

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

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

v.

SUN PHARMACEUTICAL INDUSTRIES, INC.
Patent Owner

Case IPR2024-01312

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

DECLARATION OF JOSE SASIAN

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I, Jose Sasian, declare as follows

I. INTRODUCTION

1. I am an independent consultant. I am over eighteen years of age, and I am competent to testify as to the matters set forth herein if I am called upon to do so.

2. I have prepared this Declaration for consideration by the Patent Trial and Appeal Board in the *Inter Partes* Review of U.S. Patent No. 11,697,028 (“the ’028 Patent”).

3. I have been retained as an expert in this case on behalf of Sun Pharmaceutical Industries, Inc. (“Sun Pharma”) to provide expert opinions and testimony regarding the ’028 Patent, and particularly its claims 1, 2, 4-6, 16, 17, and 19-21. I refer to those claims as the “Challenged Claims,” which are shown in Appendix A.

4. I am being compensated at my standard hourly rate of \$650.00 per hour. My compensation is not dependent on the outcome of, or any issue in relation to, the above-captioned *Inter Partes* Review. I have no interest in either party.

II. BASES FOR OPINIONS

5. 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 2002. 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

6. In forming the opinions set forth in this declaration, I have relied upon my experience and knowledge in the field of optical sciences and optical engineering as well as on certain documents listed below:

- U.S. Patent No. 11,697,028 (Ex. 1001);
- the prosecution history of U.S. Patent No. 11,697,028 (Ex. 1002);
- Biofrontera Inc., Biofrontera Bioscience GmbH, Biofrontera Pharma GmbH, and Biofrontera AG's (collectively "Biofrontera") Petition for *Inter Partes* Review IPR2024-01312 of U.S. Patent No. 11,697,028 (the "1312 Petition") and all exhibits cited therein;
- the Board's Institution Decision denying institution in IPR2024-00874 (the "874 Institution Decision"); and
- all other exhibits cited herein.

IV. EDUCATION AND EXPERIENCE

7. I am not an attorney. As shown in my *curriculum vitae*, I have extensive academic and industry experience with optical engineering. Specifically, I have over thirty years of academic and industry experience in the field of optical

sciences and optical engineering in general, including optical instrumentation, optical design, opto-mechanics, and optical fabrication and testing.

8. I am currently a full-time, tenured Professor of Optical Sciences at the Wyant College of Optical Sciences at the University of Arizona in Tucson, Arizona, a position I have held since 2001. As a professor, I teach and perform research in the field of optical design. For example, I teach my students how to design lenses and mirrors and how to think about light so that they can design useful optical systems. As part of my academic and research responsibilities I am frequently involved with the design, fabrication, testing, and mounting of optical devices.

9. From 1995 to 2001, prior to receiving tenure, I was an Associate Professor of Optical Sciences at the University of Arizona. Prior to joining the University of Arizona faculty, I was a member of the technical staff of AT&T Bell Laboratories from 1990 to 1995. From 1984 to 1988, I was a Research Assistant, and from 1989 to 1990, I was a Research Associate, in the Optical Sciences Center at the University of Arizona. From 1974 to 1984, I was an optician at the Institute of Astronomy at the University of Mexico.

10. I received a Bachelor of Science degree in Physics from the University of Mexico in 1982, a Master of Science degree in Optical Sciences from the University of Arizona in 1987, and a Ph.D. in Optical Sciences from the University of Arizona in 1988. My research areas include optical design, fabrication, and

testing of optical instruments, astronomical optics, diffractive optics, opto-mechanical design, light in gemstones, lithography optics, and light propagation.

11. At the University of Arizona, I have taught the courses Lens Design OPTI 517 (1997-present), Introduction to Aberrations OPTI 518 (2005-present), Advanced Lens Design OPTI 696A (2008, 2012, 2017, 2018), Illumination Optics Seminar (1997-2000), Introduction to Opto-mechanics OPTI 690 (1996-2000) and Optical Shop Practices OPTI 597A (1996-present). In these classes, among other things, I teach students how to design optical systems for imaging and for illumination, how to mount optical elements properly so that their physical integrity is preserved, and to properly align and test optical systems.

12. I have directed several student reports, theses, and dissertations in the area of optical design. I have lectured regarding my work, and have published, along with students and colleagues, over one hundred scientific papers in the area of optics. These include technical papers, student reports and theses done under my direction, related to optics and illumination. I also have been listed as inventor in patents or patent applications. For example:

- Jose Sasian, “Formulae for the geometrical propagation of a beam of light,” Appl. Opt. 59, G24-G32 (2020)
- Jieun Ryu, Jose Sasian, “Tolerancing a lens for LED uniform illumination,” Proc. SPIE 10377, Optical System Alignment, Tolerancing, and Verification XI, 1037703 (22 August 2017); doi: 10.1117/12.2276864

- David Burrows, Scott Wheelhouse, Jose Manuel Sasian Alvarado APPARATUS FOR SPREADING LIGHT FROM MULTIPLE SOURCES TO ELIMINATE VISIBLE BOUNDARIES THEREBETWEEN, LIGHT THERAPY DEVICES INCLUDING SUCH APPARATUS, AND METHODS,” US Patent Publication 2010/0331929, December 2010.
- Efficient EUV collector designs, US Patent 7,405,871, 2009.
- Shaped source of soft x-ray, extreme ultraviolet and ultraviolet radiation, US Patent 6,307,913, 2001.
- Scott A. Lerner and Jose M. Sasian “Use of implicitly defined optical surfaces for the design of imaging and illumination systems,” Opt. Eng. 39(7) 1796-1801, 2000.
- J. Sasian, “Lens System for traffic signal lighting,” US Patent Publication, 2008/0266665, October 2008.

13. Since 1995, I have been a consultant. My consulting work includes designing lenses for cell-phones, microscopes, and high speed photography, as well as designing a variety of optical systems for illumination. I hold patents and patent applications related to lens systems and illumination systems. I am familiar with electronics and electronic test instruments. I also have worked with or designed LEDs and other types of light sources, including light reflectors, lens collectors, light-guides, and diffusers for illumination. For example, starting in about 2009, I designed an optical system that used a single panel array of LEDs to provide uniform illumination with blue LED light. This phototherapy device was fabricated and commercially sold by Philips under the name goLITE.

14. I have been a topical editor and reviewer for the peer-reviewed journals *Applied Optics* and *Optical Engineering*. I am a fellow of the International Society for Optics and Photonics (SPIE), a fellow of OPTICA (formerly the Optical Society of America), and a lifetime member of the Optical Society of India.

15. I have served as chair for the conferences “Novel Optical Systems: Design and Optimization” (1995-2006) and “Optical Systems Alignment, Tolerancing, and Verification” (2007-2019) and co-chair for the conference “International Optical Design Conference” (2002). I have taught the course: *Advanced Lens Design: Art and Science in Japan* (2014, 2016, and 2017).

16. I have been a co-editor of approximately 24 published conference proceedings from SPIE. I am the author of the book, “Introduction to Aberrations in Optical Imaging Systems,” by Cambridge University Press, 2013; and of the book “Introduction to Lens Design,” by Cambridge University Press, 2019. I am named as an inventor on about 17 U.S. Patents, and on 3 U.S. Patent Applications.

17. A more detailed summary of my background, experience, and publications is contained in my CV attached herein as Exhibit 2002.

18. Accordingly, I am an expert in the fields of optical sciences and optical engineering in general, including optical instrumentation, optical design, and optical fabrication and testing, and have been since at least 1990.

V. LEGAL STANDARDS

19. Counsel for Sun Pharma have explained to me the legal standards that apply in this case. My understanding of those standards is described below. I am not an attorney, and I do not have formal training in the law regarding patents. I have used my understanding of the following legal principles set forth in this section in reaching my opinions.

A. Obviousness

20. 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 as a whole would have been obvious at the time the invention was made to a person of ordinary skill in the art (“POSITA”) to which the subject matter pertains. Similarly, a claim is 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 the invention was made.

21. I understand that obviousness is ultimately a question of law based on a determination of a number of factual issues. Those factual issues relate to: (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, such as commercial success, long-felt need, failure of others, and unexpected results.

22. I understand that the obviousness inquiry takes place at the time of the invention. Therefore, care must be taken to avoid the impermissible use of hindsight in an obviousness analysis. I understand that it is improper to use the invention as a plan or template for hindsight reconstruction of bits and pieces of the prior art to form the invention. For example, the inventive contribution of a patent may lie in defining a problem in a new way. By merely presenting someone of skill in the art with the identical problem and telling him or her to make the patented invention, it often becomes virtually certain that the artisan will succeed in making the invention. However, the obviousness inquiry must show by clear and convincing evidence that a POSITA at the time of the invention would have recognized the specific problem recognized by the inventor and found it obvious to perform the inventor's methods to solve that problem.

23. It is my further understanding that a patent claim composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art. There must be an apparent reason why it would have been obvious to modify the prior art to arrive at the claimed invention. Counsel for Sun Pharma has informed me that 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. I also understand that conclusory statements are insufficient to support the legal conclusion of obviousness. Instead, I understand that the Petitioner must articulate a basis on which it concludes that it would have been obvious to make the claimed invention.

25. I understand that there is no suggestion or motivation to make a modification to a prior art reference if the proposed modification would render the prior art invention unsatisfactory for its intended purpose. I also understand that an obviousness allegation cannot be supported by 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.

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

VI. LEVEL OF ORDINARY SKILL IN THE ART

27. I have been informed by Sun Pharma's attorneys that obviousness is considered from the perspective of a person of ordinary skill in the art at the time of the invention.

28. I understand that several factors are considered in determining the level of ordinary skill in the art, including the educational level of active workers in the field, the types of problems encountered in the art, the nature of the prior art solutions to those problems, prior art patents and publications, the activities of others, the sophistication of the technology involved, and the rapidity of innovations in the field.

29. Sun Pharma's attorneys have informed me that the filing date of the provisional application to which the '028 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 '028 Patent. Ex. 1015 (Grove Declaration), ¶21.

30. In my opinion, a person of ordinary skill in the art ("POSITA") at the time of the invention of the '028 Patent would have had a M.D. and/or a Ph.D. in electrical engineering, 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.

31. I met and exceeded the above qualifications for 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 '028 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.

32. 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 IPR2024-01312 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 '028 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 opinion regarding the level of skill of the POSITA, 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. Dr. Grove’s opinion contradicts the opinion of Petitioner’s expert, Dr. Bretschneider, regarding the level of skill of the POSITA in IPR2024-00874. 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 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 '028 Patent, as I understand none of the '028 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 Mazeijka). 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

33. Prior to the time of the invention, fluorescent tubes were used as light sources to illuminate a target for photodynamic therapy. *See, e.g.,* Ex. 1014 (Lundahl), 2:33-34, 5:38-46; Ex. 1001 ('028 Patent), 1:51-57 (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, 18a, 18c.

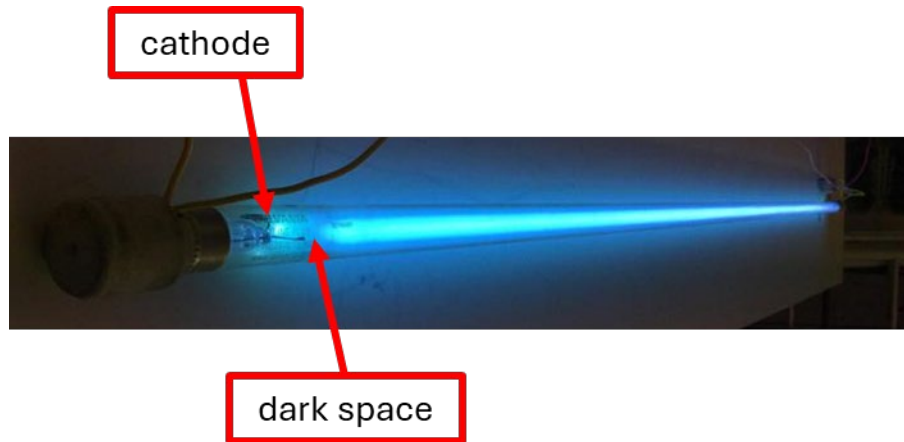
34. Fluorescent tubes are gas discharge lamps that emit light by using "an electric discharge through a low pressure gas to create a plasma which interacts with a fluorescing phosphor." Ex. 1014 (Lundahl), 5:47-50. A fluorescent tube is a "sealed glass tube with electrodes, or cathodes, at both ends" 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. Because of the low pressure in the tube, the liquid mercury evaporates to create an argon/mercury atmosphere in the tube. Ex. 1014 (Lundahl), 5:56-58.

35. 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 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.

36. Fluorescent tubes do not emit “inherently uniform” light. Ex. 1014 (Lundahl), 6:10-11; Ex. 1015 (Grove Declaration), ¶¶121-122, 129. 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.



Ex. 2010 (<https://www.lighting-gallery.net/gallery/displayimage.php?album=1601&pos=188&pid=211863>)
(annotated).

37. 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.

38. The wavelength of light emitted by a fluorescent tube is 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.

39. 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 voltage

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 current and heating are controlled by ballasts that regulate the current and voltage flowing to the electrodes. Ex. 1014 (Lundahl), 7:27-35.

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

41. LEDs, unlike fluorescent tubes, are directional light sources that emit light in a specific direction. The light rays emitted from LEDs approximate a Lambertian distribution, as shown below.

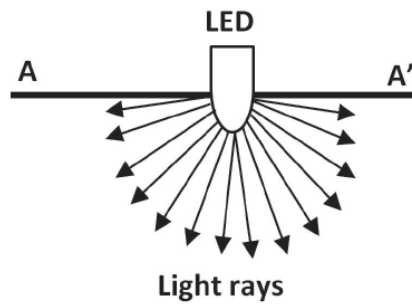


Figure 6: Scattering of the light from LEDs (Lambertian distribution); (A – A') represents the Lambertian surface in the profile view

Ex. 2013 (Ndjiongue), Fig. 6. LEDs are non-coherent light sources. Ex. 2011 (Bourget), 1944 (“LED light is of a noncoherent, narrow band.”).

42. The wavelength of light emitted by LEDs is determined by the composition of the semiconductor. The energy of light released by the electrons moving from the *n*-type layer to holes in the *p*-type is determined by the band gap of the composition of the semiconductor. Ex. 2011 (Bourget), 1944.

43. Unlike fluorescent tubes, the emission of LEDs is controlled by a constant low-current source 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”).

VIII. THE '028 PATENT

44. The '028 Patent is entitled “ADJUSTABLE ILLUMINATOR FOR PHOTODYNAMIC THERAPY AND DIAGNOSIS.” The inventors of this patent are Thomas Boyajian, Mark Carota, and Brian Mazejka.

45. The '028 Patent discloses a system and method for photodynamic therapy and diagnosis of skin diseases.

46. The '028 Patent states that “[t]he invention relates generally to 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 ('028 Patent), 1:19-22.

47. As the '028 Patent explains, “[t]he optical dead space that can occur at or near the hinges of conventional adjustable illuminators reduces the uniformity of the light along the treatment area, thereby reducing the effectiveness of PDT.” Ex. 1001 ('028 Patent), 2:41-44. As a solution to this problem, the '028 Patent discloses that it is an object of the present invention to “reduce or eliminate these dead spaces and provide for a more uniform light distribution in an adjustable illuminator designed for PDT or PD of a variety of targeted areas.” Ex. 1001 ('028 Patent), 2:52-56.

48. The '028 Patent further explains that “to further reduce or eliminate optical dead spaces, the panels are preferably coupled together using nested hinges,

thereby reducing the area in which no light source is present on the illuminator.” Ex. 1001 (’028 Patent), 3:11-14. In addition, “[i]n order to even further reduce or eliminate optical dead spaces, it is preferable that the light sources on each of the panels are individually configurable to provide specific power output to certain areas of the light sources on the panels to compensate for decreased uniformity. For example, the power outputted to each individual diode in an array of light emitting diodes (LED) may be individually adjusted.” Ex. 1001 (’028 Patent), 3:14-21.

49. As shown below, Fig. 2B of the ’028 Patent illustrates “one embodiment of a configurable illuminator according to the present invention.” Ex. 1001 (’028 Patent), 3:52-53. “The illuminator includes a main body **100**, which preferably has five individual panels **10a-10e**, each of which are connected in a rotatable manner via nested hinges **50**.” Ex. 1001 (’028 Patent), 3:54-56. Each of the five panels contains an array of light emitting diodes (LED) **60**, which preferably “extend[] as far to the edges as possible.” Ex. 1001 (’028 Patent), 3:56-64.

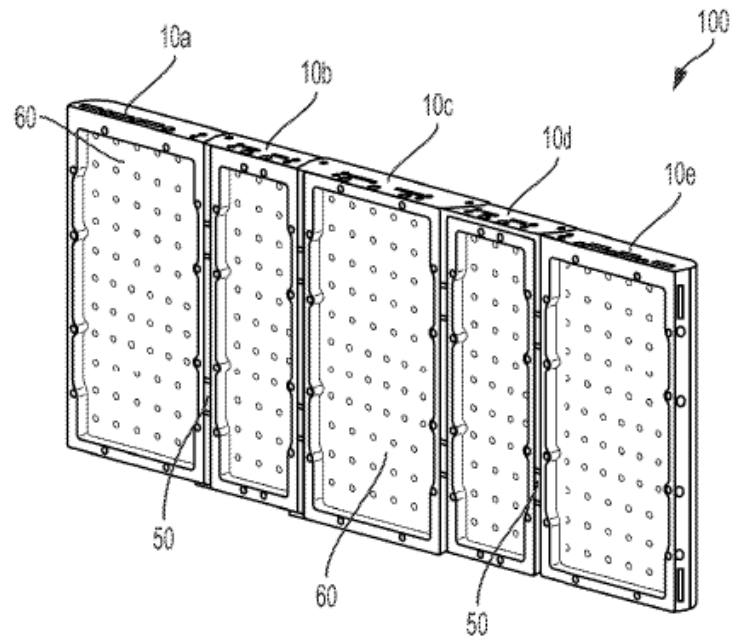


FIG. 2B

Ex. 1001 ('028 Patent), Fig. 2B.

50. As shown in further detail in Fig. 3A below, in an embodiment of the invention the “nested hinges **50**” (shown in blue) are “mounted to the inner side surfaces of adjacent panels (e.g. **10a**, **10b**) to allow for rotation of the panels.” Ex. 1001 ('028 Patent), 4:65-5:1.

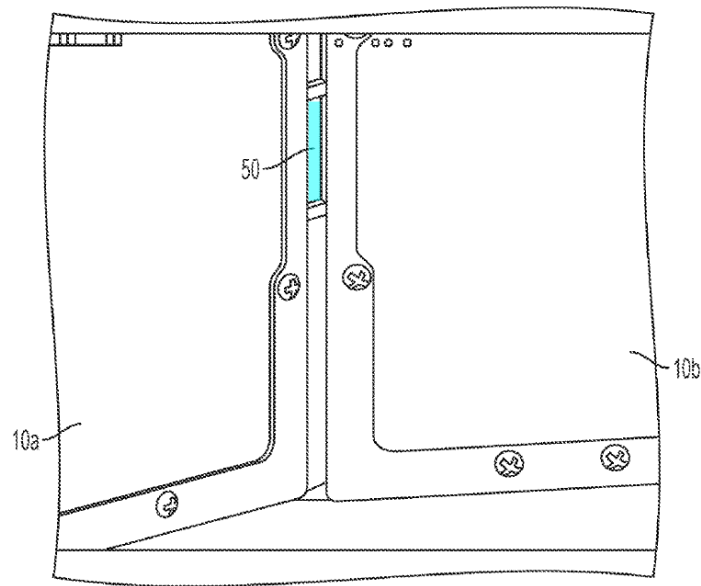


FIG. 3A

Ex. 1001 ('028 Patent), Fig. 3A (annotated).

51. As another aspect of an embodiment of the invention, the '028 Patent discloses that “the LED arrays **60** may be individually configured as shown in FIG. **5**” below. Ex. 1001 ('028 Patent), 6:24-25.

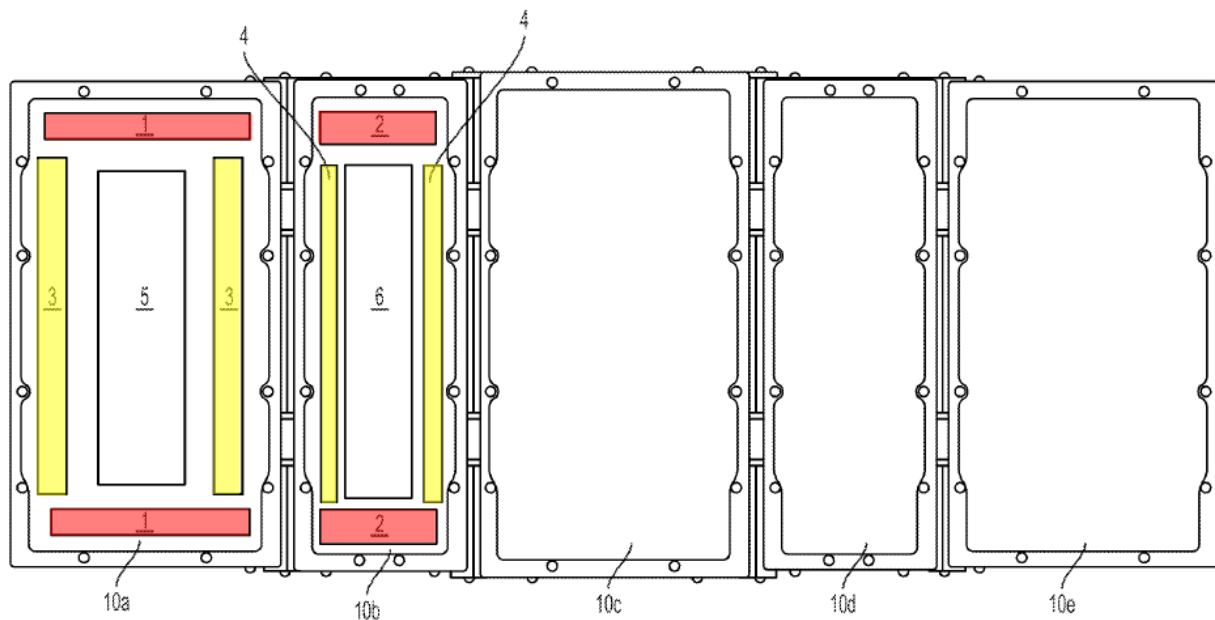


FIG. 5

Ex. 1001 ('028 Patent), Fig. 5 (annotated).

52. As shown in Fig. 5, in an embodiment of the invention “the LED arrays **60** are 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 **10a**, **10c**, and **10e**, while areas **2**, **4**, and **6** correspond to an addressable string configuration that may be included in the narrower panels **10b** and **10d**.” Ex. 1001 ('028 Patent), 6:25-31. “The 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** [shown in red] than the current supplied to areas **3** and **4** [shown in yellow] 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 (’028 Patent), 6:32-38 (emphasis added).

53. The ’028 Patent further discloses that “[a]lternatively, each panel may have a dedicated control unit to regulate power to the individual LED array on a given panel.” Ex. 1001 (’028 Patent), 5:57-59.

54. In addition, Fig. 8 of the ’028 Patent shown below “illustrates the light uniformity produced by an embodiment of the present invention.” Ex. 1001 (’028 Patent), 8:43-44.

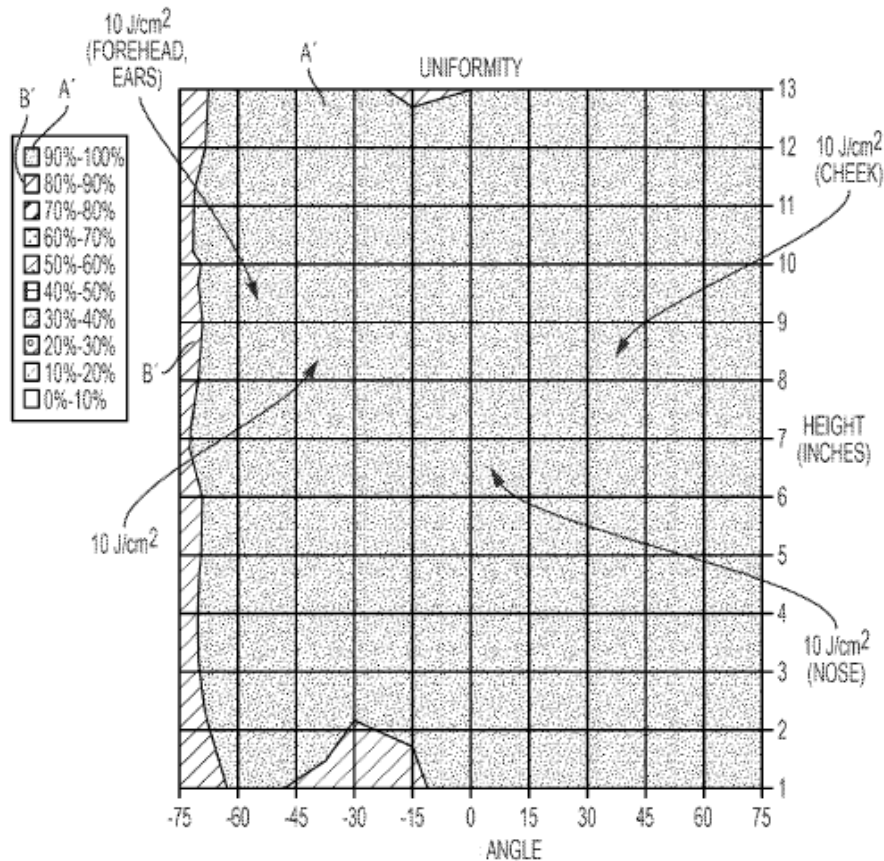


FIG. 8

Ex. 1001 (’028 Patent), Fig. 8.

55. The '028 Patent discloses that as compared with “conventional adjustable illuminators,” the light output uniformity produced by an embodiment of the illuminator of the present invention is “greatly enhanced across the patient’s face and exhibits little to no deviation from the light output measured in the center of the patient’s face to the light output measured at the edges of the patient’s face,” as shown in Fig. 8. Ex. 1001 ('028 Patent), 8:47-50.

56. The '028 Patent discloses a preferred embodiment wherein “the measured output over the emitting area is within 70% of the measured maximum over a distance of two and four inches.” Ex. 1001 ('028 Patent), 8:58-62. The '028 Patent further discloses that “[e]ven more preferably, the measured output over the emitting area is within 80% of the measured maximum over a distance of two and four inches.” Ex. 1001 ('028 Patent), 8:62-67.

57. Finally, as shown below in Fig. 4, the '028 Patent discloses an embodiment wherein the main body **100** containing the 5 LED panels is “mounted to a movable stand **80**” to “allow a user to easily move the main body **100** to the appropriate treatment position.” Ex. 1001 ('028 Patent), 5:15-20. “The stand **80** includes a base **81** and a vertical pillar **82**. The base **81** may further include wheels **87** at its bottom in order to allow the user to horizontally move the illuminator to an appropriate position.” Ex. 1001 ('028 Patent), 5:20-23; Ex. 1002 (File History of

the '028 Patent, U.S. Application No. 17/942,353), 469 (“a mobile base supported by at least four wheels”).

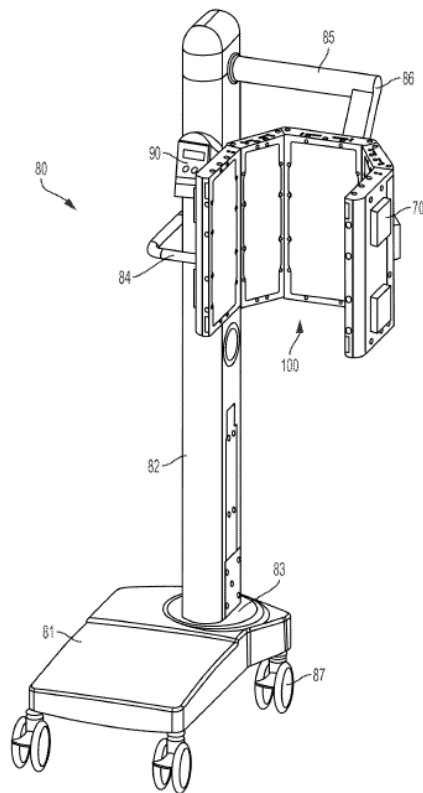


FIG. 4

Ex. 1001 ('028 Patent), Fig. 4.

IX. CLAIM CONSTRUCTION

58. I understand that Petitioner proposes that no term needs to be construed. Petition, 12. In addition, Dr. Grove states that “the claim terms are given their ordinary and customary meaning as would be understood by a person of ordinary skill in the art in the context of the entire disclosure at the time of the invention” and that he “applied this standard.” Ex. 1015 (Grove Declaration), ¶¶73-74. I also understand that the Board has not explicitly construed any terms in this proceeding

or in IPR2024-00874. 874 Institution Decision, 10 (“We agree with the parties that we need not expressly construe any claim term for purposes of rendering this Decision whether to institute the challenged claims.”). 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.

X. BIOFRONTERA’S ASSERTED PRIOR ART

A. Lundahl (Ex. 1014)

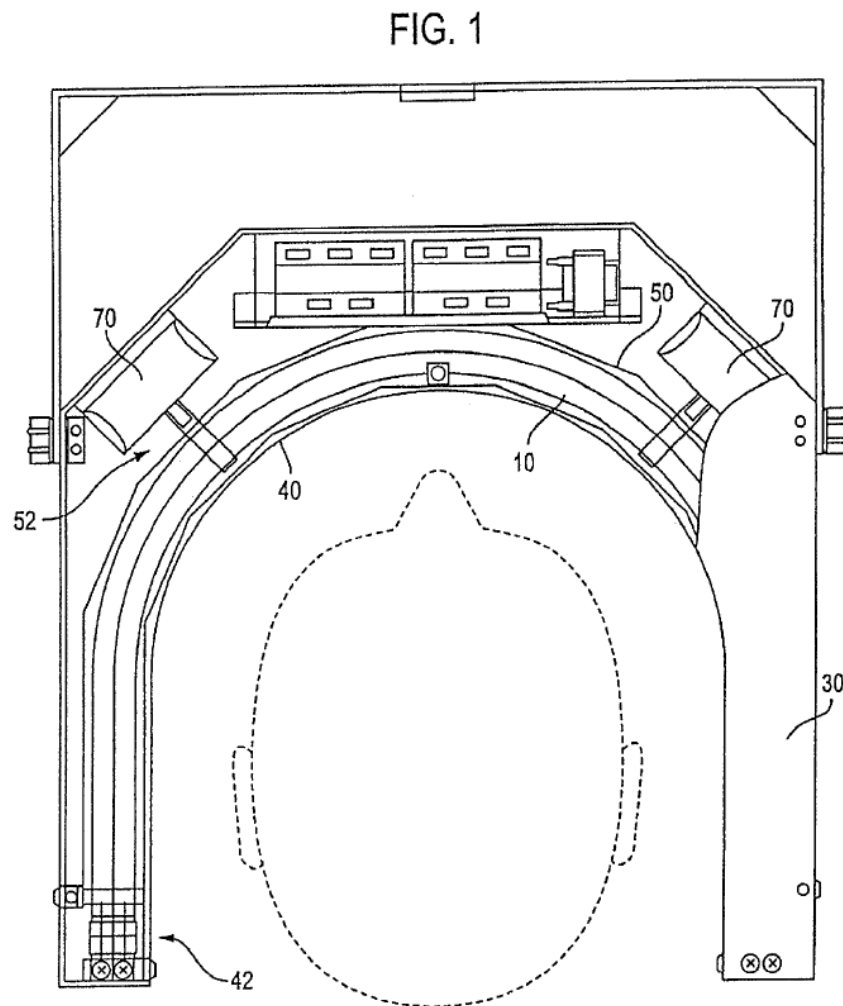
59. U.S. Patent No. 6,223,071 by Scott Lundahl et al. (“Lundahl”) is entitled “Illuminator for Photodynamic Therapy and Diagnosis Which Produces Substantially Uniform Intensity Visible Light.” Ex. 1014 (Lundahl), Cover.

60. 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.

61. Lundahl discloses an illuminator with “seven U-shaped fluorescent tubes **10(1)-10(7)** 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.

62. FIG. 1 of Lundahl “shows a partial cross section, front elevation view of an illuminator according to the present invention.”:

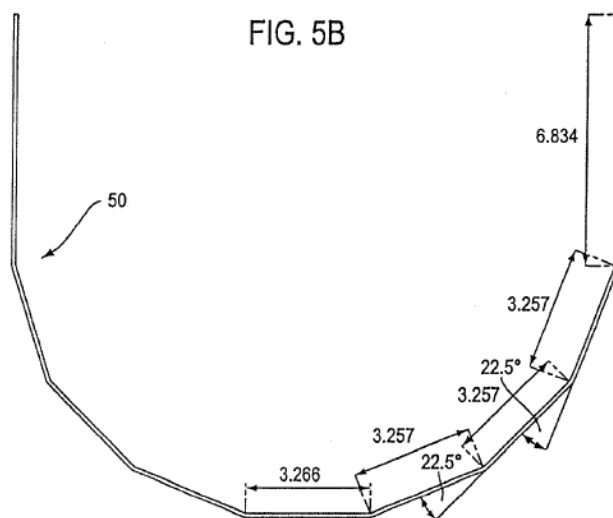


Ex. 1014 (Lundahl), FIG. 1.

63. 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

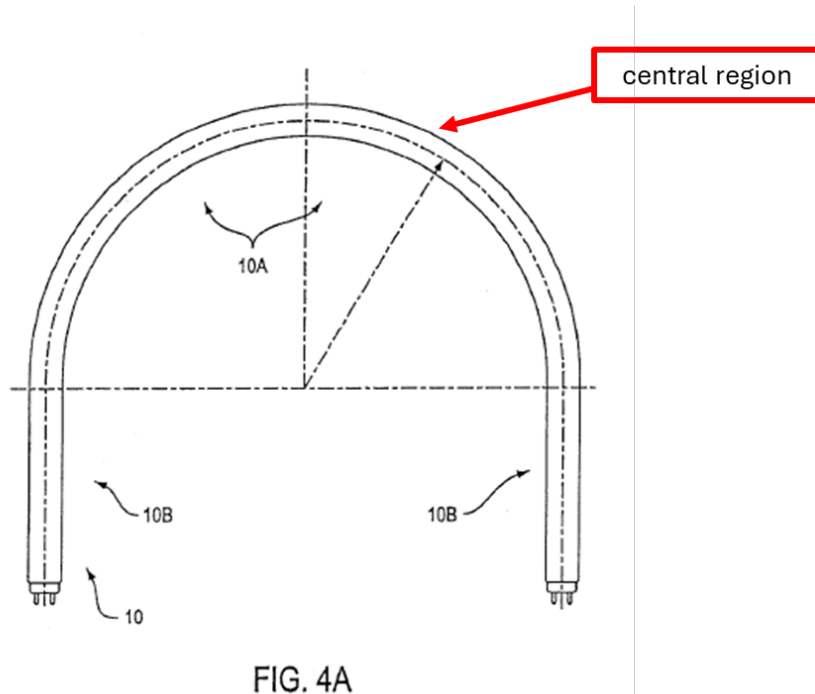
irradiance and irradiance uniformity for scalp and facial irradiation, and thus ensures that the proper visible light dosage is applied to all target areas during PDT.” Ex. 1014 (Lundahl), 6:31-42. Lundahl discloses that “the present invention is also directed to . . . other areas of the patient (e.g., arms, legs, etc.)” Ex. 1014 (Lundahl), 1:14-17.

64. 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.



Ex. 1014 (Lundahl), FIG. 5B.

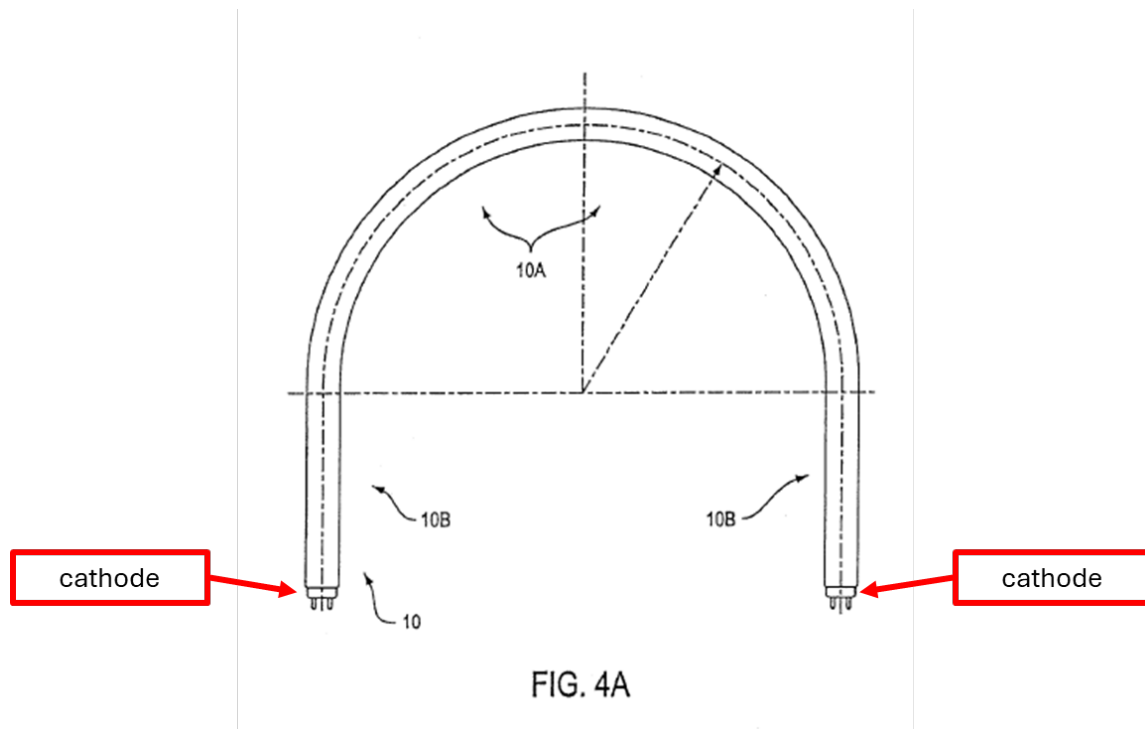
65. FIG. 4A is “a detail view of the fluorescent tube light source shown in FIG. 1.” Ex. 1014 (Lundahl), 4:66-67. As shown below in FIG. 4A, “the tubes have a generally arcuate central region **10A** and arms **10B** extending from respective ends of the central region.” Ex. 1014 (Lundahl), 5:43-46.



Ex. 1014 (Lundahl), FIG. 4A (annotated).

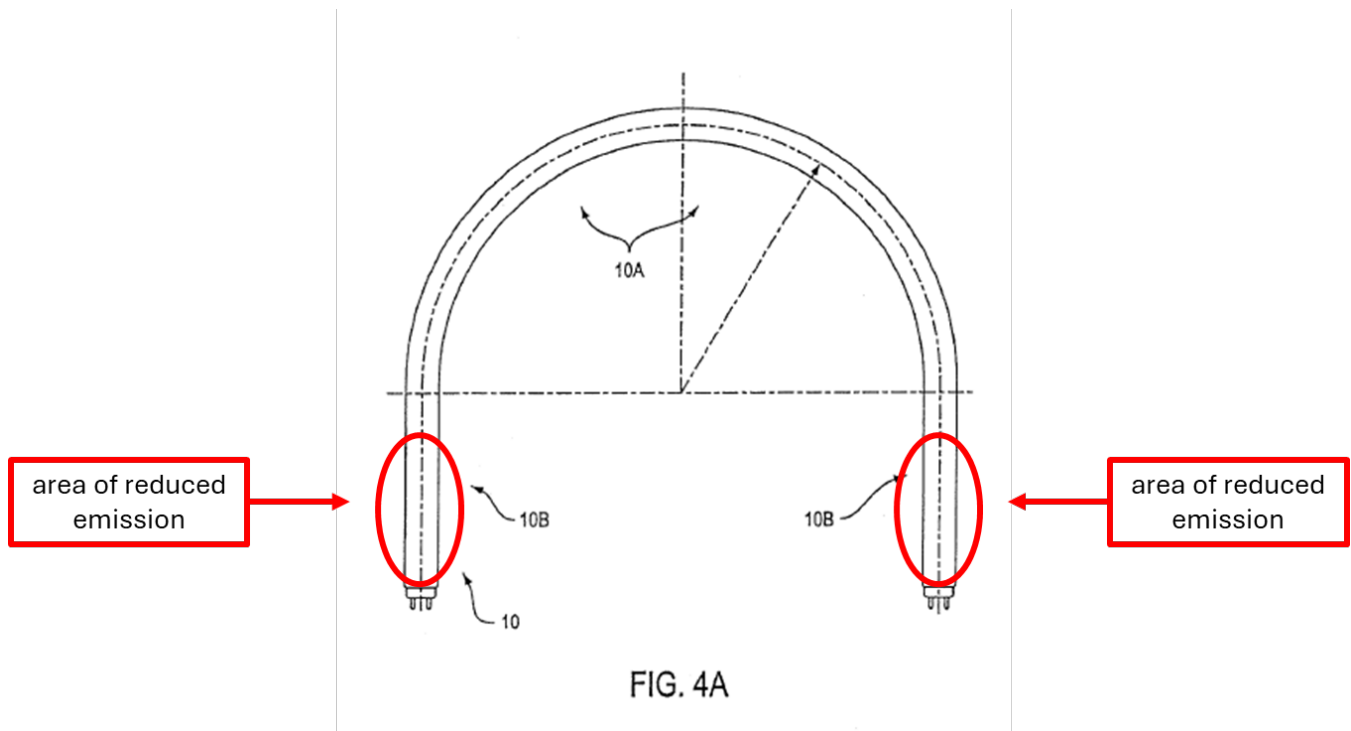
66. Lundahl discloses that “[s]ince the output irradiance for this tube increases (to a point) with tube wall temperature, the hotter central region of the tube produces higher output irradiances than the rest of the tube.” Ex. 1014 (Lundahl), 9:42-53.

67. Further, as shown below in FIG. 4A, the “fluorescent tube consists of a sealed glass tube with electrodes, or cathodes, at both ends.” (Lundahl), 5:50-52.



Ex. 1014 (Lundahl), FIG. 4A (annotated).

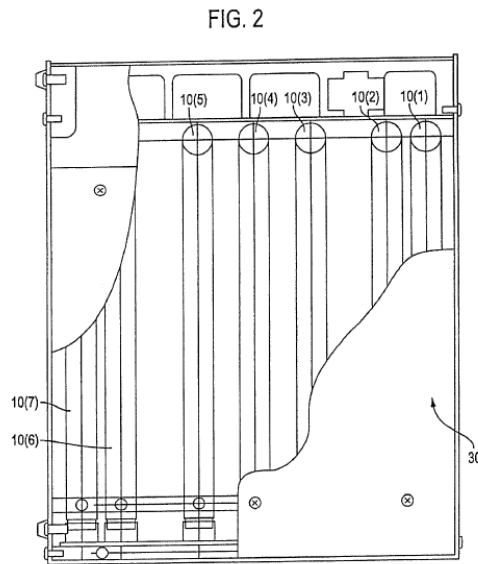
68. Lundahl discloses that “[t]he output from a fluorescent tube is not inherently uniform” and “[t]he output measured in the immediate vicinity of the cathode is typically much lower than the output over the rest of the tube.” The “area of reduced emission [shown below] is known as the Faraday dark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



Ex. 1014 (Lundahl), FIG. 4A (annotated).

69. Lundahl discloses that “[t]o avoid uniformity problems, one embodiment of the present invention uses 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.

70. 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 spacing of the fluorescent tubes **10(1)-10(7)** in FIG. 2 was chosen to achieve “desired uniformity and power output.” Ex. 1014 (Lundahl), 6:43-45.



Ex. 1014 (Lundahl), FIG. 2. 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.

71. 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), 7:11-27.

72. Lundahl further discloses that “control 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), 7:27-31, 8:46-51, 11:6-18, FIGS. 7, 8, and 9A. The ballasts “convert 120 VAC line voltage available from a standard wall output into a high frequency (~25 kHz) sinusoidal current suitable for driving fluorescent tubes.” Ex. 1014 (Lundahl), 8:51-54.

B. Larsen (Ex. 1004)

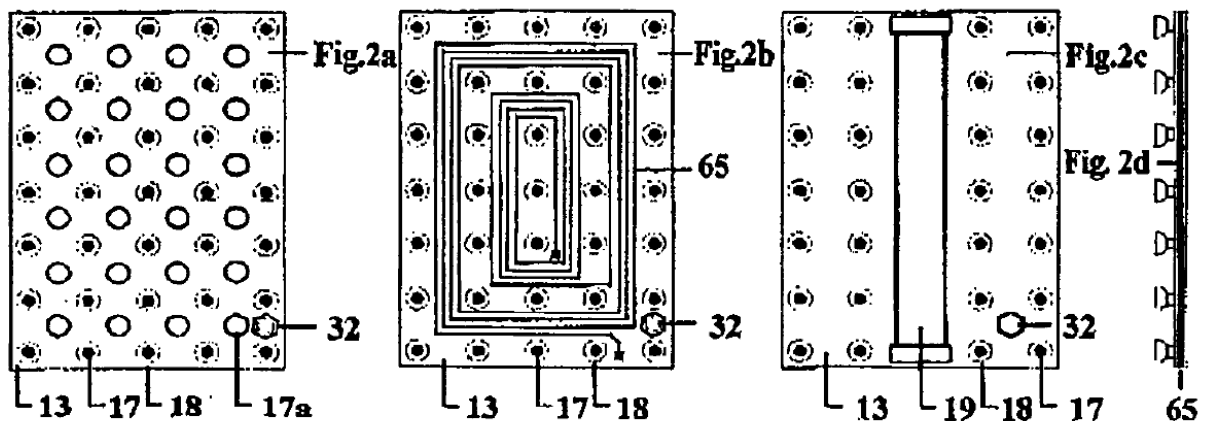
73. U.S. Patent Publication No. 2005/0075703 by Eric Larsen (“Larsen”) is entitled “Photodynamic Stimulation Device and Methods.” Ex. 1004 (Larsen), Cover.

74. 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].

75. 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]. 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].

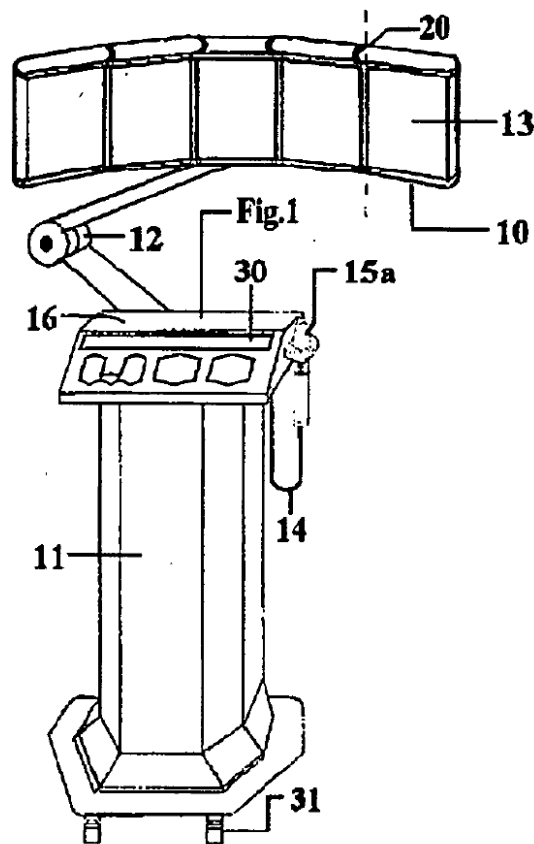
76. Larsen discloses that Figs. 2a, 2b, and 2c “illustrate details of the machine applicator of the invented device.” Ex. 1004 (Larsen), [0041]. “The FIGS. 2a, 2b, and 2c show plain surfaced printed circuit boards with light sources mounted in the applicators **13**.” Ex. 1004 (Larsen), [0070]. The printed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

77. 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].



Ex. 1004 (Larsen), Figs. 2a-2c.

78. Larsen further discloses that Fig. 1, shown below, is “a perspective drawing of the invented device.” Ex. 1004 (Larsen), [0040]. As shown 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].



Ex. 1004 (Larsen), Fig. 1.

79. 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] (“The plain surface applicators can consist of several applicators placed side by side and flexibly connected with each other through hinges, whereby the applicators are suitable for the treatment of large-area tissues such as the human back.”).

80. Larsen discloses that “[t]he applicators **13**, according to FIGS. *2a*, *2b*, and *2c* 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].

81. 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**, *17a* 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].

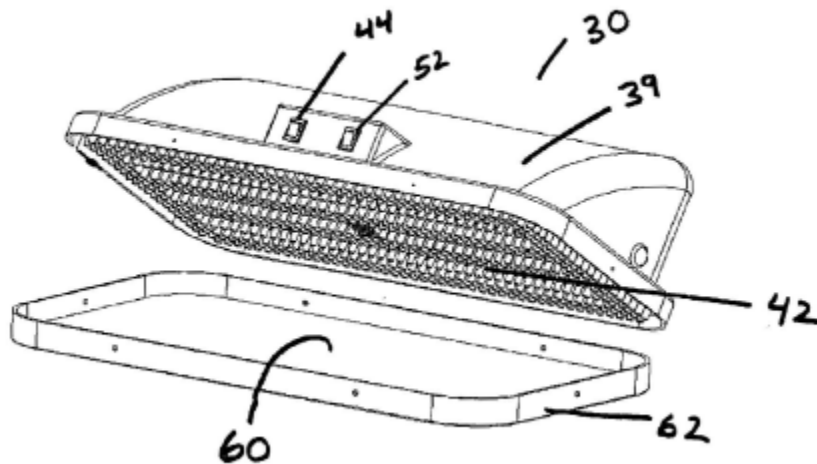
C. Bansal (Ex. 1005)

82. U.S. Patent Publication No. 2004/0068305 by Vineet Bansal et al. titled “Phototherapy System and Device.” Ex. 1005 (Bansal), Cover.

83. Bansal discloses that “[t]he present invention is a phototherapy system including a non-uniform array of light sources, a clear light diffusing panel placed between the light sources and the subject, and a target mechanism to assist in positioning the subject underneath the center of the array. With these improvements, the present invention allows for a more uniform and precise phototherapeutic light exposure.” Ex. 1005 (Bansal), [0010].

84. Fig. 2 of Bansal, shown below, is “a perspective view of a device according to the present invention.” Ex. 1005 (Bansal), [0012]. Bansal discloses that “[t]he enclosure **30** simply provides structural support for the sockets or board which hold the array of light sources **40**. (For instance, FIG 2 shows the enclosure **30** with an LED board **42**).” Ex. 1005 (Bansal), [0023].

Fig. 2

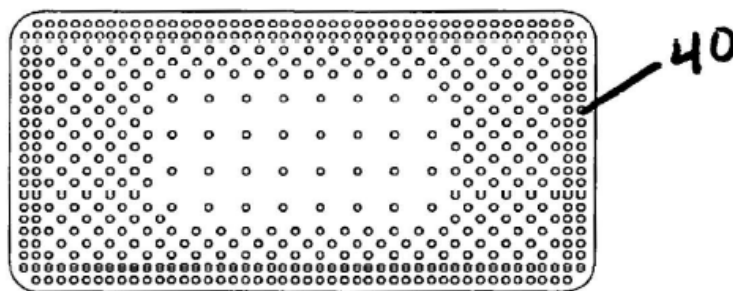


Ex. 1005 (Bansal), Fig. 2.

85. Bansal discloses that “[t]he array of light sources **40** is plurality of light sources, such as semiconductor light sources, LEDs **42**, halogen lights, incandescent

lights, low-intensity lasers, etc. The array can take a number of different non-uniform forms to achieve the goal of even exposure on the subject's skin.” Ex. 1005 (Bansal), [0025]. Bansal discloses that in one embodiment, “the density of light source distribution would vary throughout the array, such as with higher density in the periphery and a lower density in the center. In yet another version of the invention, low intensity light sources could be used in one portion of the array, and higher intensity light sources could be used in another section. This can be achieved by either using different intensity light sources or driving the light sources with a lower power in the center and a higher power on the outer edges. ... Some exemplary light source configurations are provided in FIGS. 9a-9d.” Ex. 1005 (Bansal), [0025]. Fig. 9b of Bansal is shown below.

Fig. 9b



Ex. 1005 (Bansal), Fig. 9b.

86. Bansal discloses that for phototherapeutic light sources using “a simple rectangular array” “it has been found that a 10 inches by 20 inches array of approximately 750 blue LEDs suspended 12 inches above a subject can produce sufficient intensity, approximately 35 microwatts/nm/cm², in the spectrum of

interest (400 nm to 520 nm), to be a clinically useful phototherapy device for the treatment of hyperbilirubinemia.” Ex. 1005 (Bansal), [0007].

XI. PROSECUTION HISTORY OF THE '028 PATENT

87. The Applicant filed an application to the '028 Patent on September 12, 2022. Ex. 1002 (File History of the '028 Patent, 9/12/22 U.S. Application No. 17/942,353), 435-479.

88. In an Office Action dated November 18, 2022, the Examiner rejected then-pending claims 18 and 20-22 under 35 U.S.C. 103 as “being unpatentable over Larsen (U.S. Patent No. 7,033,381, cited by Applicant) in view of Fan et al. (U.S. 2006/0253175).” Ex. 1002 (11/18/22 Office Action), 328-330. The Examiner stated that “[c]laims 3, 6, 9, and 19 ... would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.” Ex. 1002 (11/18/22 Office Action), 333.

89. In its Response dated February 16, 2023, Applicant amended then-pending independent claim 18 “to recite subject matter relating to dependent claim 19.” Ex. 1002 (2/16/23 Response), 207. Applicant amended independent claim 18 as follows:

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

a mobile base supported by at least four wheels;
a pillar perpendicular to the base;
a controller disposed to be supported by the pillar;
an arm mounted to a top portion of the pillar; and
an illuminator connected at an end of the arm, the arm being hinged to allow adjustment of a position of the illuminator relative to the base, the illuminator comprising
~~at least~~ five panels connected by hinged structures to allow continuous illumination across the ~~at least~~ five panels, wherein the ~~at least~~ five panels are individually configurable to control illumination from each of the ~~at least~~ five panels,

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, the light sources being configured to output light uniformly during at least part of a time when the treatment surface is illuminated, each of the five panels having two first edges and two second edges shorter than the two first edges, the 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, and
one or more fans mounted to at least one of the five panels.

Ex. 1002 (2/16/23 Response), 203-204. Applicant argued that “[a]mended independent claim 18 and claims 20-22 which depend therefrom are therefore allowable.” Ex. 1002 (2/16/23 Response), 207.

90. Following the amendment, the Examiner allowed claims 1, 2, 4, 5, 7-18 and 20-24 in a Notice of Allowance, issued on March 1, 2023. Ex. 1002 (Notice of Allowance), 120. The Examiner stated in her reasons for allowance that “it is in the opinion of the examiner that the art of record neither anticipates nor renders obvious ‘wherein each of the 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. 1002 (Notice of Allowance), 120.

91. The ’028 Patent issued on July 11, 2023. Ex. 1001 (’028 Patent), Cover.

XII. GROUND I: THE CHALLENGED CLAIMS ARE NOT RENDERED OBVIOUS BY THE COMBINATION OF LUNDAHL AND LARSEN

92. Petitioner asserts in Ground I that the Challenged Claims are obvious over Lundahl in view of Larsen (the challenged independent claims are bolded in the chart below).

Ground	Claims	Theory	References
I	<u>1</u> , 2, 4, <u>5</u> , 6, <u>16</u> , 17, 19, <u>20</u> , <u>21</u>	Obviousness	Lundahl, Larsen

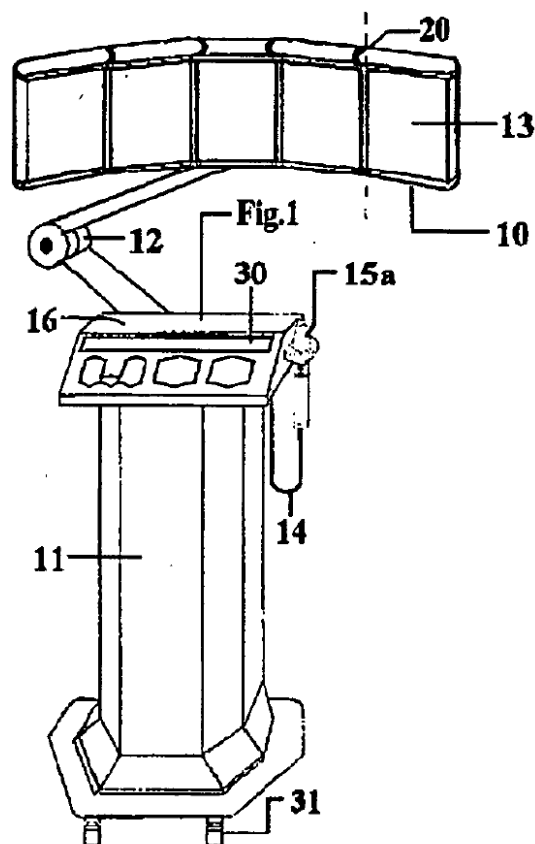
93. For at least the reasons set forth below in Sections A-E, Petitioner does not show that the combination of Lundahl and Larsen would render obvious the Challenged Claims.

A. Larsen Does Not Disclose Or Render Obvious “Hinged Structures On Inner Side Surfaces Of Adjacent Panels”

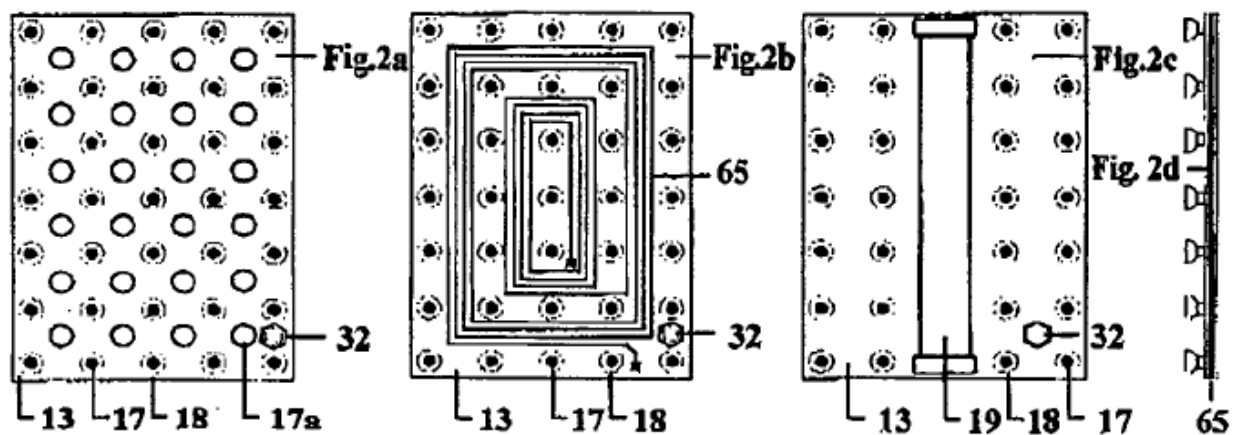
94. Independent Claims 1, 5, 20 and 21 of the ’028 Patent, from which Claims 2, 4, and 6 depend, require an “illuminator comprising five panels connected by *hinged structures on inner side surfaces of adjacent panels.*”

95. Petitioner and Dr. Grove argue that this limitation is disclosed by Larsen. Ex. 1015 (Grove Declaration), ¶¶152-156, 198-199, 246-248, 257; Petition, 35-38, 55, 69-70, 71. However, Larsen does not disclose an “illuminator comprising five panels connected by *hinged structures on inner side surfaces of adjacent panels.*”

96. First, there is no express disclosure of “*hinged structures on inner side surfaces of adjacent panels*” in Larsen. When describing Fig. 1, Larsen states only that the applicators 13 are connected by hinges **10**. Ex. 1004 (Larsen), [0072] (“For 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”) (emphasis added). In addition, element “**10**” in Fig. 1 points to the *bottom* of applicator 13, not to any inner side surface of adjacent panels.



Ex. 1004 (Larsen), Fig. 1.



Ex. 1004 (Larsen), Figs. 2a-2c.

97. Petitioner argues that, despite the clear disclosure labeling of “hinges” as “10,” the hinges are shown as element 20 in Fig. 1. Ex. 1015 (Grove Declaration), ¶154; Petition, 36-37. However, Larsen identifies “20” as the regular row

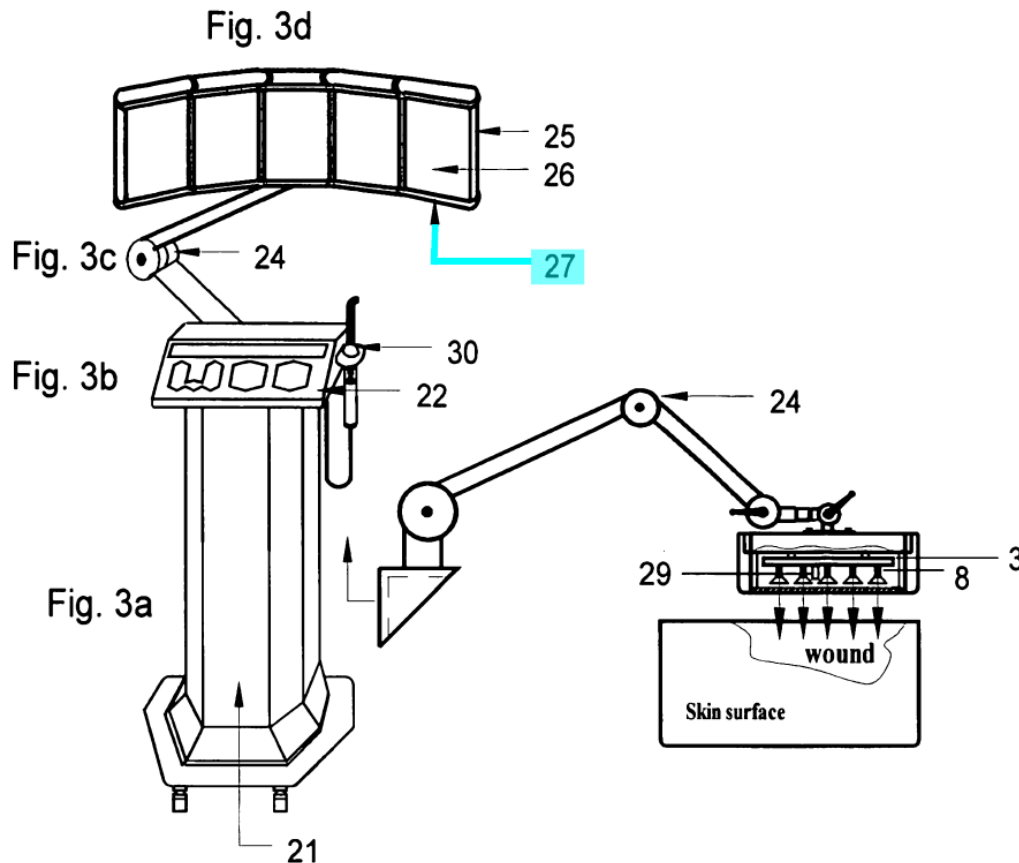
arrangements of light sources in the applicator **13**. Ex. 1004 (Larsen) [0071] (“According to FIGS. 2b and 2c *the light sources 17 are placed in regular row arrangements, i.e., 20* equidistant from each other.”) (emphasis added). A person of ordinary skill in the art reading Larsen would have understood that “hinges **10**” refers to element **10**, not element **20** in Fig. 1.

98. Petitioner argues that during prosecution an Examiner found that Larsen taught “five panels connected by a plurality of hinges **20** ... *on inner side surfaces of adjacent panels that connect panels together.*” Ex. 1015 (Grove Declaration), ¶154 (emphasis added by Petitioner); Petition 37 (citing Ex. 1009 (Office Action in 871 Application), ¶4 (citing Ex. 1004 (Larsen), Figs. 1-3, [0069], [0072], lines 1-4); Petition 37 (citing Ex. 1002 (File History of the ’028 Patent), 328 (citing Ex. 1008 (Larsen ’381 Patent), Fig. 1, 5:44-47). But there is no such disclosure in Larsen.

99. Petitioner’s argument conflicts with Larsen, which states that “applicators **13** are flexibly connected to each other through *hinges 10*” and the light sources “are placed *in regular row arrangements, i.e., 20.*” Ex. 1004 (Larsen), [0071]-[0072] (emphasis added).

100. Petitioner’s argument also conflicts with another Larsen Australian Patent Application 200143869, which claims and points to hinges 27 on the *bottom* of the applicator (shown below in blue). Ex. 2004 (Larsen AU43869), 14 (Claim

19: “a flat applicator (25) consisting of a number of individual [sic] *hinged* (27) flat elements (26), which can be adjusted in angles to each other”).

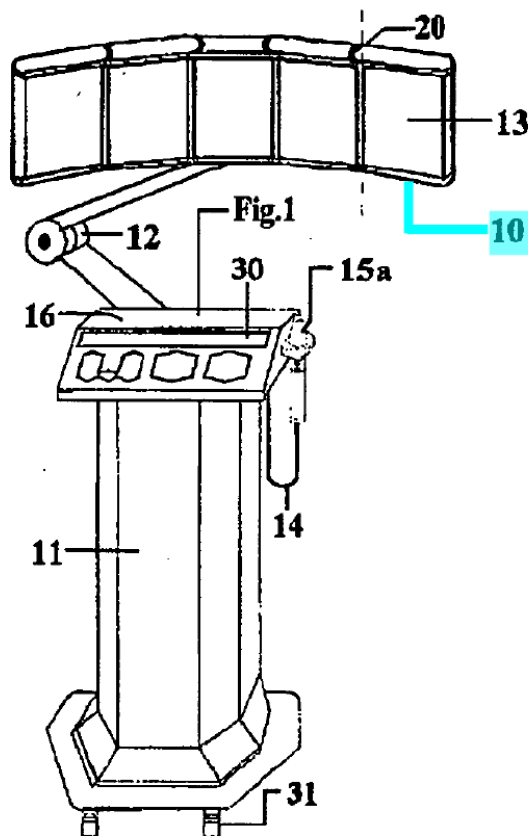


Ex. 2004 (Larsen AU43869), Fig. 3d (annotated).

101. Petitioner’s argument further conflicts with its own expert Dr. Bretschneider’s opinion that “Larsen is silent on the type of hinges.” IPR2024-00874, Ex. 1003 (Bretschneider Declaration), ¶191.

102. Second, there is no inherent disclosure of “*hinged structures on inner side surfaces of adjacent panels*” in Larsen. A person of ordinary skill in the art would have understood that the hinges in Larsen are *not necessarily* on the inner side surface of adjacent panels because Larsen states the applicators **13** are connected by

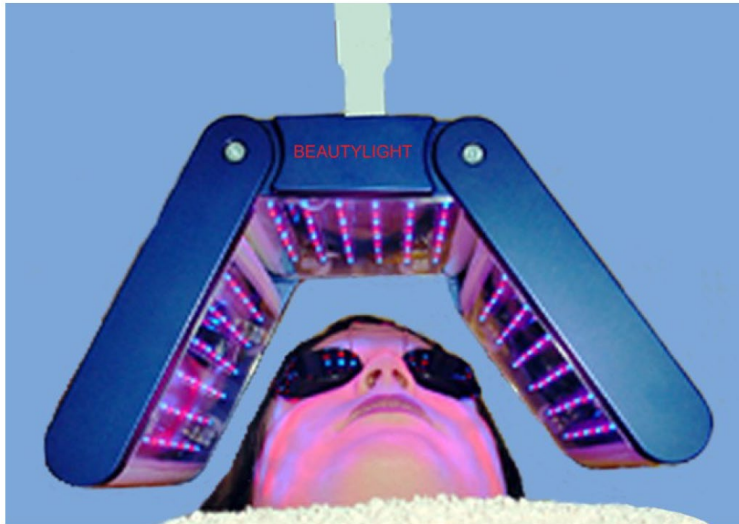
“hinges 10,” and element “10” points to the *bottom* of applicator 13 in Fig. 1 (as shown below in blue). Ex. 1004 (Larsen), [0072]. In addition and to clarify, Larsen references element 20 as the light sources “placed in regular row arrangements, i.e., 20,” and does not reference element 20 as hinges. Ex. 1004 (Larsen), [0071].



Ex. 1004 (Larsen), Fig. 1 (annotated).

103. Petitioner argues that Larsen’s hinges are on inner side surfaces of adjacent panels because “the panels (13) are nearly flush with each other.” Ex. 1015 (Grove Declaration), ¶154; Petition, 37-38. However, hinges are not necessarily on inner side surfaces of adjacent panels if the panels are “nearly flush with each other.” For example, the “BEAUTYLIGHT” illuminator marketed by MDE Medizintechnik

GmbH featured illumination panels flush with each other. Adjacent panels were connected by hinges at the *bottom* of the panels. Ex. 2005 (Beautylight), 10.



Ex. 2005 (Beautylight), 10. I understand that the BEAUTYLIGHT design depicted above was submitted to the United States Patent and Trademark Office on May 29, 2007 in connection with U.S. Trademark Application Serial No. 78214595, which listed Eric Larsen as an addressee for the applicant MDE Medizintechnik GmbH. Ex. 2005 (Beautylight), 5-10, 14. Further, a POSITA would have understood that hinges could be attached to panels in a variety of ways, including the bottom and top of panels.

104. Petitioner also argues that a “POSITA would have found it obvious and would have been motivated with a reasonable expectation of success to locate Larsen’s hinges on the inner side surfaces of adjacent panels” and “would have found it obvious to try placing the hinges on the inner side surfaces of the panels.” Ex.

1015 (Grove Declaration), ¶155; Petition, 37-38. However, Dr. Grove’s argument is conclusory and without support. He provides no evidence that such a design was known to a POSITA, or why a POSITA would have changed Larsen’s design from hinges on the bottom to inner side surfaces absent hindsight. To the contrary, a POSITA would have attached hinges on the bottom of the panels, as disclosed in Larsen and Beautylight above, and would have understood that there were numerous other designs that could have attached the hinges, for example, on the bottom or top of the panels.

105. Accordingly, Larsen does not disclose or render obvious an “illuminator comprising five panels connected by hinged structures on inner side surfaces of adjacent panels.”

B. Larsen Does Not Disclose That “The Five Panels Are Individually Configurable To Control Illumination From Each Of The Five Panels”

106. Independent Claims 16 and 21 of the ’028 Patent, from which Claims 17 and 19 depend, require that “*the five panels are individually configurable to control illumination from each of the five panels.*”

107. Petitioner and Dr. Grove argue that this limitation is disclosed by Larsen. Ex. 1015 (Grove Declaration), ¶¶228-231, 262; Petition, 63-65, 72. However, Larsen does not disclose “*the five panels are individually configurable to control illumination from each of the five panels.*”

108. Petitioner argues that “Larsen also teaches that each of the applicators is individually configurable to control illumination from each of the five applicators.” Ex. 1015 (Grove Declaration), ¶229; Petition, 64. In alleged support, Petitioner states that “[i]n Larsen, each of the applicators (13) ‘can be used in the working model according to Fig. 2a to 2c *individually*, side by side (in large numbers), or in combination with an applicator Ex. 1015 (Grove Declaration), ¶229 (citing Ex. 1004 (Larsen), [0070]) (emphasis added by Petitioner); Petition, 64. However, when read in context this statement does not disclose that “the five panels are individually configurable to control illumination from each of the five panels.” Petitioner did not address the preceding and succeeding sentences of Larsen’s paragraph [0070], which make clear that the subject of the quoted sentence is the *printed circuit boards*, not “each of the applicators 13.” In full, Larsen states that “[t]he FIGS. 2a, 2b and 2c show plain surfaced *printed circuit boards* with light sources mounted in the applicators 13. *These* can be used in the working model according to FIG. 2a to 2c individually, side by side (in large numbers) or in combination with an applicator. Furthermore *the printed circuit boards* on which the light sources are mounted can favourably be produced as multilayer, also containing the electromagnetic field transmitter coils 65 shown in FIG. 2d.” Ex. 1004 (Larsen), [0070] (emphasis added). Petitioner’s reading of Larsen’s disclosure (*i.e.*, with “applicators 13” as the subject instead of “printed circuit boards”) is

nonsensical because it would require that the applicators be used in combination with an applicator. When properly read in context, Larsen discloses that the working model can use an individual printed circuit board, printed circuit boards side by side (in large numbers) or in combination with an applicator, not that “the five panels are individually configurable to control illumination from each of the five panels.”

109. Petitioner argues that during prosecution of the '028 Patent the Examiner found that the Larsen '381 Patent disclosed this limitation. Ex. 1015 (Grove Declaration), ¶229 fn.8; Petition, 64 (citing Ex. 1002 (File History of the '028 Patent), 328). But there is no such disclosure in Larsen. As discussed above, when properly read in context, Larsen discloses that the working model can use an individual printed circuit board, printed circuit boards side by side (in large numbers) or in combination with an applicator, not that “the five panels are individually configurable to control illumination from each of the five panels.”

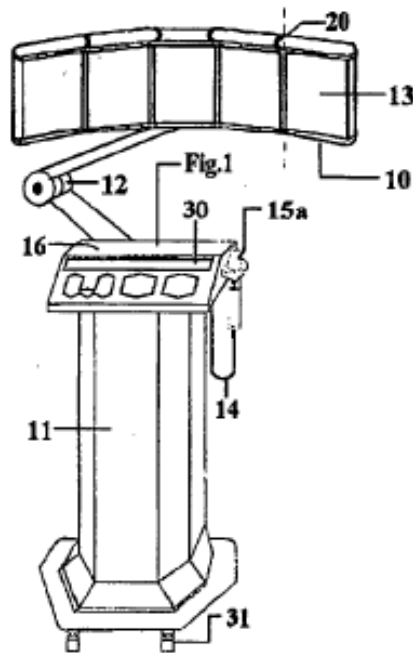
110. Petitioner also relies on Larsen’s disclosure that “[u]sing the control mechanism, ‘the invented device is adjustable within a relatively large range with reference to duration, amplitude and frequency of surge of current, so that the semiconductor diodes 17, 17a and 18, as well as laser 17 diodes with the same realisation as semiconductor diode 17, can be used as light sources.’” Ex. 1015 (Grove Declaration), ¶229 (citing Ex. 1004 (Larsen), [0074]); Petition, 64. Petitioner is again mischaracterizing Larsen’s disclosure. The subject of the quoted

sentence is the *invented device*, not the *applicators*. Ex. 1004 (Larsen), [0074] (“With 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, 17a and 18, as well as laser 17 diodes with the same realisation as semiconductor diode 17, can be used as light sources.”) (emphasis added). Larsen thus discloses that the *invented device* as a whole is adjustable, not that each of the five applicators is individually configurable to control illumination from each of the five panels.

111. Petitioner also relies on Larsen’s disclosure that “[t]he control mechanism includes ‘a switch select system for operating different types of semiconductor diodes 17 and/or with laser diodes. Both semiconductor diodes and/or laser diodes with tuneable wavelengths can be operated, which is a great advantage, and therefore the printed circuit boards can be equipped with a more intensive radiation effect.’” Ex. 1015 (Grove Declaration), ¶229 (citing Ex. 1004 (Larsen), [0074]); Petition, 64. However, Larsen’s disclosure of a “switch select system” and “semiconductor diodes and/or laser diodes with tuneable wavelengths” does not support that Larsen is *individually* tuning the diodes. A POSITA reading Larsen would have understood that *the control mechanism* is controlling *the invented device*, not that the panels are individually configurable to control illumination from each of the five panels. For example, Larsen discloses that “[d]isplay 30 shows

pertinent treatment data, such as current pulse frequency, pulse length, pulse amplitude and pulse modulation. *With 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, 17a and 18, as well as laser 17 diodes with the same realisation as semiconductor diode 17, can be used as light sources. *For that purpose the control mechanism is equipped with a switch select system* for operating different types of semiconductor diodes 17 and/or with laser diodes. Both *semiconductor diodes and/or laser diodes with tuneable wavelengths* can be operated, which is a great advantage, and therefore the printed circuit boards can be equipped with a more intensive radiation effect.” Ex. 1004 (Larsen), [0074], *see also* [0071] (“The light sources 17 are adjustable and can radiate light in at least three wavelengths within the wavelength area 300-2000 nm. ... *The light sources 17a (FIG. 2a) radiate light with a wavelength of 350-500 nm, i.e., blue light.*”) (emphasis added).

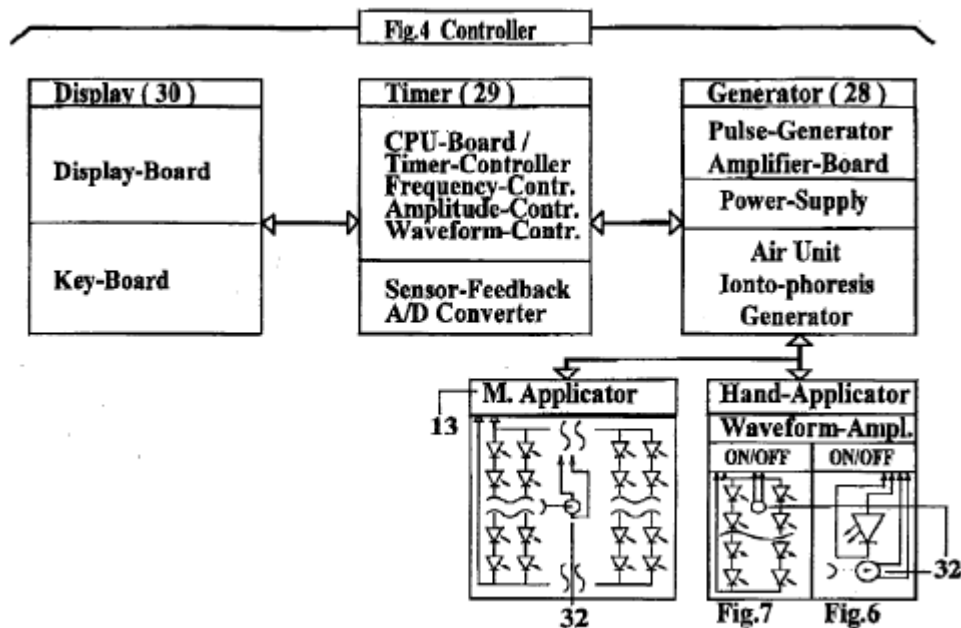
112. Petitioner also argues that “[e]ach of the applicators is connected to a control mechanism 16.” Ex. 1015 (Grove Declaration), ¶229 (citing Ex. 1004 (Larsen), Figs. 1 and 4); Petition, 64. However, in FIG. 1 of Larsen, only one control mechanism 16 for the entire device is shown, not one control mechanism 16 per applicator 13.



Ex. 1004 (Larsen), Fig. 1.

113. This is in contrast to the '028 Patent, which discloses that “each panel may have a dedicated control unit to regulate power to the individual LED array on a given panel.” Ex. 1001 ('028 Patent), 5:57-59.

114. FIG. 4 of Larsen “is a circuit block diagram of *a control unit, which supplies the applicators.*” Ex. 1004 (Larsen), [0043]. Each applicator 13 is supplied by the same control mechanism 16.



Ex. 1004 (Larsen), FIG. 4.

115. Additionally, Larsen consistently refers to “the control mechanism 16” and never to multiple control mechanisms. Ex. 1004 (Larsen), Abstract (“The stand is freely moveable on wheels and includes *a control mechanism* whereby the various parameters for therapy can be adjusted and switched on and off.”), [0027] (“The stand, freely moveable on wheels, consists of *a control mechanism*, on which the desired therapy data can be adjusted and the device can be switched ON and OFF.”), [0030] (“At 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. The applicator contains a polarization filter, which is placed directly in front of the

diodes. *The control mechanism* is also connected with a hand applicator, which is constructed for treatment of small tissue areas, e.g. acupuncture points and trigger points (pain points).”), *see also* [0069], [0073], [0074], [0079] (emphasis added).

116. Petitioner further argues that “each applicator is individually configurable, since each one can be adjusted by the controller based on feedback from its own sensors.” Ex. 1015 (Grove Declaration), ¶230; Petition, 65. In alleged support, Petitioner relies on Larsen’s disclosure that “each applicator includes sensors that ‘measure the amount of energy radiated away from the skin surface, which is indicative of the total energy penetrating into the tissue.’...A ‘sensor 32a is also contained in at least one of the machine applicators, measuring the temperature change of the radiated tissue, whereby the control unit can react with a feedback regulation of the radiation parameters depending on the therapy indication, location and (PDT) light sensitive substance used.” Ex. 1015 (Grove Declaration), ¶230 (citing Ex. 1004 (Larsen), [0079]-[0080], FIGS. 2a-2c); Petition, 65. However, Larsen’s disclosure of sensors 32 in the applicators 13 does not teach that each applicator is adjusted individually based on the feedback received at the sensors. In fact, Larsen teaches that “[a]n 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] (emphasis added). Thus, Larsen does not disclose changing the amount of energy emitted by each applicator 13.

117. Dr. Grove further references “Larsen, ¶285,” “Larsen, ¶286,” and “Larsen, [0286]-[0287].” Ex. 1015 (Grove Declaration), ¶¶228-230. There are no such paragraphs in Larsen.

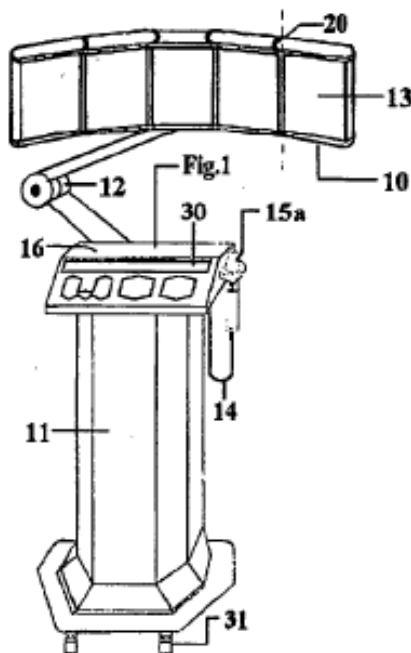
118. Accordingly, Larsen does not disclose “the five panels are individually configurable to control illumination from each of the five panels.”

C. Larsen Does Not Disclose Or Render Obvious “A Mobile Base Supported By At Least Four Wheels”

119. Independent Claim 16 of the ’028 Patent, from which Claims 17 and 19 depend, requires that the system for photodynamically diagnosing or treating a patient comprises “a mobile base supported by *at least four wheels*.”

120. Petitioner and Dr. Grove argue that this limitation is disclosed by Larsen. Ex. 1015 (Grove Declaration), ¶¶213-216; Petition, 58-59. However, Larsen does not disclose “a mobile base supported by *at least four wheels*.”

121. First, Petitioner argues that Fig. 1 of Larsen “discloses a mobile base supported by at least four wheels.” Ex. 1015 (Grove Declaration), ¶213; Petition, 58. However, Larsen does not expressly disclose that the device is “supported by at least four wheels,” because Fig. 1 of Larsen shows only two wheels (see below).



Ex. 1004 (Larsen), Fig. 1. This is confirmed by Petitioner’s own expert, Dr. Bretschneider, who acknowledged that “only two wheels are shown in Fig. 1 of Larsen.” IPR2024-00874, Ex. 1003 (Bretschneider Declaration), ¶109.

122. Petitioner argues that “Larsen teaches that the device is ‘freely moveable on wheels’” and therefore “Larsen *necessarily* discloses that the base has at least four wheels in order to provide stability.” Ex. 1015 (Grove Declaration), ¶214 (citing Ex. 1004 (Larsen), [0027], [0069]); Petition, 58-59 (emphasis added). However, Petitioner only provides conclusory statements and does not show that Larsen *necessarily* discloses that the base has at least four wheels to provide stability and be freely moveable. For example, if Larsen’s device had three wheels, it would not “require a user to tilt the entire system forward to move the system” or “create

an unbalanced system which would significantly impair the ability of a user to move the system,” as Dr. Bretschneider argued. IPR2024-00874, Ex. 1003 (Bretschneider Declaration), ¶265. A POSITA would have understood that the device would still have been stable and freely moveable on *three wheels*. For example, U.S. Patent 4,832,294, which issued May 23, 1989, describes a stand for a medical device with three wheels that “rolls smoothly, easily and stably over irregular surfaces.” Ex. 2006 (US 4,832,294), 2:4-8, 2:20-29, FIG. 1. Thus, the base of Larsen’s device does not *necessarily* have at least four wheels.

123. Petitioner argues that during prosecution of the ’028 Patent the Examiner found in the Larsen ’381 Patent, “it is inherent that there are [at] least two more wheels, for a total of 4, in order for the device to be stable.” Ex. 1015 (Grove Declaration), ¶214 (citing Ex. 1002 (File History of the ’028 Patent), 328 (citing Fig. 1 of Larsen ’381 Patent); Petition, 58-59. However, the Examiner provides no support for her conclusory statement. As discussed above, there were other known possibilities such as a stand for a medical device with *three wheels* that “rolls smoothly, easily and stably over irregular surfaces.” Ex. 2006 (US 4,832,294), 2:4-8, 2:20-29, FIG. 1.

124. Dr. Grove acknowledges that “[i]nherency may not be established by probabilities or possibilities.” Ex. 1015 (Grove Declaration), ¶30. The possibility

that Larsen's device may have four wheels does not establish that Larsen's device *necessarily* has "a mobile base supported by *at least four wheels*."

125. Finally, Petitioner argues that "it would have been obvious to POSITA to use at least four wheels to support the stand/pillar of Larsen, since it was well known that a four-wheeled stand is much more stable than a stand with only three wheels." Ex. 1015 (Grove Declaration), ¶215; Petition, 59. However, Petitioner does not cite to any evidence to support the assertions that "a four-wheeled stand is much more stable than a stand with only three wheels" and four wheels result in "more stability compared to only three wheels." Ex. 1015 (Grove Declaration), ¶215; Petition, 59. Petitioner's argument is conclusory and without support. Moreover, it was known that stands with three wheels provided good stability, as a device with three wheels has each of its wheels in contact with the floor, while a device with four wheels may not have simultaneously each of its wheels in contact with the floor thus creating instability. For example, U.S Patent 4,832,294, which issued May 23, 1989, described a stand for a medical device with three wheels that "rolls smoothly, easily and stably over irregular surfaces." Ex. 2006 (US 4,832,294), 2:4-8, 2:20-29.

126. Accordingly, Larsen does not disclose or render obvious "a mobile base supported by at least four wheels."

D. Petitioner Has Not Shown That A POSITA Would Have Been Motivated To Combine Lundahl With Larsen With A Reasonable Expectation Of Success

127. Petitioner argues that “[a] POSITA would be motivated to combine the teachings of Lundahl and Larsen to incorporate the hinged panel LED displays of Larsen into the PDT device of Lundahl.” Ex. 1015 (Grove Declaration), ¶¶118-137, 178; Petition, 25-34; Ex. 1016 (Ehrenreich Declaration), ¶¶67-74. Specifically, Petitioner argues that a POSITA would have been motivated to: (1) “modify the fixed, curved U-shape of Lundahl” to incorporate Larsen’s solution of “hinged panels,” and (2) “incorporate Larsen’s solution of disposing light sources, specifically LEDs, on the surface of the light applicators to Lundahl’s device.” Petition, 30, 32; Ex. 1015 (Grove Declaration), ¶¶125-127, 129-130. However, Petitioner does not show that a POSITA would have been motivated to combine Lundahl with Larsen in the manner proposed with a reasonable expectation of success for at least the reasons set forth below.

1. Petitioner Has Not Shown That A POSITA Would Have Been Motivated To Modify Lundahl’s Device With Larsen’s Panels Or Would Have Had A Reasonable Expectation Of Success In Doing So

128. Petitioner argues that “[a] POSITA would be motivated to combine the teachings of Lundahl and Larsen to incorporate the hinged panel LED displays of Larsen into the PDT device of Lundahl,” and that a POSITA “motivated to increase

the flexibility of the device” would have understood that “the easiest way to modify the fixed, curved U-shape of Lundahl would be to incorporate hinged panels that could be individually adjusted to account for variations in head shape/size or other anatomy selected for treatment.” Ex. 1015 (Grove Declaration), ¶¶118-128; Petition, 25-31; Ex. 1016 (Ehrenreich Declaration), ¶¶67-74. However, Petitioner fails to show that a POSITA would have been motivated to modify Lundahl’s device to incorporate Larsen’s panels, or that a POSITA would have been motivated to modify Lundahl’s device to comprise “*five panels*” as required by the Challenged Claims as explained below.

129. **First**, Petitioner fails to explain why a POSITA would have been motivated to combine Lundahl’s device with Larsen’s panels when Lundahl’s U-shaped device was already optimized to provide the desired irradiance and irradiance uniformity. For example, Lundahl states that “[t]he U-shape 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.” Ex. 1014 (Lundahl), 6:31-33. In addition, Lundahl states that “the ‘U’ shape *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), 6:39-45. In fact, Lundahl reports that when using its optimized U-shaped fluorescent tube system, “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. 1014 (Lundahl), 15:22-27.

130. Petitioner argues that Larsen's teachings would have motivated a POSITA to "incorporate Larsen's solution" "to provide the desired irradiance and irradiance uniformity to all target areas during PDT." Ex. 1015 (Grove Declaration), ¶127; Petition, 30. But, this precise solution was already taught by Lundahl, which discloses that its "U" shape *"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), 6:39-45.

131. Petitioner also argues that the "inflexibility of the fixed U-shape of Lundahl" "would not allow for proper treatment of other parts of the anatomy requiring AK treatment including the arms, back, chest, and hands," and "a POSITA would have been motivated to find solutions." Ex. 1015 (Grove Declaration), ¶¶122-126; Ex. 1016 (Ehrenreich Declaration), ¶¶42-43, 72; Petition, 28-30. However, Lundahl discloses that "the present invention is also directed to . . . other areas of the patient (e.g., arms, legs, etc.)." Ex. 1014 (Lundahl), 1:14-17.

132. **Second**, a POSITA would have been discouraged from incorporating Larsen's five panels into Lundahl's U-shaped device because a POSITA would have

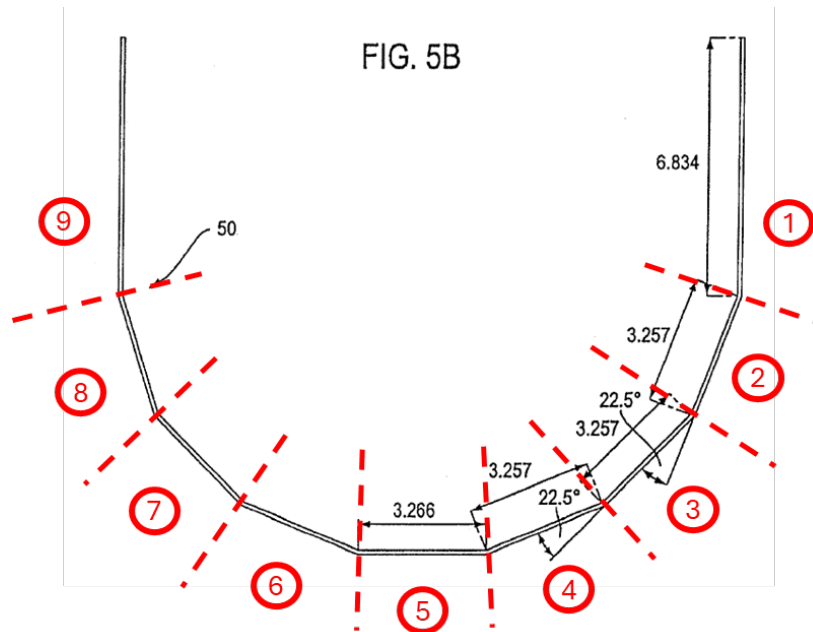
understood that such modification would have created unwanted corners and gaps between the panels that would not deliver a uniform light dose. In fact, Lundahl criticizes the “problem” of “flat emitting surface[s]” that “would not deliver a uniform light dose to all contours of the face simultaneously because the non-planar facial and scalp surfaces could not be placed at a constant distance from the emitting surface.” Ex. 1014 (Lundahl), 4:28-34. Instead, Lundahl teaches that to “ameliorate this problem, the present invention uses a U-shaped emitting surface that more closely follows the contours of the human face and scalp, and minimizes lamp to target distance variations which in turn minimizes irradiance variations at the target.” Ex. 1014 (Lundahl), 4:33-38.

133. Petitioner argues that incorporating Larsen’s applicators would “permit[] an even and gap-free radiation of the surface.” Petition 41-42; Ex. 1015 (Grove Declaration), ¶164. But, Petitioner ignores that Larsen’s purported “gap-free” radiation is achieved only by a scan engine which “move[s] the light sources with linear movements.” Ex. 1004 (Larsen), [0072] (“[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*, whereby a correctly adjusted scan length and frequency gives the radiated surface a total radiation at the necessary wavelengths without leaving any unradiated gaps”). Petitioner does not explain how or why a POSITA would have combined Lundahl’s PDT device that

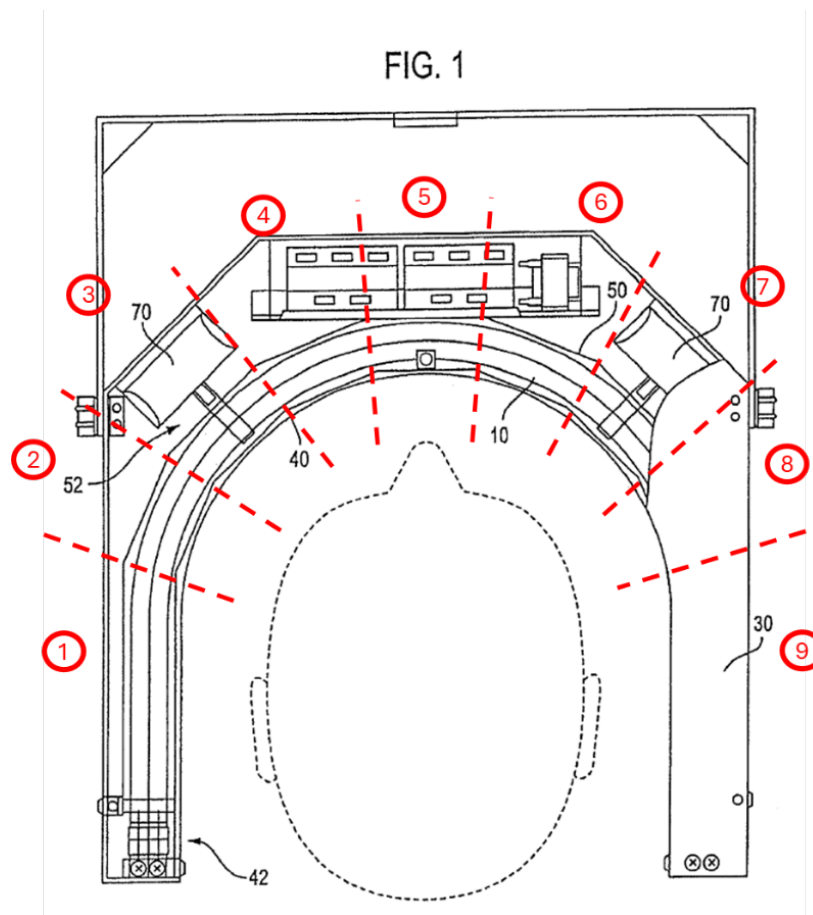
controls the light sources at *stationary positions* with Larsen’s scan engine that controls the light sources with *linear movements*. Compare Ex. 1014 (Lundahl), FIG. 1, 5:34-35 (“FIG. 1 shows the position of the patient’s head and nose); Ex. 1015 (Grove Declaration), ¶219 (citing Lundahl’s control system for Claim 16(c)) with Ex. 1004 (Larsen), [0072] (“electrical scan engine 66, which can move the light sources with linear movements”); Ex. 1015 (Grove Declaration), ¶235 (citing Larsen’s scan engine for Claim 16(i)). Petitioner fails to reconcile Lundahl’s and Larsen’s fundamentally different modes of operation or explain how the alleged combination would have uniformly illuminated a treatment surface, as required by the claims.

134. **Third**, Petitioner does not explain why a POSITA would have been motivated to incorporate *five* panels, as required by all Challenged Claims. Petitioner would not have been motivated to modify Lundahl’s U-shaped fluorescent tube device to incorporate *five* panels absent hindsight.

135. In fact, a POSITA reading Lundahl’s disclosure would have been discouraged from incorporating *five* panels. As shown in FIG. 5B and FIG.1, Lundahl’s reflector 50 that conforms to the configuration of the tubes has *nine* segments—*not five*—with each segment starting at a bend in the reflector as shown below:



Ex. 1014 (Lundahl), FIG. 5B (annotated).



Ex. 1014 (Lundahl), FIG. 1 (annotated). Lundahl teaches that reflector 50 (with nine segments) “*is bent to approximately conform to the configuration of the tubes,*” and “*increases both the output irradiance and the uniformity of the output distribution.*”

Ex. 1014 (Lundahl), 8:62-67, 5:30-32. Thus, a POSITA properly reading Lundahl as a whole would have been led away from modifying Lundahl to incorporate *five* panels (as opposed to *nine*).

136. Lundahl teaches that its U-shaped device with reflectors bent to approximately conform to the configuration of the tubes was optimized to “minimize[] 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 “provide[] the desired irradiance and irradiance uniformity for scalp and facial irradiation, and thus ensure[] that the proper visible light dosage is applied to all target areas during PDT.” Ex. 1014 (Lundahl), 6:31-35, 6:39-42. As discussed above, a POSITA would have recognized that modifying Lundahl’s device to incorporate *five* panels would no longer “provide the desired irradiance and irradiance uniformity to all target areas during PDT,” which Petitioner alleges as purported motivation to combine (Ex. 1015 (Grove Declaration), ¶127; Petition, 30).

137. Furthermore, Petitioner fails to show that a POSITA would have had a reasonable expectation of success in combining Lundahl’s device with Larsen’s panels to arrive at the claimed invention. Dr. Grove argues 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." Ex. 1015 (Grove Declaration), ¶128; Petition, 31. However, Dr. Grove's single conclusory statement is without support. He provides no evidence as to how or why a POSITA would have reasonably expected that modifying Lundahl's device with Larsen's five panels would have uniformly illuminated the treatment surface of a patient, as required by the claims. As discussed above, incorporating five panels into Lundahl's device would have created gaps where light is not emitted between the panels. With gaps between panels, a POSITA would not have reasonably expected success, for example, that the combined device would uniformly illuminate the treatment surface of a patient.

2. Petitioner Has Not Shown That A POSITA Would Have Been Motivated To Modify Lundahl's Device To Incorporate Larsen's LEDs Or Would Have Had A Reasonable Expectation Of Success In Doing So

138. Petitioner argues that "[a] POSITA was also motivated to modify Lundahl to incorporate LEDs as taught by Larsen rather than the fluorescent tubes." Ex. 1015 (Grove Declaration), ¶¶129-131; Petition, 31-32. However, Petitioner has not shown that a POSITA would have been motivated to modify Lundahl's device to incorporate LEDs as taught by Larsen with a reasonable expectation of success, for at least the following reasons.

139. **First**, Petitioner argues that a POSITA would have been “motivated to modify Lundahl to incorporate LEDs *as taught by Larsen* rather than the fluorescent tubes.” Ex. 1015 (Grove Declaration), ¶¶129-131; Petition, 31-32. But, Petitioner does not modify Lundahl’s device to incorporate LEDs “*as taught by Larsen*.” Instead, Petitioner cherry-picks Larsen’s LEDs, while ignoring Larsen’s teachings that the LEDs are “placed in regular row arrangements, i.e., 20 equidistant from each other.” Ex. 1004 (Larsen), [0071] (“the light sources 17 are placed in regular row arrangements, i.e., 20 equidistant from each other”); FIGS. 2a-2c; [0072] (“[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, whereby a correctly adjusted scan length and frequency gives the radiated surface a total radiation at the necessary wavelengths without leaving any unradiated gaps”). Petitioner cannot ignore the teachings of Larsen as a whole, while arguing at the same time that a “POSITA would have understood that Larsen’s applicator is configured to uniformly illuminate a treatment surface of the patient.” Ex. 1015 (Grove Declaration), ¶164; Petition, 41-42.

140. Additionally, Petitioner fails to explain why a POSITA would have abandoned fluorescent tubes, when Larsen teaches to use fluorescent tubes for PD and PDT. Ex. 1004 (Larsen), [0102], (“a standard UV light tube, and in between, the flattened oval tubes containing the light sources for the photodynamic therapy

(PDT)”), [0071] (“According to FIGS. 2*b* and 2*c* the light sources 17 are placed in regular row arrangements, i.e., 20 equidistant from each other, whereby, according to FIG. 2*c*, one applicator 13, in addition to the diodes 17 *has a light source 19.*”), [0071] (“The *light source 19 formed as a tube* can be selected for radiating blue light or fluorescent light within the wavelength area of 300-450 nm for photodiagnostics (PD)”), [0111] (“...photodynamic diagnostics (PD) may be employed to determine absorption. PD comprises viewing the target area under illumination of a particular spectral content (such as from a fluorescent light) and observing apparent colour change of the target tissue”), [0029] (“A diagnostic system (PD) containing a fluorescent light source and optics for photodiagnosis during the treatment is also included in the applicator.”), FIG. 2*c*.

141. **Second**, Petitioner proposes modifying Lundahl’s PDT device with Larsen’s LEDs without explaining how or why a POSITA would have expected the combined Lundahl/Larsen system to work. Lundahl’s fluorescent tube system and Larsen’s LED system are fundamentally different designs. For example, Petitioner relies on Lundahl’s PDT device and control system, which “controls the ballast voltage (and tube output).” Ex. 1015 (Grove Declaration), ¶219 (citing Ex. 1014 (Lundahl), 11:19-29 (“Lundahl teaches that ‘[a]ccording to a preferred embodiment of the present invention, an electronic *control system 110* consists of six functional blocks. A microcontroller 200 is the central processing unit; it contains firmware

which reads the system sensors, determines the system status, *controls the ballast voltage (and tube output)*"); Petition, 60. But, Petitioner fails to explain how Lundahl's control system that supplies the voltage for the ballasts could work with Larsen's LEDs. Lundahl discloses that the control system that supplies the voltage for the ballasts that drive the fluorescent tubes produces a high voltage. Ex. 1014 (Lundahl), 5:58-61 ("[a]pplication of a *sufficiently high voltage potential* across the cathodes causes the emission of electrons from the cathode, which diffuse along the length of the tube and ionize the argon/mercury vapor."), 8:46-54 ("ballasts convert *120 VAC line voltage*"). In contrast, LEDs require a low-voltage input to prevent damage. Ex. 2011 (Bourget), 1944 ("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*"). A POSITA would have been discouraged from combining Lundahl's device and control system with Larsen's LEDs as proposed by Petitioner because a POSITA would have been concerned that the 120 V voltage supplied by the control system to the ballasts would damage or destroy the LEDs. Ex. 2011 (Bourget), 1944-45.

142. Furthermore, Petitioner has not shown that a POSITA would have had a reasonable expectation of success in combining Lundahl's device with Larsen's LEDs to arrive at the claimed invention. Dr. Grove argues that a "POSITA would

have had a reasonable expectation of success in combining Lundahl with Larsen, because both references describe similar illuminators and the conversion from fluorescent tubes to LEDs was a routine practice prior to 2015.” Ex. 1015 (Grove Declaration), ¶131; Petition, 32. However, Dr. Grove’s single conclusory statement is without support. For example, he provides no evidence that the thermal rejection, power supply, control, and optical subsystem for LEDs was routine. In fact, Bourget reported that LEDs “cannot simply be purchased, wired up, and turned on if a high performance level is expected. Careful thought must be placed into the design of the thermal rejection, power supply, control, and optical subsystems of any LED lighting system.” Ex. 2011 (Bourget), 1945. In addition, Dr. Grove provides no evidence as to how or why a POSITA would have reasonably expected that the combination of Lundahl’s fluorescent tube system with Larsen’s LEDs as proposed by Petitioner would have uniformly illuminated the treatment surface of a patient, as required by the claims.

143. In analyzing Petitioner’s alleged motivations, I also considered the declaration of Petitioner’s dermatologist, Dr. Ehrenreich, regarding the commercial BLU-U device (Ex. 1016), and Dr. Roberts’ declaration in response (Ex. 2015). As an initial matter, Petitioner and Dr. Ehrenreich do not show that the commercial BLU-U device practices the Lundahl patent at issue in Petitioner’s Grounds. Dr. Ehrenreich argues that the “BLU-U shape,” which is described in Lundahl, “makes

it hard to treat, hands, arms, and necks and upper chests.” Ex. 1016 (Ehrenreich Declaration), ¶¶42-43, 72. However, Dr. Ehrenreich does not address Lundahl’s actual teaching that the invention is “directed to . . . other areas of the patient (e.g., arms, legs, etc.),” as discussed above. Ex. 1014 (Lundahl), 1:14-17. In any event, I note that Dr. Roberts explains that the BLU-U has been used effectively on the arms, legs, chest, and back of patients. Ex. 2015 (Roberts Declaration), ¶¶28-45. Dr. Ehrenreich also argues that “his own experience provides motivation to make modifications” to BLU-U and Lundahl. Ex. 1016 (Ehrenreich Declaration), ¶¶42-45, 67-74. However, Dr. Ehrenreich does not explain what those modifications would be. He also does not explain how or why a POSITA would have combined the cited references with a reasonable expectation of success absent hindsight. In fact, regarding alleged “modifications,” Dr. Ehrenreich simply defers to “an *engineer* with qualifications for designing medical treatment lamps.” Ex. 1016 (Ehrenreich Declaration), ¶¶73-74.

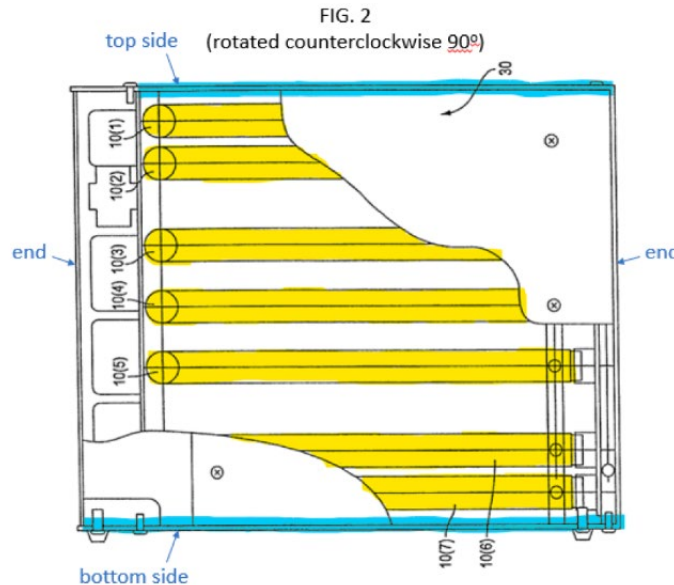
144. In sum, Petitioner does not show that a POSITA would have been motivated to combine Lundahl with Larsen in the manner proposed with a reasonable expectation of success.

E. Lundahl In View Of Larsen Does Not 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”

145. Independent Claims 1, 5, 16, 20 and 21, from which all other Claims depend, require “*wherein each of the 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.*”

146. 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), ¶¶175-181, 204-205, 238, 254-255, 264-265; Petition, 46-49, 56, 67, 71, 73. However, Lundahl does not disclose or render obvious this limitation in combination with Larsen for the reasons set forth below.

147. **First**, Petitioner rotates Lundahl FIG. 2 on its side and labels in blue color a “top side,” a “bottom side,” and an “end”:

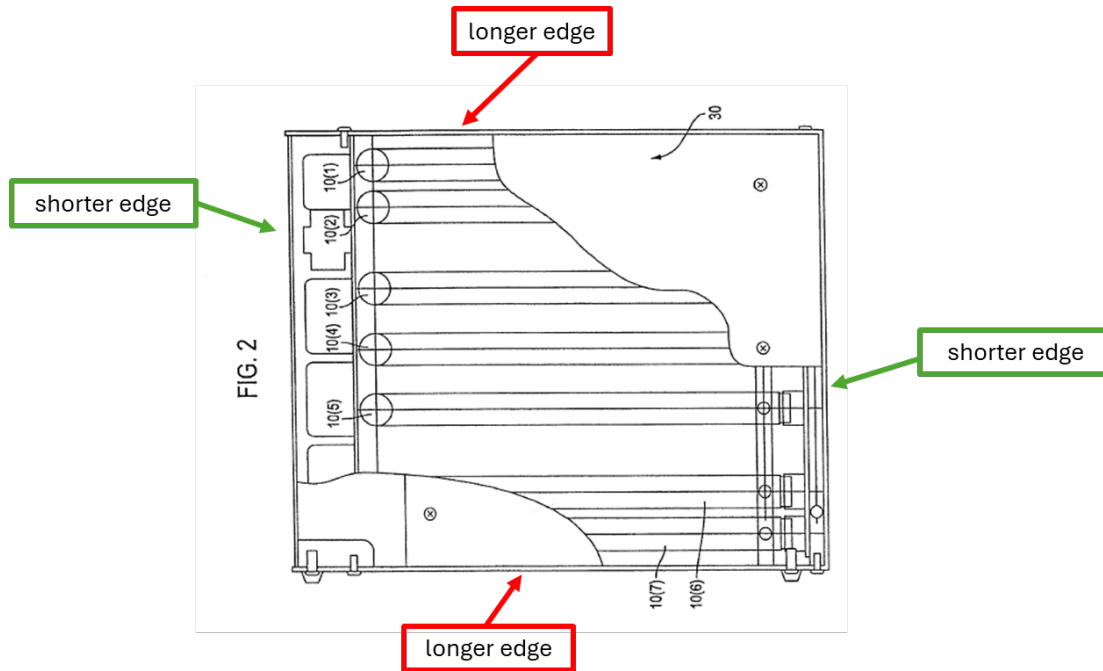


Ex. 1015 (Grove Declaration), ¶175; Petition, 46-47. Based on this depiction of FIG. 2, Petitioner argues that “POSITA would have understood that the tubes of Lundahl are spaced to emit a higher intensity of light proximate the top and bottom sides compared to the intensity of light emitted not proximate the top and bottom sides.”

Ex. 1015 (Grove Declaration), ¶176; Petition, 47-48.

148. 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 edges labeled “end” are the *shorter* edges. When read as a whole, the claim limitation 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*. Lundahl’s disclosure does not meet the claim requirements because the “top

side” and “bottom side” that Petitioner alleges emit a higher intensity of light are the *longer edges*, not the *shorter edges* required by the claims as shown below:

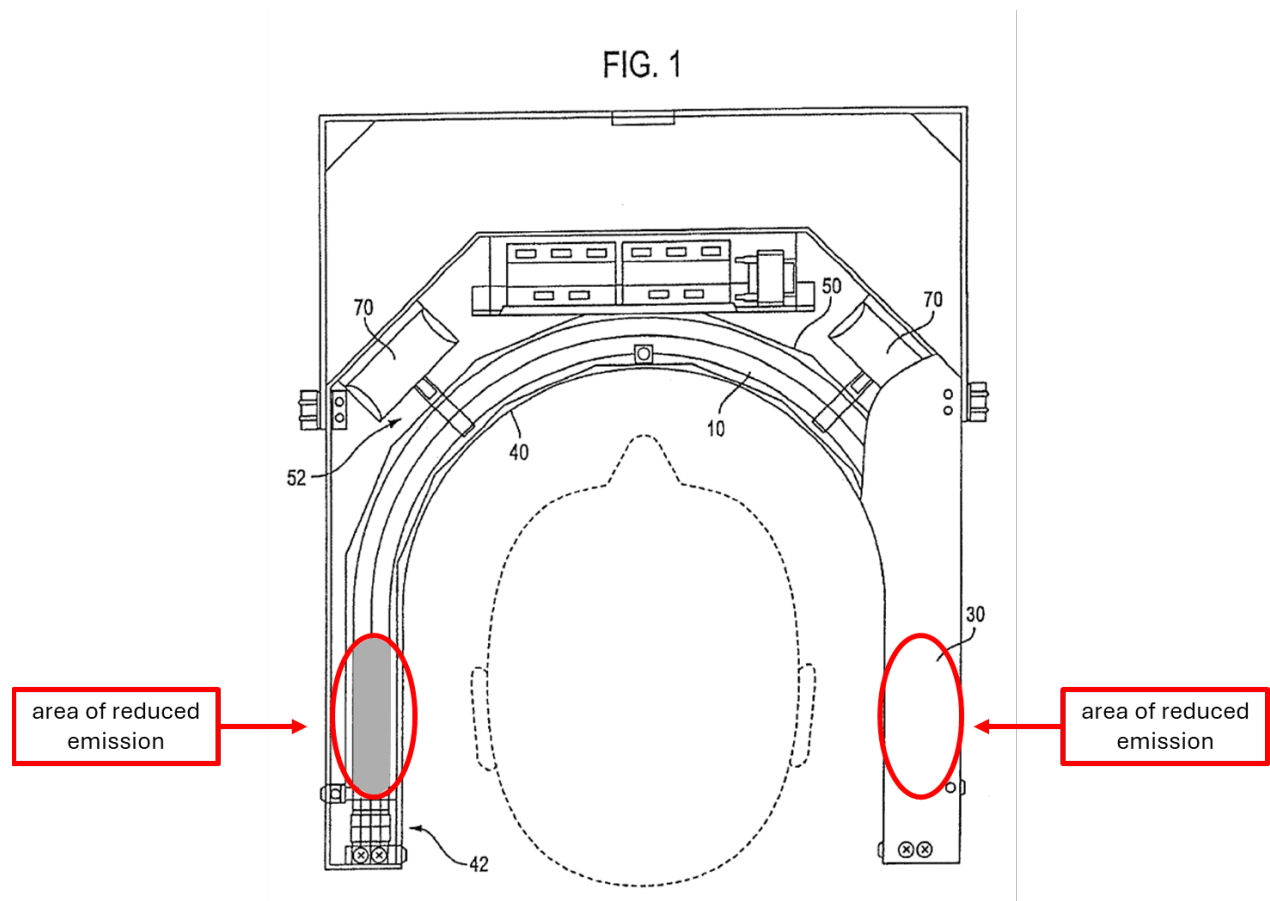


Ex. 1014 (Lundahl), FIG. 2 (annotated); *see also* FIG. 1. Lundahl discloses that “[t]he overall dimensions of the unit are approximately 38 cm H×45 cm W×44.5 cm D,” indicating that the *top and bottom edges are longer than the left and right edges*. Ex. 1014 (Lundahl), 5:31-33. Additionally, Lundahl 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 46 cm wide* (approximately 2850 cm²), with a *minimum therapeutically active area 30 cm high by 46 cm wide* (approximately 1350 cm².” Ex. 1014 (Lundahl), 5:38-43. Therefore, the *top and bottom sides* are the *longer edges* with a length of 46 cm and the *sides* are the *shorter edges* with a

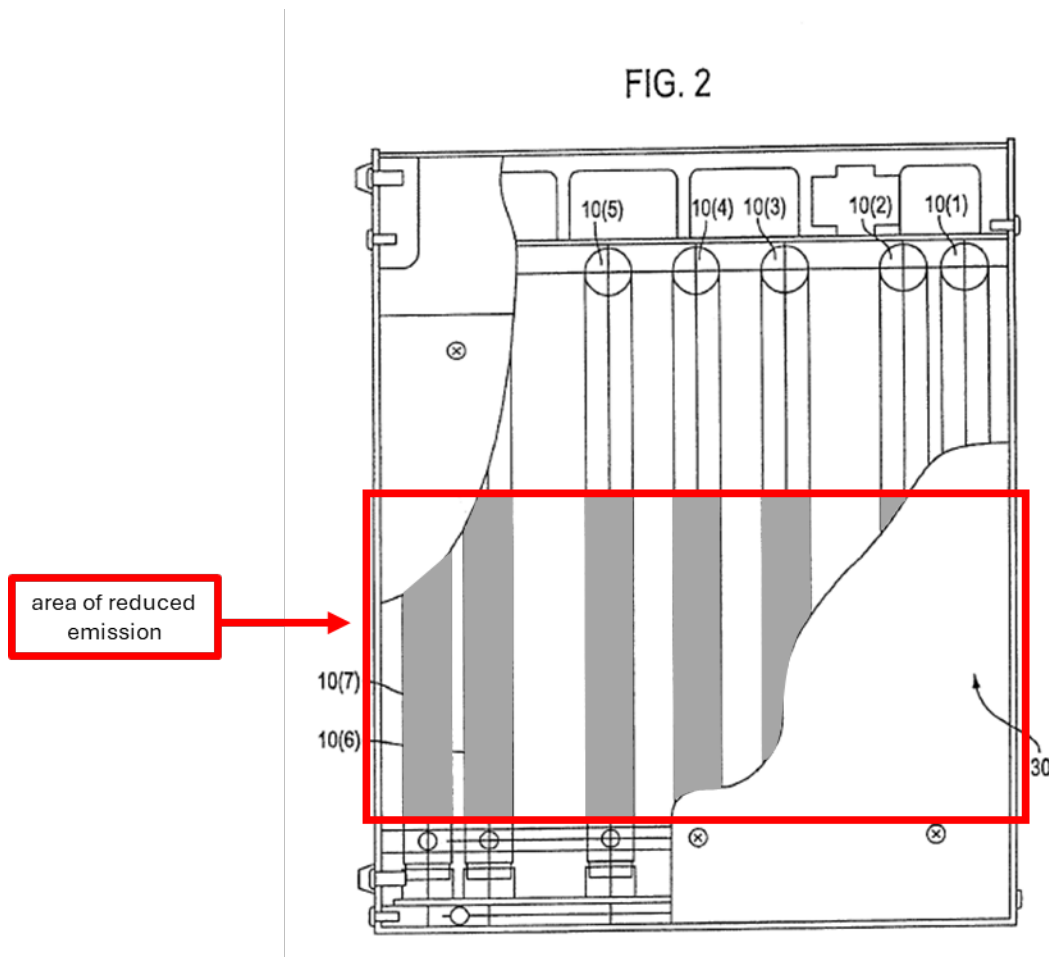
height of 30 cm. Thus, Lundahl's disclosure relied on by Petitioner (Ex. 1015 (Grove Declaration), ¶¶175-176) does not meet the claim requirements because the "top side" and "bottom side" that Petitioner alleges emit a higher intensity of light are the *longer edges*, not the *shorter second edges* required by the claims.

149. **Second**, Petitioner has not shown that modifying Lundahl's device to incorporate 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.*" Petitioner 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), ¶¶178-179, Petition, 49. However, Petitioner has not shown that the alleged resulting device would meet the claim limitation. Petitioner relies on Lundahl's "light distribution" while ignoring Lundahl's teachings as a whole. Dr. Grove's depiction that allegedly results by combining Lundahl's "PDT device and light distribution" with Larsen's LEDs 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 occurs because ionized gas in the area near the cathode does not emit as much UV to excite the

phosphor. 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), 6:18-22. Dr. Grove ignores Lundahl’s express teaching of “area[s] of reduced emission,” as shown 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), ¶129; Petition, 31.

150. Dr. Grove does not read the claim limitation as a whole, which requires that “each of the 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.” Dr. Grove’s depiction of the alleged

“resulting device” contradicts Lundahl’s teaching that the “arrangement” of light sources has “low output areas” and “areas of reduced emission.” Ex. 1015 (Grove Declaration), ¶178; Ex. 1014 (Lundahl), 6:10-21. Dr. Grove argues that the alleged “resulting device,” “while 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 Larson [*sic*] compared to regions not proximate to the second edges.” Ex. 1015 (Grove Declaration), ¶179. However, a POSITA applying Lundahl’s teachings of “light distribution” would have understood that some of the panels of the alleged “resulting device” (Ex. 1015 (Grove Declaration), ¶178) would have had “*area[s] of reduced emission*” as shown in FIG. 1 and FIG. 2 above. The light emitted proximate the second edges of each panel would *not* be a higher intensity than the light emitted not proximate the second edges, because of the “low output areas” on at least the outer panels. Thus, even if a POSITA would have combined “the PDT device and light distribution of Lundahl” with Larsen’s panels of LEDs, Petitioner has not shown that the “resulting device” would render obvious the claim limitation, requiring “each of the 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.”

151. Accordingly, Petitioner has not shown that Lundahl in view of Larsen renders obvious “*wherein each of the 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.*”

XIII. GROUND II: THE CHALLENGED CLAIMS ARE NOT RENDERED OBVIOUS BY THE COMBINATION OF LUNDAHL, LARSEN, AND BANSAL

152. Petitioner asserts in Ground II that the Challenged Claims are obvious over Lundahl in view of Larsen and in further view of Bansal (the challenged independent claims are bolded in the chart below).

Ground	Claims	Theory	References
II	1 , 2, 4, 5 , 6, 16 , 17, 19, 20 , 21	Obviousness	Lundahl, Larsen, Bansal

153. For at least the reasons set forth below in Sections A-E, Petitioner does not show that the combination of Lundahl, Larsen, and Bansal would render obvious the Challenged Claims.

A. Larsen Does Not Disclose Or Render Obvious “Hinged Structures On Inner Side Surfaces Of Adjacent Panels”

154. Independent Claims 1, 5, 20 and 21 of the '028 Patent, from which Claims 2, 4, and 6 depend, require an “illuminator comprising five panels connected by *hinged structures on inner side surfaces of adjacent panels.*”

155. Petitioner incorporates by reference Ground 1, arguing only that this limitation is “taught for the same reasons provided in Ground 1.” Ex. 1015 (Grove Declaration), ¶¶266, 277; Petition, 73, 77.

156. Accordingly, I incorporate herein by reference my previous analysis for Ground 1, and for the same reasons set forth in Section XII.A above, Larsen does not disclose or render obvious an “illuminator comprising five panels connected by hinged structures on inner side surfaces of adjacent panels” under Ground 2.

B. Larsen Does Not Disclose That “The Five Panels Are Individually Configurable To Control Illumination From Each Of The Five Panels”

157. Independent Claims 16 and 21 of the '028 Patent, from which Challenged Claims 17 and 19 depend, require that “*the five panels are individually configurable to control illumination from each of the five panels.*”

158. Petitioner incorporates by reference Ground 1, arguing only that this limitation is “taught for the same reasons provided in Ground 1.” Ex. 1015 (Grove Declaration), ¶¶266, 277; Petition, 73, 77.

159. Accordingly, I incorporate herein by reference my previous analysis for Ground 1, and for the same reasons set forth in Section XII.B above, Larsen does not disclose or render obvious “the five panels are individually configurable to control illumination from each of the five panels” under Ground 2.

C. Larsen Does Not Disclose Or Render Obvious “A Mobile Base Supported By At Least Four Wheels”

160. Independent Claim 16 of the '028 Patent, from which Claims 17 and 19 depend, requires that the system for photodynamically diagnosing or treating a patient comprises “a mobile base supported by *at least four wheels*.”

161. Petitioner incorporates by reference Ground 1, arguing only that this limitation is “taught for the same reasons provided in Ground 1.” Ex. 1015 (Grove Declaration), ¶¶266, 277; Petition, 73, 77.

162. Accordingly, I incorporate herein by reference my previous analysis for Ground 1, and for the same reasons set forth in Section XII.C, Larsen does not disclose or render obvious “a mobile base supported by at least four wheels” under Ground 2.

D. Petitioner Has Not Shown That A POSITA Would Have Been Motivated To Combine Lundahl, Larsen, And Bansal With A Reasonable Expectation Of Success

163. Petitioner argues that a “POSITA would have been motivated with a reasonable expectation of success to incorporate the non-uniform light arrangement of Bansal into the combination of Lundahl and Larsen.” Ex. 1015 (Grove Declaration), ¶¶138-145, 268-269; Petition, 73-74. However, Petitioner does not show that a POSITA would have been motivated to combine Lundahl, Larsen, and Bansal, or that a POSITA would have reasonably expected success in doing so.

164. For at least the same reasons explained above in Section XII.D, a POSITA would not have been motivated to combine Lundahl and Larsen with a reasonable expectation of success. Petitioner fails to show that a POSITA would have been motivated to modify Lundahl's device to comprise "*five* panels," as required by the Challenged Claims, and fails to show how or why a POSITA would have been motivated to modify Lundahl's U-shaped device to incorporate Larsen's panels. In addition, Petitioner does not modify Lundahl's device to allegedly incorporate LEDs "as taught by Larsen," and POSITA would have been discouraged from combining Lundahl's device and control system with Larsen's LEDs because a POSITA would have been concerned that the 120 V voltage supplied by the control system to the ballasts would damage or destroy the LEDs.

165. Additionally, Petitioner argues that Bansal further supports the motivation to "uniformly illuminate a treatment surface of the patient" in light of its teachings to "allow[] for a more uniform and precise phototherapeutic light exposure' and 'to achieve the goal of even exposure to the subject's skin.'" Ex. 1015 (Grove Declaration), ¶¶138-145, 268-269 (citing Ex. 1005 (Bansal), [0010], [0025]); Petition, 73-74. However, Petitioner fails to show that a POSITA would have been motivated to combine Lundahl, Larsen, and Bansal, or how the combined Lundahl/Larsen/Bansal system could work.

166. **First**, Lundahl’s fluorescent tube system and Bansal’s LED system are fundamentally different designs. Bansal’s system has a “plurality of light sources, such as semiconductor light sources, LEDs 42.” Ex. 1005 (Bansal), [0025]. A POSITA would have been discouraged from combining Lundahl’s device and control system with Bansal’s LEDs, because a POSITA would have been concerned that the 120 V voltage supplied by the control system to the ballasts would damage or destroy the LEDs. *See* Section XII.D.2 above.

167. **Second**, Petitioner fails to reconcile the differences between Lundahl, Larsen, and Bansal. For example, as explained above in Section XII.D.1, Petitioner does not explain how or why a POSITA would have combined Lundahl’s device using control system 110 that controls the light sources at *stationary* positions with Larsen’s scan engine which “move[s] the light sources with *linear movements*.” Ex. 1004 (Larsen), [0072] (“[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*, whereby a correctly adjusted scan length and frequency gives the radiated surface a total radiation at the necessary wavelengths without leaving any unradiated gaps”). Unlike Larsen’s LEDs that require “linear movements,” Bansal’s array of LEDs and light diffusing panel are “*center[ed] ... over the subject*” during treatment. Ex. 1005 (Bansal), [0030], [0035], FIG. 2. Petitioner does not explain how or why a POSITA would have combined

Lundahl's control system 110 that controls the light sources at *stationary* positions with Larsen's scan engine that "move[s] the light sources with *linear movements*," and further with Bansal's LEDs and diffusing panel that are "*center[ed]...over the subject*" during treatment. Petitioner fails to reconcile Lundahl's, Larsen's, and Bansal's fundamentally different modes of operation or explain how when combined they could uniformly illuminate a treatment surface, as required by the claims.

168. In addition, Bansal teaches that: "[f]or instance, it has been found that a 10 inches by 20 inches array of approximately 750 blue LEDs *suspended 12 inches above a subject* can produce sufficient intensity." Ex. 1005 (Bansal), [0007]. Petitioner does not reconcile Bansal's teaching of *LEDs* at a distance of *12 inches* with Lundahl's teaching of *fluorescent tubes* at a distance of *2 and 4 inches*, relied on by Petitioner. Ex. 1015 (Grove Declaration), ¶171 (citing Ex. 1014 (Lundahl), 15:22-27); Petition 45. Again, Petitioner cherry-picks the LEDs from Bansal, while ignoring the teachings of the references as a whole, and fails to explain how the combined device would allow treatment within approximately four inches of the treatment surface, as required by the claims.

169. Furthermore, Petitioner has not shown that a POSITA would have had a reasonable expectation of success in combining Lundahl's device with Larsen and further with Bansal's LEDs to arrive at the claimed invention. Dr. Grove argues that a POSITA would have had a reasonable expectation of success in combining the

references because “all three references describe similar illuminators for using light to treat conditions on a patient’s skin.” Ex. 1015 (Grove Declaration), ¶269; Petition, 74. However, Dr. Grove does not provide any evidence for his conclusory statement. Moreover, Dr. Grove provides no evidence for his conclusory statement that “the conversion from fluorescent tubes to LEDs was a routine practice prior to 2015.” Ex. 1015 (Grove Declaration), ¶131. As explained above in Section XII.D.2, a POSITA would have understood that LEDs “cannot simply be purchased, wired up, and turned on if a high performance level is expected. Careful thought must be placed into the design of the thermal rejection, power supply, control, and optical subsystems of any LED lighting system.” Ex. 2011 (Bourget), 1945.

170. In sum, Petitioner does not show that a POSITA would have been motivated to combine Lundahl with Larsen and further with Bansal in the manner proposed with a reasonable expectation of success.

E. Lundahl In View Of Larsen And Further In View of Bansal Does Not 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”

171. Independent Claims 1, 5, 16, 20 and 21, from which all other Challenged Claims depend, require “*wherein each of the 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.”

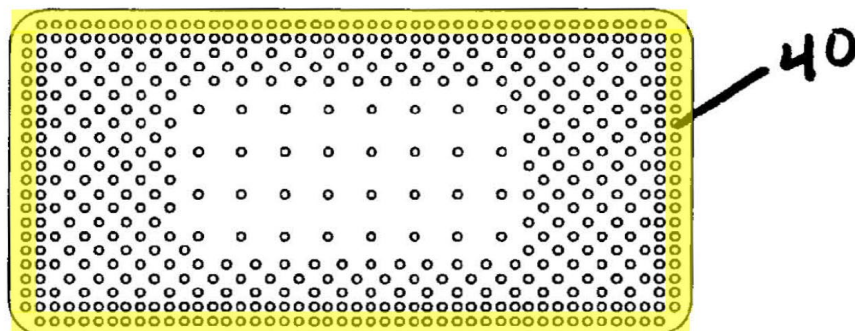
172. Petitioner argues that “Bansal[’s] teachings are in addition to what Lundahl and Larsen already teaches as discussed in Ground 1.” Ex. 1015 (Grove Declaration), ¶271; Petition, 75. Petitioner relies on Bansal for its purported disclosure of “*the light sources are arranged such that a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges.*” Ex. 1015 (Grove Declaration), ¶¶271-275; Petition, 75-77. However, Lundahl in view of Larsen, and further in view of Bansal does not render obvious this limitation.

173. In alleged support of this limitation, Petitioner relies on Bansal’s teaching of “varying ‘the density of light source distribution . . . throughout the array, ***such as with higher density in the periphery and a lower density in the center.***” Ex. 1015 (Grove Declaration), ¶272 (emphasis added by Petitioner); Petition, 75-76. Petitioner further relies on claim 10 of Bansal, which recites “[t]he phototherapy device according to claim 9, wherein said array has a *peripheral area with a first density of light sources*, and a *central area with a second density of light sources*, and wherein the light sources are distributed so that said first density is higher than said second density.” Ex. 1015 (Grove Declaration), ¶272 (emphasis added); Petition, 75-76.

174. However, none of Bansal’s disclosures teach “*wherein each of the 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.*” When read as a whole, the claim limitation 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*, including at least light emitted proximate the longer first edges.

175. Bansal does not meet the claim requirements because it discloses that the intensity of light emitted *proximate both the second edges and the first edges* (e.g., shown in yellow below) is higher than the intensity of light emitted *in the center* of the array. See Ex. 1015 (Grove Declaration), ¶272-273 (citing Ex. 1005 (Bansal), [0025] (“higher density in the periphery and a lower density in the center”; “lower power in the center and a higher power on the outer edges”), claim 10, Fig. 9b; Petition, 75-77.

Fig. 9b



Ex. 1005 (Bansal), Fig. 9b (annotated).

176. Petitioner fails to account for the requirement of each of the '028 Patent claims that the intensity of light emitted proximate the shorter second edges must be higher than the intensity of light emitted not proximate the second edges, which includes at least light emitted proximate the first edges. Petitioner states that “Figure 9b of Bansal shows one embodiment where more light sources are placed near the edges of the panel compared to the light sources in the center.” Ex. 1015 (Grove Declaration), ¶272; Petition, 76. But, Bansal discloses higher intensity (or density) of lights *around all edges* of the panel,” as Petitioner acknowledged. IPR2024-00874, Ex. 1003 (Bretschneider Declaration), ¶154 (“Bansal’s solution provides higher intensity (or density) of lights *around all edges* of the panel”) (emphasis added); IPR2024-00874, Petition, 18 (“Second, Larsen’s scan engine is configured to only move the lights along a single axis, while Bansal’s solution provides higher intensity (or density) of lights *around all edges* of the panel.”) (emphasis added). Bansal’s disclosure of a higher intensity (or density) of lights *around all edges* of the panel does not disclose “*a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges.*”

177. Petitioner ignores the clear distinction in the specification and claims of '028 Patent between the second edges and first edges of the panels. For example,

the specification discloses in Fig. 5 that “areas 1 and 2” proximate the second edges (shown in red) “emit a higher intensity of light than areas 3 and 4” proximate the first edges (shown in yellow). Ex. 1001 ('028 Patent), 6:33-38.

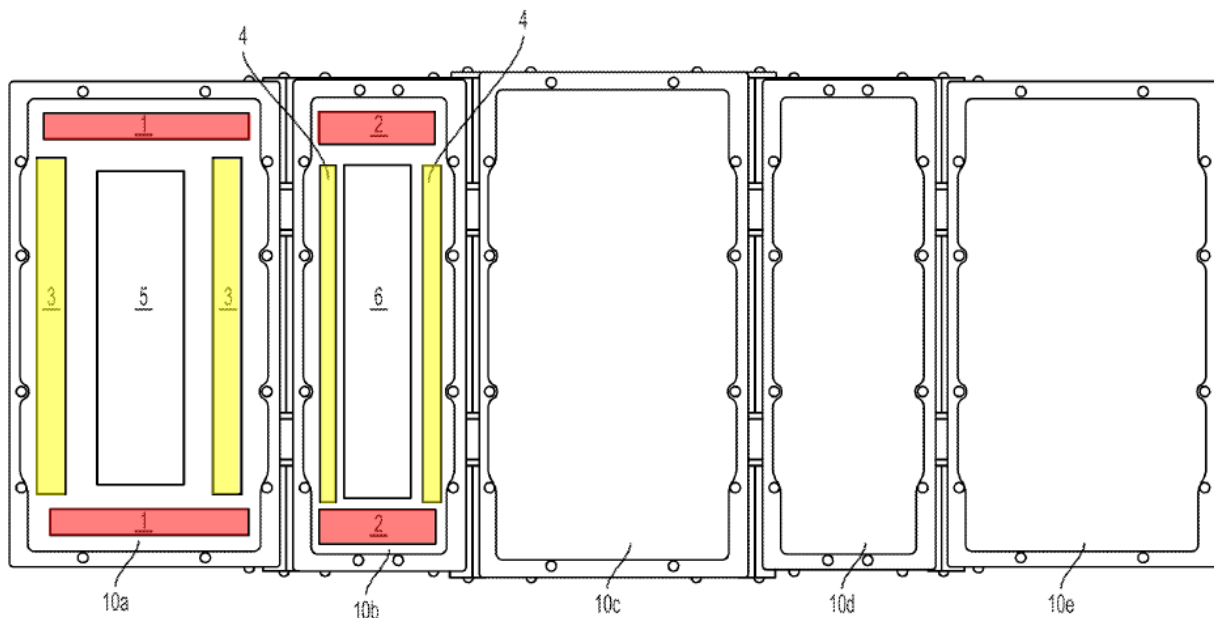


FIG. 5

Ex. 1001 ('028 Patent), Fig. 5 (annotated). In contrast, “Bansal’s solution provides higher intensity (or density) of lights *around all edges* of the panel.” IPR2024-00874, Ex. 1003 (Bretschneider Declaration), ¶154 (emphasis added).

178. When the claim limitation is read as a whole, “wherein each of the 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 limitation distinguishes between the second

edges of the panel (shown in red) and at least the first edges (shown in yellow). Bansal does not make this distinction and therefore fails to meet this claim limitation.

179. Accordingly, Lundahl in view of Larsen, in further view of Bansal, does not render obvious “*wherein each of the 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. CONCLUSION

180. 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.

11-25-2024

Date

Jose Sasian

Jose Sasian, Ph.D.

**APPENDIX A: THE CHALLENGED CLAIMS 1, 2, 4-6, 16, 17, and 19-21
OF THE '028 PATENT**

1. A system for photodynamically diagnosing or treating a patient, comprising:
an illuminator comprising five panels connected by hinged structures on inner side surfaces of adjacent panels; and
light sources disposed on surfaces of the five panels, the illuminator being configured to uniformly illuminate a treatment surface of the patient via the light sources,
one of the five panels being positioned as a center panel configured to face the treatment surface, and two or more of the five panels being configured to be angled relative to the center panel,
wherein the five panels are positioned to allow treatment within approximately four inches of the treatment surface, and
wherein each of the 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. The system of claim 1, wherein the illuminator is configured to output red light at a dose of 30 J/cm² to 150 J/cm².
4. 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.
5. A method of photodynamically diagnosing or treating a patient, comprising:
administering 5-aminolevulinic acid (ALA) to the patient;
positioning an illuminator proximate to the patient, *the illuminator comprising five panels connected by hinged structures on inner side surfaces of adjacent panels; and*
uniformly illuminating a treatment surface of the patient with light sources disposed on the five panels of the illuminator, the five panels being positioned to allow treatment within approximately four inches of the treatment surface,

wherein each of the 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.

6. The method of claim 5, wherein the illuminating comprises outputting red light during at least part of the time when the treatment surface is illuminated.
16. A system for photodynamically diagnosing or treating a patient, comprising:
 - a mobile base supported by at least four wheels;*
 - a pillar perpendicular to the base;
 - a controller disposed to be supported by the pillar;
 - an arm mounted to a top portion of the pillar; and
 - an illuminator connected at an end of the arm, the arm being hinged to allow adjustment of a position of the illuminator relative to the base, the illuminator comprising:
 - five panels connected by hinged structures to allow continuous illumination across the five panels, wherein the five panels are individually configurable to control illumination from each of the five panels,*
 - light sources disposed on surfaces of the five panels, the illuminator being configured to uniformly illuminate a treatment surface of the patient via the light sources, the light sources being configured to output light uniformly during at least part of a time when the treatment surface is illuminated, *each of the five panels having two first edges and two second edges shorter than the two first edges, the 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, and*
 - one or more fans mounted to at least one of the five panels.
17. The system of claim 16, wherein one of the five panels is positioned as a center panel configured to face the treatment surface, and two or

more of the five panels are configured to be angled relative to the center panel.

19. The system of claim 16, wherein the light sources are configured to output red light during at least part of the time when the treatment surface is illuminated.
20. A system for photodynamically diagnosing or treating a patient, comprising:
an illuminator comprising five panels connected by hinged structures on inner side surfaces of adjacent panels, wherein the illuminator is configured to output light at a variable irradiance density during treatment; and
light sources disposed on surfaces of the five panels, the illuminator being configured to uniformly illuminate a treatment surface of the patient via the light sources,
one of the five panels being positioned as a center panel configured to face the treatment surface, and two or more of the five panels being configured to be angled relative to the center panel,
wherein the five panels are positioned to allow treatment within approximately four inches of the treatment surface, and
wherein each of the 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.
21. A system for photodynamically diagnosing or treating a patient, comprising:
an illuminator comprising five panels connected by hinged structures on inner side surfaces of adjacent panels; and
light sources disposed on surfaces of the five panels, the illuminator being configured to uniformly illuminate a treatment surface of the patient via the light sources,
one of the five panels being positioned as a center panel configured to face the treatment surface, and two or more of the five panels being configured to be angled relative to the center panel,
wherein the five panels are positioned to allow treatment within approximately four inches of the treatment surface,

wherein the five panels are individually configurable to control illumination from each of the five panels, and

wherein each of the 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.