

Case IPR2024-00874
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.

DUSA PHARMACEUTICALS, INC.
Patent Owner

Case IPR2024-00874

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.¹ (“Sun Pharma”) to provide expert opinions and testimony regarding the ’028 Patent, and particularly its claims 1-8, 10, 11, 13, 14, and 16-21. 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.

¹ I understand that DUSA Pharmaceuticals, Inc., the named Patent Owner, merged with Sun Pharmaceutical Industries, Inc. effective March 31, 2024, with Sun Pharmaceutical Industries, Inc. remaining as the surviving corporation.

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 of U.S. Patent No. 11,697,028 (the "Petition") and all exhibits cited therein; 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. 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, 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. Bretschneider have referenced this date as the "time of invention" for the Challenged Claims of the '028 Patent. Ex. 1003 (Bretschneider Declaration), ¶34.

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 also recognize that Dr. Bretschneider's and my opinions differ slightly as to the level of a POSITA. See Ex. 1003 (Bretschneider Declaration), ¶37. I do not see the differences as material, and my opinions set forth in this Declaration would not change if Dr. Bretschneider's proposed level of ordinary skill were adopted.

VII. THE '028 PATENT

33. 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.

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

35. 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.

36. 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.

37. 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.

38. 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.

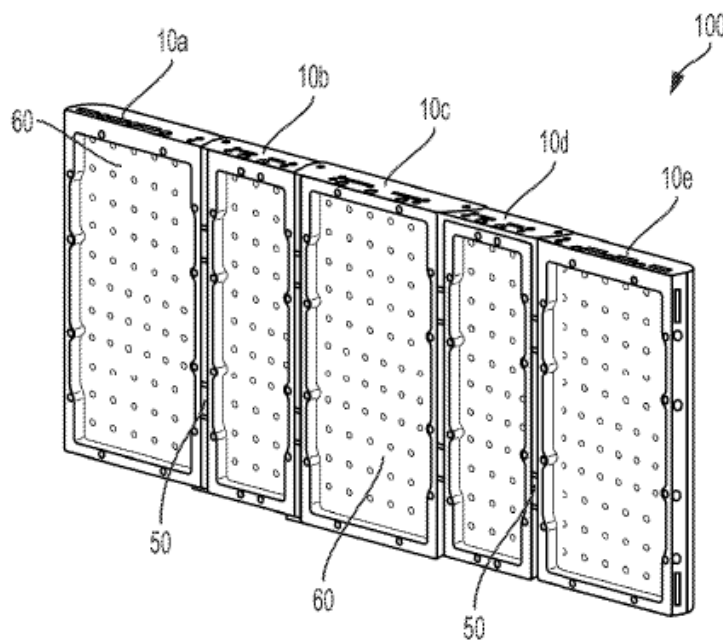


FIG. 2B

Ex. 1001 (’028 Patent), Fig. 2B.

39. 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.

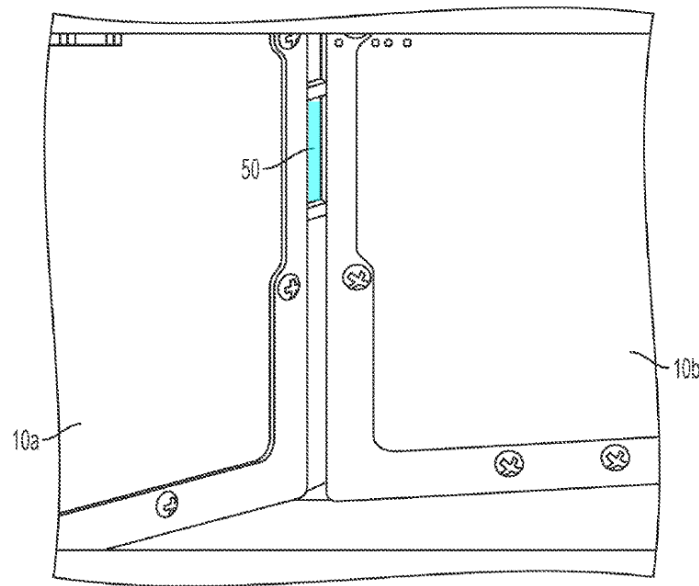


FIG. 3A

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

40. 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.

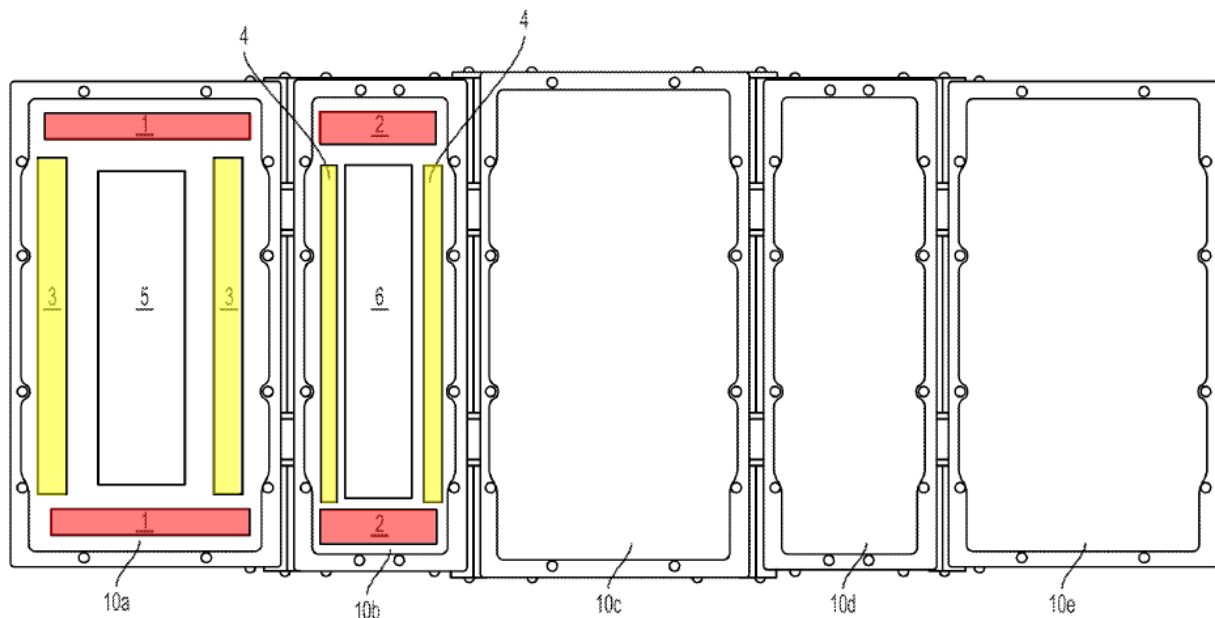


FIG. 5

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

41. 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).

42. 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.

43. 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.

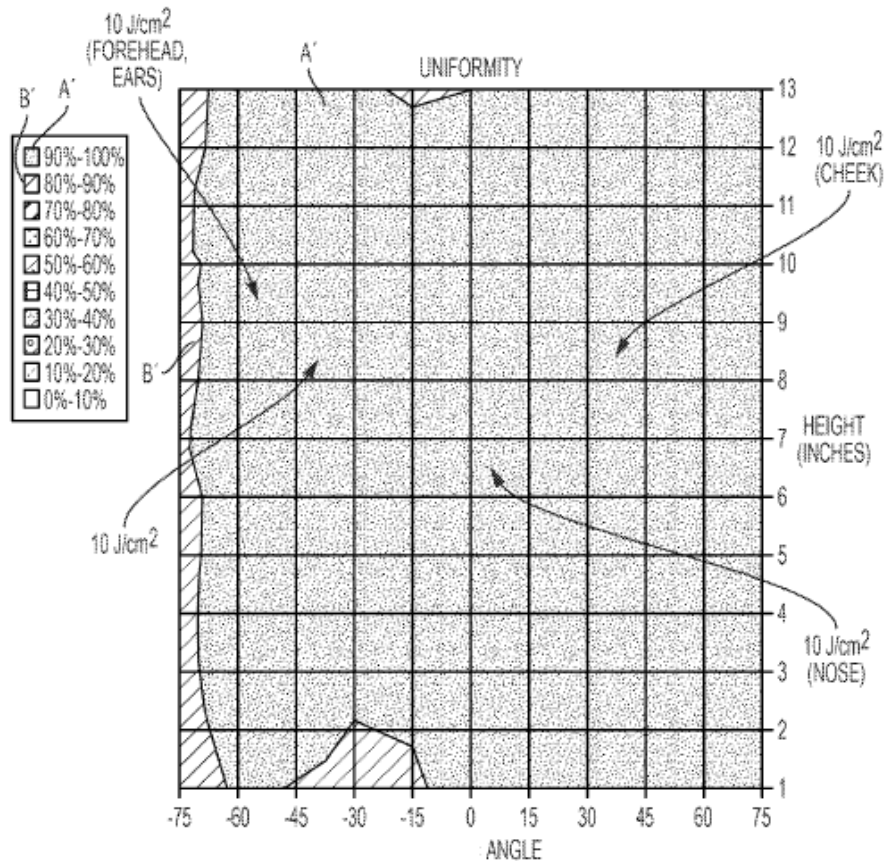


FIG. 8

Ex. 1001 (’028 Patent), Fig. 8.

44. 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.

45. 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.

46. 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”).

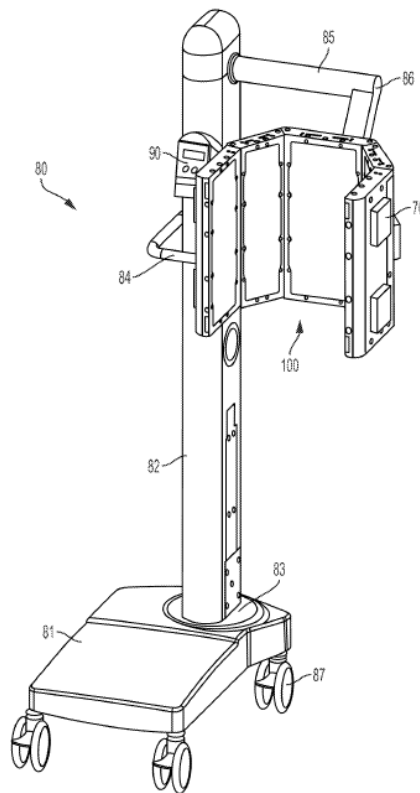


FIG. 4

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

VIII. CLAIM CONSTRUCTION

47. I understand that Petitioner and Dr. Bretschneider propose that no terms need to be construed, and that the claim terms be given their ordinary and customary meaning as would have been understood by a POSITA at the time of the invention. Petition, 8-9; Ex. 1003 (Bretschneider Decl.), ¶¶100-101. I also understand that the Board has not explicitly construed any terms in this proceeding. 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 district court.

IX. BIOFRONTERA’S ASSERTED PRIOR ART

A. Larsen (Ex. 1004)

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

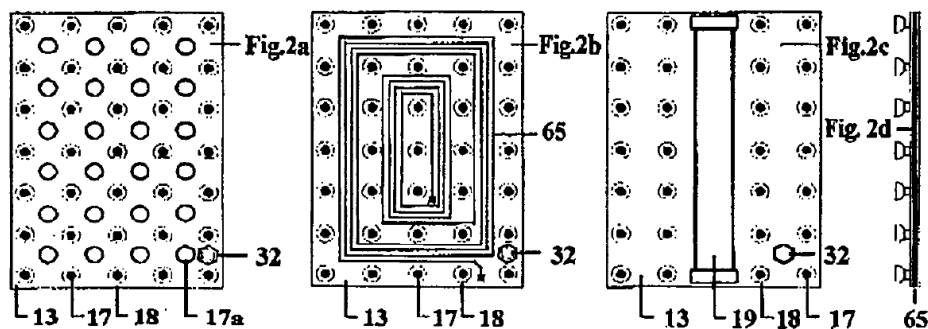
49. Larsen discloses that “the present invention provides a device with changeable applicators using a light and/or laser radiation of several wavelength ranges suited for the photodynamic stimulation of the cell energy in living cells, in particular human cells of both surface and underlying tissue.”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

50. 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].

51. 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].

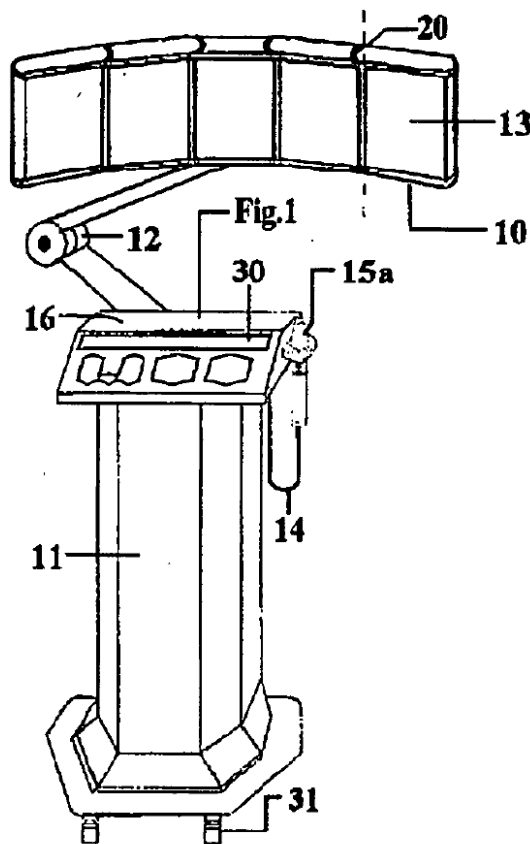
52. As shown in Figs. 2b and 2c below, “the light sources **17** are placed in regular row arrangements, i.e., **20** equidistant from each other.” Ex. 1004 (Larsen), [0071].



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

53. 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.

54. 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.”).

55. Larsen discloses that “[t]he applicators **13**, according to FIGS. 2*a*, 2*b*, and 2*c* are equipped with sensors **32** arranged between the semiconductor and/or laser diodes **17**.” Ex. 1004 (Larsen), [0079]. The “[s]ensors **32** measure the amount of energy radiated away from the skin surface, which is indicative of the total energy penetrating into the tissue. Taking into account individual variations from patient to patient, the exposure can be determined according to the measurements taken by the sensors **32** so that the correct amount of therapeutic energy (Joule/cm²) reaches the tissue. An increase of the registered amount of energy can be achieved by the invented device by increasing the operating potential (and thereby the pulse amplitude) or the pulse frequency and/or prolonging the duration of the treatment time through an adjustment of the control mechanism **16**. Ex. 1004 (Larsen), [0079].

56. 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].

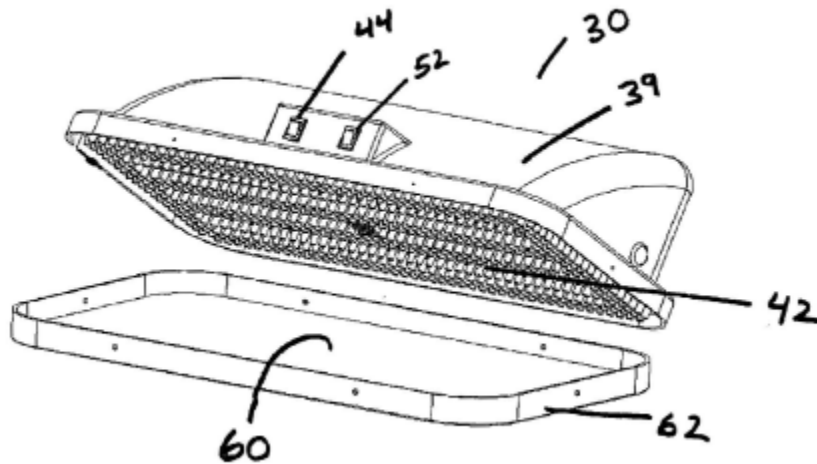
B. Bansal (Ex. 1005)

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

58. 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].

59. 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].

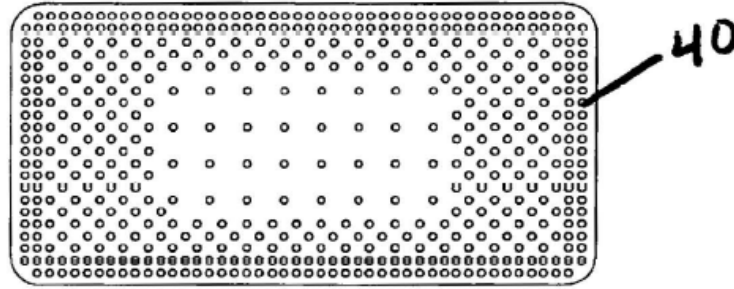
Fig. 2



Ex. 1005 (Bansal), Fig. 2.

60. 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.

61. 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].

C. Jones (Ex. 1006)

62. U.S. Patent Publication No. 2014/0067024 by Ross Peter Jones et al. is titled “Dual Panel Photodynamic Therapy Lamp.” Ex. 1006 (Jones), Cover.

63. Jones discloses that “[t]he present invention relates to a dual panel photodynamic therapy lamp, and a method of using the dual panel photodynamic therapy lamp.” Ex. 1006 (Jones), [0002].

64. Jones discloses that “[a]ccording to an exemplary embodiment of the present invention, a photodynamic therapy lamp comprises two lamp modules each lamp module comprising a two-dimensional array of LEDs and each of the lamp

modules are configured to be movable between a first position in which an angle between the lamp modules is from 157 degrees to 180 degrees, and a second position in which the angle between the lamp modules is from 50 degrees to 70 degrees.” Ex. 1006 (Jones), [0014].

65. As shown below, Figs. 3A and 3B of Jones “illustrate an angled orientation of the lamp modules **21** of the exemplary embodiment of a photodynamic therapy lamp **10** according to the present invention.” Ex. 1006 (Jones), [0079].

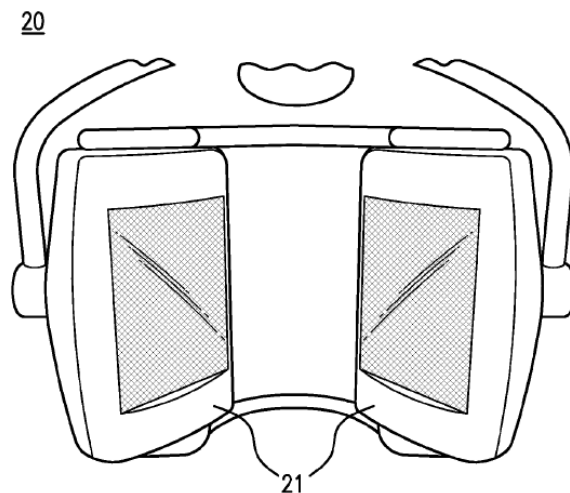


FIG. 3A

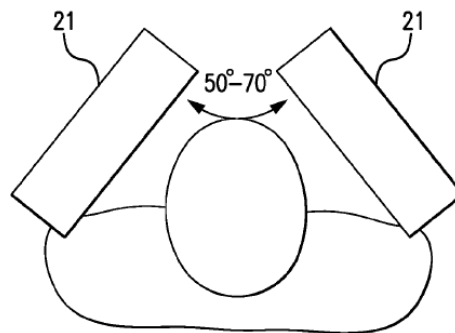


FIG. 3B

Ex. 1006 (Jones), Figs. 3A and 3B.

66. Jones discloses that “[i]n the angled orientation, i.e. the second position, the lamp modules **21** are rotated relative to each other and at least partially facing toward each other, such that an angle between the two lamp modules **21** is from 50 degrees to 70 degrees, preferably from 55 degrees to 65 degrees, more preferably from 58 degrees to 62 degrees, and most preferably 60 degrees. In addition, in the angled orientation, the inner edges of the two lamp modules **21** may be separated from each other by a gap of approximately $136\text{ mm} \pm 2\text{ mm}$. In this angled orientation, a contoured surface may be treated, e.g. a patient's face as illustrated in FIG. **3B** which shows the treatment of a sitting patient's face (top view) or lying patient's face (viewed from the anterior end).” Ex. 1006 (Jones), [0079].

67. Jones discloses that “illumination is carried out with the Nedax® lamp comprising two lamp modules **21** comprising each a two-dimensional array of 256 LEDs which provide red light at an average wavelength of 632 nm and a matching array of lenses.” Ex. 1006 (Jones), [0120]. “The lamp modules **21** are positioned at a distance of 5-8 cm from the face.” Ex. 1006 (Jones), [0120], *see also* [0024] (“when the photodynamic therapy device is in use, a distance between the lamp modules and a treatment surface of a patient is between about 5 cm to about 8 cm,” [0041] (“The aligning of the lamp modules in the first position includes positioning the lamp modules a predetermined distance from the treatment area. The predetermined distance is preferably from about 5 cm to about 8 cm.”), [0094]

(“when the photodynamic therapy lamp of the invention is used for the photodynamic therapy treatment of the patient’s face, the operator positions the lamp modules in the second position, i.e. angled orientation and places the lamp head with a distance of 5-8 cm from the patient’s face in such way that the arrays of LEDs are oriented towards the patient’s face (as shown in FIG. 3B.”); [0117]-[0124] (Examples 1-6).

X. PROSECUTION HISTORY OF THE ’028 PATENT

68. 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.

69. 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.

70. 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.

71. 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.

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

XI. GROUNDS 1-3: PETITIONER DOES NOT SHOW THAT THE COMBINATIONS OF LARSEN, BANSAL AND JONES, OR LARSEN, BANSAL, JONES AND ANDERSON, OR LARSEN, BANSAL, JONES AND MACKINNON WOULD RENDER OBVIOUS THE CHALLENGED CLAIMS

73. Petitioner and Dr. Bretschneider assert three grounds each involving Larsen, Bansal, and Jones (the independent claims are bolded in the chart below).

Ground	Claims	Theory	References
I	1 , 2, 4, 5 , 6-8, 16 , 17-19, 20 , 21	Obviousness	Larsen, Bansal, Jones
II	2-4	Obviousness	Larsen, Bansal, Jones, Anderson
III	10-11, 13-14	Obviousness	Larsen, Bansal, Jones, Mackinnon

74. As discussed above, I understand 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. For at least the reasons set forth below in Sections A-E, Petitioner and Dr. Bretschneider do not show that the combinations of Larsen, Bansal and Jones, or Larsen, Bansal, Jones and Anderson, or Larsen, Bansal, Jones and Mackinnon would render obvious the Challenged Claims.

A. Larsen 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”

75. 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.*”

76. Petitioner acknowledges that Larsen does not expressly teach the higher intensity limitation. Petition, 36 (“Larsen *does not expressly teach* that the light sources on its applicators 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”). Larsen discloses that the light sources on its applicators are “placed in regular row arrangements, i.e., **20** equidistant from each other” as shown in Figs. 2b and 2c. Ex. 1004 (Larsen), [0071].

77. Petitioner and Dr. Bretschneider instead rely 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* for every one of the independent claims. Petition, 11-12, 17-21, 36-38, 44, 56, 61-62; Ex. 1003 (Bretschneider Declaration), ¶¶120-121, 151-162, 219-221, 246-247, 295, 314, 325. However, Bansal does not disclose this limitation in combination with Larsen.

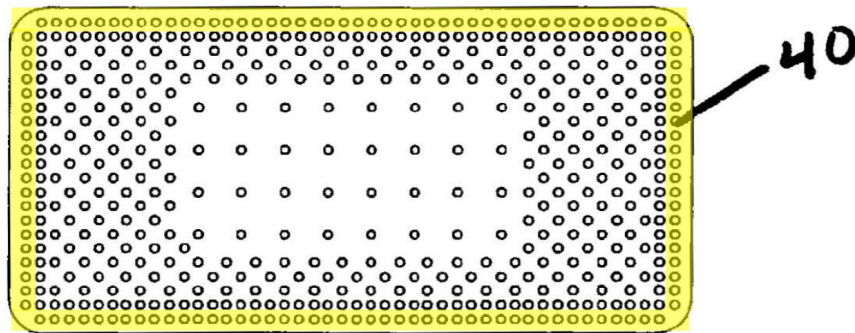
78. In alleged support, Petitioner and Dr. Bretschneider rely on Bansal's teaching that "[i]n another embodiment, the density of light source distribution would vary throughout the array, such as with *higher density in the periphery and a lower density in the center*. In yet another version of the invention, 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 around the edges*." Petition, 36-37; Ex. 1003 (Bretschneider Declaration), ¶219 (citing Ex. 1005 (Bansal), [0025]-[0026], Fig. 9b) (emphasis added). They further rely 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.” Petition, 36-37; Ex. 1003 (Bretschneider Declaration), ¶219 (emphasis added).

79. 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.

80. 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 Petition, 37; Ex. 1003 (Bretschneider Declaration), ¶219 (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 around the outer edges”), Fig. 9b.

Fig. 9b



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

81. Petitioner and Dr. Bretschneider fail 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 and Dr. Bretschneider state that “Bansal’s solution provides higher intensity (or density) of lights *around all edges* of the panel.” Ex. 1003 (Bretschneider Declaration), ¶154 (emphasis added); 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). However, 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.*”

82. Dr. Bretschneider argues that a “POSITA would have understood that the second edges of the ’028 Patent’s panel are coincident with the periphery of the panel.” Ex. 1003 (Bretschneider Declaration), ¶219 (“A POSITA would have understood that the second edges of the ’028 Patent’s panel are coincident with the periphery of the panel and hence that Bansal’s explicitly described embodiment teaches ‘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’ found in claim 1(f) of the ’028 Patent.”). However, Dr. Bretschneider 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.

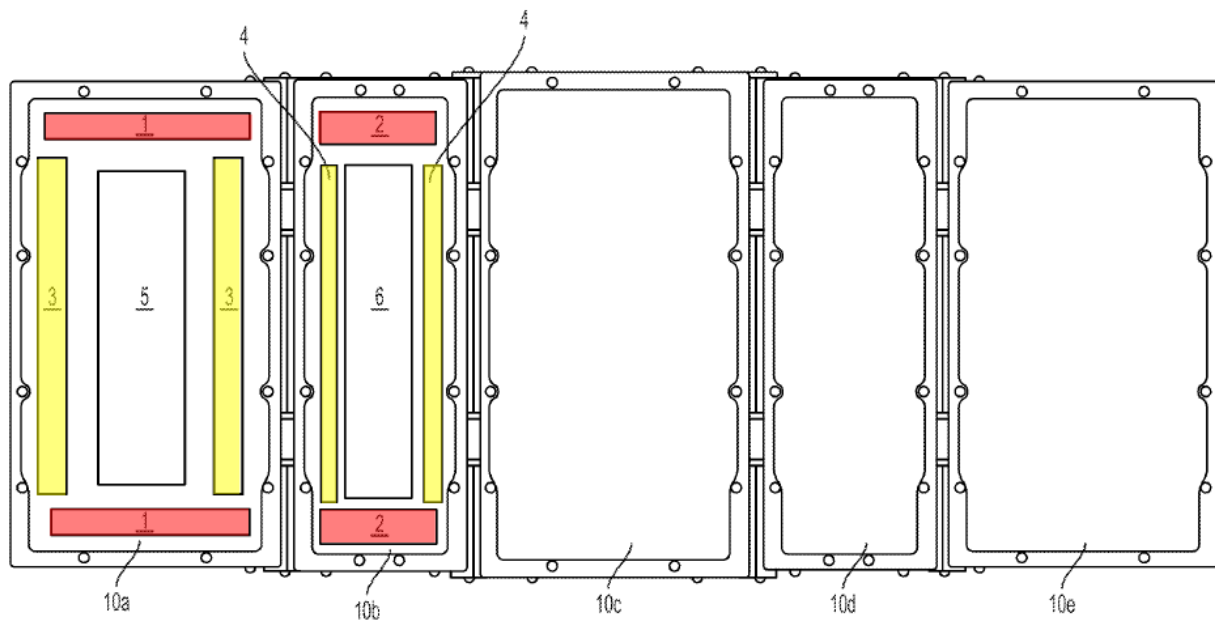


FIG. 5

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

83. 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.

84. Accordingly, Larsen in 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.”

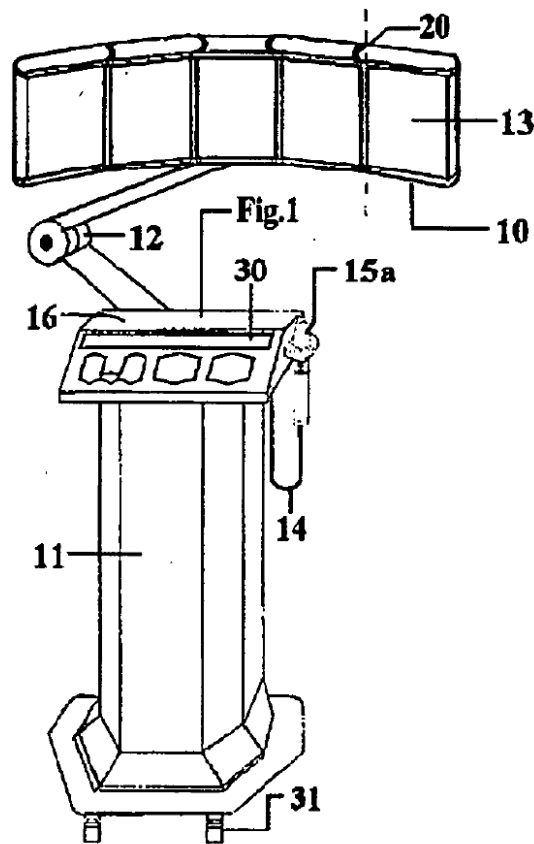
B. Larsen Does Not Disclose Or Render Obvious “Hinged Structures On Inner Side Surfaces Of Adjacent Panels”

85. Independent Claims 1, 5, 20 and 21 of the '028 Patent, from which Claims 2-4, 6-8, 10-11, and 13-14 depend, require an “illuminator comprising five panels connected by *hinged structures on inner side surfaces of adjacent panels*.”

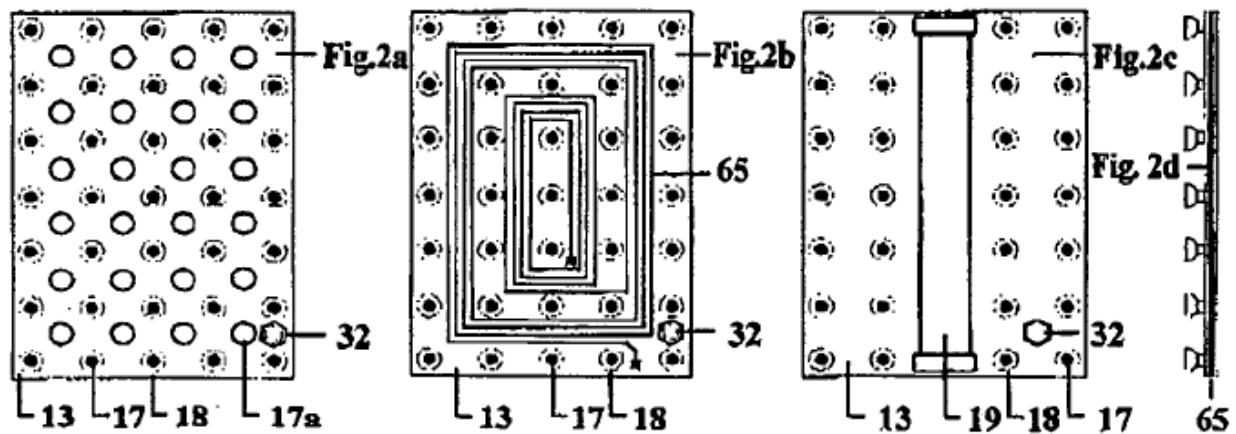
86. Petitioner and Dr. Bretschneider argue that this limitation is disclosed by Larsen. Petition 10, 26-29, 43, 59, 61; Ex. 1003 (Bretschneider Declaration), ¶¶190-197, 239-240, 308, 316. However, Larsen does not disclose an “illuminator comprising five panels connected by *hinged structures on inner side surfaces of adjacent panels*.”

87. 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), Fig. 2.

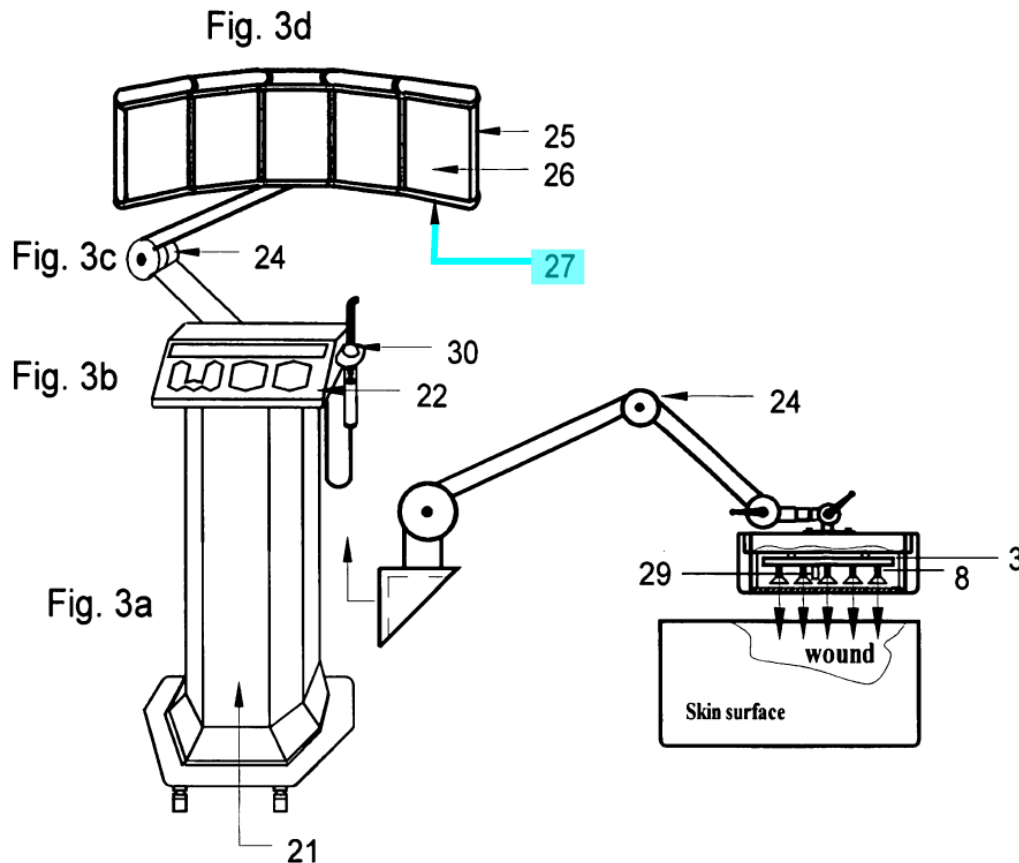
88. Petitioner argues that, despite the clear disclosure labeling of “hinges” as “**10**,” the hinges are shown as element **20** in Fig. 1. Petition, 28. However, Larsen identifies “**20**” as the regular row arrangements of light sources in the applicators 13. Ex. 1004 (Larsen) [0071] (“According to FIGS. 2*b* and 2*c* the light sources 17 are placed in regular row arrangements, i.e., **20** equidistant from each other.”) (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.

89. 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.*” Petition 28; Ex. 1003 (Bretschneider Declaration), ¶191 (citing EX1009, ¶4; EX1002, 328). But there is no such disclosure in Larsen.

90. 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).

91. Petitioner’s argument also conflicts with another Larsen Australian Patent Application 2001438869, which claims and points to hinges 27 on the *bottom* of the applicator (shown below in blue). Ex. 2004 (Larsen AU4386901), 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”).



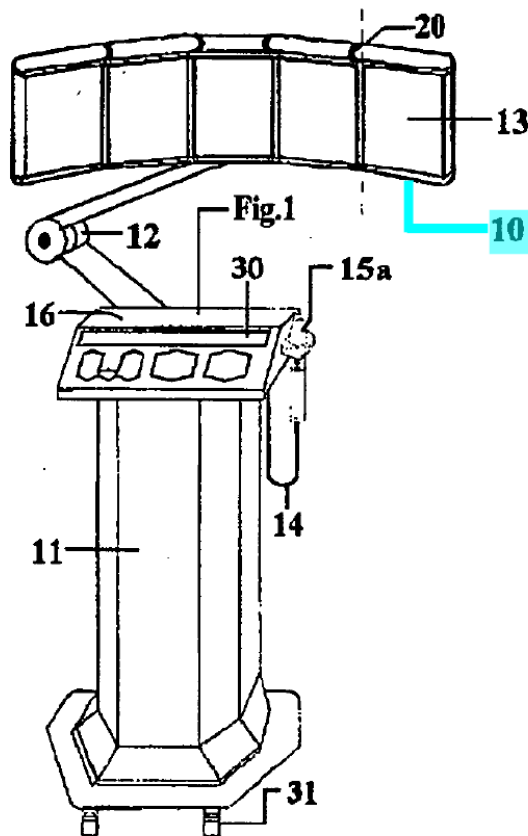
Ex. 2004 (Larsen AU4386901), Fig. 3d (annotated).

92. Petitioner’s argument further conflicts with Dr. Bretschneider, who states that “Larsen is silent on the type of hinges.” Ex. 1003 (Bretschneider Declaration), ¶191.

93. Second, there is no inherent disclosure of “*hinged structures on inner side surfaces of adjacent panels*” in Larsen. Petitioner and Dr. Bretschneider argue “the hinges must *necessarily* be on the inner side surfaces of the panels” because they “connect[] one edge with the other,” and “by inspection a person of ordinary

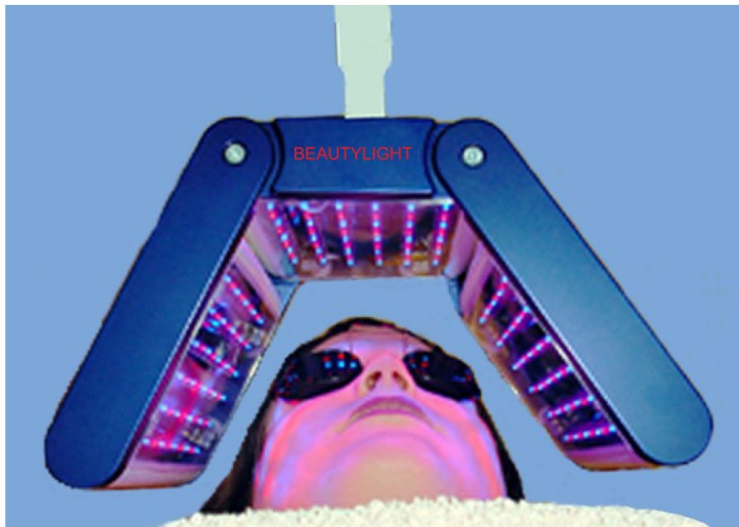
skill in the art would note that the panels in Larsen's illustrated embodiment of Fig. 1 are spaced exceptionally close together in a manner consistent with the use of hinges on the inner side surfaces of adjacent panels, as shown by the flush arrangement of the panels (13)." Petition, 28 (emphasis added); Ex. 1003 (Bretschneider Declaration), ¶¶191-192, 195. However, as Dr. Bretschneider explains in his legal standards section, "the prior art reference inherently discloses the claim element *only* if the prior art reference must *necessarily* include the undisclosed claim element. Inherency may not be established by probabilities or possibilities." Ex. 1003 (Bretschneider Declaration), ¶43 (emphasis added).

94. 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).

95. Petitioner’s argument that “the hinges must necessarily be on the inner side surfaces of the panels” is inaccurate. Petition, 28. The hinges are not necessarily on inner side surfaces of adjacent panels if the panels are “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.

96. Dr. Bretschneider and Petitioner also argue that a POSITA “would have found it obvious to try placing the hinges on the inner side surfaces of the panels.” Petition, 28-29; Ex. 1003 (Bretschneider Declaration), ¶¶193-197. However, Dr. Bretschneider’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. Nor does he provide any support for his statement that “hinges on the

inner side surfaces of adjacent panels is one of an extremely limited number of locations for hinges.” Ex. 1003 (Bretschneider Declaration), ¶197. 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.

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

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

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

99. Petitioner and Dr. Bretschneider argue that this limitation is disclosed by Larsen. Petition, 20-22, 53-55, 62; Ex. 1003 (Bretschneider Declaration), ¶¶285-288, 320-323. However, Larsen does not disclose “*the five panels are individually configurable to control illumination from each of the five panels*”.

100. Petitioner and Dr. Bretschneider argue that “Larsen teaches individual control of each illuminator (i.e., panel).” Ex. 1003 (Bretschneider Declaration),

¶285; Petition, 54. In alleged support, Petitioner and Dr. Bretschneider rely on Larsen’s disclosure 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. In 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.” Ex. 1003 (Bretschneider Declaration), ¶285 (citing Ex. 1004 (Larsen), [0072]); Petition, 53. However, nothing in this disclosure teaches individual control of each applicator.

101. Petitioner and Dr. Bretschneider also state 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.’” Petition, 54; Ex. 1003 (Bretschneider Declaration), ¶286 (citing Ex. 1004 (Larsen), [0070]) (emphasis added by Petitioner). 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 and Dr. Bretschneider

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."

102. Petitioner argues that during prosecution of the '028 Patent the Examiner found that the Larsen '381 Patent taught "the panels can be controlled individually." Petition, 54 (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.”

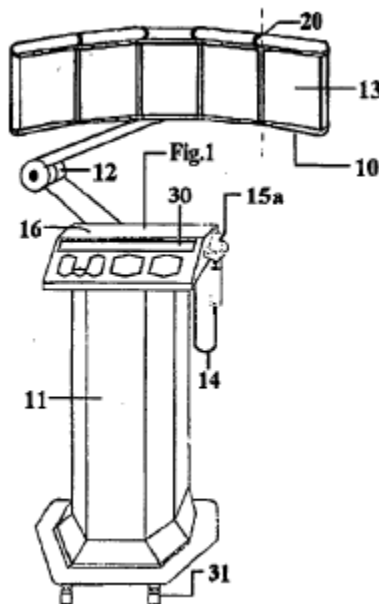
103. Petitioner and Dr. Bretschneider also rely on Larsen’s disclosure that “[u]sing the control mechanism, ‘the invented device is adjustable within a relatively large range with reference to duration, amplitude and frequency of surge of current, so that the semiconductor diodes 17, 17a and 18, as well as laser 17 diodes with the same realisation as semiconductor diode 17, can be used as light sources.’” Petition, 54; Ex. 1003 (Bretschneider Declaration), ¶286 (citing Ex. 1004 (Larsen), [0074]). 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.

104. Petitioner and Dr. Bretschneider also rely 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.” Petition, 54; Ex. 1003 (Bretschneider Declaration), ¶286 (citing Ex. 1004 (Larsen), [0074]). However, Larsen’s disclosure of “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).

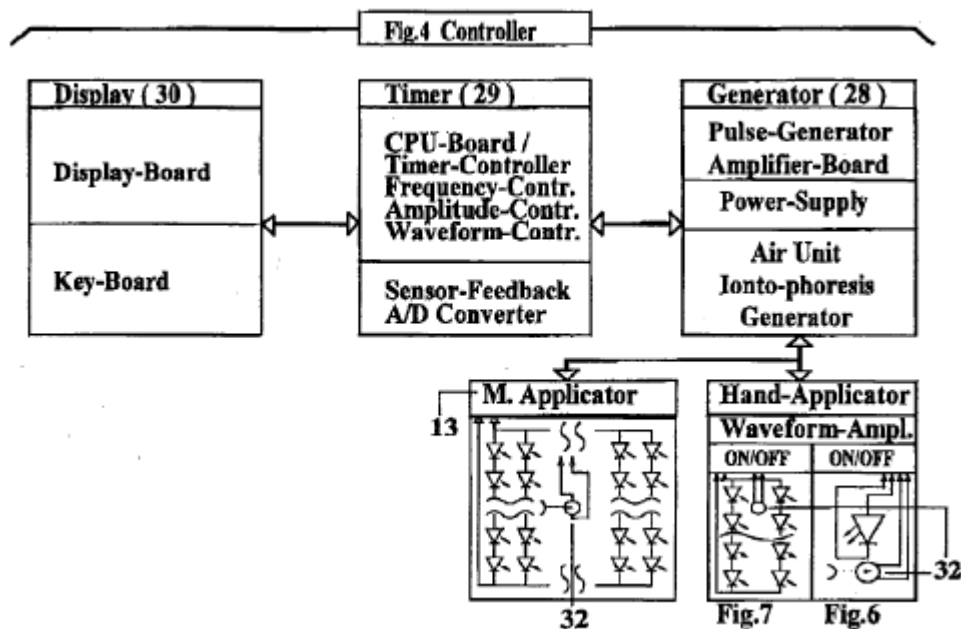
105. Petitioner and Dr. Bretschneider also argue that “[e]ach of the applicators is connected to a control mechanism 16.” Ex. 1003 (Bretschneider Declaration), ¶286 (citing Ex. 1004 (Larsen), [0070] and FIGS. 1 and 4); Petition, 54. However, paragraph [0070] does not mention the control mechanism 16. 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.

106. 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.

107. 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.

108. 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).

109. 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.” Petition, 54-55; Ex. 1003 (Bretschneider Declaration), ¶287. 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.’” Petition, 54-55; Ex. 1003 (Bretschneider Declaration), ¶287 (citing Ex. 1004 (Larsen), [0079]-[0080]).

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.

110. Accordingly, Larsen does not disclose "the five panels are individually configurable to control illumination from each of the five panels."

D. Petitioner Has Not Shown That A POSITA Would Have Been Motivated To Combine Larsen (As Modified By Bansal) With The Treatment Distance Described In Jones With A Reasonable Expectation Of Success

111. Independent Claims 1, 5, 20 and 21 of the '028 Patent, from which Claims 2-4, 6-8, 10-11, and 13-14 depend, require "wherein the five panels are positioned to allow treatment *within approximately four inches of the treatment surface.*"

112. The Petitioner acknowledges that "Larsen *does not expressly teach* that the five panels are positioned to allow treatment within approximately four inches of the treatment surface." Petition, 34 (emphasis added). Larsen discloses only that

jointed arm 12 “allows the positioning of the applicators 13 in front of, or above, a tissue area while maintaining a correct positioning distance.” Ex. 1004 (Larsen), [0073].

113. Petitioner and Dr. Bretschneider argue that Jones teaches “a distance between the lamp modules and the treatment area between about 5 cm to 8 cm” and a “POSITA would have found it obvious and would have been motivated with a reasonable expectation of success to incorporate the treatment distance described in Jones into Larsen.” Petition, 24-26, 34-35, 44, 60, 62; Ex. 1003 (Bretschneider Declaration), ¶¶169-172, 212-216, 241-243, 312, 319. However, Petitioner and Dr. Bretschneider fail to show that a POSITA would have been motivated to combine Larsen’s device, as modified by Bansal, with Jones’s treatment distance of about 5-8 cm with a reasonable expectation of success for at least the reasons set forth below.

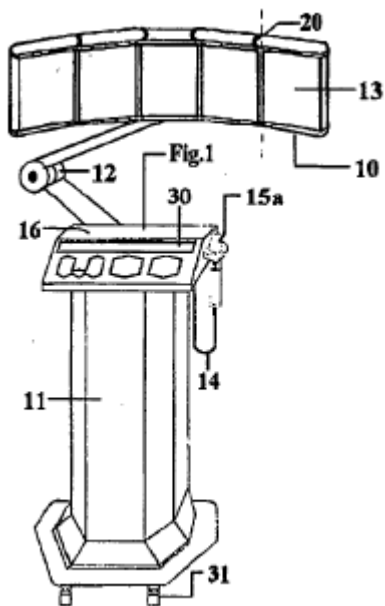
114. A POSITA would not have been motivated to apply Jones’s teaching of a treatment distance of about 5-8 cm to Larsen’s device (as modified by Bansal) because Bansal teaches that it was found that phototherapeutic light sources “arranged into uniform arrays, typically in a rectangular pattern” that are “*suspended 12 inches above a subject*” “can produce an acceptable average light intensity for phototherapy treatment.” Ex. 1005 (Bansal), [0007] (“In the past, phototherapeutic light sources have been arranged into uniform arrays, typically in a rectangular pattern. Such a configuration can produce an acceptable average light intensity for

phototherapy treatment. For 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*, 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.”) (emphasis added). Petitioner and Dr. Bretschneider fail to explain why a POSITA would have been motivated to combine Larsen (as modified by Bansal) with Jones’s treatment distance of 5-8 cm (1.97-3.15 inches) when Bansal teaches that an array “suspended *12 inches* above a subject” “*can produce an acceptable average light intensity for phototherapy treatment.*” *Id.*

115. In addition, Petitioner and Dr. Bretschneider fail to show that a POSITA would have been motivated to apply Jones’s teaching of a treatment distance of about 5-8 cm to Larsen’s device (as modified by Bansal) with a reasonable expectation of success given the multiple significant differences between such devices as discussed below.

116. First, Larsen and Jones’s devices differ in the number and configuration of panels on the illumination device. Larsen discloses a device with 5 panels and “an adjustable scan system, which permits an even and *gap-free* radiation of the surface.” Ex. 1004 (Larsen), [0028], Fig. 1. Larsen’s device does not “leav[e] any unradiated gaps.” Ex. 1004 (Larsen), [0072] (“In each applicator the printed circuit board carrying the light sources is connected to a small electrical scan engine 66,

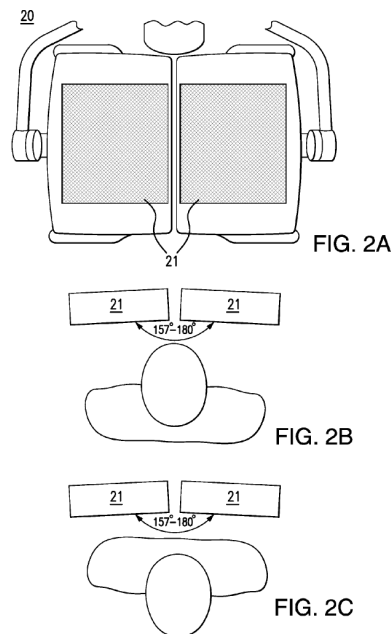
which can move the light sources with linear movements, whereby a correctly adjusted scan length and frequency gives the radiated surface a total radiation at the necessary wavelengths *without leaving any unradiated gaps.*”). In fact, Petitioner argues that Fig. 1 shows “the inner edges of each of the panels (13) are flush with each other.” Petition, 29; Ex. 1003 (Bretschneider Declaration), ¶¶191, 196-197.



Ex. 1004 (Larsen), Fig. 1.

117. Jones, on the other hand, discloses a “dual panel photodynamic therapy lamp” and distinguishes devices with more than two panels, stating that “the arrangement of 4 panels makes the lamp fairly complex” and it “will also have considerable weight.” Ex. 1006 (Jones), [0002], [0011]. Moreover, as shown in Figs. 2 and 3 below, Jones discloses that “[a] gap between the lamp modules in the first position exists,” and “[a] gap between the lamp modules in the second position

exists.” Ex. 1006 (Jones), [0015] (“A gap between the lamp modules in the first position exists. Said gap in said first position is preferably *approximately 16 mm.*”), [0016] (“A gap between the lamp modules in the second position exists. Said gap in said second position is preferably *approximately 136 mm.*”); *see also* [0078] (“In addition, in the planar orientation, *the inner edges of the two lamp modules 21 may be separated from each other by a gap of approximately 16 mm±2 mm.*”), [0079] (“In addition, in the angled orientation, *the inner edges of the two lamp modules 21 may be separated from each other by a gap of approximately 136 mm±2 mm.*”).



Ex. 1006 (Jones), Fig. 2.

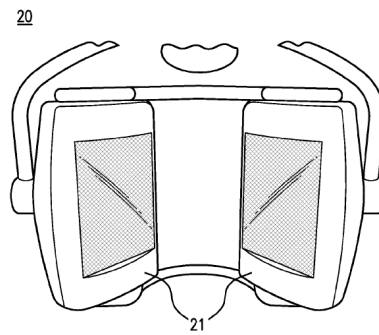


FIG. 3A

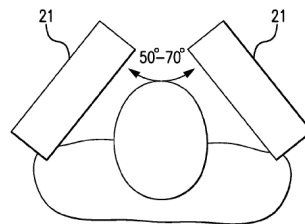


FIG. 3B

Ex. 1006 (Jones), Figs. 3A and 3B. A POSITA would not have been motivated to combine Larsen's device with five panels that "permits an even and gap-free radiation of the surface" with the 5-8 cm treatment distance taught by Jones for an entirely different device with two panels and an angled gap between panels.

118. Second, Larsen and Jones differ in the way that they deliver light. Larsen discloses that "[t]he light sources 17 and 17a are mounted with *reflectors* 18." Ex. 1004 (Larsen), [0070] ("The light sources 17 and 17a are mounted with *reflectors* 18, which collect the radiation and bundle it in front of the applicator 13."), Figs. 2a-2c, [0028] ("The 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.”). In contrast, Jones discloses for the embodiments with a treatment distance of 5-8 cm that the array of LEDs is covered by a “*matching array of lenses*.” Ex. 1006 (Jones), [0120] (“illumination is carried out with the Nedax® lamp comprising two lamp modules 21 comprising each a two-dimensional array of 256 LEDs which provide red light at an average wavelength of 632 nm and a *matching array of lenses*. The two lamp modules 21 of the lamp are positioned in an angled orientation, i.e., second position for the treatment of the face at an angle of 60 degree. *The lamp modules are positioned at a distance of 5-8 cm from the face.*”), [0092] (“each lamp module comprising a two-dimensional array of 256 LEDs and a *matching array of lenses*...are positioned at a *distance of 5-8 cm from the face*”), see also [0080] (“The array of LEDs is covered by a *matching array of lenses* 26, e.g., made of polycarbonate, that are configured to *collimate the light emitted from the LEDs*.”), [0017] (“According to an exemplary variant of the present invention, *the LEDs are collimated LEDs*. The term ‘collimated’ in the context of the invention means that the rays of light from each LED have reduced divergence without being perfectly parallel such that there is some overlap of rays from one LED with neighboring LEDs. The collimated LEDs include optical mirrors or lenses, preferably lenses. In a preferred embodiment *a single lens is provided for each LED*.”), [0072] (“As an example, in a most preferred embodiment, each lamp module of the photodynamic therapy lamp according to the invention comprises a

two-dimensional array of LEDs which consists of 256 LEDs and a *matching two-dimensional array of lenses which consists of 256 lenses.*”), [0117]-[0124] (Examples 1-6) (emphasis added).

119. A POSITA would have understood that the optical effects of the reflectors disclosed by Larsen can be significantly different than the optical effects of the lenses in the embodiments disclosed by Jones, and such differences can impact the treatment distance. Specifically, Larsen teaches that “the diodes are mounted with reflectors, which collect the radiation and bundle them in front of the applicator.” Ex. 1004 (Larsen), [0028]. This is in contrast with Jones’s teaching of lenses that collimate the light, which results in parallel rays of light. A POSITA would have understood that the LEDs of Larsen’s device mounted with reflectors deliver light in a very different way (*i.e.*, divergent forward-emitted light with the bundled radiation collected by the reflectors) than the LEDs of Jones’s device with matching lenses (*i.e.*, parallel light collimated by the lenses). Given this difference in directing the emitted rays of light, a POSITA would not have been motivated to apply the treatment distance of 5-8 cm used in Jones’s embodiments to Larsen’s device (as modified by Bansal).

120. Third, Larsen and Jones differ in the positioning of the device. Larsen discloses that “[i]n each applicator the printed circuit board carrying the light sources is connected to a small electrical scan engine 66, which can *move the light sources*

with linear movements.” Ex. 1004 (Larsen), [0072], [0028] (“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.”). In contrast, Jones discloses that “the lamp modules include *locking elements configured to lock the lamp modules* in the first and second positions.” Ex. 1006 (Jones), [0020], [0039], [0070], [0074], [0086], [0087], Fig. 5. Jones emphasizes the need to “maintain the precise positioning of the lamp modules.” Ex. 1006 (Jones), [0070] (“In order to *maintain the precise positioning of the lamp modules* according to the present invention in either of the planar or angled orientations, i.e. first and second position, the photodynamic therapy lamp according to the invention may be provided with *locking positions and/or locking elements that facilitate correct positioning* of the lamp modules in the first and second position and that prevent unwanted movement of the lamp modules during treatment. For example, a locking element may hold each lamp module in the first position, and the same or a different locking element may hold each lamp module in the second position. In addition, the locking positions and/or locking elements may provide positive feedback to an operator in order to ensure precise positioning of the lamp modules for treatment, thereby further reducing potential sources of error.”), [0074], [0086], [0087]. A POSITA would not have been motivated to combine Larsen’s device that moves during treatment to “permit[] an even and gap-free radiation of the surface” with the distance taught by

Jones for a device that *locks* to “maintain the precise positioning of the lamp modules.”

121. In combining Larsen (as modified by Bansal) with Jones’s teaching of 5-8 cm, Petitioner and Dr. Bretschneider appear to be using improper hindsight to cherry-pick Jones’s treatment distance, without any explanation of why a POSITA would have been motivated to apply such distance to an entirely different lamp configuration of Larsen as modified by Bansal.

122. Petitioner and Dr. Bretschneider further argue that “the distance between the illuminator and the treatment surface is a result effective variable” and “[d]etermining an optimum distance would have required nothing more than routine experimentation, which would have permitted POSITA using Larsen’s applicators to arrive at the optimal distances described in Jones.” Petition, 25; Ex. 1003 (Bretschneider Declaration), ¶169. However, Petitioner and Dr. Bretschneider do not provide any evidence supporting their statement that a POSITA would have arrived at Jones’s alleged “optimal distance” of 5-8 cm for a significantly different device, as opposed to Bansal’s treatment distance of 12 inches, as discussed above.

123. Petitioner and Dr. Bretschneider make conclusory statements regarding “routine experimentation” without any explanation of how or why a POSITA would have determined that Jones’s described distances of 5-8 cm were the “optimal distances” for Larsen’s device (as modified by Bansal). Petitioner and Dr.

Bretschneider's argument that a POSITA would have arrived at Jones's treatment distance of 5-8 cm with routine experimentation conflicts with Bansal's disclosure that an array "suspended *12 inches* above a subject" "can produce an acceptable average light intensity for phototherapy treatment." Ex. 1005 (Bansal), [0007].

124. Moreover, even if considered, determining whether Jones's 5-8 cm treatment distance could have been applied to Larsen's device (as modified by Bansal) would have required undue experimentation, at least because of the significant differences between the devices, including: (1) Larsen's device with five panels that "permits an even and gap-free radiation of the surface" as compared with Jones's device with two panels and a "gap" between panels, (2) Larsen's LEDs with "reflectors" as compared with Jones's LEDs with "a matching array of lenses," and (3) Larsen's "light sources with linear movements" as compared with Jones's lamp modules that are "lock[ed]" in order to "maintain the precise positioning of the lamp." Petitioner does not address these differences between Larsen's and Jones's devices, as discussed above. Nor does Petitioner address the variety of other factors that can affect the treatment distance and radiation received at the treatment surface, such as light intensity, dose of treatment, treatment time, wavelength, size of the panels, number of light sources, arrangement of light sources, distance between light sources, and location of the area to be treated on the patient.

125. Petitioner and Dr. Bretschneider further argue that “it may be necessary and would be desirable to place the panels of Jones at a further distance of about four inches (about 10 cm), and a POSITA would have been motivated to do so.” Ex. 1003 (Bretschneider Declaration), ¶¶213-214; Petition 35. However, the argument that a POSITA would have been motivated to combine Larsen (as modified by Bansal) with Jones’s treatment distance increased to about four inches fails for the same reasons as discussed above in paragraphs 111-124.

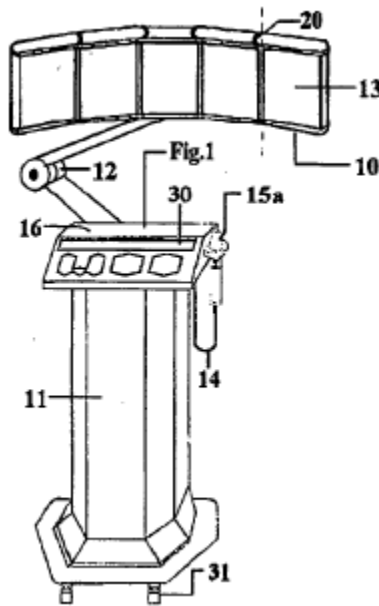
126. Accordingly, a POSITA would not have been motivated to combine Larsen’s device (as modified by Bansal) with the treatment distance described in Jones with a reasonable expectation of success.

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

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

128. Petitioner and Dr. Bretschneider argue that this limitation is disclosed by Larsen. Petition, 48-50; Ex. 1003 (Bretschneider Declaration) ¶¶98, 109-110, 138, 171, 262-267. However, Larsen does not disclose “a mobile base supported by *at least four wheels*.”

129. First, Petitioner argues that Fig. 1 of Larsen (shown below) “discloses a mobile base supported by at least four wheels.” Petition, 48-49. However, as Dr. Bretschneider acknowledges, “only two wheels are shown in Fig. 1 of Larsen.” Ex. 1003 (Bretschneider Declaration), ¶109. Larsen does not expressly disclose that the device is “supported by at least four wheels.”



Ex. 1004 (Larsen), Fig. 1.

130. Petitioner argues that “Larsen *necessarily* discloses that the base has at least four wheels in order to provide stability.” Petition, 49 (emphasis added). Dr. Bretschneider argues that “[a] POSITA would understand that if Larsen’s system only possessed the two wheels visible in Fig. 1, the system would rest on the back of the base which would require a user to tilt the entire system forward to move the system. This would create an unbalanced system which would significantly impair

the ability of a user to move the system and the system would thus not be ‘freely moveable.’” Ex. 1003 (Bretschneider Declaration), ¶265.

131. However, Petitioner and Dr. Bretschneider do 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 argues. 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.

132. Dr. Bretschneider further argues that “the generally hexagonal shape of the base of the device in Fig. 1 of Larsen would be most stable and freely moveable with at least four wheels.” Ex. 1003 (Bretschneider Declaration), ¶110. Once again, this argument merely establishes the possibility that Larsen’s device has four wheels.

133. As I discussed above, Dr. Bretschneider acknowledges that “[i]nherency may not be established by probabilities or possibilities.” Ex. 1003 (Bretschneider Declaration), ¶43. 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*."

134. 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." Petition, 49 (citing Ex. 1002 (File History of the '028 Patent), 328). 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.

135. Finally, Petitioner and Dr. Bretschneider argue 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." Petition, 49; Ex. 1003 (Bretschneider Declaration), ¶¶266-267. However, neither Petitioner nor Dr. Bretschneider 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." Petition, 49-50; Ex. 1003 (Bretschneider Declaration), ¶¶265-266. This 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.

136. Accordingly, Larsen does not disclose or render obvious “a mobile base supported by at least four wheels.”

XII. CONCLUSION

137. For at least the above reasons, Petitioner and Dr. Bretschneider 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.

08/16/2024
Date

Jose Sasian
Jose Sasian, Ph.D.

APPENDIX A: THE CHALLENGED CLAIMS 1-8, 10-11, 13-14, AND 16-21 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.
3. The system of claim 1, wherein the illuminator is configured to output light at an irradiance density of 10 mW/cm² to 30 mW/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.
7. The method of claim 5, wherein the illuminating comprises outputting blue light during at least part of the time when the treatment surface is illuminated.
8. The method of claim 5, further comprising changing intensities of the light sources of the illuminator with a controller in accordance with information received from at least one sensor relating to a curvature of the treatment surface.
10. The method of claim 5, further comprising determining a size of the treatment surface of the patient using a sensor.
11. The method of claim 10, further comprising adjusting an overall light dose with a controller based on the determined size of the treatment surface.
13. The method of claim 5, further comprising determining a shape of the treatment surface of the patient using a sensor.
14. The method of claim 13, further comprising adjusting an overall light dose with a controller based on the determined shape of the treatment surface.
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.
18. The system of claim 16, wherein the light sources are configured to output blue light during at least part of the time when the treatment surface is illuminated.
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.