004 (Larsen), Fig. 2c. The cathodes of the light source 19 are at the ***shorter edges*** of the applicator. Because fluorescent tubes have "area[s] of reduced emission" at the cathodes (Ex. 1014 (Lundahl), 6:10-16), a POSITA would have understood that the intensity of light is ***lower*** proximate the ***shorter edges*** than not

proximate the shorter edges of the applicator. Therefore, a POSITA would have been discouraged from pursuing a higher intensity near the shorter edges.

175. Petitioner and Dr. Grove argue that Lundahl in view of Larsen renders obvious "*the light sources are arranged such that a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges*" because the light sources in the alleged resulting device are closer together at the shorter edges. Ex. 1015 (Grove Declaration), ¶¶191-195; Petition, 50-53. However, a POSITA would understand that both Lundahl and Larsen teach to have a ***lower*** intensity at the second shorter edges.

176. Accordingly, Petitioner has not shown that Lundahl in view of Larsen renders obvious "*wherein each of the at least five panels has two first edges and two second edges shorter than the two first edges, and the light sources are arranged such that a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges*."

B. Ground 2: Claims 1, 3, 5, 8, 17, 18 and 20 Are Not Obvious Over Lundahl In View Of Larsen And Further In View Of Hente

177. Independent claims 1, 8, and 20 of the '512 Patent require "*wherein each of the at least five panels has two first edges and two second edges shorter than the two first edges, and the light sources are arranged such that a higher intensity*

of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges."

178. Petitioner and Dr. Grove rely only on their "previous analysis provided in Ground 1," arguing that Lundahl in view of Larsen renders obvious this limitation. Ex. 1015 (Grove Declaration), ¶234; Petition, 65. Petitioner and Dr. Grove's repeated arguments for the combination of Lundahl, Larsen, and Hente again fail for the same reasons. As explained in Section XIII.A, Lundahl in view of Larsen does not render obvious "*wherein each of the at least five panels has two first edges and two second edges shorter than the two first edges, and the light sources are arranged such that a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges*."

C. Ground 3: Claims 17 And 18 Are Not Obvious Over Lundahl In View Of Larsen, Hente And Further In View Of Perutz

179. Independent claims 1, 8, and 20 of the '512 Patent require "*wherein each of the at least five panels has two first edges and two second edges shorter than the two first edges, and the light sources are arranged such that a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges*."

180. Petitioner and Dr. Grove rely only on their arguments presented in Grounds 1 and 2, arguing that Lundahl in view of Larsen renders obvious this

limitation. Ex. 1015 (Grove Declaration), ¶¶254, 260; Petition, 78. Petitioner and Dr. Grove's repeated arguments for the combination of Lundahl, Larsen, Hente, and Perutz again fail for the same reasons. As explained in Section XIII.A, Lundahl in view of Larsen does not render obvious "*wherein each of the at least five panels has two first edges and two second edges shorter than the two first edges, and the light sources are arranged such that a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges*."

XIV. OBJECTIVE INDICIA SUPPORT THE NON-OBVIOUSNESS OF THE CHALLENGED CLAIMS OF THE '512 PATENT

181. The patentability of the Challenged Claims is supported by secondary considerations of nonobviousness, including commercial success and industry praise.

A. The Claimed Invention is Commercially Successful

182. Biofrontera's RhodoLED® XL is a "red light-emitting LED lamp, which is used exclusively in combination with Ameluz® gel for lesion-directed and field-directed treatment of actinic keratoses of mild-to-moderate severity on the face and scalp." Ex. 2043 (RhodoLED XL User Manual), 4. The RhodoLED® XL's main components are the lamp head, the spring arm, the control unit, and the mobile base with castors including wheels. *Id.*, 8.

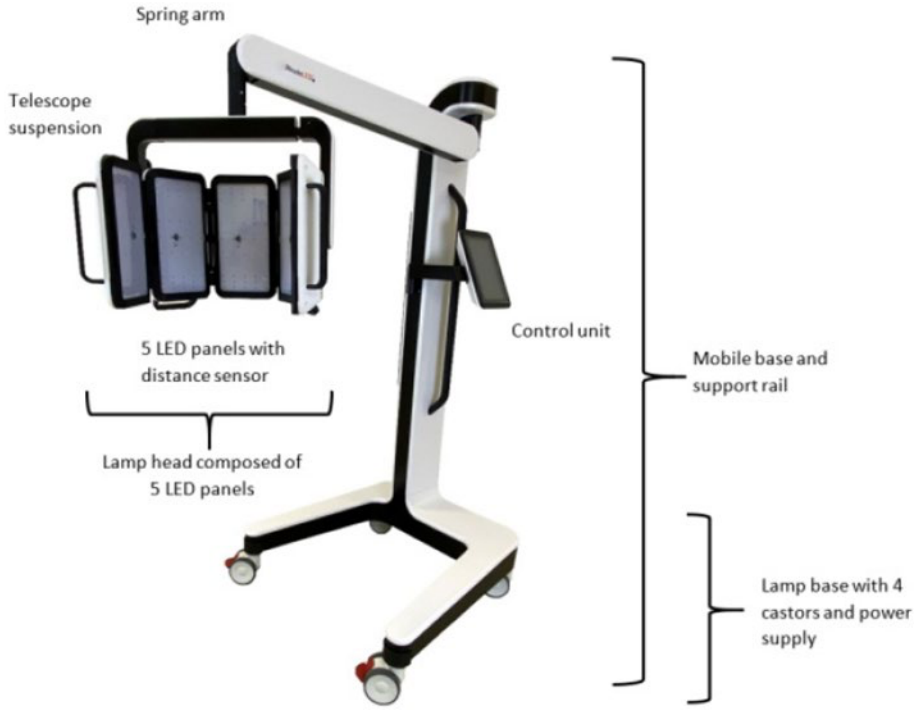


Figure 2: RhodoLED® XL main components

Ex. 2043 (RhodoLED XL User Manual), Figure 2.

183. The "RhodoLED® XL has 45 LEDs per panel with a total of 5 panels (225 LEDs), which emit a uniform, visible red light." *Id.*, 7. The LEDs are distributed on each panel in a specific way such that they are more densely packed towards the upper and lower edges than in the center region of each panel to "optimize[] the homogeneity of illumination over the treated skin." *Id.*, 7.

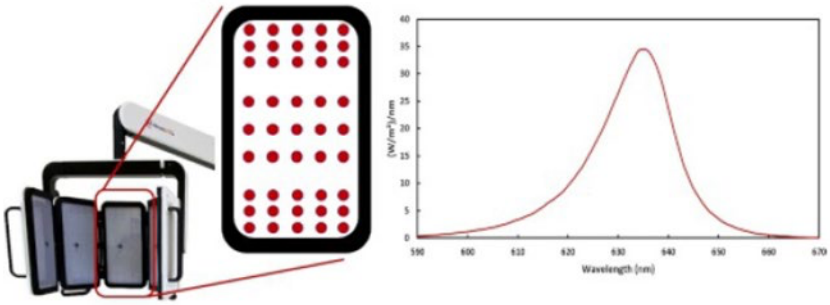


Figure 1: LED panels with LED distribution and emission spectrum of RhodoLED® XL LEDs.

Ex. 2043 (RhodoLED XL User Manual), Figure 1.

184. In 2021, the FDA approved Biofrontera's RhodoLED® XL device for treatment of mild and moderate actinic keratosis, in combination with Ameluz®. Ex. 2044 (10/22/2021 – Global Newswire Article). In June 2024, Biofrontera started commercial distribution of the RhodoLED® XL. Ex. 2045 (6/24/2024 – BioSpace Article).

185. As discussed in the attached Appendix B, Biofrontera's device practices at least exemplary claim 1 of the '512 Patent. The RhodoLED® XL embodies the claimed features of the '512 Patent and is coextensive with them.

186. The claims of the '512 Patent are directed to novel systems and methods that provide uniform illumination during PDT treatment without optical dead spaces. The patented features of the claimed invention include: (1) an adjustable five-panel design, (2) uniform illumination of the treatment surface of a patient, and (3) an LED arrangement which provides for a higher intensity of light emitted proximate the shorter edges of the panels.

187. The commercial success of Biofrontera's RhodoLED® XL is a result of the combined patented features of the claimed invention and the benefits enabled by those features, such as illumination over a larger treatment area.

188. As compared to the RhodoLED® XL, which embodies the claimed features of the '512 Patent, the original RhodoLED® (shown below) is a single panel device that lacks the claimed features of the '512 Patent.

Ex. 2056, 2 (Picture of original RhodoLED®).

189. Biofrontera touts the inclusion of the claimed features of the ’512 Patent in the RhodoLED® XL and the benefits enabled by those claimed features in its marketing materials. For example, in the ITC proceeding, Mark Baldyga, Biofrontera Inc.’s Vice President of Sales and Marketing, testified that Biofrontera gave a presentation about the RhodoLED® XL and Ameluz to Biofrontera customers at Pariser Dermatology in Virginia. Ex. 2039 (Baldyga ITC Deposition Transcript.), 37:13-42:1 (discussing Ex. 2040 (Baldyga Ex. 6, Presentation Slides); *id.*, 44:1-8. Mr. Baldyga testified that the purpose of the presentation was to encourage customers to purchase the RhodoLED® XL device. *Id.*, 40:6-11. That presentation emphasized several features of the RhodoLED® XL device, which practice the claims of the ’512 Patent. Biofrontera touts the inclusion of the claimed features in their RhodoLED® XL. For example, the presentation highlighted how the RhodoLED® XL device outputs uniform light to photodynamically treat patients using ALA together with a five-panel illuminator in a curved configuration, where LEDs are arranged on each panel such that there is a higher intensity of light emitted proximate the shorter edges, as seen in the presentation slides reproduced below.

Biofrontera

RETHINKING THE TREATMENT OF AKs: ADVANCES IN PHOTODYNAMIC THERAPY

Mark Baldyga – VP Sales, Marketing & Market Access
Samantha Widdicombe – VP Corporate Strategy & Key Accounts
Jon Lyons, PhD, MBA – VP Medical & Scientific Affairs

1

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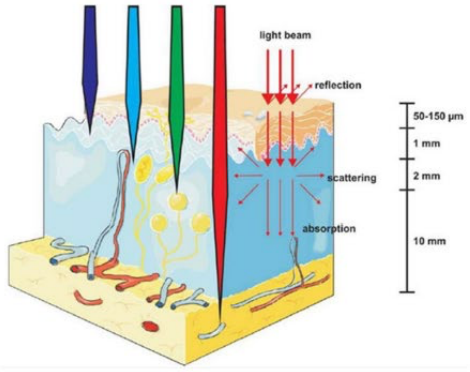
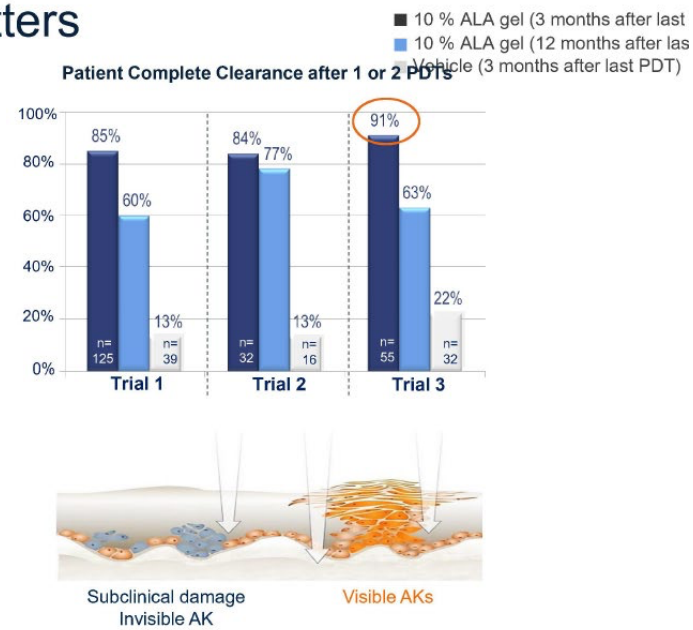
Biofrontera

Why Red Light PDT Matters





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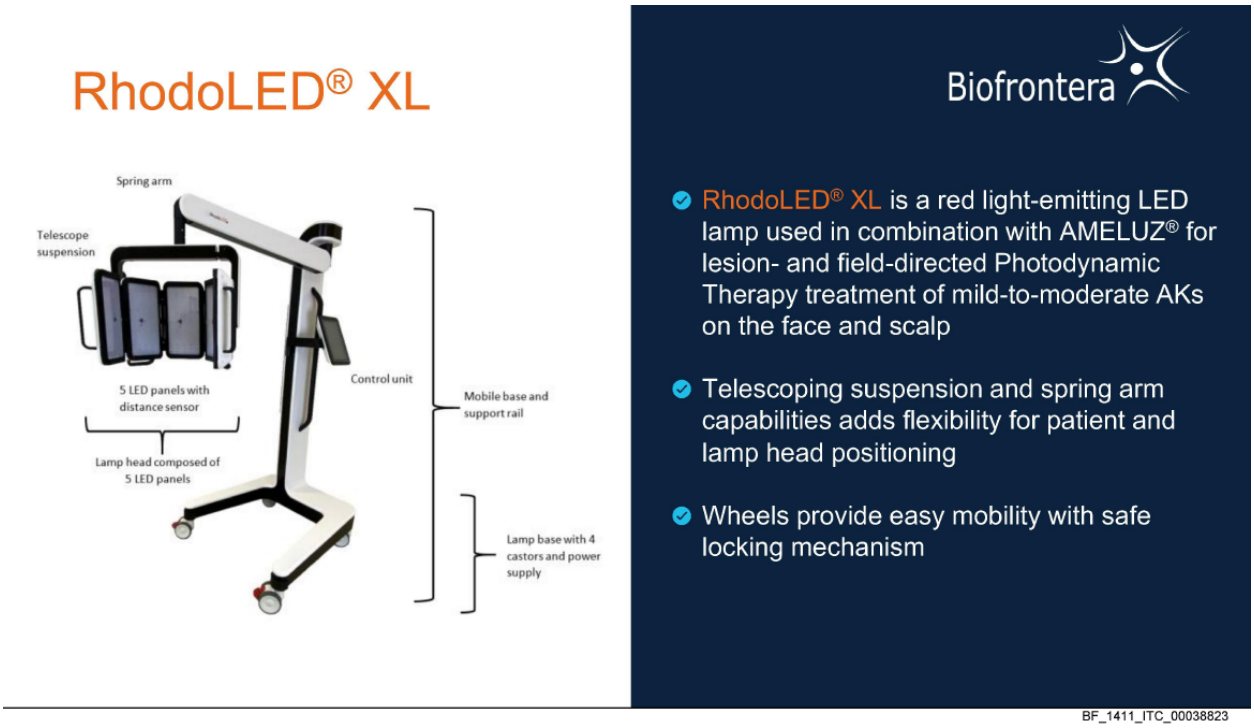
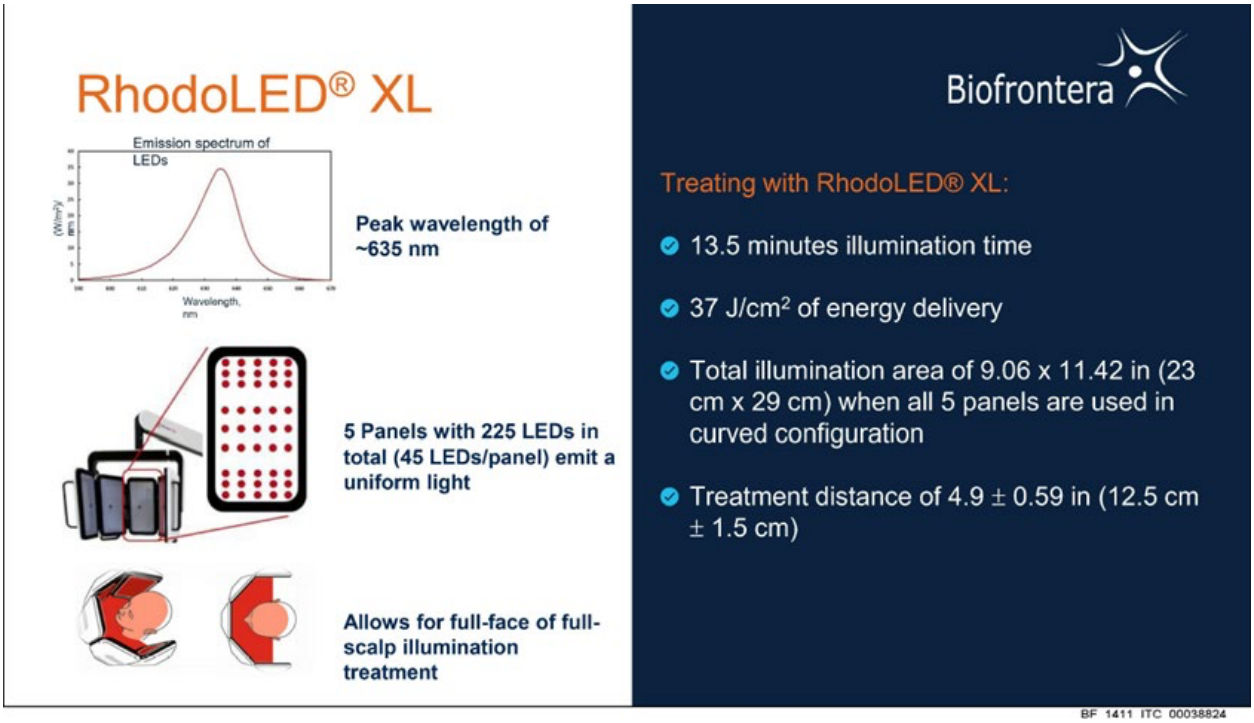


Ex. 2040 (Baldyga Ex. 6, Presentation Slides), 1, 5, 6.

190. In particular, the slide reproduced below from that presentation touts the features of the patented invention and benefits enabled by those features. The slide emphasizes that the RhodoLED® XL includes "***5 Panels*** with 225 LEDs in total" which emits "***a uniform light***," and includes a graphic that has ***all five panels illuminated***, next to the text "[a]llows for full-face o[r] full-scalp illumination treatment." Ex. 2040 (Baldyga Ex. 6 - Presentation Slides), 7; Ex. 2039 (Baldyga ITC Deposition Transcript), 44:18-46:21. Mr. Baldyga confirmed that, in reference to the slide reproduced below, "another one of the features that was advertised with the customer was that the ***RhodoLED XL includes five panels with this particular***

LED arrangement that we see here." Ex. 2039 (Baldyga ITC Deposition Transcript), 44:9-45:11.



Ex. 2040 (Baldyga Ex. 6, Presentation Slides), 7.

191. Mr. Baldyga testified that following this presentation, Biofrontera customers at Pariser Dermatology in Virginia have used the RhodoLED® XL with Ameluz to photodynamically treat a patient. Ex. 2039 (Baldyga ITC Deposition Transcript), 37:13–44:8.

192. According to Mr. Baldyga, the five panels of the RhodoLED® XL are different from the original RhodoLED device and allow for a larger illumination area. Ex. 2039 (Baldyga ITC Deposition Transcript), 46:2-5, 48:3-21. Mr. Baldyga also testified that he has received feedback from healthcare providers that "***they like***

having the five panels versus the one panel" because "***you can treat a patient's full face with one treatment. On our original lamp, you cannot do that***." *Id.* at 58:15-59:6.

193. Biofrontera's marketing materials for the RhodoLED® XL and Ameluz® describe "the treatment process" for patients and how the healthcare provider for the patient will apply Ameluz® and "illuminate the area with RhodoLED® XL lamp," for example, as reproduced below:

Ex. 2041 (Baldyga Ex. 5, Promotional Piece), 5. Mr. Baldyga confirmed, in reference to the photo of the RhodoLED® XL in the Biofrontera promotional material, that the arrangement of groups of LEDs on the panel are visible, and that, "***based on the graphics shown here, the top group of LEDs are spaced closer together compared to the center group***" and that "***the bottom group of LEDs are also spaced closer together compared to the center group***." Ex. 2039 (Baldyga ITC

Deposition Transcript), 36:13–37:9; *see id.* at 33:2-16. Biofrontera's User Manual for the RhodoLED® XL that is distributed to customers also explains how the RhodoLED® XL emits a "***uniform, visible red light***" and stresses the importance of the LED arrangement on each of the five panels: "The ***LEDS are distributed on each panel in a specific way (see Figure 1), such that they are more densely packed towards the upper and lower edges than in the center region of each panel.*** This distribution optimizes the homogeneity of illumination over the treated skin." Ex. 2043 (RhodoLED XL User Manual), 7.

194. Here, as discussed above, the marketing materials for the RhodoLED® XL prominently showcase the patented features, including the adjustable five-panel design, uniform illumination, and LED arrangement, and the benefits enabled by those features.

195. I have reviewed the declaration of Sun Pharma's economic expert, Dr. Vander Veen. I understand from Dr. Vander Veen that the increase of Biofrontera's sales and the rapid uptake of the RhodoLED® XL since launch as compared to the sales of the original RhodoLED® is evidence of commercial success as a result of the patented features. Ex. 2048 (Declaration of Thomas Vander Veen), ¶¶27-33, 46. Further, I understand from Dr. Vander Veen that the continued sales of the RhodoLED® XL at a higher price point than the original RhodoLED® is indicative

of the patented features of the accused RhodoLED® XL device driving the commercial success. Ex. 2048 (Declaration of Thomas Vander Veen), ¶¶34-36, 46.

196. Biofrontera has discussed the commercial success of the RhodoLED® XL device as result of the patented features covered by the '512 Patent. In December 2024, Biofrontera stated that it "started commercial distribution of the RhodoLED XL in June 2024 and has seen ***rapid uptake in the US market since launch***." Ex. 2046 (12/23/2024 Article – Biofrontera Announces 100 RhodoLED XL Machines Now Placed in the US Market), 1. Biofrontera also announced that it had placed the 100th commercial RhodoLED® XL device in the United States market. *Id*. "We are delighted that the RhodoLED XL Lamp has had such an enthusiastic reaction from dermatologists who perform PDT, with more than 10% of offices using Ameluz already installing one," stated Hermann Luebbert, Chief Executive Officer and Chairman of Biofrontera Inc. *Id.* Luebbert went on to say, "It is remarkable to have placed this many in such a short span of time post launch." *Id.* In addition to the marketing materials discussed above, this announcement also touted the patented features of the claimed invention, specifically the five-panel design feature. *Id*.

> The RhodoLED XL was approved by the FDA for use in combination with Ameluz® in 2022 and was launched in June of this year. Since then, it has seen rapid adoption by offices who had previously used Ameluz and those who are new to the product, with 100 now being installed since launch. ***The main difference between the company's existing BF-RhodoLED lamp and the new RhodoLED***

> ***XL is the number of LED panels which allows a larger surface area to be illuminated*** during a single PDT treatment with Ameluz®.

197. In this same announcement, Biofrontera's customers discussed the benefits enabled by the patented features. For example, one customer stated, "[w]e were thoroughly impressed by the ***lamp's robust yet elegant design***, as well as its exceptional maneuverability and ***adjustability***, which made it ideal for Photodynamic Therapy (PDT) treatments in our offices. . . The ***larger illumination area*** has significantly increased our patient throughput while also enhancing the overall quality of care and patient experience." Ex. 2046 (12/23/2024 Article – Biofrontera Announces 100 RhodoLED XL Machines Now Placed in the US Market), 1.

198. Biofrontera further discussed the commercial success of the RhodoLED® XL device as a result of the patented features covered by the '512 Patent in March 2025. *See* Ex. 2047 (3/21/25 Article). Biofrontera reported "record total revenues of $37.3 million for 2024, reflecting a 9.5% increase from $34.1 million in 2023." *Id.*, 1. "The ***growth was primarily driven by*** increases in Ameluz® sales volume and unit price, and ***the successful launch of our RhodoLED® XL Lamp***." *Id.* Hermann Luebbert, Chief Executive Officer and Chairman of Biofrontera Inc., stated, "We are encouraged by the sales of the RhodoLED® XL lamp which is a considerable advance over previous FDA-

approved Photodynamic Therapy devices. It has proven to be ***simple to maneuver*** and ***capable of accommodating various patient treatment positions*** in order to optimize ease of use." *Id.*, 1-2. Biofrontera placed "100 [RhodoLED XL lamps] since the launch in June 2024 through December 31, 2024" and "72 Rhodo-LED® lamps during 2024." *Id.*, 1.

199. The March 2025 Q4 Earnings Call provided more detail. *See* Ex. 2057 (March 2025 - Q4 2024 Earnings Call). Luebbert called the RhodoLED XL "state-of-the-art" and stated that "[p]roviding a larger PDT lamp to our customers is an important milestone in our overall strategy." *Id.*, 3. He further stated that "[the RhodoLED XL] provides clinicians with the ability to illuminate a larger treatment area in a single session, which is particularly advantageous for treating extensive fields with multiple actinic keratosis lesions." *Id.* According to Luebbert, "[t]reating larger fields is a second milestone in our overall strategy and complements the availability of a larger lamp." *Id.*

200. As another example of touting the claimed features, when Biofrontera launched the commercial distribution of the RhodoLED® XL in June 2024, Biofrontera touted the five-panel design feature of the RhodoLED® XL that enables a larger illumination area, stating "[i]n comparison to Biofrontera's existing lamp, the RhodoLED XL offers a larger illumination area with five panels compared to one." Ex. 2045 (June 24, 2024 BioSpace Article RhodoLED XL Launch and

Approval), 1. In this same article, Hermann Luebbert, CEO of Biofrontera Inc. stated, "I'm pleased to say we have already shipped three of these new devices to customers in our first week of launch and the response from dermatology organizations across the US has been very encouraging." *Id.* And again, in an announcement that Biofrontera received FDA approval for the RhodoLED® XL, a press release stated, "The new PDT lamp enables the illumination of larger areas, enabling the simultaneous treatment of several actinic keratoses distant from each other." Ex. 2044 (10/22/2021 – Global Newswire Article), 1.

201. Further, I understand from Biofrontera's Form 10-K for the fiscal year ending on December 31, 2024 that the launch of Biofrontera's RhodoLED® XL Lamp resulted in sales of RhodoLED® XL Lamps of $1.1 million. Ex. 2055 (Biofrontera 10K), 51.

202. Accordingly, the evidence above demonstrates commercial success of the claimed invention.

B. The Claimed Invention Enjoys Industry Praise

203. The inventions of the '512 Patent, which are practiced by Biofrontera's RhodoLED® XL, have received recognition and praise from the industry.

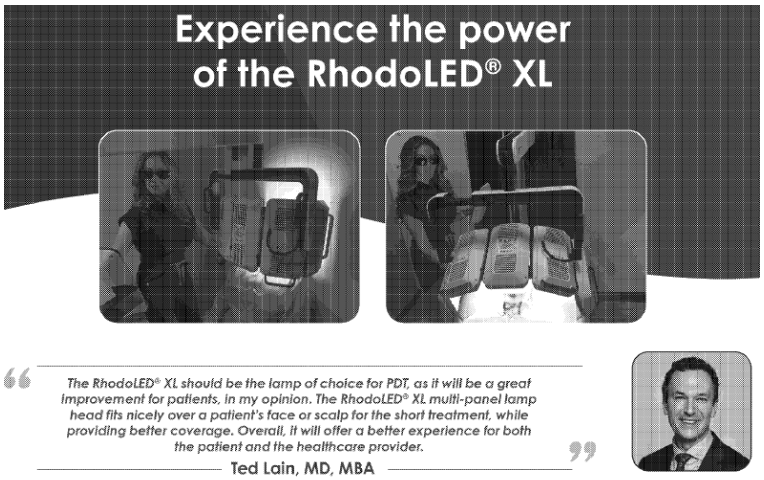
204. For example, the RhodoLED® XL was called an "innovative device [that] represents a significant advancement in the treatment of PDT with state-of-the-art engineering." Ex. 2045 (6/24/2024 Article), 1. Dr. David Cleaver of Cleaver

Dermatology stated that "[t]he advanced features and versatility of [the RhodoLED XL] represent a considerable upgrade on what has been available until now and will allow us to provide our patients with the highest standard of care." *Id.*, 2. Additionally, an article by Dermatology Times called the RhodoLED XL a "state-of-the-art red light emitting LED lamp . . . designed to revolutionize photodynamic therapy . . . aimed at enhancing the ease of use for health care providers by being highly maneuverable and capable of accommodating various patient treatment positions." Ex. 2054 (7/2/2024 Dermatology Times Article), 1.

205. Dr. Ted Lain similarly praised the RhodoLED® XL, which practices the claimed invention, stating:

> The RhodoLED® XL should be the lamp of choice for PDT, as it will be a great improvement for patients, in my opinion. The RhodoLED® XL multi-panel lamp head fits nicely over a patient's face or scalp for the short treatment, while providing better coverage. Overall, it will offer a better experience for both the patient and the healthcare provider.

Ex. 2042 (Baldyga Ex. 4, RhodoLED XL Trifold), 4.



206. The industry praise for the RhodoLED® XL was a result of the features covered by the '512 Patent, including (1) an adjustable five-panel design, (2) uniform illumination of the treatment surface of a patient, and (3) an LED arrangement that provides for a higher intensity of light emitted proximate the shorter edges of the panels, as well as the benefits enabled by these patented features such as illumination over a large treatment area and enhanced adjustability of the device.

207. For example, Mr. Baldyga testified that "another one of the features that was advertised with the customer was that the ***RhodoLED XL includes five panels with this particular LED arrangement*** that we see here." Ex. 2039 (Baldyga ITC Deposition Transcript), 44:9–45:11. One customer stated, "[w]e were thoroughly impressed by the ***lamp's robust yet elegant design***, as well as its exceptional maneuverability and ***adjustability***, which made it ideal for Photodynamic Therapy (PDT) treatments in our offices. . . The ***larger illumination***

area has significantly increased our patient throughput while also enhancing the overall quality of care and patient experience." Ex. 2046 (12/23/2024 Article), 1.

C. There Is Nexus Between the '512 Patent Claimed Invention and the Objective Evidence of Nonobviousness

208. There is a nexus between the '512 Patent claimed invention and the objective evidence of nonobviousness. The evidence discussed above is the direct result of the combination of features claimed in the claims of the '512 Patent. It is the claimed combination of features and the benefits enabled by those features that have driven commercial success and garnered praise in the industry. As discussed above, Biofrontera prominently showcased and received praise for the RhodoLED® XL, which it touted "offers a larger illumination area with five panels compared to one," "uniform distribution of the treatment surface that's being treated," and "five panels with [the] particular LED arrangement." The prior art does not render obvious the combination of those patented features, as I discuss above in Sections XII and XIII.

XV. CONCLUSION

209. For at least the above reasons, Petitioner and its experts have not shown that the Challenged Claims are obvious.

I hereby declare that all statements made herein of my knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

May 12, 2025

Date

Nan Marie Jokerst, Ph.D.

APPENDIX A: THE CHALLENGED CLAIMS 1, 3, 5, 8, 17, 18 and 20 OF THE '512 PATENT

1[pre] A system for photodynamically diagnosing or treating a patient, comprising:

1[a] an illuminator comprising at least five panels connected by nested hinges on inner side surfaces of adjacent panels,

1[b] light sources disposed on surfaces of the at least five panels, the illuminator being configured to uniformly illuminate a treatment surface of the patient via the light sources,

1[c] one of the at least five panels positioned as a center panel configured to face the treatment surface, and two or more of the at least five panels being configured to be angled relative to the center panel,

1[d] wherein each of the at least five panels has two first edges and two second edges shorter than the two first edges, and the light sources are arranged such that a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges.

3. The system of claim 1, wherein the illuminator is configured to output red light at a dose of about 30 J/cm^2 to about 150 J/cm^2.

5. The system of claim 1, wherein a plurality of the light sources are configured to emit light having a wavelength in a range of 400 nm to 700 nm.

8[pre] A method of photodynamically diagnosing or treating a patient, comprising:

8[a] administering 5-aminolevulinic acid (ALA) to the patient;

8[b] positioning an illuminator proximate to the patient, the illuminator comprising at least five panels connected by nested hinges on inner side surfaces of adjacent panels; and

8[c] uniformly illuminating a treatment surface of the patient with light sources disposed on the at least five panels of the illuminator,

8[d] wherein each of the at least five panels has two first edges and two second edges shorter than the two first edges, and the light sources are arranged such that a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges.

17. The method of claim 8, wherein at least one panel includes a recess configured to receive a flange of one of the nested hinges.

18. The method of claim 17, wherein the recess is positioned at an inner side surface of the at least one panel.

20[pre] A system for photodynamically diagnosing or treating a patient, comprising:

20[a] an illuminator comprising at least five panels connected by nested hinges on inner side surfaces of adjacent panels, the nested hinges being configured so as to allow continuous illumination across the at least five panels,

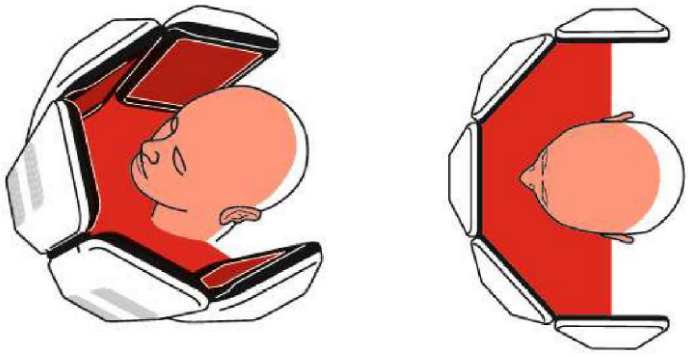
20[b] light sources disposed on surfaces of the at least five panels, the illuminator being configured to uniformly illuminate a treatment surface of the patient via the light sources,

20[c] one of the at least five panels positioned as a center panel configured to face the treatment surface, and two or more of the at least five panels being configured to be angled relative to the center panel,

20[d] wherein each of the at least five panels has two first edges and two second edges shorter than the two first edges, and the light sources are arranged such that a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges.

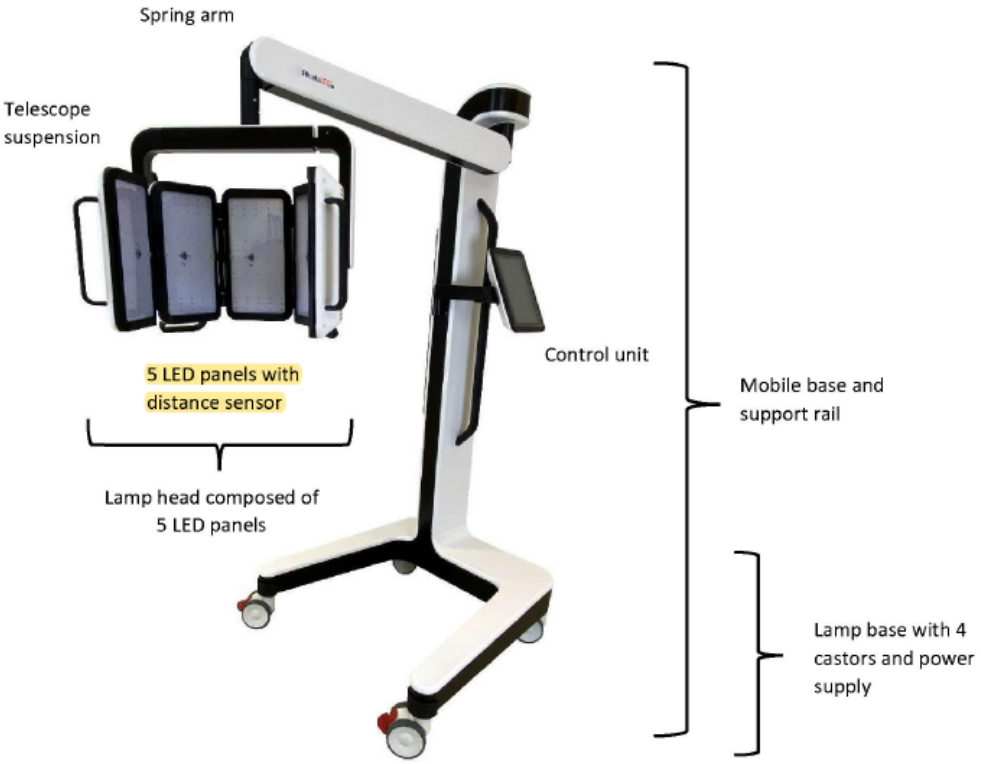
APPENDIX B: CLAIM CHART FOR U.S. PATENT NO. 11,445,512

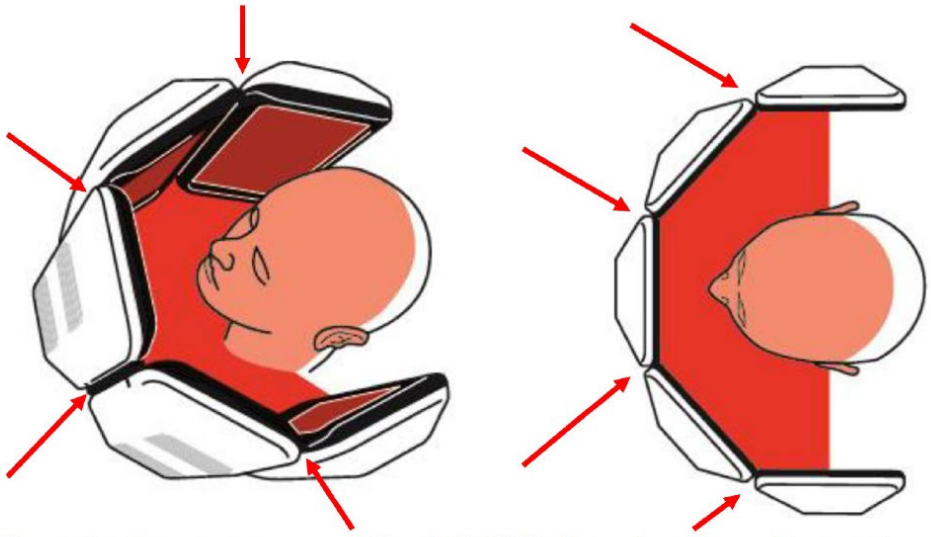
'512 Patent Claim 1	Biofrontera RhodoLED® XL, Individually or in Combination with Ameluz®, Practices Exemplary Claim 1 of the '512 Patent
1[pre] A system for photodynamically diagnosing or treating a patient, comprising:	The RhodoLED® XL is a system for photodynamically diagnosing or treating a patient. For example, the RhodoLED® XL includes an "LED lamp for . . . photodynamic therapy." "Ameluz® and medical device RhodoLED® XL have been approved in combination for photodynamic therapy." "The RhodoLED® XL has been developed for use in photodynamic therapy in combination with Ameluz® gel. . . . Any other use or combination of use is prohibited." The RhodoLED® XL "is indicated for the lesion-directed and field-directed treatment of actinic keratoses of mild-to-moderate severity on the face and scalp." The RhodoLED® XL's "[i]ntended use" is for "lesion-directed and field-directed treatment of actinic keratoses of mild-to-moderate severity on the face and scalp." RhodoLED® XL Biofrontera Deep in dermatology **Foreword** Thank you for choosing the RhodoLED® XL LED lamp for your photodynamic therapy. RhodoLED® XL has been developed in accordance with applicable technical standards to provide high energy efficiency as well as constant light emission at the desired wavelength. Your lamp must be installed and maintained by a qualified Biofrontera technician and used only in accordance with the instructions in this manual. You may request the latest printed version covering this model from Biofrontera at any time. Our drug Ameluz® and medical device RhodoLED® XL have been approved in combination for photodynamic therapy; the only approved use of our lamp is in combination with Ameluz® gel. This user manual provides important RhodoLED® XL product details, precautions and warnings, and operating instructions. For Ameluz®, please use its US prescribing information. The Ameluz® prescribing information includes information on how to use the gel along with contraindications, warnings and precautions and dosage and administration. **Thorough reading and use of both this user manual and the Ameluz® USPI is required prior to treatment.** **Our combination Ameluz®/RhodoLED® XL for photodynamic therapy is only to be used by physicians or healthcare professionals.**

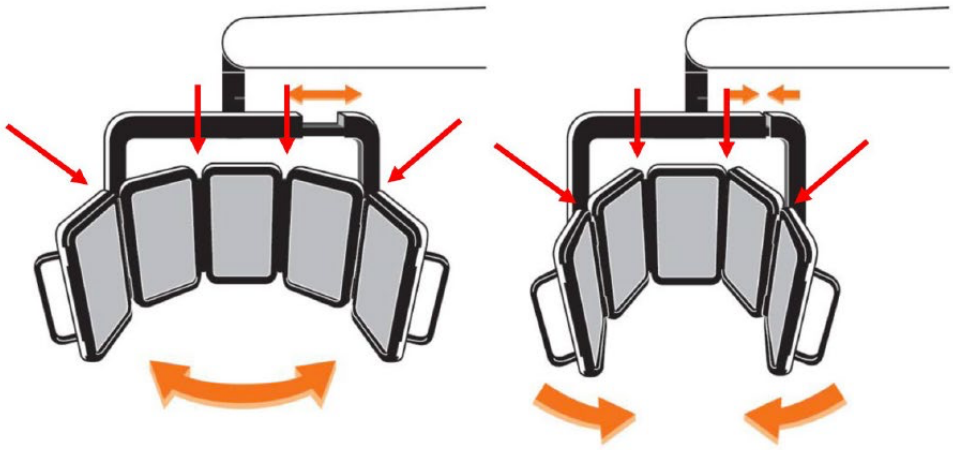
’512 Patent Claim 1	Biofrontera RhodoLED® XL, Individually or in Combination with Ameluz®, Practices Exemplary Claim 1 of the ’512 Patent
	Ex. 2043, at 2 (annotated). RhodoLED® XL Biofrontera Deep in dermatology 3 Warnings and Precautions The RhodoLED® XL has been developed for use in photodynamic therapy in combination with Ameluz® gel (excitation wavelength 635 nm). Any other use or combination of use is prohibited. Ex. 2043, Sec. 3. RhodoLED® XL Biofrontera Deep in dermatology 8.4.6 Treatment Area The illumination area of RhodoLED® XL is 9.06 x 11.42 inch (23 cm x 29 cm) when all panels are arranged in the standard curved shape. This usually allows a full-face illumination. However, face and head sizes are subject to strong variations between patients. As a rough guidance, the midlines of the outer two panels marks the outer boundaries of the illumination area (see Figure 13 as guidance). ***Note:* The RhodoLED® XL LED panels should only be used in curved shape and not in fully unfolded form. This is necessary to ensure the application of 37 J/cm² during the illumination.**  **Figure 13:** Treatment area of RhodoLED® XL from the side and in top view. Ex. 2043, Sec. 8.4.6, Fig. 13.

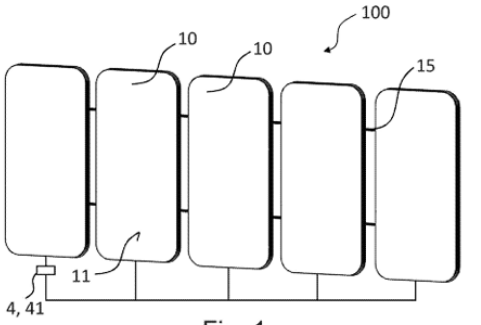
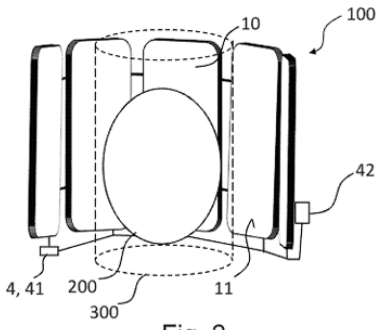
'512 Patent Claim 1	Biofrontera RhodoLED® XL, Individually or in Combination with Ameluz®, Practices Exemplary Claim 1 of the '512 Patent
	----------INDICATIONS AND USAGE---------- AMELUZ, a porphyrin precursor, in combination with photodynamic therapy using BF-RhodoLED or RhodoLED XL lamp, is indicated for the lesion-directed and field-directed treatment of actinic keratoses of mild-to-moderate severity on the face and scalp (1). Ex. 2060 (Ameluz Prescribing Information), at 1. RhodoLED® XL — Biofrontera, Deep in dermatology 14.2 Label on LED Panels ..... 29 14.3 Description of Symbols ..... 30 15 Electromagnetic compatibility ..... 31 **1 Intended Use** RhodoLED® XL is a red light-emitting LED lamp, which is used exclusively in combination with Ameluz® gel for lesion-directed and field-directed treatment of actinic keratoses of mild-to-moderate severity on the face and scalp. **2 RhodoLED® XL - General Description** RhodoLED® XL is comprised of three main components, the lamp head, an easily adjustable spring arm, and the mobile base with castors for smooth transport. In addition, the lamp has a convenient touchscreen monitor and aids for positioning the lamp head. The device is connected to the mains via a fixed mains supply cable. Ex. 2043, Sec. 1, 2. Additionally, U.S. Patent No. 11,235,169 (the "'169 Patent") covers the RhodoLED® XL. *See* Ex. 2058 (3/14/2022 Article) ("Biofrontera Inc … announced today that the previously granted U.S. patent No. 11,235,169 (the '169 patent) for the BF-RhodoLED® XL illumination device is now listed in the … Orange Book."). Claim 1 of the '169 Patent is directed to an "Illumination device for photodynamic therapy." Ex. 2059, 32:30. The patent further states that "[t]his disclosure relates to an illumination device

’512 Patent Claim 1	Biofrontera RhodoLED® XL, Individually or in Combination with Ameluz®, Practices Exemplary Claim 1 of the ’512 Patent
	for photodynamic therapy and a method for treating a skin disease.” *Id.*, 1:16-18.
1[a] an illuminator comprising at least five panels connected by nested hinges on inner side surfaces of adjacent panels,	The RhodoLED® XL includes an illuminator comprising at least five panels connected by nested hinges on inner side surfaces of adjacent panels. For example, the RhodoLED® XL includes a lamp head with five panels connected by nested hinges on inner side surfaces of adjacent panels. The RhodoLED® XL includes a “[l]amp head” with “5 LED panels.” The LED panels are connected with hinges on the inner side surfaces of adjacent panels (shown below with red annotations).

'512 Patent Claim 1	Biofrontera RhodoLED® XL, Individually or in Combination with Ameluz®, Practices Exemplary Claim 1 of the '512 Patent
	RhodoLED® XL Biofrontera Deep in dermatology **4.2 RhodoLED® XL Components** The RhodoLED® XL consists of the following main components (Figure 2): • Lamp head with telescope suspension • Spring arm • Control unit • Mobile base (includes support rail, castors and power supply)  **Figure 2:** RhodoLED® XL main components Ex. 2043, Fig. 2 (annotated).

’512 Patent Claim 1	Biofrontera RhodoLED® XL, Individually or in Combination with Ameluz®, Practices Exemplary Claim 1 of the ’512 Patent
	2 RhodoLED® XL - General Description RhodoLED® XL is comprised of three main components, the lamp head, an easily adjustable spring arm and the mobile base with castors for smooth transport. In addition, the lamp has a convenient touchscreen monitor and aids for positioning the lamp head. The device is connected to the mains via fixed mains supply cable. Ex. 2043, Sec. 2.  **Figure 13:** Treatment area of RhodoLED® XL from the side and in top view. Ex. 2043, Fig. 13 (annotated).

’512 Patent Claim 1	Biofrontera RhodoLED® XL, Individually or in Combination with Ameluz®, Practices Exemplary Claim 1 of the ’512 Patent
	 **Figure 5:** Movement range of the lamp head. Ex. 2043, Fig. 5 (annotated). Claim 1 of the ’169 Patent states “the illumination device comprising five or more electro-magnetic radiation emitting units.” Ex. 2059, 32:31-32. “According to at least one embodiment, the illumination device comprises three or more, for example four or more, such as five or more, radiation emitting units.” *Id.*, 11:50-53. Furthermore, the ’169 patent states that in “an exemplary embodiment of the illumination device 100,” “hinges 15 are used between the radiation emitting units.” *Id.*, 21:58-64. “[T]he radiation emitting units are pivotally connected to each other. For example, they are connected to each other via hinges.” *Id.*, 11:12-15.

’512 Patent Claim 1	Biofrontera RhodoLED® XL, Individually or in Combination with Ameluz®, Practices Exemplary Claim 1 of the ’512 Patent
	U.S. Patent Feb. 1, 2022 Sheet 1 of 9 US 11,235,169 B1  Fig. 1  Fig. 2 Ex. 2059, Figs. 1 and 2.
1[b] light sources disposed on surfaces of the at least five panels, the illuminator being configured to uniformly illuminate a treatment surface of	The RhodoLED® XL includes light sources disposed on surfaces of the at least five panels, the illuminator being configured to uniformly illuminate a treatment surface of the patient via the light sources. For example, the RhodoLED® XL includes LEDs disposed on the surface of five panels. The RhodoLED® XL has “45 LEDs per panel with a total of 5 panels (225 LEDs).” For example, the RhodoLED® XL’s lamp head is configured uniformly illuminate a treatment surface of the patient via the LEDs. The five LED panels are configured to “emit a uniform, visible red light. The typical peak wavelength is approximately 635

’512 Patent Claim 1	Biofrontera RhodoLED® XL, Individually or in Combination with Ameluz®, Practices Exemplary Claim 1 of the ’512 Patent
the patient via the light sources,	nm with a half-band width of 16 nm.” The maximum deviation of the intensity over the treatment area is approximately 20%. The typical irradiance having a plus/minus range of 20%, as well as the maximum deviation of intensity over the treatment area equaling 20%, meets the construction of “uniformly illuminate” which requires that the measured irradiance at a treatment surface of the patient is at least within 60% of the measured maximum. Both metrics mean that the measured irradiance at a treatment surface will be at least within 60% of the measured maximum, as the difference between the minimum and maximum irradiance cannot be greater than 40% if the maximum deviation from the typical irradiance is 20% in either direction. This means that the measured irradiance of light at the treatment surface is at least within 60% of the measured maximum. **4.1 Light emitting diodes (LED)** RhodoLED® XL is a red-light emitting LED lamp, comprised of three main components, the lamp head, an easily adjustable spring arm, and the mobile base with castors for smooth transport. In addition, the lamp has a convenient touchscreen monitor and aids for positioning the lamp head. RhodoLED® XL has 45 LEDs per panel with a total of 5 panels (225 LEDs), which emit a uniform, visible red light. The typical peak wavelength is approximately 635 nm with a half-band width of 16 nm. Ex. 2043, Sec. 4.1 (annotated).

'512 Patent Claim 1	Biofrontera RhodoLED® XL, Individually or in Combination with Ameluz®, Practices Exemplary Claim 1 of the '512 Patent

RhodoLED® XL

Biofrontera
Deep in dermatology

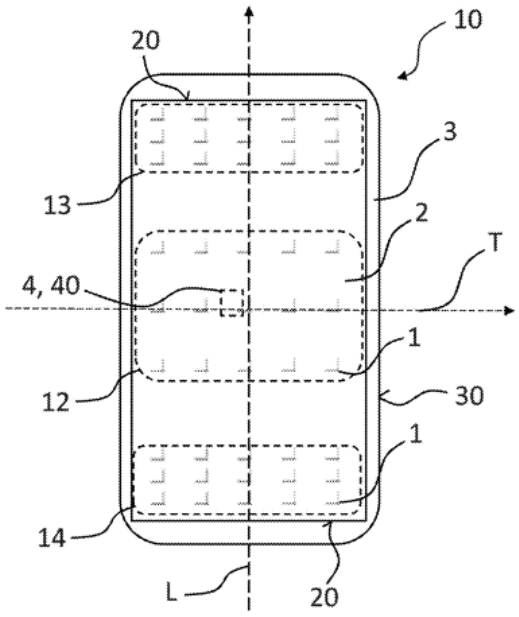
13.2 Specification

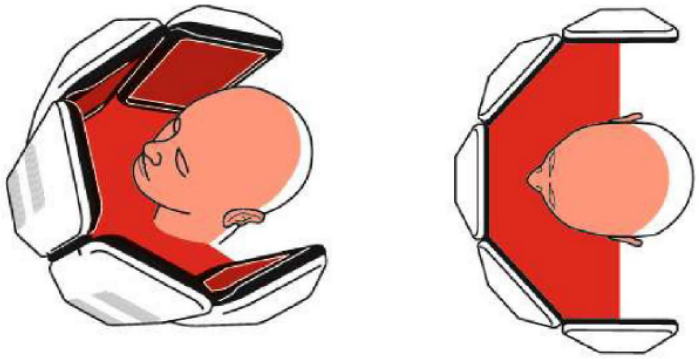
Type	RhodoLED® XL Medical device class III; Device of protection class 1
Certification	UL certified E513735
Software Version No.	g2.12.00.3739
Service interval	Biofrontera recommends performing service every 2 years
Number of LEDs	225
Typical peak wavelength	635 nm ± 5 nm
Light dose	Approx. 37 J/ cm^2 at 4.9 inch (12.5 cm) distance, 13.5 min
Typical irradiance	approx. 46 mW/cm^2 ± 20 % at 4.9 inch (12.5 cm) distance
Max irradiance	approx. 55 mW/cm^2 at 4.9 inch (12.5 cm) distance
Illuminated area	An area of 9.06 x 11.42 inch (23 cm x 29 cm) is illuminated using all panels in curved shape.
Max. deviation of the intensity over the treatment area	Approx. 20 %

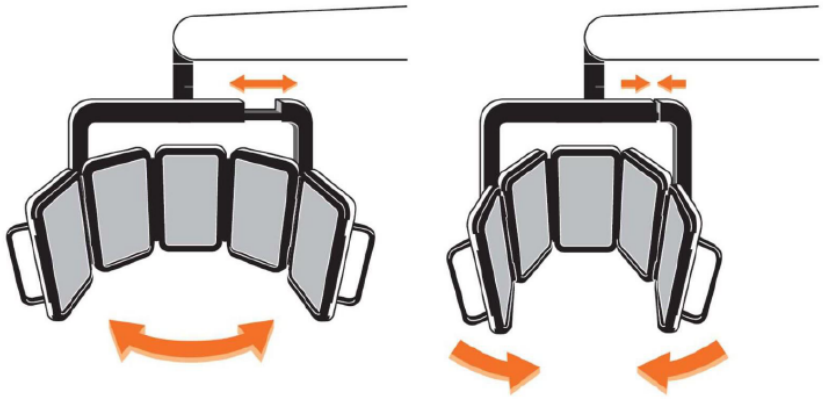
Ex. 2043, Sec. 13.2 (annotated).

Additionally, I tested the RhodoLED® XL device and confirm it "irradiat[es] 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" under the parties' agreed-to construction of the "uniformly illuminates" limitations.

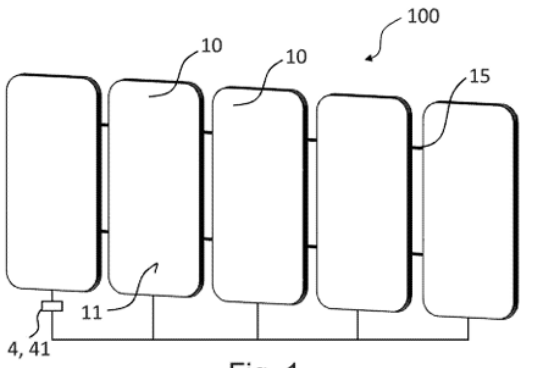
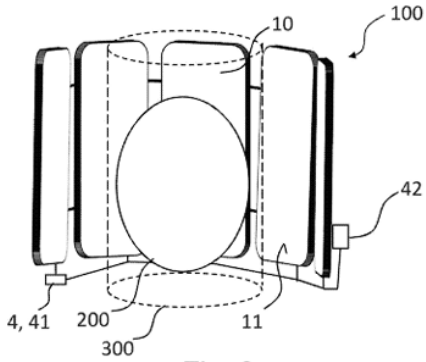
Claim 1 of the '169 Patent states, "each electromagnetic radiation emitting unit comprising several radiation sources." Ex. 2059, 32:33-34. "According to at least one embodiment, the at least one radiation source is an optoelectronic component, for example a light emitting diode (LED) and/or a surface mountable component." *Id.*, 8:54-57.

’512 Patent Claim 1	Biofrontera RhodoLED® XL, Individually or in Combination with Ameluz®, Practices Exemplary Claim 1 of the ’512 Patent
	 Fig. 3 Ex. 2059, Fig. 3.
1[c] one of the at least five panels positioned as a center panel configured to face the treatment surface, and two or more of the at least five panels being configured	The RhodoLED® XL includes wherein at one of the at least five panels being positioned as a center panel configured to face the treatment surface, and two or more of the at least five panels being configured to be angled relative to the center panel. For example, “[t]he RhodoLED® XL LED panels should only be used in curved shape and not in fully unfolded form.” The LED panel orientation “can be changed from a curved shape to an unfolded form by pulling the holding bracket apart.” In the “curved shape,” the center panel is configured to face the treatment surface, such as the patient’s head, while the remaining four panels are configured to be angled relative to the center panel. For example, “the size of the treatment area is 9.06 x 11.42 inch . . . for all panels in a curved shape.”

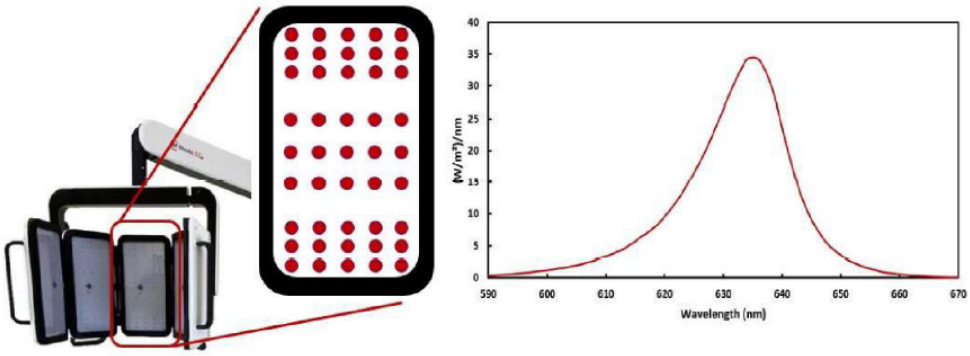
'512 Patent Claim 1	Biofrontera RhodoLED® XL, Individually or in Combination with Ameluz®, Practices Exemplary Claim 1 of the '512 Patent
to be angled relative to the center panel,	8.4.6 **Treatment Area** The illumination area of RhodoLED® XL is 9.06 x 11.42 inch (23 cm x 29 cm) when all panels are arrange in the standard curved shape. This usually allows a full-face illumination. However, face and head sizes are subject to strong variations between patients. As a rough guidance, the midlines of the outer two panels marks the outer boundaries of the illumination area (see Figure 13 as guidance). ***Note:* The RhodoLED® XL LED panels should only be used in curved shape and not in fully unfolded form. This is necessary to ensure the application of 37 J/cm² during the illumination.**  **Figure 13:** Treatment area of RhodoLED® XL from the side and in top view. Ex. 2043, Fig. 13. The RhodoLED® XL LED panels should only be used in curved shape and not in fully unfolded form. This is necessary to ensure the application of 37 J/cm² during the illumination. Ex. 2043, Sec. 3. The illumination area of the LED lamp is 9.06 x 11.42 inch (23 cm x 29 cm) for all panels in a curve shape. Ex. 2043, Sec. 4.1.

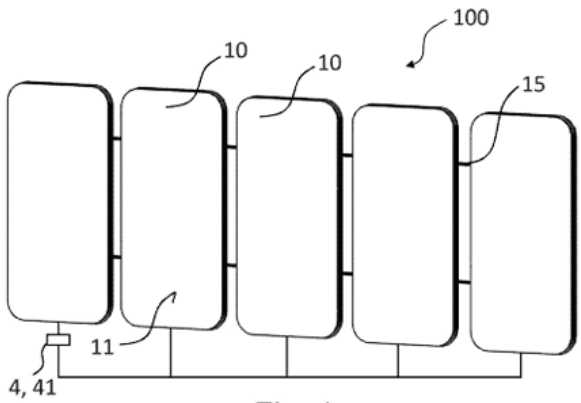
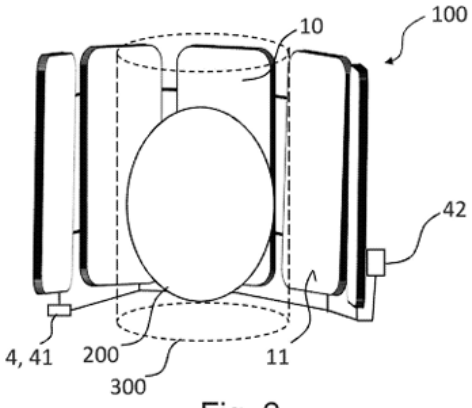
’512 Patent Claim 1	Biofrontera RhodoLED® XL, Individually or in Combination with Ameluz®, Practices Exemplary Claim 1 of the ’512 Patent
	The orientation of the panels can be changed from a curved shape to an unfolded form by pulling the holding bracket apart (Figure 5).  **Figure 5:** Movement range of the lamp head. Ex. 2043, Sec. 8.2, Fig. 5. The size of the treatment area is 9.06 x 11.42 inch (23 cm x 29 cm) for all panels in a curved shape. Ex. 2043, Sec. 8.4.8. The ’169 Patent states: “For example, a first radiation emitting unit constitutes a center radiation emitting unit. A second and a third radiation emitting unit may be arranged adjacent to the first radiation emitting unit on the left and right side, i.e. on opposite sides, of the first radiation emitting unit, respectively, and may be configured to be arranged such that they are tilted towards each other, e.g. so that main radiation axes of the second and third radiation emitting units cross, e.g. in the object location. The value of the angle between the second and the first radiation emitting unit may be the same as the

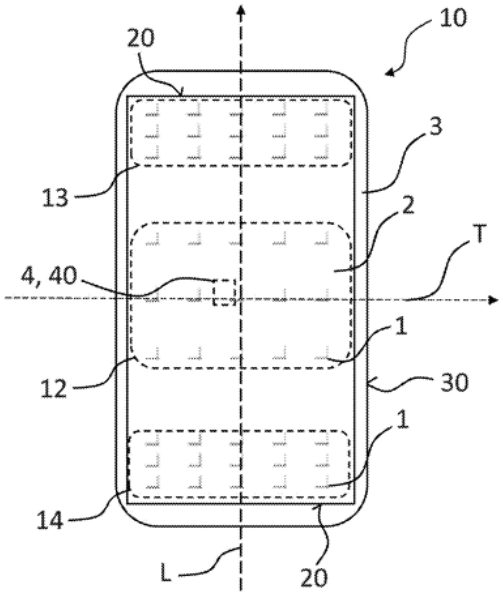
’512 Patent Claim 1	Biofrontera RhodoLED® XL, Individually or in Combination with Ameluz®, Practices Exemplary Claim 1 of the ’512 Patent
	value of the angle between the third and the first radiation emitting unit. A fourth radiation emitting unit may be arranged adjacent to the second radiation emitting unit on the left side of the second radiation emitting unit, i.e. on the side remote from the first radiation emitting unit. A fifth radiation emitting unit may be arranged adjacent to the third radiation emitting unit on the right side of the third radiation emitting unit, i.e. on the side remote from the first radiation emitting unit. The first, second and third radiation emitting units may therefore be arranged between the fourth and the fifth radiation emitting units. The fourth and the fifth radiation emitting units may be configured to be arranged such that they are tilted towards each other so that main radiation axes of the fourth and fifth radiation emitting unit cross, e.g. in the object location. The value of the angle between the fourth and the first radiation emitting unit may be the same as the value of the angle between the fifth and the first radiation emitting unit.” Ex. 2059, 12:14-40

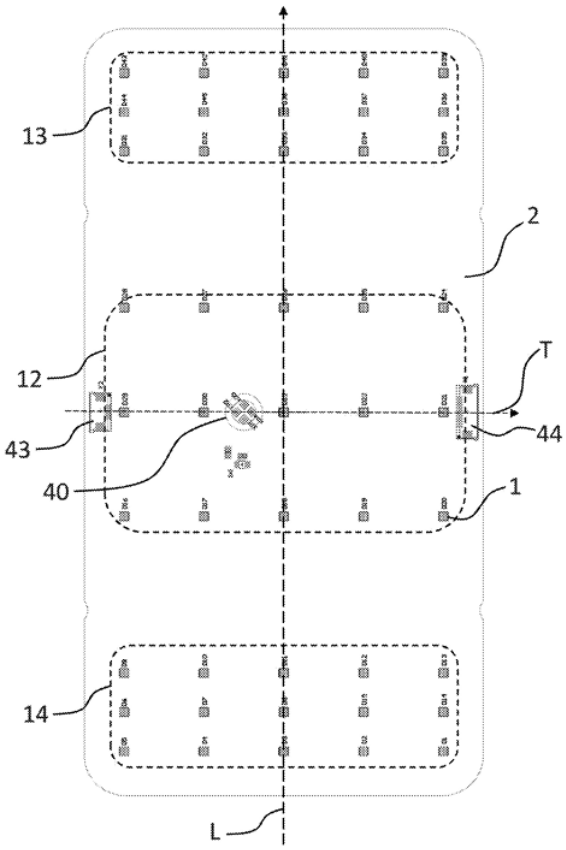
’512 Patent Claim 1	Biofrontera RhodoLED® XL, Individually or in Combination with Ameluz®, Practices Exemplary Claim 1 of the ’512 Patent
	U.S. Patent Feb. 1, 2022 Sheet 1 of 9 US 11,235,169 B1  Fig. 1  Fig. 2 Ex. 2059, Figs. 1 and 2.
1[d] wherein each of the at least five panels has two first edges and two second edges shorter than the two first edges, and the light sources are	The RhodoLED® XL includes wherein each of the at least five panels has two first edges and two second edges shorter than the two first edges, and the light sources are arranged such that a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges. For example, each of the RhodoLED® XL’s five panels are rectangular, such that for each panel, there are two first edges (the sides), and two second edges, where the second edges are shorter than the first two edges. The RhodoLED® XL’s LEDs each have “a fixed LED light intensity.” The LEDs are arranged such that a higher intensity of

’512 Patent Claim 1	Biofrontera RhodoLED® XL, Individually or in Combination with Ameluz®, Practices Exemplary Claim 1 of the ’512 Patent
arranged such that a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges.	light is emitted proximate the second edges (i.e., the shorter edges) compared to the intensity of light emitted not proximate the second edges. For example, the “LEDs are distributed on each panel in a specific way (see Figure 1), such that they are more densely packed towards the upper and lower edges than in the center region of each panel.” **Figure 14:** Low light intensity for correct adjustment of LED panels Ex. 2043, Fig. 14.

’512 Patent Claim 1	Biofrontera RhodoLED® XL, Individually or in Combination with Ameluz®, Practices Exemplary Claim 1 of the ’512 Patent
	 **Figure 1:** LED panels with LED distribution and emission spectrum of RhodoLED® XL LEDs. The RhodoLED® XL LEDs are calibrated such that the skin being treated receives a light dose of approximately 37 J/cm² under the following conditions: - Illumination time of 13.5 minutes - Treatment distance of 4.9 ± 0.6 inch (12.5 cm ± 1.5 cm) The illumination area of the LED lamp is 9.06 x 11.42 inch (23 cm x 29 cm) for all panels in a curved shape. The LEDs are distributed on each panel in a specific way (see Figure 1), such that they are more densely packed towards the upper and lower edges than in the center region of each panel. This distribution optimizes the homogeneity of illumination over the treated skin. Ex. 2043, Sec. 4.1, Fig. 1. 8.4.4 **The Treatment Profile** The RhodoLED® XL has a fixed LED light intensity which ensures the application of 37 J/cm² within the 13.5-minute treatment time. Ex. 2043, Sec. 8.4.4.

’512 Patent Claim 1	Biofrontera RhodoLED® XL, Individually or in Combination with Ameluz®, Practices Exemplary Claim 1 of the ’512 Patent
	U.S. Patent Feb. 1, 2022 Sheet 1 of 9 US 11,235,169 B1  Fig. 1  Fig. 2 Ex. 2059, Figs. 1 and 2.

’512 Patent Claim 1	Biofrontera RhodoLED® XL, Individually or in Combination with Ameluz®, Practices Exemplary Claim 1 of the ’512 Patent
	 Fig. 3 Ex. 2059, Fig. 3. “The radiation emitting unit 10 of FIG. 3 is, for example, used for all radiation emitting units 10 in the illumination device 100 of FIGS. 1 and 2.” *Id*., 24:67-25:3. “In the second 13 and the third 14 group, the radiation sources 1 are arranged more densely on the radiation source carrier 2 than in the first group 12. Thus, the occupancy density of the radiation source carrier 2 with radiation sources 1 in the second 13 and third 14 group is greater than in the first group 12.” *Id.*, 25:49-54. “As can also be seen in FIG. 3, the distance between two adjacent groups 12, 13, 14 is greater than a distance between the radiation sources 1 within a group 12, 13, 14 (the distance between two adjacent groups is the shortest distance between two radiation sources 1 of these two groups).” *Id.*, 25:57-61.

’512 Patent Claim 1	Biofrontera RhodoLED® XL, Individually or in Combination with Ameluz®, Practices Exemplary Claim 1 of the ’512 Patent
	 Fig. 4 Ex. 2059, Fig. 4. “FIG. 4 shows an exemplary embodiment of a radiation emitting unit 10 in a true-to-scale view.” *Id.,* 26:17-18.