

**EXPERT DECLARATION OF ERIC BRETSCHNEIDER, PH.D., FOR
INTER PARTES REVIEW OF U.S. PATENT NO. 11,697,028**

BIOFRONTERA EXHIBIT 1003

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IPR2024-01312

Biofrontera Inc. et al v. Sun Pharmaceutical et al

Sun Pharmaceutical's Exhibit 2082

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I. INTRODUCTION

1. I, Eric Bretschneider, submit this declaration in support of a Petition for *Inter Partes* Review of United States Patent No. 11,697,028 (“the ’028 Patent”), owned by DUSA Pharmaceuticals, Inc., (“DUSA” or “Patent Owner”). I have been retained in this matter by McGuireWoods (“Counsel”) on behalf of BIOFRONTERA INC., BIOFRONTERA BIOSCIENCE GMBH, BIOFRONTERA PHARMA GMBH, and BIOFRONTERA AG (collectively, “Biofrontera” or “Petitioner”).

2. I make this declaration based upon by personal knowledge. I am over the age of 21 and am competent to make this declaration.

3. The statements herein include my opinions and the bases for those opinions, which relate to at least the following documents of the pending *inter partes* review petition:

- U.S. Patent No. 11,697,028 by Thomas Boyajian et al. entitled “Adjustable Illuminator for Photodynamic Therapy and Diagnosis” (“the ’028 Patent”) (Ex. 1001)
- File History for U.S. Patent No. 11,697,028 (Ex. 1002)
- U.S. Patent Publication No. 2005/0075703 by Eric Larsen entitled “Photodynamic Stimulation Device and Methods” (“Larsen”) (Ex. 1004)
- U.S. Patent Publication No. 2004/0068305 by Vineet Bansal et al. entitled “Phototherapy System and Device” (“Bansal”) (Ex. 1005)

- U.S. Patent Publication No. 2014/0067024 by Ross Peter Jones et al. entitled “Dual Panel Photodynamic Therapy Lamp” (“Jones”) (Ex. 1006)
- WO 02/13788 by Richard Anderson entitled “Topical Aminolevulinic Acid-Photodynamic Therapy for Acne Vulgaris” (“Anderson”) (Ex. 1007)
- WO 99/56827 by Scott Lundhal et al. entitled “Illuminator for Photodynamic Therapy” (“Lundhal”) (Ex. 1011)
- WO 05/030328 by Nicholas Mackinnon et al. entitled “Apparatus and Methods for Performing Phototherapy, Photodynamic Therapy and Diagnosis” (“Mackinnon”) (Ex. 1012)

4. My materials considered for forming my opinions herein have included at least the above-referenced documents. A full list of materials considered may be found in Appendix A.

5. I understand that Petitioner retained me using Round Table Group (“RTG”), and that RTG is being compensated at a rate of \$695 per hour for my time spent in preparing this declaration. Regardless of my compensation in this matter, the opinions herein are my own, and I have no stake in the outcome of the review proceeding. My compensation does not depend in any way on the outcome of Petitioner’s petition.

II. QUALIFICATIONS

6. I am qualified by education and experience to testify as an expert in the field of LED photodynamic panel design. Attached, as Appendix B, is a copy of my curriculum vitae detailing my experience and education. Additionally, I provide the following overview of my background as it pertains to my qualifications for providing expert testimony in this matter.

7. I have a comprehensive background on the full range of LED production technologies, including MOCVD hardware/process, fabrication, LED chip and package testing and reliability, optical design, thermal management, color conversion, and SSL fixture/lamp design, integration, and reliability. I am a member of the University of Florida Department of Chemical Engineering Advisory Board. I have been a Conference Chair for LED Measurement and Standards. I also am a member of a number of professional societies, including SPIE, Materials Research Society, and Illuminating Engineering Society (including a member of numerous committees, including the IES test procedures committee). I have a Ph.D. in Chemical Engineering from the University of Florida (1997) and a BSE in Chemical Engineering from Tulane University (1989). I have direct experience with MOCVD hardware design, MOCVD process development (including AlGaAs, AlInGaP, and GaN materials), wafer characterization, die fabrication, LED test and reliability (die, package, and fixture level), LED package design (optical, thermal, and color-

conversion), and design of LED lighting fixtures. I was the Director of IP for an LED public company. I have extensive industry experience as set forth in my CV attached as Appendix B to this report, and I am an inventor or named author on over 45 patents and publications, including LED patents relating to national security matters.

8. I have 30 years of experience with lighting, lighting fixtures, displays, and LEDs, including a comprehensive background on a full range of LED technologies, including solid state lighting (SSL) fixture/lamp design, integration, and reliability, LED chip and package testing and reliability, fabrication, optical design, thermal management, color conversion, and Metal-Organic Chemical Vapor Deposition ("MOCVD") hardware/process.

9. Throughout the course of my career, I have designed and transferred into manufacturing over 150 different LED-based lighting products, including LED lighting products designed to be installed in fixtures and in different lighting environments and applications. I have also designed and transferred into manufacturing dozens of different LED chips and packages for a variety of different applications.

10. I am currently the Chief Technology Officer at EB Designs & Technology. In that capacity, I am, among other things, responsible for the design of solid-state lighting technologies for clients ranging from startups to Fortune 100

companies. I previously served as Chief Technology Officer at QuarkStar, LLC., from 2016 until 2023. QuarkStar is primarily a technology development company that is focused on new approaches to improving performance and efficiency of products that rely on LED light sources.

11. I also served as a member of the University of Florida's Department of Chemical Engineering Advisory Board for 25 years from 1998 until 2022. During my tenure on this Advisory Board, I served as Chair for a total of 8 years. I also served on the Dean's Advisory board for the College of Engineering at the University of Florida from 2007-2009 and 2017-2022. I have been a Conference Chair for LED Measurement and Standards. I am also a member of a number of professional societies, including the International Society for Optics and Photonics (SPIE), Optica, the Materials Research Society, The American Society of Agricultural and Biological Engineers (ASABE), and the Illuminating Engineering Society (IES).

12. Inside the IES, I am a founding member of the Science Advisory Panel which has oversight over all testing and technical committees and work groups inside the IES. I am also a full member of the Test Procedures Committee which develops test, measurement and reliability standards for lighting fixtures. Inside the Test Procedures Committee, I serve as chair of the projections and reliability subcommittee which develops reliability standards for LED based lighting products including utilizing all forms of lighting technologies. I recently lead the work group

that revised TM-21 which is the internationally accepted standard for predicting reliability of LED packages. I also developed a new mathematical model that for the first time allows prediction of the color shift of an LED package over its time. This model is the basis for a new IES standard known as TM-35. Which predicts the rate of color shift for LED products over time.

13. I joined the IES in 2006 and have been a member of the Test Procedures Committee since that time. As a result, I have been an active participant in the development of testing standards related and have helped to formalize the terminology for solid state lighting since the beginnings of the industry. Additionally, I also serve on the IES Color Committee and the IES Photobiology Committee.

14. Prior to my position at EB Designs & Technology, I served as the Director of Engineering at HeathCo, LLC. In that capacity, I was responsible for advanced technology/product development related to solid-state lighting, sensors, notifications, and control products.

15. Prior to my position as Director of Engineering at HeathCo, I was at the Elec-Tech International Co., Ltd., where I held the positions of Chief Engineer, ETi Lighting Research Institute and VP of Research and Development, ETi Solid State Lighting. In my Elec-Tech capacities, my responsibilities included developing all technology and product roadmaps for markets in North America, China, Europe, and

Japan. I designed and developed LEDs, LED packages and LED based lighting products for all of these markets.

16. Between 2008 and 2011, I was at Lighting Science Group Corporation (LSG), first as a product development manager, and my responsibilities included developing solid state lighting products, then as VP of Research, and my responsibilities included developing advanced LED models for product development and production control. In these roles, I was involved in the design and manufacture of numerous LED-based lighting fixtures and products. The products I helped launch included LSG's C2D (Curb to Door) products. These products were designed to be installed in outdoor locations including wall packs, parking lots, and streetlights. These fixtures, and in particular the wall pack fixtures in particular, were also suitable for installation in public transportation areas. Additionally, I helped develop horticultural light products and human health related products and technology for Lighting Science Group.

17. Between 2004 and 2008, I was at Toyoda Gosei North America, where I was a sales manager, and my responsibilities included managing and developing LED die and package sales accounts from the eastern region of North America. I was also tasked with providing technical support for the entire western hemisphere. The support I provided included design of LED packages and design of lighting fixtures and products that incorporated LED packages. My support included aiding

customers in design of panel light-based fixtures for direct-view displays in indoor and outdoor environments. I also provided significant design support for several customers for both edge-lit and back lit displays for small electronics, computer display and entertainment applications. Additionally, I provided design support for customers using LEDs in photodynamic therapy applications.

18. Between 2003 and 2004, I was at Beeman Lighting, where I was Director of Solid State Lighting Engineering, and my responsibilities included leading development of solid state lighting systems and materials.

19. Between 1998 and 2003, I was at Uniroyal Optoelectronics where I held a number of positions including Team Leader for the Epitaxial Growth and Materials Characterization areas, Sr. Epi Scientist, Director of Intellectual Property, University Relations and Government Contracts. My responsibilities included MOCVD hardware modification, epitaxial process development as well as design, development and testing of new LED chip structures for both AlInGaP and GaN-based material systems. I was also responsible for providing technical support and assistance to customers on topics related to use of LED chips, design of LED packages and design of LED based lighting products and systems. This support included both optical and thermal design of LED packages and LED lighting products.

20. During my time at Uniroyal, I also provided design support for several customers for phototherapy products. These included phototherapy products that operated at near UV wavelengths and deep red wavelengths. This involved design and development of LEDs with peak wavelengths in the range of 415-420 nm for treatment of sebaceous gland disorders (e.g. acne) as well as design of single and multi-panel lighting units for treatment systems in phototherapy. These single and multi-panel assemblies were used for facial treatments as well as other parts of the human body. My work on the panel light sources included optical and thermal management design as well as the electrical configuration of the LEDs.

21. During the design process for these single and multi-panel assemblies, it was important to achieve a uniform distribution of light on the treatment surface, as this was a well-known goal of any light source. While these panels were for use in phototherapy and not PDT, the design principles on the panel side are the same in both applications.

22. Other medical products that I worked on from 1998 to 2003 at Uniroyal included implantable light sources for photoactivated chemotherapy protocols for the Paul Allen Foundation.

23. During my time at Uniroyal from 2000 until 2003, I also consulted with NASA to develop horticultural lighting panels based on an early chip on board (COB) product, called the Hex, that I helped develop with a sister company called

Norlux Corporation. The Hex products incorporated multiple LED chips of different types (emission wavelengths) and independent control of the optical energy emitted at different wavelengths.

24. From 1996 to 1998 I worked at Emcore Corporation as a Process Engineer. There I was responsible for qualifying MOCVD capital equipment for production and manufacturing process development for epitaxial structures. Some of the processes I developed included both AlInGaP and GaN based LED structures.

25. I have also authored and presented over 50 publications, presentations, and seminars, and I am a named inventor on more than 45 issued US patents as well as dozens of foreign patents. I am also a named inventor on over 25 pending US and foreign patents. A number of these patents were for devices with LED light sources and phototherapeutic applications.

26. I earned a Ph.D. in Chemical Engineering from the University of Florida in 1997, where my graduate work focused on development of optoelectronic devices, including novel silicon based visible LEDs and sulfide based TFELD structures and zinc selenide blue LEDs.

27. In 1989, I worked for Shell Oil Corporation in Norco, LA. I was tasked with modeling heat exchanger performance for the crude oil distillation column in order to identify cost saving opportunities. I developed an improved model for determining the operating efficiency of heat exchange units that incorporated

determined the economic impact on different operating conditions. The model was designed to be compatible with all major operating units on site and resulted in costs savings of over \$20 million/year at the Norco Facility alone. My work was quickly adopted throughout the entire corporation and has resulted in sustained annual cost savings of approximately \$500 million/year.

28. Based on the above education and experience, I believe that I have a detailed understanding of the state of the art during the relevant period, as well as a sound basis for opining how persons of ordinary skill in the art at that time would understand the claim terms and technical issues in this case.

29. I have previously served as a testifying expert witness in prior patent cases as set forth on Appendix B.

30. The opinions stated in this declaration are based on my own personal knowledge and professional judgment; if called as a witness during any proceeding in this matter I am prepared to testify competently about them.

31. In forming my opinions, I have considered the materials discussed and cited herein, including the asserted patents, the prosecution histories of the patents, and prior art references discussed herein, and any other references referred to or cited in this declaration.

32. Additional details regarding my qualifications and background can be found in my CV (Appendix B).

III. PERSON OF ORDINARY SKILL IN THE ART

33. I understand that the content of a patent (including its claims) and prior art should be interpreted the way a person of ordinary skill in the art would have interpreted the material at the time of invention.

34. I understand that the '028 Patent, filed on September 12, 2022, is a continuation of Application No. 16/791,004, filed on February 14, 2020 (now U.S. Patent No. 11,446,512), which is a division of Application No. 15/292,731, filed on October 13, 2016 (now U.S. Patent No. 10,589,122), which claims priority to Provisional Application No. 62/241,902, filed on October 15, 2015. Accordingly, I understand that the “time of invention” for claims 1–8, 10, 11, 13, 14, and 16-21 of the '028 Patent is October 15, 2015. All of the prior art references my opinions are based on were published more than a year before the earliest effective filing date (October 15, 2015).

35. In addition to my testimony as an expert, I am prepared to testify as someone who actually practiced in the field from 2002 to the present, who actually possessed at least the knowledge of a person of ordinary skill in the art in that time period and as of the earliest effective filing date, and who actually worked, supervised and recruited others possessing at least the knowledge of a person of ordinary skill in the art in that time period and as of the earliest effective filing date.

36. I understand that the person of ordinary skill is a hypothetical person who is assumed to be aware of all the pertinent information that qualifies as prior art. In addition, the person of ordinary skill in the art makes inferences and takes creative steps.

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

IV. LEGAL UNDERSTANDING

38. I have a general understanding of validity based on my experience with patents and my discussions with counsel.

39. I have a general understanding of prior art and priority dates based on my experience with patents and my discussions with counsel.

40. I understand that an invention by another must have been patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of a particular patent claim in order to qualify as “prior art” under 35 U.S.C. § 102(a)(1), or that the invention by another must be described in a patent or published application that was effectively filed before the effective filing date of a particular patent claim in order to qualify as “prior art” under 35 U.S.C. § 102(a)(2). I understand that Petitioner has the burden of proving that any particular reference is prior art.

41. I have a general understanding of anticipation based on my experience with patents and my discussions with counsel.

42. I understand that anticipation analysis is a two-step process. The first step is to determine the meaning and scope of the asserted claims. Each claim must be viewed as a whole, and it is improper to ignore any element of the claim. For a claim to be anticipated under U.S. Patent law: (1) each and every claim element must be identically disclosed, either expressly or inherently, in a single prior art reference;

(2) the claim elements disclosed in the single prior art reference must be arranged in the same way as in the claim; and (3) the identical invention must be disclosed in the single prior art reference, in as complete detail as set forth in the claim. Where even one element is not disclosed in a reference, the anticipation contention fails. Moreover, to serve as an anticipatory reference, the reference itself must be enabled, i.e., it must provide enough information so that a person of ordinary skill in the art can practice the subject matter of the reference without undue experimentation.

43. I further understand that where a prior art reference fails to explicitly disclose a claim element, 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. The fact that an element may result from a given set of circumstances is not sufficient to prove inherency. I have applied these principles in forming my opinions in this matter.

44. I have a general understanding of obviousness based on my experience with patents and my discussions with counsel.

45. I understand that a patent claim is invalid under 35 U.S.C. § 103 as being obvious only if the differences between the claimed 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 that art. An obviousness analysis requires consideration of four factors: (1) scope and content of the prior art relied

upon to challenge patentability; (2) differences between the prior art and the claimed invention; (3) the level of ordinary skill in the art at the time of the invention; and (4) the objective evidence of non-obviousness, such as commercial success, unexpected results, the failure of others to achieve the results of the invention, a long-felt need which the invention fills, copying of the invention by competitors, praise for the invention, skepticism for the invention, or independent development.

46. I understand that a prior art reference is proper to use in an obviousness determination if the prior art reference is analogous art to the claimed invention. I understand that a prior art reference is analogous art if at least one of the following two considerations is met. First a prior art reference is analogous art if it is from the same field of endeavor as the claimed invention, even if the prior art reference addresses a different problem and/or arrives at a different solution. Second, a prior art reference is analogous art if the prior art reference is reasonably pertinent to the problem faced by the inventor, even if it is not in the same field of endeavor as the claimed invention.

47. I understand that a claim may be obvious in view of a single prior art reference, without the need to combine references, if the elements of the claim that are not found in the reference can be supplied by the knowledge or common sense of one of ordinary skill in the relevant art. However, I understand that it is inappropriate to resolve obviousness issues by a retrospective analysis or hindsight

reconstruction of the prior art and that the use of “hindsight reconstruction” is improper in analyzing the obviousness of a patent claim.

48. I further understand that the law recognizes several specific guidelines that inform the obviousness analysis. First, I understand that a reconstructive hindsight approach to this analysis, i.e., the improper use of post-invention information to help perform the selection and combination, or the improper use of the listing of elements in a claim as a blueprint to identify selected portions of different prior art references in an attempt to show that the claim is obvious, is not permitted. Second, I understand that any prior art that specifically teaches away from the claimed subject matter, i.e., prior art that would lead a person of ordinary skill in the art to a specifically different solution than the claimed invention, points to non-obviousness, and conversely, that any prior art that contains any teaching, suggestion, or motivation to modify or combine such prior art reference(s) points to the obviousness of such a modification or combination. Third, while many combinations of the prior art might be “obvious to try”, I understand that any obvious to try analysis will not render a patent invalid unless it is shown that the possible combinations are: (1) sufficiently small in number so as to be reasonable to conclude that the combination would have been selected; and (2) such that the combination would have been believed to be one that would produce predictable and well understood results. Fourth, I understand that if a claimed invention that arises from

the modification or combination of one or more prior art references uses known methods or techniques that yield predictable results, then that factor also points to obviousness. Fifth, I understand that if a claimed invention that arises from the modification or combination of one or more prior art references is the result of known work in one field prompting variations of it for use in the same field or a different one based on design incentives or other market forces that yields predictable variations, then that factor also points to obviousness. Sixth, I understand that if a claimed invention that arises from the modification or combination of one or more prior art references is the result of routine optimization, then that factor also points to obviousness. Seventh, I understand that if a claimed invention that arises from the modification or combination of one or more prior art references is the result of a substitution of one known prior art element for another known prior art element to yield predictable results, then that factor also points to obviousness.

49. I understand that it must be shown that one having ordinary skill in the art at the time of the invention would have had a reasonable expectation that a modification or combination of one or more prior art references would have succeeded.

50. I understand that obviousness does not require physical combination or bodily incorporation, but rather consideration of what the combined teachings would have suggested to a POSITA at the time of the invention.

51. I understand that a dependent claim incorporates each and every limitation of the claim from which it depends. Thus, my understanding is that if a prior art reference fails to anticipate an independent claim, then that prior art reference also necessarily fails to anticipate all dependent claims that depend from the independent claim. Similarly, my understanding is that if a prior art reference or combination of prior art references fails to render obvious an independent claim, then that prior art reference or combination of prior art references also necessarily fails to render obvious all dependent claims that depend from the independent claim.

V. KNOWLEDGE OF A PERSON OF ORDINARY SKILL IN THE ART

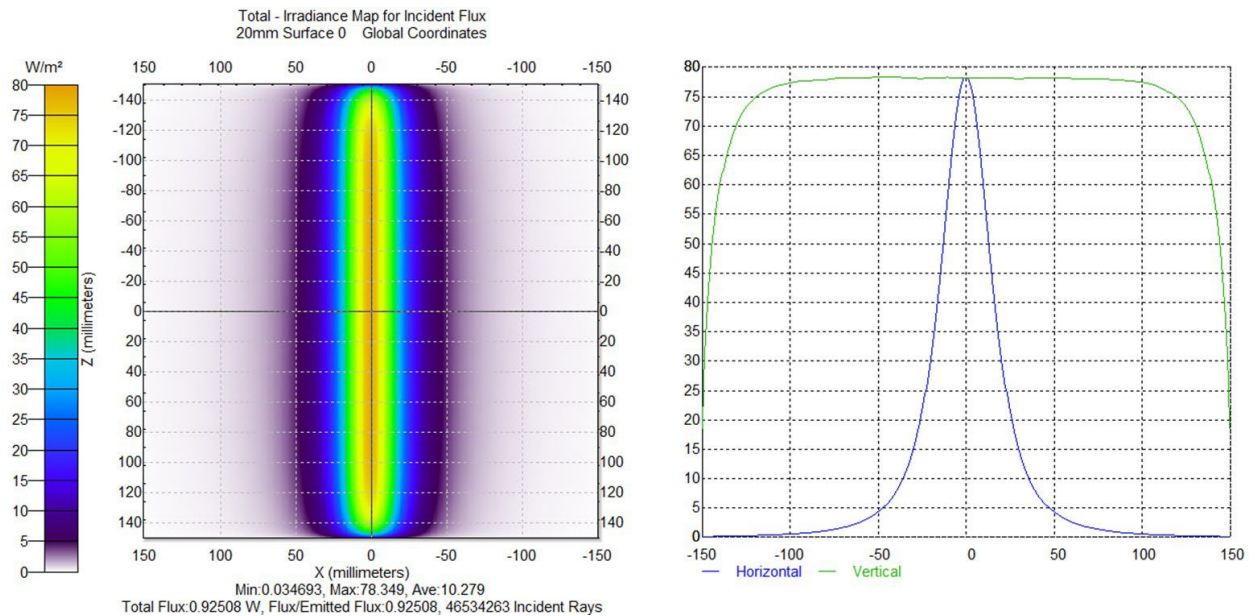
52. A person of ordinary skill in the art would be well aware of optical design considerations, related to achieving uniform irradiance or equivalently delivering a uniform dose to a surface.

53. Within the field of optical design, the concepts of far-field and near-field are relevant to the present case. In the far-field, irradiance follows an inverse square relationship. This means that doubling the distance results in decrease in irradiance by a factor of four. Traditionally, the far field condition is defined as 6-10x that maximum dimension of a light source. At that distance, the light source can be effectively treated as a point source without introducing significant error.

54. In the near field, irradiance will not follow an inverse square relationship and the behavior of irradiance with respect to distance will depend on the geometry of a light source. For linear light sources, in the near-field, irradiance will vary as approximately the inverse of the distance.

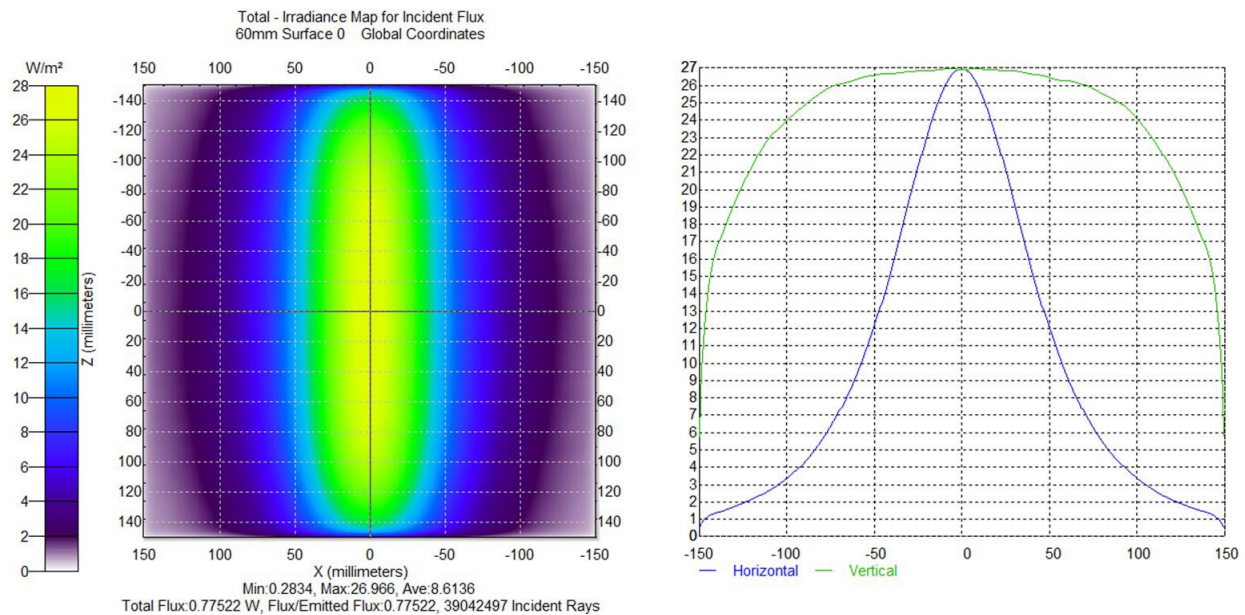
55. To demonstrate this, a linear light source with width of 5 mm and a length of 300 mm was modeled in TracePro, which is a commercial optical design software package that uses ray tracing to simulate and design optical systems. In the simulation, the irradiance was calculated for a planar target with dimensions of 300 mm x 300 mm was calculated at distances of 20 mm, 40 mm, 60 mm, 80 mm, and

100 mm. The figure below shows the irradiance at a distance of 20 mm from the linear light source.



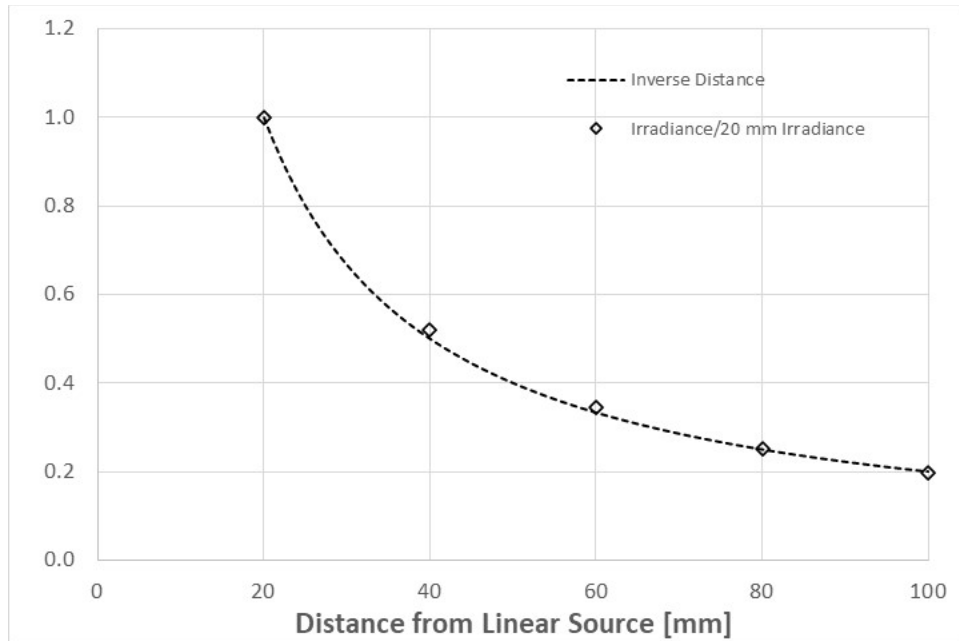
56. It is noted that the irradiance along the axis of the linear light source is highly uniform as would be expected for near-field conditions. The irradiance at the center is about 78.34 W/m².

57. The figure below shows the irradiance at a distance of 60 mm from the linear light source.



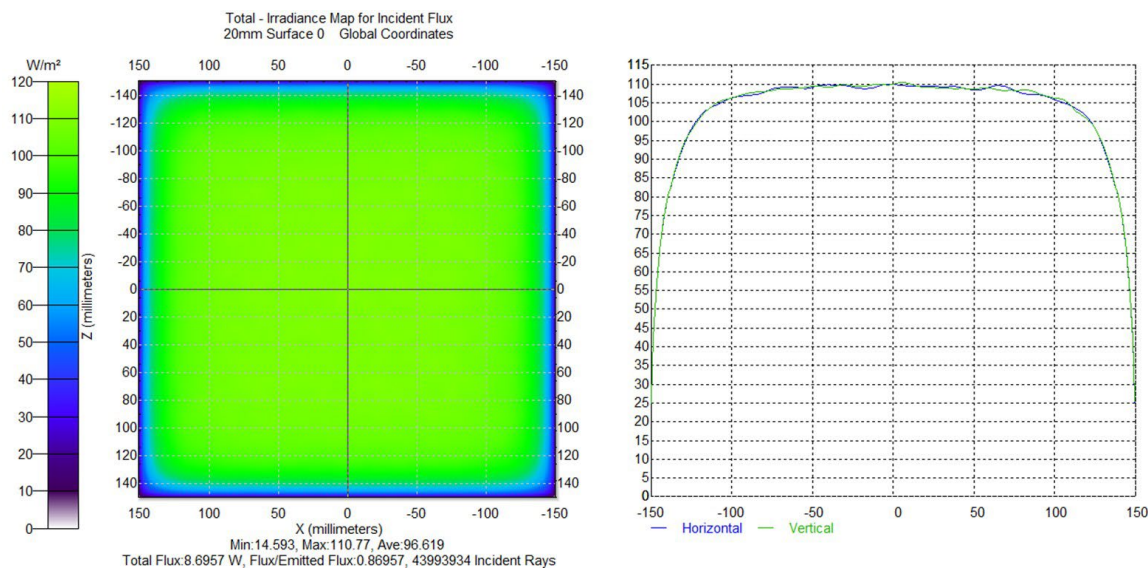
58. Edge effects (non-uniform irradiance) are more evident at this distance, but the irradiance near the central portion remains highly uniform. Notably, the irradiance at the center has decreased to about 26.966 W/m² which is approximately 1/3 the irradiance at 20 mm, consistent with an inverse relationship between irradiance and distance.

59. The plot below shows the peak irradiance normalized to the peak irradiance at 20 mm and a true inverse distance relationship. It is readily evident that the irradiance of a linear light source in the near field closely follows an inverse relationship.

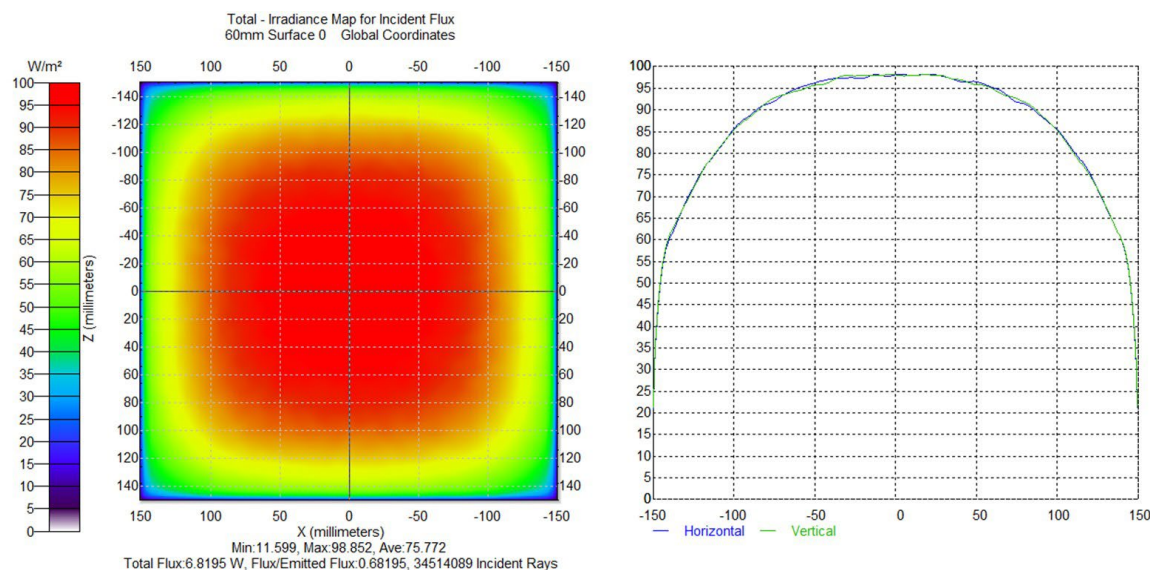


60. In order to demonstrate the behavior of a planar light source, a similar model was created in TracePro using a 300 mm x 300 mm light source and a series of planes located at 20 mm, 40 mm, 60 mm, 80 mm, and 100 mm from the light source.

61. The plot below shows the irradiance at 20 mm from the light source.



62. As expected, the irradiance of a planar light source in the near field is highly uniform. Moreover, in the near field, irradiance is a weak function of distance. This is shown in the image below which shows the irradiance at a distance of 60 mm from the planar light source.



63. The table below shows the maximum irradiance as a function of distance. As expected, the maximum irradiance is only a weak function of distance and is essentially constant to within about $\pm 10\%$ over distances between 20 mm and 80 mm (from less than 1 inch to over 3 inches).

Distance (mm)	Max. Irradiance (W/m ²)
20	110.77
40	105.82
60	98.852
80	90.566
100	81.936

64. For these reasons, a POSITA would understand¹ that it is a fundamental principles of optics that irradiance (and hence dosage) is essentially uniform for planar light sources in the near field. Importantly, even small differences in distance do not significantly change the irradiance (or dose) so long as a nominally uniform light source is used.

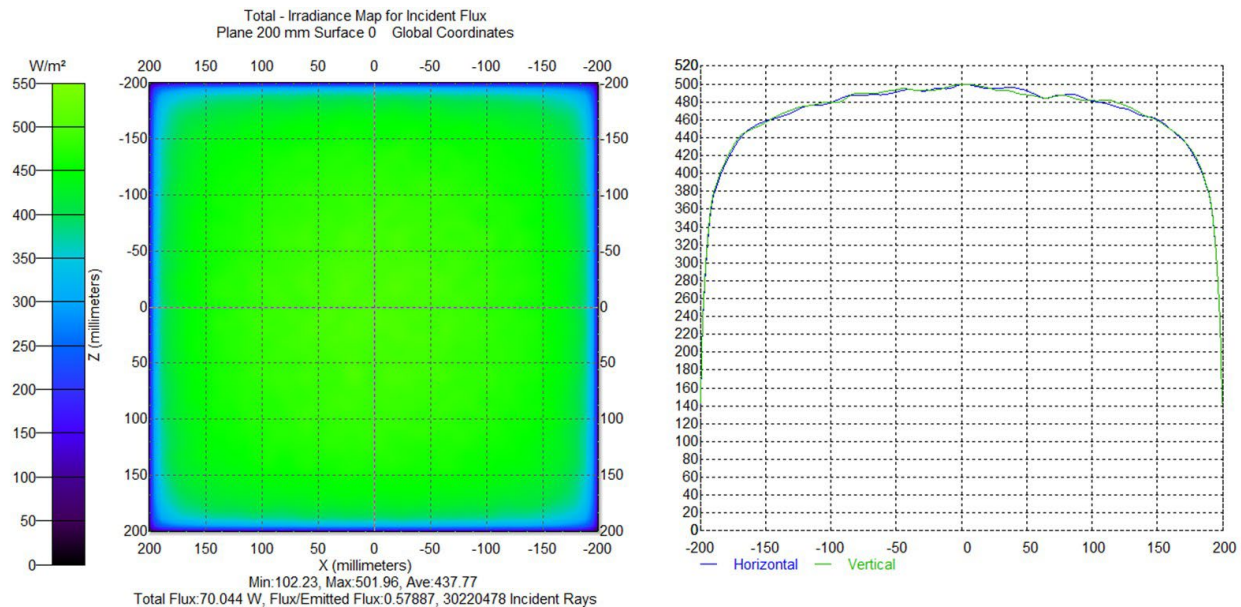
65. Further, when using arrays of small light sources, such as LEDs, a person of ordinary skill in the art would also be aware that edge effects could be compensated for by increasing the areal density of LEDs, or increasing the drive level (power input) to LEDs near the peripheral areas of a panel.

66. The examples discussed above utilized light sources with a Lambertian emission pattern. A Lambertian emitter is relatively unfocused and has a beam angle (angular span where the intensity falls to half that of the maximum value) of about 120°. A POSITA would be aware that LEDs with more focused light output could also be used and that such focused outputs would enable highly uniform irradiance to be achieved at even greater distances.

67. The TracePro model of the LED array was modified to LEDs with a beam angle of about 30°. The resulting irradiance map at 200 mm (about 8 inches) is shown below. As can be seen, the uniformity at 200 mm for LEDs with a narrower

¹ References throughout to what a POSITA would know or understand means a POSITA's knowledge or understanding as of the earliest effective filing date of the '028 Patent.

emission pattern is superior to that of LEDs with a Lambertian emission pattern at 20 mm.



68. These examples demonstrate the knowledge of a person of ordinary skill in the art with respect to design of two-dimensional light sources using arrays of LEDs and the ease of creating an LED-based panel light source capable of delivering uniform irradiance for a variety of applications.

69. This understanding of the knowledge of a person of ordinary skill in the art is evidenced in U.S. Patent Publication No. 2004/0127961 (hereinafter referred to as “Whitehurst.” Whitehurst was published on July 1, 2004 and claims priority to U.S. Patent Application No. 09/815,348 filed on March 23, 2001.

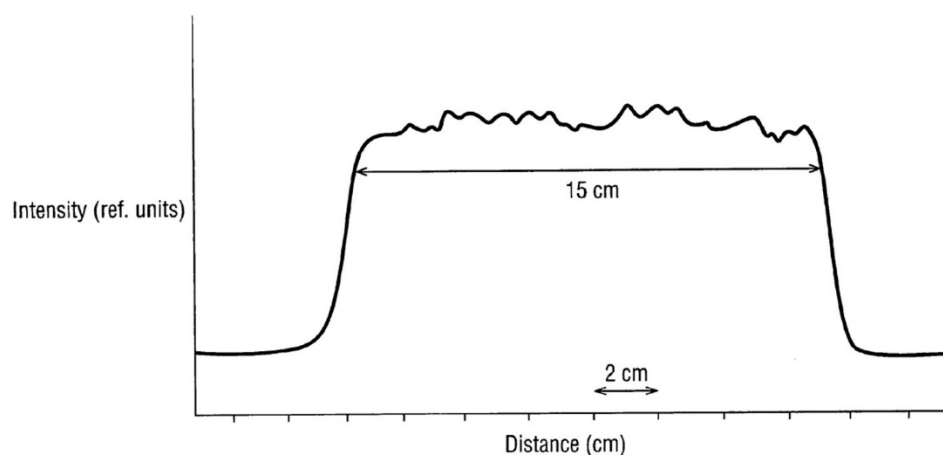
70. Whitehurst teaches an LED based photodynamic therapy system. “The present invention relates to a non-coherent light source for use in therapy such as

photodynamic therapy (PDT), particularly using light emitting diodes (LED's).” [Whitehurst ¶0003].

71. Whitehurst teaches “The LEDs L are arranged so as to produce a substantially uniform illumination of $\pm 0.10\%$ or less across a treatment field by Selecting the beam divergence and spacing of the LED's L so that their individual beams overlap without causing substantial peaks or troughs in intensity. In the example shown in FIG. 4, uniformity of $\pm 0.6\%$ is achieved. In this embodiment, no optical system is needed between the LEDs and the patient; instead, the light is emitted directly from the LEDs onto the patient.” [Whitehurst ¶0047].

72. Indeed, the reproduction of Fig. 4 of Whitehurst below is highly similar to the TracePro simulations discussed above illustrating the uniformities that can be achieved using arrays of LEDs as a PDT light source.

FIG. 4

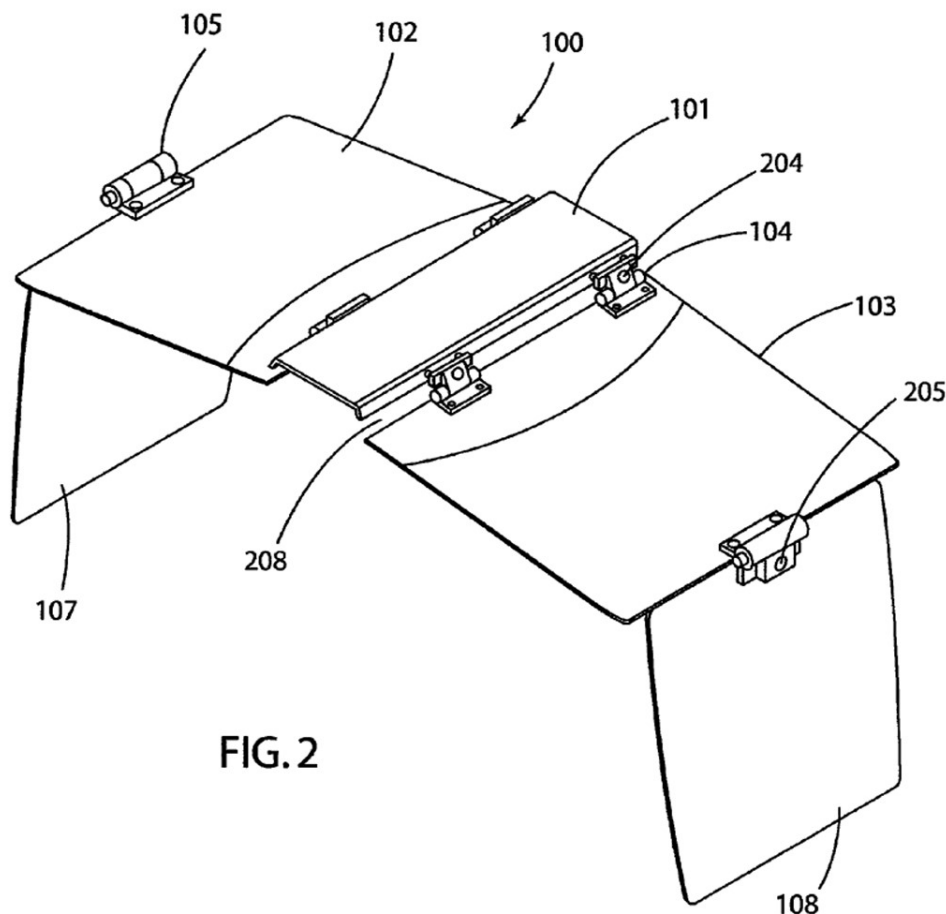


73. Further, a POSITA would also be aware of the use of phototherapy systems that incorporate multiple panels connected by hinge structures. U.S. Patent No. 7,517,101 (hereinafter referred to as a “Tobin”) was granted on April 4, 2009 and was filed on March 27, 2007. The background of Tobin describes “An apparatus is desired to allow the treatment of human skin disease and cosmetic abnormalities in an easier manner.” [Tobin 1:13-14]. This is understood to describe a phototherapy device.

74. One embodiment of Tobin is described “The reference number 100 (FIGS. 1-2) generally designates a convertible lamp array device embodying the present invention. In the illustrated example, the convertible lamp array device 100 comprises spine 101, a first side panel 102, and a second side panel 103, with the first side panel 102 and the second side panel 103 being rotatably attached to the spine 101.” [Tobin 3:3-9]. Tobin further clarifies that the spine and side panels comprise light sources. “Electrical light sources, shown in more detail in FIGS. 11 and 12, are located on inner surfaces of the first side panel 102, the second side panel 103 and a bottom surface of the spine 101. A first wing panel 107 and a second wing panel 108 are rotatably attached to the first side panel 102 and the second side panel 103, respectively. In the illustrated example, the first wing panel 107 and the second wing panel 108 are rotatably attached to the first side panel 102 and the second side panel 103 by lower hinges 105. Although only one hinge 105 is illustrated as

connecting the first wing panel 107 and the second wing panel 108 to the first side panel 102 and the second side panel 103, it is contemplated that any number of hinges 105 could be used or that the first wing panel 107 and the second wing panel 108 could be rotatably attached to the first side panel 102 and the second side panel 103 in any manner.” [Tobin 3:22-37].

75. Fig. 2 of Tobin is reproduced below and it is clearly evident that the spine and the side panels have different sizes.

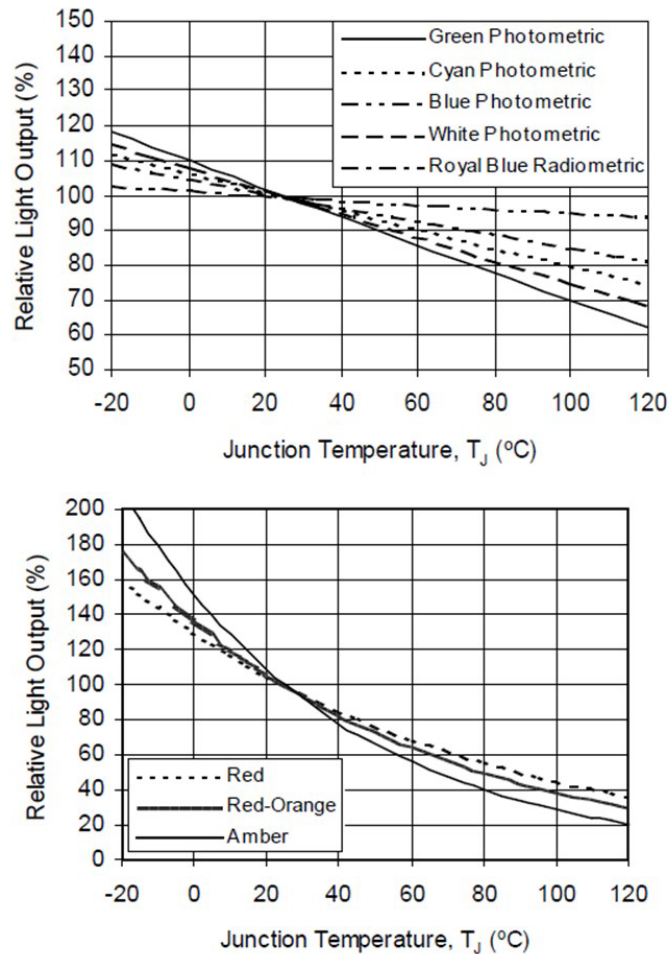


76. Tobin explicitly describes that panels may be of different sizes and states the desirability of delivering a uniform distribution of light. “Aspects of the

convertible lamp array devices 100 and 210 of the present invention include an absence of heat sinks and stands to produce a smaller, lighter device that can be carried by a clinician from room to room, a constant-torque application mechanism that resides in the hinges to produce a device that is self-supporting, illumination panels that comprise one smaller, rectangular panel bounded on both longer sides by two larger, substantially square panels to product a device that emits a more uniform distribution of radiation onto a face and nose of a patient”. [Tobin 6:62-7:4].

77. A person of ordinary skill in the art would also be aware of the effects of temperature on the operation and reliability of LEDs. In particular, a POSITA would know that the efficiency of LEDs decreases as the operating temperature increases. Indeed, this information is commonly found on the specification sheets for LEDs. The images below are for LED products from Lumileds, which is a well-known, domestic LED company. [DS23 Technical Datasheet at p7]. As can be seen, the relative light output for LEDs of different colors all decrease as temperature increases.

Light Output Characteristics



78. Similarly, a POSITA would also be aware of the use of accelerated lifetime testing based via high temperature operation in standards including MIL-HDBK-217F. [HDBK pp6-2, 6-19]. Such standards utilize high operating temperature to increase the degradation rate of electronic devices. Absent device specific reliability testing, MIL-HDBK-217F would direct a POSITA to assume that lifetime of LEDs is decreased by a factor of 2x for every 25°C increase in operating temperature. [HDBK p6-19].

VI. THE '028 PATENT

A. Priority Dates

79. I note that the '028 Patent claims priority to several earlier patent applications, the earliest of which, U.S. Provisional Application No. 62/241,902, was filed on October 15, 2015. ['028 Patent at (60))].

80. I am not aware at this time of any basis for an assertion of a priority date that would be earlier than October 15, 2015. My usage of the foregoing alleged priority dates for my analyses to follow does not mean that I agree that any claims of the '028 Patent should be accorded this priority date. Even still, the references on which I base my opinions were all published well before October 15, 2015.

B. The '028 Patent's Specification

81. It is noted that the '028 Patent uses the term “illuminator” to describe light panels for PDT/PT applications. This is technically incorrect as an illuminator would be used to provide illumination – light for the purpose of being seen. The relevant unit for illumination would be the lumen which is a psychophysical unit related to the amount of light as perceived by the human eye. PDT/PT applications are based on delivering a specified irradiance (energy of light per area) for a specified time and hence the correct technical term would be “radiator”. Throughout my analysis here, I treat the term “illuminator” as synonymous with “radiator”.

82. The '028 Patent teaches “ [A]n 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.” [‘028 Patent 1:20-22]. A POSITA would understand that in the context of the '028 Patent, “distribution of visible light” refers to the irradiance delivered by the light source, that is to say, the intensity distribution of light incident on a surface.

83. The '028 Patent uses the acronyms “PDT” and “PD” for the terms “photodynamic therapy” and “photodynamic diagnosis” respectively. The '028 Patent further explains the general approach for PDT or PD. “ [A] patient is first administered a photoactivatable agent or a precursor of a photo activatable agent that accumulates in the tissue to be treated or diagnosed. The area in which the photoactivatable agent is administered is then exposed to visible light, which causes chemical and/or biological changes in the agent. These changes allow the agent to then selectively locate, destroy, or alter the target tissue while, at the same time, causing only mild and reversible damage to other tissues in the treatment area.” [‘028 Patent 1:36-45].

84. The '028 Patent teaches that it is desirable for the power output to be uniform. “For effective treatment, it is desirable to have a power output that is uniform in intensity and color.” [‘028 Patent 1:50-51].

85. The '028 Patent also teaches that adjusting the power input to certain areas of panels is one way to improve uniformity. "In 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." ['028 Patent 3:14-21].

86. The '028 Patent also teaches that light exposure will decrease with increased distance from the light source (i.e., panel). "In addition, a 'fall off' increases as the distance between the light source and the point on the surface increases." ['028 Patent 6:8-10].

87. In order to compensate for intensity fall off and improve uniformity, the '028 Patent teaches changing the intensity of some LEDs to compensate for fall off. "In order to increase the uniformity of light exposure to the treatment area while maintaining a practical size of the illuminator, the LED arrays 60 may be individually configured to increase the intensity of light emitting from certain diodes to compensate for this fall-off effect." ['028 Patent 6:18-23].

88. Specifically, the '028 Patent teaches increasing the intensity of light emitted from LEDs at the edges of panels. "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 than the current supplied to areas 3 and 4 such that areas 1 and 2 emit a higher intensity of light than areas 3 and 4. Similarly, a higher current may be supplied to areas 3 and 4 than the current supplied to areas 5 and 6. Thus, a higher intensity of light is emitted overall from the edges, which may allow for a reduction in any fall-off effect.” [‘028 Patent 6:32-40].

89. Exemplary embodiments of the ‘028 Patent are described as being able to achieve uniformities of 60% to 80%. “In one embodiment, the measured output over the active emitting area (over the entire active emitting area) is within 60% of the measured maximum (over the entire active emitting area) measured with a cosine response detector over all operation distances. More preferably, the measured output over the emitting area is within 70% of the measured maximum over a distance of two and four inches. Even more preferably, the measured output over the emitting area is within 80% of the measured maximum over a distance of two and four inches.” [‘028 Patent 8:58-67].

90. Confusingly, the ‘028 Patent refers to Lambert’s cosine law in reference to a special and specific type of surface. “For example, under Lambert’s cosine law, light intensity at a given point on a ‘Lambertian’ surface (such as skin) is directly proportional to the cosine of the angle between the incoming ray and the normal to the surface. Thus, a ray of light that is directed to the front of a curved surface (e.g., a head of a patient) will arrive in a substantially perpendicular manner to that area

and will result in 100% absorbance. However, a ray of light that arrives at a side edge of the curved surface will arrive in a substantially parallel manner. According to Lambert's cosine law, the intensity, and thus absorption, of the light at the side edge will approach zero, making treatment at that area ineffective.” [’028 Patent 5:62-6:7]. This, however, is contrary to a POSITA’s understanding of “Lambert’s Law” in the field of optics. Further, perpendicular incidence of light does not necessarily equate to 100% absorbance as skin reflects significant amounts of light over the entire visible spectrum. [Cooksey, C.C., “Reference Data set and Variability Study for Human Skin Reflectance,” (2019)].

91. Lambert’s Law is defined as “[t]he law that the illumination of a surface by a light ray varies as the cosine of the angle of incidence between the normal to the surface and the incident ray.” [McGraw-Hill Dictionary of Scientific and Technical Terms (5th Ed.) p. 1104]. Further, a POSITA would understand a Lambert surface (or Lambertian surface) to be “[a]n ideal, perfectly diffusing surface for which the intensity of reflected radiation is independent of direction.” [McGraw-Hill Dictionary of Scientific and Technical Terms (5th Ed.) p. 1104].

92. The ‘028 Patent appears to identify a “Lambertian surface” as a special surface and not a fundamental matter of geometry, as the ‘028 Patent’s description of a “Lambertian surface” applies to all surfaces and hence is devoid of any meaning.

93. While this confusion does not appreciably alter the teachings of the patent, it does suggest that the inventors of the '028 Patent were not fully familiar with standard optical terms and may have lacked a full understanding of optical principles.

94. The '028 Patent includes 21 claims. I have been informed by counsel that Claims 1-8, 10, 11, 13, 14, and 16-21 are the subject of the *Inter Partes* Review petition.

C. The '028 Patent's Prosecution History

95. The '028 Patent was filed on September 12, 2022, as application number 17/942,353. I summarize here the actions most relevant to the grounds of unpatentability set forth in the present Petition. On November 18, 2022, the Examiner issued a non-final office action rejecting filed claims 18 and 20-22 as being obvious over the combination of U.S. Patent No. 7,033,381 ("Larsen '381 Patent") in view of U.S. Publication No. 2006/0253175 ("Fan"). [Prosecution History, Office Action Dated Nov. 18, 2022]. The Examiner also indicated that filed claims 3, 6, 9, and 19 included allowable subject matter. [Nov. 18, 2022 Office Action, ¶22].

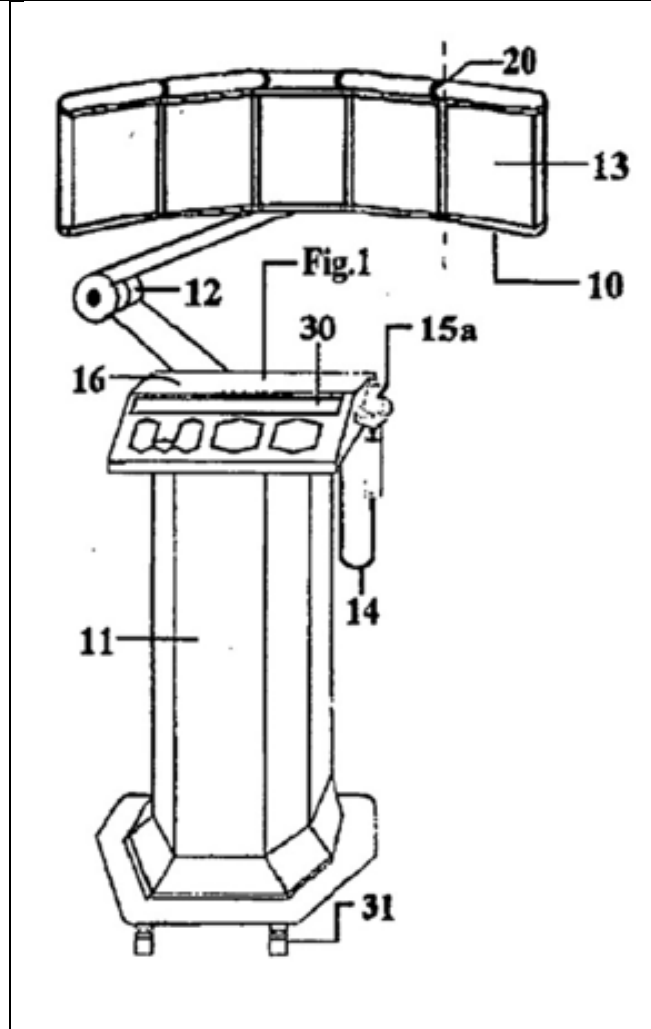
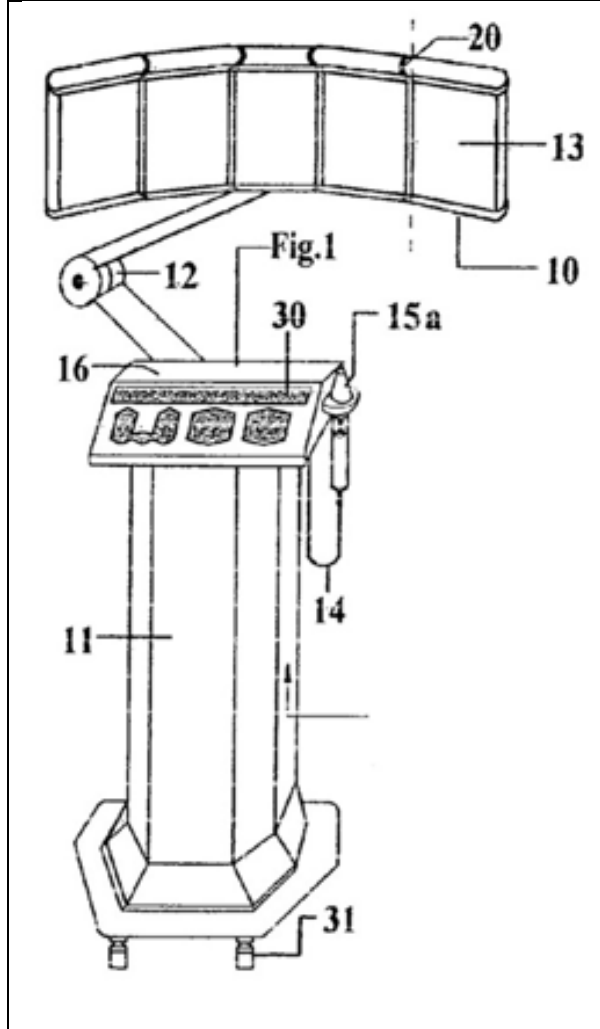
96. In its response on February 16, 2023, Patent Owner amended claim 18 and added new claims 23 and 24 to incorporate the allowed limitations of claim 3, 6, and 19. [Prosecution History, pages 199-205 (Response dated Feb. 16, 2023)].

97. On March 1, 2023, the Examiner issued a Notice of Allowance stating that the prior art of record did not anticipate or 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.” [Prosecution History, page 120 (Notice of Allowance dated March 1, 2023)].

98. It is noted that during prosecution of the ‘028 Patent, the examiner cited a daughter patent of the Larsen reference (U.S. Patent No. 7,033,381) which included a figure 1 identical to that of the Larsen reference cited here. The examiner found “Claims 18 and 20-22 are rejected under 35 U.S.C 103 as unpatentable over Larsen (U.S. Patent No. 7,033,381, cited by Applicant in view of Fan et al. (U.S. 2006/0253175, cited by Applicant). Regarding claim 18, Larsen discloses a system for photodynamically diagnosing or treating a patient (see Abstract), comprising: a mobile base supported by at least four wheels 31 (see base shown in Figure 1 and wheels 31 shown and described in col. 5, lines 14-15, where although only two wheels are shown, it is inherent that there are at least two more wheels, for a total of 4, in order for the device to be stable); a pillar 11 perpendicular to the base (see Figure 1); a controller 16 disposed to be supported by the pillar (see Figure 1); and an illuminator connected at an end of the arm (shown by five interconnected panels

13 in Figure 1), the arm being hinged to allow adjustment of a position of the illuminator relative to the base (see Figures 1 and 3 which show the hinged arm and joints/hinges 25/26/27), the illuminator comprising at least five panels 13 connected by hinged structures 10 (see Figure 1 and col. 5, lines 44-47) 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 (see col. 5, lines 19-22, which describes that the panels can be controlled individually), light sources 17 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 (see col. 6, lines 14-22, where the ‘constant effect’ described is considered the claimed ‘configured to uniformly illuminate.’ [Nov. 18, 2022 Office Action, ¶12].

99. For reference, I have reproduced Fig. 1 of both Larsen references below. As can be seen, the figures are identical and the examiner’s conclusions regarding the teachings of the Larsen ‘381 patent mirror my own conclusions with respect to the teachings of Larsen in my analysis below. This is because Larsen and the Larsen ‘381 patent share much of the same disclosure.



VII. CLAIM CONSTRUCTION

100. I understand that claim construction is a matter of law. I understand that under the claim construction standard applied by the Board, specific claim terms are given their ordinary and customary meaning as would be understood by a person of ordinary skill in the art in the context of the entire disclosure at the time of the invention. I also understand that limitations from the specification are not to be read into the claims. The specification, however, can inform a person of ordinary skill in the art as to ordinary and customary meaning, and the subject matter excluded from that ordinary and customary meaning. In addition, I understand that a person of ordinary skill in the art would look to explanations and arguments made by the applicants during prosecution to inform the meaning of the claims of the '028 Patent.

101. I have applied this standard in forming my opinions offered below.

VIII. SUMMARY OF REFERENCES RELIED ON FOR UNPATENTABILITY

A. Larsen (Ex. 1004)

102. U.S. Patent Application No. 2005/0075703 (hereinafter referred to as “Larsen”) was published on April 7, 2005 and claims priority to a foreign patent application filed on January 22, 2001. I understand that Larsen qualifies as prior art because it was published before the earliest effective filing date of the ‘028 Patent.

103. Larsen teaches a device for photodynamic therapy applications. “The present invention relates in general to electrotherapy devices and more particularly to devices and methods for photodynamic and electromagnetic stimulation of living tissue, directly and also indirectly, by stimulation of photosensitive substances introduced into or onto living tissue.” [Larsen ¶0001].

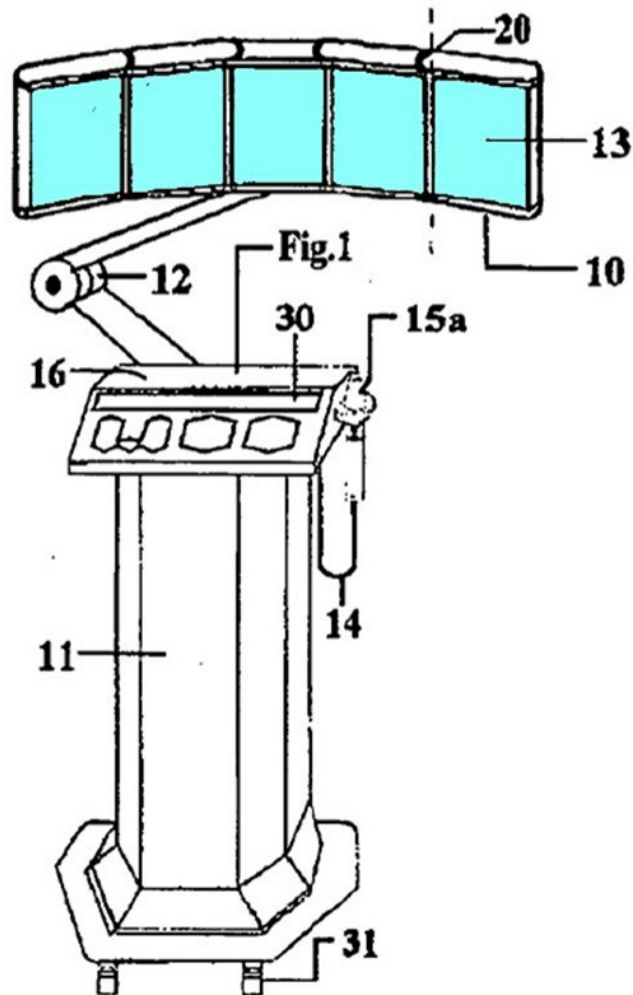
104. “Treatments have included the application of substances Such as photoflim, 5-aminolevulan acid, hematoporphyrin, verteporfin, chlorins, phthalodyanines, phenothiazine, and benzoporphyrin-derivative monoacid-A (ATMPn) onto or into tissue for healing solar keratoses, basal cell carcinoma, melanomas, etc. such substances are known as ‘biopharmaceuticals’ and treatment with these substances has been called biopharmaceutical therapy. Therapy involving the application of biopharmaceuticals and their subsequent activation by light after they have been absorbed into tissue has been called photodynamic therapy (PDT).” [Larsen ¶0011].

105. Larsen teaches the desirability and use of phototherapy equipment that can emit light over a large range of wavelengths from 300 nm to 2000 nm. “A device able to deliver an intensive light radiation with selective multiple wavelengths within the wavelength area of 300-2000 nm and electromagnetic fields is not at present available. Thus the invention is aimed at creating a device for intensive photodynamic therapy, which is capable of stimulating photodynamic energy of selective multiple light and/or laser radiation within a wavelength range of 300-2000 nanometers, capable of treatment with pulsating electromagnetic fields, and can also be used for stimulating light sensitive biopharmaceuticals.” [Larsen ¶0025]. A POSITA would have understood that this range of wavelengths includes ultraviolet light, visible light, and infrared light.

106. Larsen also teaches use of semiconductor light sources mounted on multiple panels connected with hinges. “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. 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.” [Larsen ¶¶0027-0028].

107. Larsen describes that use of panels connected with hinges allows panels to be placed equidistant from the skin surface and prevent gaps (e.g., regions of low irradiance). “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, 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.” [Larsen ¶0072].

108. The use of multiple panels connected with hinges is illustrated in Fig. 1 of Larsen. In the annotated reproduction of Fig.1 of Larsen below, I have highlighted Larsen’s applicators (i.e., panels) in light blue.



109. Although only two wheels are shown in Fig. 1 of Larsen, a person of skill in the art would have understood that at least four wheels would be present in Larsen's device. "The device consists of a stand, to which machine applicators are connected by means of a jointed arm. 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. 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.” [Larsen ¶0027].

110. If Larsen’s device included only the two wheels visible in Fig. 1 of Larsen, then the back end of Larsen’s device of Fig. 1 would rest on the floor and the device would not be freely moveable. A POSITA would have known that at least four wheels are required for a device such as the one shown in Fig. 1 of Larsen to be stable and freely moveable. Moreover, 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. This is consistent with the opinion of the examiner regarding the identical figure in the Larsen ‘381 patent.

111. Additionally, Larsen teaches the use of a light sensor to control the amount of light delivered to a patient. “With the aid of light sensors the advanced control-system is able to test the patients for the require radiation does in order to avoid over-stimulation.” [Larsen ¶0008]. “At least one of the applicator elements is equipped with feedback sensors controlling the patient’s response to the therapy, and via an automatic regulation system in the control mechanism it is possible to optimize the therapy results.” [Larsen ¶0030].

112. Larsen’s sensors are further able to compensate for patient to patient variations and ensure the desire amount of energy is delivered. “The applicators 13, according to the FIGS. 2a, 2b and 2c are equipped with sensors 32 arranged between

the semiconductor and/or laser diodes 17. For therapeutic uses it is typically intended to apply a given amount of energy (Joule/cm²) per irradiated surface of tissue, which can be adjusted at the control mechanism 16. Sensors 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 variation from patient to patient, the exposure can be determined according to the measurement 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. 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.” [Larsen ¶¶0079-0080].

113. Larsen is from the same field of endeavor as the '028 Patent, which also describes illuminators for PDT. [‘028 Patent, 1:26-2:6]. Larsen is also directed to the same problem as the '028 Patent, namely, an illuminator that can provide an

“even and gap-free radiation of the surface with multiple wavelengths of light.” [Larsen ¶0028]. Therefore, Larsen is analogous art to the ’028 Patent.

B. Bansal (Ex. 1005)

114. U.S Patent Application No. 2004/0068305 (hereinafter referred to as “Bansal”) was filed on October 7, 2002 and published on April 8, 2004. I understand that Bansal qualifies as prior art because it was published before the earliest effective filing date of the ’028 Patent.

115. Bansal teaches a phototherapy device. “This invention relates to devices and methods for the phototherapeutic treatment of illness and diseases.” [Bansal ¶0002].

116. Bansal’s phototherapy device utilizes LEDs as a light source. “A number of different light sources can be used for phototherapy. Traditionally, broadband sources have been used, such as fluorescent, halogen, or incandescent light. However, it has been recently been suggested that light emitting diodes (LEDs) can be an effective phototherapeutic light source.” [Bansal ¶0006].

117. Bansal teaches that arrays of LEDs can be used to deliver levels of irradiance suitable for phototherapy applications. “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 (2400 nm to 520 nm), to be a clinically useful phototherapy device for the treatment of hyperbilirubinemia.” [Bansal ¶0007].

118. Additionally, Bansal teaches that using a uniform array of LEDs may lead to non-uniform irradiance which will limit the effectiveness of phototherapy. “[T]he distribution of light from a simple rectangular array will not be uniform. The intensity will be significantly higher underneath the center of the array than around the periphery. Thus, parts of the subject's skin will receive sufficient light intensity, but other parts will not, thereby limiting the effectiveness of the phototherapy.” [Bansal ¶0008].

119. Bansal emphasizes the importance of uniformity and teaches that standards have been developed which recommend uniformity levels for delivered light intensities. “Additionally, if the subject is not placed directly under the center of the array, he or she will not receive the full benefit of the delivered light energy. To address these concerns as they apply to phototherapy for jaundiced infants, the IEC (International Electronics Commission) has developed a standard that describes a method to measure the uniformity of phototherapeutic light. This standard also recommends that the ratio between lowest and highest intensity portions of the light delivered to the infant be greater than 0.4. See IEC 60601-2-50 (2000): ‘Medical

Electrical Equipment-Part 2-50: Particular Requirements for the Safety of Infant Phototherapy Equipment.”” [Bansal ¶0009]. The presence of uniformity recommendation in an international standard for a PT application reinforces the understanding that a POSITA would be aware of the importance of delivering a uniform dose of light and would always strive to improve uniformity.

120. Bansal ameliorates non-uniform light intensities by using a non-uniform array of light sources, including arrays in which the density of light sources near the periphery is higher than the density of light sources near the center. Alternatively, Bansal also teaches the use of higher intensity light sources in different portions of the array. “In 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 on the outer edges.” [Bansal ¶0025].

121. Figures 9a-d of Bansal reproduced below illustrate a number of different variable density LED arrays.

Fig. 9a

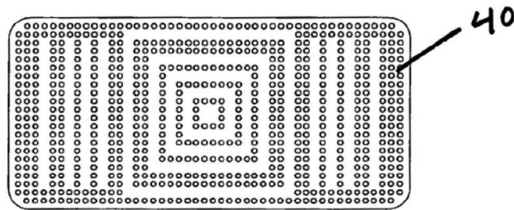


Fig. 9b

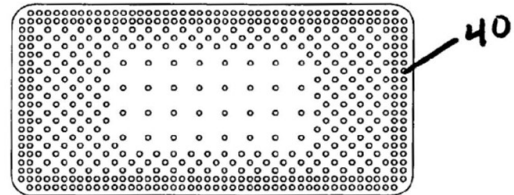


Fig. 9c

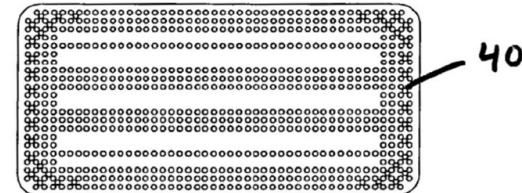
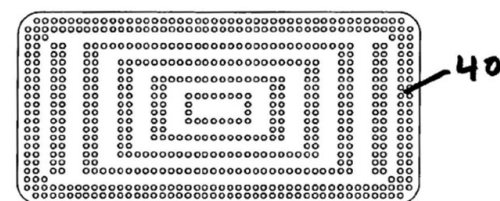


Fig. 9d



122. Bansal is from the same field of endeavor as the '028 Patent, which also describes illuminators for treatment purposes. ['028 Patent 1:26-2:6]. Bansal is also directed to the same problem as the '028 Patent, namely, an illuminator that can “achieve substantially uniform distribution of light on a subject.” [Bansal, Abstract]. Therefore, Bansal is analogous art to the '028 Patent.

123. Importantly, Bansal teaches a method of improving the uniformity of light delivered by panels lights in PDT/PT applications. Given the clear evidence

that a POSITA would understand the importance of delivering uniform light, a POSITA would be motivated to combine the teachings of Larsen and Bansal.

124. Additionally, Bansal also teaches methods and means to control the temperature of LEDs which improves their efficiency, the amount of light delivered (at a constant energy) and lifetime.

125. As discussed above, product specifications from LED manufacturers include information that shows light output (at constant current) decreases as the operating temperature of an LED increases. For this reason alone, a POSITA would be well aware of the potential benefits related to controlling and reducing the operating temperature of LEDs. Given this knowledge, a POSITA would be motivated to combine the teachings of Bansal with respect to controlling and reducing LED operating temperature with Larsen and also with Jones.

C. Jones (Ex. 1006)

126. U.S. Patent Application 2014/0067024 (hereinafter referred to as “Jones”) was filed on October 5, 2012 and published on March 6, 2014. I understand that Jones qualifies as prior art because it was published before the earliest effective filing date of the ‘028 Patent.

127. Jones teaches a photodynamic therapy system that includes lamp modules (i.e., panels) with a variable angle between the modules. “According 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.” [Jones ¶0014].

128. Jones further teaches mounting the LEDs on a heat sink and use of cooling unit. “According to an exemplary variant of the present invention, each lamp module further comprises a substrate on which the array of LEDs is mounted and a heat sink. In a preferred embodiment, the substrate is the heat sink. According to an exemplary variant of the present invention, each lamp module comprises a housing having an optical window, within the housing there is provided the two-dimensional array of LEDs, a substrate on which the array of LEDs is mounted, a heat sink, a cooling unit configured to cool the array of LEDs and at least one driver module. In a preferred embodiment, the substrate is the heat sink.” [Jones ¶¶0026-0027].

129. Jones further clarifies that the light output of LEDs may be affected by higher operating temperatures, which can result in reduced light output and a shift in wavelength. “The efficacy of the LEDs for PDT is temperature dependent. That is, with higher temperatures when the lamp 10 is in use and the LEDs generate heat, there is a reduction in luminous output and a shift of wavelength to a higher

wavelength. A reduced luminous output requires an extension of the illumination time to achieve a predetermined light dose. Thus, if the temperature of the LEDs is not controlled, the illumination time may be variable and extended to achieve the predetermined light dose. By controlling the temperature of the LEDs using an appropriate cooling system, the illumination time may be set as a fixed parameter. In a preferred embodiment, in order to ensure delivery of the predetermined light dose, the drive current for the LEDs is variable and adapted in operation to meet delivery of the light dose within a fixed illumination time.” [Jones ¶0082].

130. Jones teaches use of a variety of different methods to cool LEDs during operating including heat sinks, fans, or liquid cooling. “The lamp modules 21 may preferably include a cooling system to maintain the temperature of the LEDs for optimal performance. Preferably, the lamp modules 21 may be cooled by forced-air cooling. For example, each lamp module 21 may include heat sinks to which the LED arrays are directly mounted, and fans and associated ducts behind each array of LEDs that provide effective forced-air cooling. Alternatively or additionally, the lamp module 21 may be cooled by convective air cooling using, for example, heat sinks, and/or by liquid cooling using a coil and pump. The choice of cooling system may depend on various factors, including, for example, weight, cost, complexity, temperature uniformity, noise, and reliability.” [Jones ¶0083].

131. The devices of Jones are not limited to using a single wavelength of LEDs and include multiple wavelength LEDs in the same device. “According to an exemplary variant of the present invention each LED emits red light, preferably red light at a nominal wavelength of approximately $632\text{ nm} \pm 5\text{ nm}$, and more preferably a nominal wavelength of 636 nm . According to another exemplary variant of the present invention each LED emits blue light, preferably blue light at a nominal wavelength of approximately $417 \pm 5\text{ nm}$. According to another exemplary variant of the present invention each array of LEDs consists of a subset of LEDs that emits red light and another subset of LEDs that emits blue light. Preferably, each subset contains the same number of LEDs.” [Jones ¶0032].

132. Jones further teaches useful levels of delivered irradiance and dosage. “According to an exemplary variant of the present invention an irradiance (fluence rate) of the array of LEDs is from 30 to 150 mW/cm^2 , preferably from 40 to 100 mW/cm^2 and most preferably from 46 mW/cm^2 to 68 mW/cm^2 , e.g. 46 mW/cm^2 and 68 mW/cm^2 . According to an exemplary variant of the present invention a light dose of the array of LEDs is from about 1 to 99 J/cm^2 , more preferably from 5 to 80 J/cm^2 and most preferably from 10 to 70 J/cm^2 .” [Jones ¶¶0033-0034].

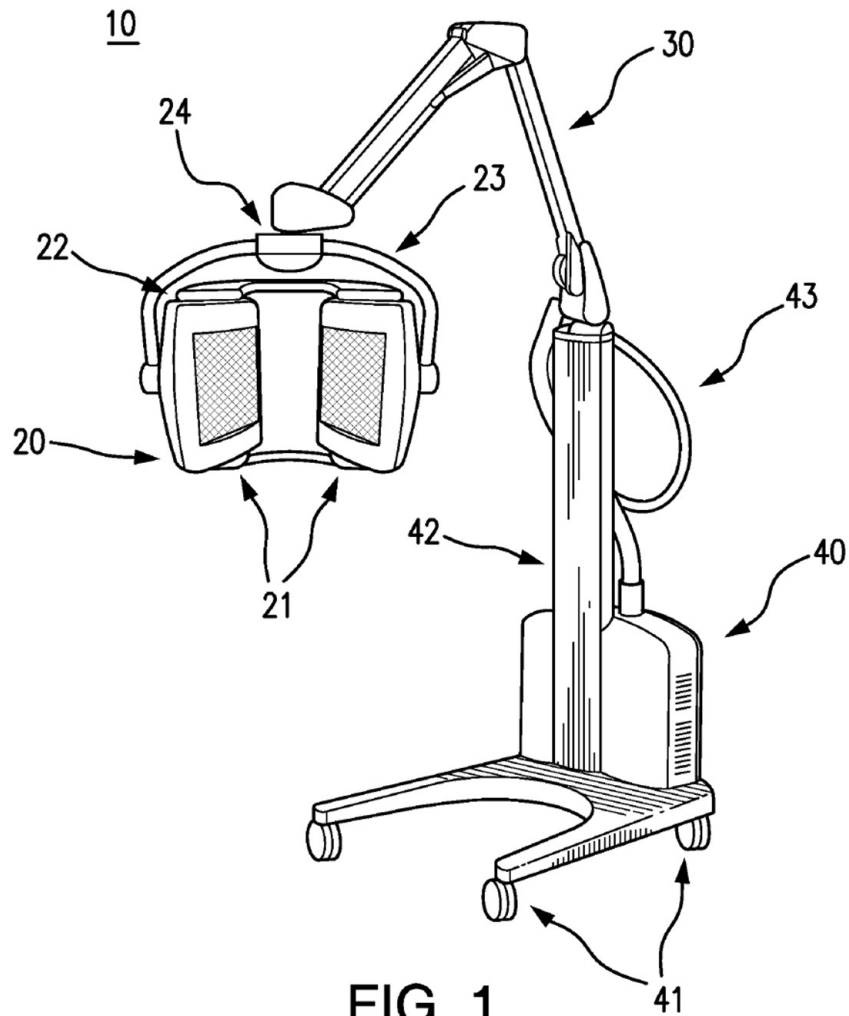
133. In addition, Jones teaches the desirability and importance of delivering uniform irradiance and light dosages. “Moreover, due to positioning the two lamp modules in the specific angles described for the first and second position, the

selected treatment area (e.g. larger relatively flat surfaces and contoured surface of a patient) are homogeneously illuminated. Thus all parts of the selected treatment area receive the same light dose, thereby facilitating shorter treatment times, fewer required operator functions for treatment, and most importantly, ensuring a safe and efficient treatment. In this regard, photodynamic treatment success is dependent on both drug dose and light dose. For example, if a part of a treatment area receives a light dose which is greater than what is required, potential treatment side effects including pain, redness and/or edema can occur. On the other hand, if a part of the treatment area receives a light dose which is less than what is required, potential treatment failures include ineffective/insufficient treatment, and/or potential re-treatment” [Jones ¶0068].

134. Jones also teaches a useful distance between the lamp modules and the patient is between about 5 cm to 8 cm. “According to an exemplary variant of the present invention, when the photodynamic therapy lamp is in use, a distance between the lamp modules and a treatment surface of a patient is between about 5 cm and 8 cm.” [Jones ¶0024, see also ¶0041, ¶¶0092-0095, ¶0117, ¶0120, ¶¶0122-0124].

135. Similar to Larsen, Jones also teaches use of wheels on the base to allow simple and easy movement of the system. “In addition, the base 40 may include wheels 41, and associated brakes, so that the photodynamic therapy lamp 10 can be

moved and temporarily held stationary.” [Jones ¶0077]. The wheels of the system of Jones can be seen in the reproduction of Fig. 1 Jones below.



136. Although only three wheels are visible in Fig. 1 of Jones, a POSITA would understand that at least four wheels must be present in order to allow easy movement of the unit. If the system of Jones had only three wheels, the base would be unbalanced and prone to tilting or falling during movement.

137. Jones is from the same field of endeavor as the '028 Patent, which also describes PDT illuminators. ['028 Patent, 1:26-2:6]. Jones is also directed to the same problem as the '028 Patent, namely, an illuminator with multiple lamp modules that can be positioned so that “the selected treatment area (e.g. larger relatively flat surfaces and contoured surface of a patient) are homogeneously illuminated.” [Jones ¶0068]. Therefore, Jones is analogous art to the '028 Patent.

138. Larsen, Bansal, and Jones are analogous art to the '028 Patent and all teach the importance of delivering uniform light in PDT/PT application. Further, both Larsen and Jones teach similar constructions using multiple light panels attached to an arm as well as a base with at least four wheels to allow easy movement of the system. For these reasons, a POSITA would naturally seek to combine the teachings of these references as they are in the same field of endeavor and seek to accomplish the same task in highly similar ways.

D. Anderson (Ex. 1007)

139. International Patent Application No. WO03/13788 (hereinafter referred to as “Anderson”) was filed on August 13, 2001 and published on February 21, 2002. I understand that Anderson qualifies as prior art because it was published before the earliest effective filing date of the '028 Patent.

140. Anderson teaches photodynamic therapy using 5-aminolevulinic acid or ALA. “The present invention is based, at least in part, on the discovery that 5-

aminolevulinic acid (ALA) described infra, in combination with an energy source, e.g., photo (light) therapy, can be used to modulate, e.g., treat, sebaceous gland disorders, e.g., eliminate, inhibit, or prevent occurrence or reoccurrence of the skin disorder. Topically-applied ALA is taken up by epithelial cells and metabolized via the porphyrin pathway to protoporphyrin IX (PpIX), the precursor of heme. PpIX is a photosensitizer that accumulates not only in the epidermal cells, but also the pilosebaceous units. When intense light, e.g., visible light, red light, light with a wavelength range of between about 320 and 700 nm, is delivered to the ALA-treated skin, PpIX is excited into a triplet state, which reacts with oxygen to produce singlet oxygen, causing membrane damage and cell destruction. Topical ALA may directly enter hair follicles, where sebaceous glands actively synthesize and retain PpIX.” [Anderson, p2:12-23].

141. Anderson also discusses light sources suitable for PDT using ALA. “The present invention pertains to methods for treating skin disorders associated with sebaceous follicles by topically applying 5-aminolevulinic acid (ALA) to a section of skin afflicted with a sebaceous gland disorder, wherein the ALA is converted into PpIX which is then activated by energy that penetrates outer layers of epidermis. A sufficient amount of the ALA infiltrates the afflicted section of skin, is converted into PpIX, and is exposed to sufficient energy to cause the PpIX to become photodynamically activated, thereby treating the sebaceous gland

disorder. In one embodiment, the sebaceous gland disorder is acne. Suitable energy sources for photodynamic treatment include flash lamp based sources and lasers, such as Nd:YAG, Alexandrite, flash lamp-pumped dyes and diodes. Alternatively, the energy source can also be a continuous wave energy source.” [Anderson, p2:29-3:8]. A POSITA reviewing Anderson would have understood that the description of “diodes” and “a continuous wave energy source” is consistent with light emitting diodes or LEDs.

142. This understanding is explicitly confirmed by Anderson. “Suitable energy sources include a wide range of pulsed or continuous electromagnetic sources including, optical energy emitted by the sun, ultraviolet light generators, flash lamp based sources and lasers, such as Nd: YAG, Alexandrite, and flash lamp-pumped dye lasers and diode lasers. Alternatively, the energy source can be a continuous wave energy source, such as arc lamps, tungsten-halogen lamps and light-emitting diodes.” [Anderson p8:6-11, see also 11:5-8].

143. Anderson also teaches desirable energy dosages for PDT. “Generally, the range of energy applied to the skin surface ranges from 1 J/cm² to about 200 J/cm², preferably from about 25 J/cm² to about 200 J/cm², and most preferably about 100 J/cm².” [Anderson p8:13-15]. “Generally, sunlight is the energy source for PDT stimulation and the total fluence of energy is between 1 and about 100 J/cm², preferably between about a and about 50 J/cm² and most preferably between about

10 and about 40 J/cm².” [Anderson p11:5-8]. “For photodynamic effects, lower average irradiance exposures given over longer exposure time would be appropriate for example approximately 10-100 mW/cm² for about 100-2000 seconds (total fluence, 1-200 J/cm²). For photodynamic effect, light sources such as light-emitting diodes, incandescent lamps, xenon arc lamps, lasers or sunlight can be used.” [Anderson p20:23-27].

144. Anderson is from the same field of endeavor as the '028 Patent, which also describes PDT illuminators for light therapy in conjunction with 5-ALA. ['028 Patent, 1:26-2:6]. Thus, Anderson is analogous art to the '028 Patent.

145. More generally, Anderson teaches prescriptions – doses and application methods of pharmaceutical compounds along with desirable fluences of light to achieve medically desirable goals. Anderson does not explain or describe a system in detail for regulating and delivering the light energy portion of the prescriptions. In this aspect it is the perfect complement to Larsen, Bansal, and Jones, all of which focus on how to deliver therapeutic amounts of light.

146. A POSITA using the equipment of Larsen, Bansal, and Jones would have been motivated to include the various doses in Anderson (both in terms of irradiance and total energy) to achieve medically desirable results.

E. Mackinnon (Ex. 1012)

147. International Patent Application No. WO 2005/030328 (hereinafter referred to as “Mackinnon”) was filed on September 27, 2004 and published on April 7, 2005. I understand that Mackinnon qualifies as prior art because it was published before the earliest effective filing date of the ‘028 Patent.

148. Mackinnon describes a device for use in PDT. [Mackinnon, 1:21-22, 3:13-16, 14:14-22]. The light sources can include “red, green and blue LEDs or other desired lamps and photo generators.” [Mackinnon, 4:5-6]. Mackinnon’s system selects desired wavelength, intensity, and duration suitable for activating different drugs for PDT. [Mackinnon, 11:15-20]. Mackinnon’s system includes a projection system which “may match the shape and size of the illumination area to correspond to the shape and size of a target region discerned by an imaging system, for example an imaging sensor and image processing system of an endoscope or surgical microscope, such as those discussed herein.” [Mackinnon, 21:23-27].

149. Mackinnon is from the same field of endeavor as the ‘028 Patent, which also describes PDT illuminators for light therapy in conjunction with different photodynamic drugs. [’028 Patent, 1:26-2:6]. Thus, a POSITA clearly understands that Mackinnon is analogous art to the ‘028 Patent.

IX. MOTIVATIONS TO COMBINE PRIOR ART REFERENCES

A. Motivations to Combine Larsen with Bansal

150. A POSITA would be motivated to combine Larsen and Bansal. As discussed above, both Larsen and Bansal are in the same field of endeavor (i.e., photodynamic therapy and phototherapy) and both utilize panels with arrays of LEDs mounted on them and both emphasize the importance of delivering uniform amounts of light.

151. A person of ordinary skill in the art would understand that the gaps between adjacent panels could lead to regions of low irradiance on the patient's skin. Larsen's applicators are designed to provide an "even and gap-free radiation of the surface with multiple wavelengths of light." [Larsen, ¶0028]. Larsen also recognizes that using multiple light panels allows for better treatment of different surface areas of a patient, such as the back, to allow for "equidistant positioning of the applicators 13 above the skin." [Larsen, ¶0072]. A POSITA would have been motivated to use Bansal's non-uniform LED arrays which include a higher density of LEDs at the periphery of panels to ameliorate lower irradiance regions at the junction of two of Larsen's panels. Bansal's Figures 9a-9d provide examples of this. [Bansal, ¶¶0008, 0025].

152. Alternatively, a POSITA would have been motivated to use Bansal's teaching of increasing the intensity of light emitted by LEDs located on the

peripheral regions of panels with the hinged panel design of Larsen to achieve the same result. Bansal provides several solutions to this problem, including (1) providing higher intensity lights at the edges of the panel compared to areas not proximate to the edges, and/or (2) providing a higher density of light sources at the edges of the panel compared to areas not proximate to the edges. [Bansal ¶¶0025, Figs. 9a-9d]. Both embodiments of Bansal would improve the uniformity of light levels at and near the junction of Larsen's panels which a POSITA would understand is a desirable goal.

153. A POSITA would also have a reasonable expectation of success in combining Larsen with Bansal, because both references describe similar illuminators for using light to treat conditions on a patient's skin. [Larsen, Fig. 1]; [Bansal, Fig. 1]. Larsen states that each of the light sources (17) "are adjustable," and a POSITA would have understood how to increase the current to certain light sources at the edge of the applicator using Larsen's controller. [Larsen, ¶¶0071, 0074, 0077-0079]. Bansal similarly describes a switch (44) that is used to control the light sources, and "can provide for operation in either a high or low intensity mode or a potentiometer could be added to provide a more precise control or larger range on the intensity of phototherapy provided." [Bansal, ¶0026]. A POSITA would have found it obvious to incorporate Bansal's switch 44 into Larsen's controller to provide more precise

control of the intensity of light from LEDs at the edges of the applicator, as taught by Bansal.

154. I note that Larsen's applicators include "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," [Larsen, ¶0072]. This scan engine would not have dissuaded a POSITA from modifying Larsen in view of Bansal, since the scan engine would have been a less effective way to achieve more uniform illumination compared to Bansal's solution. This is because the scan engine can only move lights linearly in one direction at a time, which would only decrease unradiated gaps on the portion of the treatment surface towards which the light sources are being moved (as opposed to Bansal, which would eliminate unradiated gaps across the entire treatment surface). Additionally, the scan engine appears to be configured to only move the lights linearly in a single direction, while Bansal's solution provides higher intensity (or density) of lights around all edges of the panel. A POSITA would have understood how to incorporate Bansal's solution with the scan engine, since the scan engine could still operate with more lights (or higher intensity lights) placed at the edges of Larsen's panels.

155. Additionally, the combination of Larsen with Bansal would simply have been a combination of prior art elements (increasing the intensity of light

sources at the edges of Larsen's applicators, as taught by Bansal) according to known methods (adding LEDs to the circuit board at locations closer to the edge of the applicator and/or increasing the light intensity of the LEDs at locations closer to the edge of the applicator) to yield predictable results (more uniform distribution of light on the surface of the patient's skin).

156. Further, a person of ordinary skill in the art would also have understood that incorporating Bansal's panels would deliver superior irradiance uniformity which would improve the accuracy of Larsen's sensors as the delivered light dosage would be more uniform over the entire treatment area.

157. In Larsen, "[t]he Figs. 2a, 2b and 2c show plain surfaced printed circuit boards with light sources mounted in the applicators 13." [Larsen, ¶0070]. These circuit boards can be used "individually, side by side (in large numbers) or in combination with the applicator." Id. Larsen teaches that each applicator can have "large numbers" of circuit boards, and thus a large number of energy sensors located at different points on each applicator. Furthermore, "[t]he applicators 13, according to the Figs. 2a, 2b and 2c are equipped with sensors 32 arranged between the semiconductor and/or laser diodes 17." [Larsen, ¶0079].

158. The sensors 32 "measure the amount of energy radiated away from the skin surface, which is indicative of the total energy penetrating into the tissue." [Larsen, ¶0079]. According to Larsen, "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.” [Larsen, ¶0079, claim 13].

159. These teachings would have motivated a POSITA to selectively increase the intensity of certain LED lights on the perimeter of Larsen’s applicators (as described in Bansal) in response to sensors at the edge of Larsen’s applicator detecting less energy radiated away from the skin surface closer to the edges of the applicator compared to sensors detecting more energy being radiated away from the skin surface in the center of the treatment area.

160. Such a modification would have been well within the understanding and capabilities of a POSITA and would have required minimal time, effort and the changes could be accomplished at a minimal cost.

161. Indeed, the changes could be accomplished by a simple redesign of the circuit boards on which Larsen’s LEDs are mounted to change the density of LED packages or to allow differential current control through LEDs located on the periphery of the LED boards.

162. Additionally, a POSITA would have had a reasonable expectation of success, since the outputs from Larsen’s sensors already feed into the control panel for the applicators. [Larsen, Fig. 4, ¶¶ 0030, 0079-0080]. A POSITA would have expected that light intensity at the edges of Larsen’s applicators could be increased in response to measurements received from Larsen’s sensors, particularly because

both Larsen and Bansal describe selectively controlling the light sources. [Larsen, ¶¶0071, 0074, 0077-0079; Bansal, ¶0026].

163. The combination would be nothing more than combining known prior art elements to yield predictable results and require routine skill in the art.

B. Motivations to Combine Larsen and Bansal with Jones

164. Similarly, a POSITA would be motivated to combine Jones with Larsen and Bansal. To begin with Jones, Larsen and Bansal are all in the same field of endeavor (PDT and/or PT) using panel-mounted LED devices.

165. Notably, a POSITA would be aware that LED efficiency (light output) and lifetime would decrease at higher operating temperatures for illuminators such as Larsen's and Bansal's. Larsen itself states "semiconductor diodes tend to overheat during use, which causes a decrease in the effectiveness of the device." [Larsen ¶0006]. A POSITA would also have known that temperature changes affect the wavelengths of the light sources, which must be carefully controlled for specific absorption bands used for PDT. A POSITA would understand that Jones' cooling fans for the LEDs would allow the LEDs to maintain lower operating temperatures which would increase the efficiency (light output) of LEDs as taught by Jones. [Jones ¶¶0028, 0083-0084, Figure 4D].

166. This combination of Larsen and Bansal with Jones would simply have been a combination of prior art elements (adding Jones' cooling fan to Larsen's

applicators) according to known methods to yield predictable results (more effective applicators). A POSITA would have also had a reasonable expectation of success, since Larsen and Jones both describe illuminators with multiple panels for use in PDT. [Larsen ¶¶0028-0079, Fig. 1; Jones, Abstract, Fig. 1]. And a POSITA would have expected that installing one or more fans on the applicators would successfully cool them down to prevent overheating, particularly where Larsen's applicators have been modified with Bansal's non-uniform light distribution.

167. Additionally, there were finite number of known, predictable solutions for cooling the LED circuits in Larsen's applicators (as modified by Bansal), such as a fan or a heat sink (both described in Jones). A POSITA would have found it obvious to try incorporating one or more fans into Larsen to cool the light sources of Larsen's applicators. The resulting increased effectiveness of Larsen's applicators would have been predictable to POSITA.

168. Further, Jones teaches LED panels that capable of emitting multiple wavelengths which would improve the utility of the systems of Larsen and Bansal.

169. Additionally, as discussed above, Jones teaches useful irradiance levels and dosage/fluences, as well as optimal distances for PDT/PT applications. [Jones ¶¶0041, 0024, 0092, Fig. 8A]. And a POSITA would have known that the distance between the illuminator and the treatment surface is a result-effective variable, since it directly impacts the radiation received at the treatment surface. Determining an

optimum distance would have required nothing more than routine experimentation, which would have permitted a POSITA using Larsen's applicators to arrive at the optimal distances described in Jones. This modification would have involved nothing more than using known techniques (using Jones' optimized distance between the lamp and treatment surface) to improve similar devices (Larsen's PDT applicators) in the same way. And a POSITA would have had a reasonable expectation of success, given Jones and Larsen's similar design and purpose.

170. A POSITA would have also expected to successfully use Larsen's mobile base and jointed arm to position the applicators at an optimized distance from the treatment surface, as described by Jones. [Larsen ¶0073, Fig. 3]. This information would inform a POSITA of the desirable LED performance metrics when designing a system that combined the teachings of Larsen, Bansal, and Jones. Specification of suitable LEDs for PDT/PT applications would necessarily be within the capabilities of a POSITA as systems are designed to operate within certain parameters and Jones merely clarifies suitable parameters.

171. It is further noted that both Larsen and Jones both teach movable systems that incorporate four wheels. Notably, the examiner determined that Larsen disclosed a mobile base supported by at least four wheels. [Non-final rejection dated Nov. 18, 2022 Office Action, ¶12].

172. Similar to the discussion above regarding Larsen and Bansal, the combination of Larsen, Bansal, and Jones would be nothing more than combining known prior art elements to yield predictable results and requires routine skill in the art.

C. Motivations to Combine Larsen, Bansal, and Jones with Anderson

173. As discussed above, Larsen's device is designed to deliver "an intensive light radiation with selective multiple wavelengths" in order to provide intensive photodynamic therapy to a patient. [Larsen ¶¶0025-0026]. The device uses PDT to activate chemical reactions in photosensitive chemicals introduced into or onto the tissue. [Larsen ¶¶0107-0111]. Larsen further teaches that the energy output from its applicators is adjustable "within a relatively large range with reference to duration, amplitude and frequency of surge of current." [Larsen ¶0074].

174. A POSITA considering Larsen would have been motivated to seek other references describing varying wavelengths, irradiance densities, and total energy for PDT treatment. Anderson teaches use of topically applied 5-aminolevulinic acid (ALA) along with exposure to intense light in the wavelength range of 320 to 700 nm to treat sebaceous skin disorders. [Anderson 2:12-23]. Anderson is silent on hardware systems to delivered specified fluences of light for PDT. As such, it would have been well within the capability of a person of ordinary skill in the art to combine Anderson with Larsen, Bansal, Jones or any combination

thereof as Larsen, Bansal, and Jones all teach PDT systems capable of delivering the wavelengths of light and fluences of light prescribed by Anderson after application of the various pharmaceutical agents described by Anderson.

175. More specifically, Anderson teaches that “ [f]or photodynamic effects, lower average irradiance exposures given over longer exposure time would be appropriate for example approximately 10-100 mW/cm² delivered for about 100-2000 seconds (total fluence, 1-200 J/ cm²).” [Anderson 20:23-25]. And Anderson teaches that “[w]hen intense light, e.g., visible light, red light, light with a wavelength range of between about 320 and 700 nm, is delivered to the ALA-treated skin, PpIX is excited into a triplet state, which reacts with oxygen to produce singlet oxygen, causing membrane damage and cell destruction.” [Anderson 2:19-22]. Anderson’s treatment provides “optimized conditions for treatment of skin.” [Anderson 2:26]. A POSITA would have been motivated to incorporate Anderson’s varying irradiance densities over varying time periods to achieve better photodynamic effects in the combination of Larsen’s applicators with Jones and Bansal.

176. Anderson also teaches that “[i]n general, the wavelength range for therapeutic treatment is from about 320 nm to about 700 nm, preferably from about 550 to about 700 nm, more preferably from about 550 to about 600 nm.” [Anderson 8:16-18]. It would have been well within the capability of a POSITA to configure

the light sources of Bansal to provide light in wavelengths that span the ranges taught by Anderson, since the benefits of these different wavelengths of light were well known at the time of the invention.

177. As such the teachings and hardware designs of Larsen, Bansal, Jones, and any combinations therefore dovetail with the pharmaceutical prescriptions (compounds, fluences, and wavelengths of light) of Anderson. The combination of Larsen, Bansal, and Jones with Anderson would simply have been a combination of prior art elements (varying the wavelengths of light, irradiance density, and/or total fluence from Larsen's light sources, as taught by Anderson) according to known methods to yield predictable results (more effective photodynamic effects). And a POSITA would have had a reasonable expectation of success, since Larsen's controller and applicators support a large range with respect to duration, amplitude and frequency of surge current for the light sources on the applicators. Based on the capabilities of Larsen's controller, a POSITA would have had a reasonable expectation of success in achieving the wavelengths of light, irradiance levels and total energy described in Anderson.

178. A POSITA would have also known that the wavelengths of light, irradiance density, and total fluence are result-effective variables, since they directly impact the photodynamic effects at the site of the treatment area. Configuring Larsen's applicators to output red light at an irradiance density of 10 mW/cm² to 30

mW/cm², to output total energy between 30-150 J/cm², or to output light at wavelengths of 400-700 nm would have required nothing more than routine experimentation. This operation would have involved nothing more than combining prior art elements according to known methods to yield predictable results. And I am not aware of any unexpected results associated with the claimed ranges compared to the prior art. A POSITA would have had a reasonable expectation of success, given the capability of Larsen's controller discussed above.

179. Indeed, once both the irradiance density and the irradiance dose (or fluence) are known, determining the treatment time is simply a matter of dividing the dose by the irradiance energy as follows: $\text{J/cm}^2 \div \text{mW/cm}^2 = \text{seconds}$.

D. Motivations to Combine Larsen, Bansal, and Jones with Mackinnon

180. Larsen's applicators include a controller that can adjust the light dosage based on feedback received from sensors. [Larsen ¶¶0079-0080, Figs. 2a-2c, Fig. 4]. Larsen's panels are also individually configurable and controllable, and can treat various surfaces. [Larsen ¶¶0070-0072, 0074]. In order to improve the effectiveness of Larsen's applicators to treat different sizes and shapes on the surface of the patient's skin, a POSITA would have been motivated to look to Mackinnon, which provides an imaging sensor and image processing system on a PDT light source which can determine the size and shape of the treatment surface (e.g., a cancerous skin lesion) and then modify the illumination accordingly based on the

detected size and shape. [Mackinnon 21:23-22:6]. Indeed, Larsen's applicators are designed to treat skin lesions (such as melanoma and basal cell carcinoma). [Larsen [Larsen ¶0107]. This combination of Larsen, Bansal and Jones with Mackinnon would simply have been a combination of prior art elements (adding the sensor and image processing system of Mackinnon to Larsen's applicators and controller) according to known methods to yield predictable results (better treatment of the surface of a patient's skin in response to size and shape feedback).

181. A POSITA would have had a reasonable expectation of success, since the outputs from Larsen's other sensors already feed into the control panel for the applicators. [Larsen Fig. 4, ¶¶0030, 0079-0080]. A POSITA would have expected that Mackinnon's image sensors and processing system could be readily incorporated into Larsen's controller, particularly because both Larsen and Mackinnon describe selectively controlling the light sources. Larsen, ¶¶0070, 0074, 0077-0079]; [Mackinnon 21:23-22:6, 34:18-25]. And both Larsen and Mackinnon are designed for PDT applications using medical optical systems. [Larsen Abstract]; [Mackinnon 8:20-23, 11:15-23].

182. Another reason a POSITA would have been motivated to combine Mackinnon with Larsen is because one of the benefits of Mackinnon's system is that it "is more power friendly, produces less heat, thereby possibly requiring fewer or less robust parts, and in addition should assist in increasing the longevity of various

parts of the system due, for example, to the reduced heat generated and the reduced electricity transmitted and the reduced light transmitted.” [Mackinnon 29:27-30:3]. A POSITA would have been motivated to add the imaging sensor and processing system of Mackinnon to the Larsen, Bansal, and Jones combination to reduce the heat and power of the applicators. Both Larsen and Jones recognize how excessive heat diminishes the effectiveness of the applicators. [Larsen ¶0006];[Jones ¶0082]. A POSITA would have had a reasonable expectation that adding Mackinnon’s sensor and image processing capabilities to the Larsen, Bansal, Jones combination would lead to less heat and power consumption.

X. GROUNDS OF UNPATENTABILITY

183. In my opinion, Larsen in view of Bansal, further in view of Jones renders obvious at least claims 1, 2, 4-8, and 16-21 of the '028 Patent for at least the reasons described herein.

184. Larsen in view of Bansal, further in view of Jones, further in view of Anderson renders obvious at least claims 2-4 of the '028 Patent for at least the reasons described herein.

185. Larsen in view of Bansal, further in view of Jones, further in view of Mackinnon renders obvious at least claims 10, 11, 13, and 14 of the '028 Patent for at least the reasons described herein.

186. My specific analysis of Larsen, Bansal, Jones, Anderson, and Mackinnon with respect to every claim element of Claims 1-8, 10, 11, 13, 14, and 16-21 of the '028 Patent is given herein.

187. I am unaware of any secondary considerations that would support a finding of non-obviousness with respect to claims 1-8, 10, 11, 13, 14, or 16-21 of the '028 Patent.

A. Larsen in view of Bansal, further in view of Jones renders obvious at least claims 1, 2, 4-8, and 16-21 of the '028 Patent

'028 Patent: Claim 1

1. A system for photodynamically diagnosing or treating a patient, comprising:

[a] an illuminator comprising five panels connected by hinged structures on inner side surfaces of adjacent panels; and

[b] 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,

[c] 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,

[d] wherein the five panels are positioned to allow treatment within approximately four inches of the treatment surface, and

[e] wherein each of the five panels has two first edges and two second edges shorter than the two first edges, and

[f] 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.

Claim 1[preamble]: “1. A system for photodynamically diagnosing or treating a patient, comprising:”

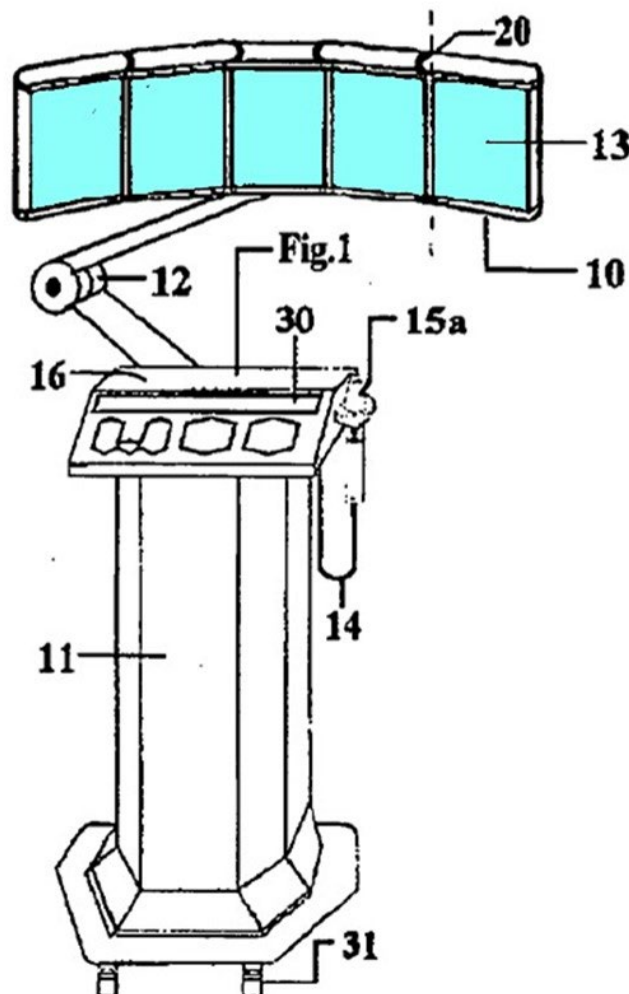
188. Larsen teaches a photodynamic treatment system. “The present invention provides a device with changeable applicators using a light and/or laser radiation of several wavelength ranges suited for the photodynamic stimulus of the cell energy in living cells, in particular human cells of both surface and underlying tissue.” [Larsen ¶0026, see also ¶¶0001, 0037].

189. Therefore, in my opinion, Larsen discloses this claim limitation.

Claim 1(a): “an illuminator comprising five panels connected by hinged structures on inner side surfaces of adjacent panels; and”

190. Larsen teaches an illuminator comprising five panels connected by hinge structures. “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, whereby the applicators are suitable for the treatment of for example, the backs of humans and so become adjustable for equidistant positioning of the applicators 13 about the skin.” [Larsen ¶0072]. In the annotated reproduction of Fig. 1 of Larsen below, I have highlighted Larsen’s applicators (panels) in light blue. By inspection, this embodiment of Larsen shows five panels.



191. Whiles Larsen is silent on the type of hinges, 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). I also note that the USPTO has already confirmed this reading. When reviewing the same disclosure in the Larsen ’381 Patent, the Examiner determined that the above-quoted disclosure of Larsen taught “at least five panels [] connected by hinged structures [].” [Nov. 18, 2022 Office Action, ¶12 (citing Larsen ’381 Patent Figure 1, 5:44-47)]. Similarly, during the prosecution of Application No. 17/009,871, the Examiner reviewed Larsen and determined that it taught “five panels connected by a plurality of hinges 20 (indicated as 10 in the specification, but shown as element 20 in the Figures) on inner side surfaces of adjacent panels that connect panels together . . .” [March 23, 2021 Office Action, ¶4 (citing Larsen, Figures 1-3, ¶¶[0069], [0072], lines 1-4)].

192. For this reason, it is my opinion that Larsen discloses this claim limitation.

193. Even absent this observation, a POSITA would have understood that it is desirable to minimize the gaps or spacings between LED elements and hence between adjacent panels to minimize the regions of lower irradiance at surfaces

facing adjacent panels, and would have found it obvious to place the hinges on the inner side surfaces of Larsen's panels.

194. Larsen teaches the importance and desirability of uniform irradiance. "The applicators are also equipped with an adjustable scan system, which permits an even and gap-free radiation of the surface with multiple wavelengths of light." [Larsen ¶0028]. Larsen clearly teaches a POSITA the importance of even and gap free irradiance (i.e., uniform irradiance) as the described scanner adds significant cost and complexity and would only be incorporated if uniform irradiance were an important goal.

195. Further Larsen describes a location for hinges that is consistent with the hinges being located on inner side surfaces of adjacent panels. "[A]ccording to FIG. 1, several applicators are flexibly connected to each other through hinges 10, respectively connecting one edge with the other." [Larsen ¶0072]. A POSITA would understand that if the hinges connect one edge to another that they must necessarily be located on adjacent edges and the only adjacent edges suitable for placement of hinges are those along the inner side surfaces of adjacent panels.

196. Alternatively, a POSITA would have been motivated to place the hinges on the inner side surfaces of Larsen's panels in order to obtain the flush arrangement shown in Figure 1. Such a modification would have involved nothing

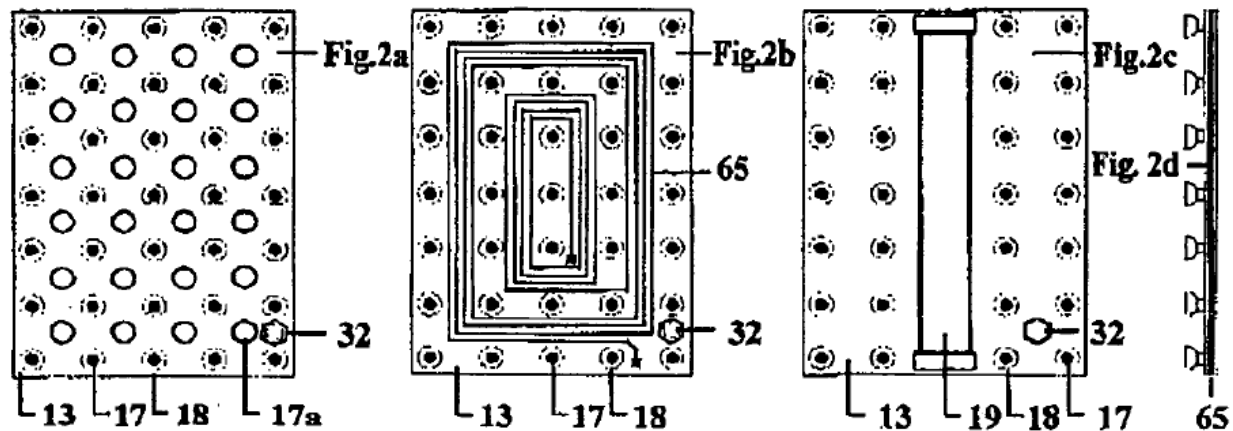
more than the use of a known prior art element according to known methods to yield predictable results.

197. Moreover, the use of hinges on the inner side surfaces of adjacent panels is one of an extremely limited number of locations for hinges, and is well within the capabilities of a POSITA to incorporate into a design. Importantly, a POSITA would be highly motivated to use hinges located on the inner side surfaces of adjacent panels once the goal of achieving uniform light exposure is understood. A POSITA would have found it obvious to try placing the hinges on the inner side surfaces of the panels, with a reasonable expectation of success, since a POSITA would have known that hinges located on the inside surfaces of the applicator would allow them to be positioned in a flush arrangement as shown in Figure 1.

198. Therefore, in my opinion, Larsen discloses this claim limitation or renders this claim limitation obvious.

Claim 1(b): “*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,*”

199. As discussed above, Larsen discloses that light sources are disposed on the surfaces of the five panels (the applicators in Larsen). Figures 2a-2c of Larsen show “plain surfaced printed circuit boards with light sources mounted in the applicators 13.” [Larsen ¶0070].



200. Larsen's applicators are mounted in a shifting order "with semiconductor diodes (LED) and/or laser diodes 17 and 17a (in the following called light sources), whereby shifting the order of the light sources 17 means, that the respective light source 17a of one row is placed at the point of intersection of the two diagonals through the two respective light sources 17, which are placed adjoining on both sides." [Larsen ¶0070]. The light sources can be placed in regular row arrangements. [Larsen ¶0071].

201. Larsen describes an adjustable scan system which permits even and gap-free (i.e., uniform) illumination of a treatment surface. Larsen further teaches "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, 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." [Larsen ¶0072]. I note that during

prosecution of Patent No. 11,446,512 (the “’512 Patent”), which is the direct parent of the ’028 Patent, the Examiner reviewed this same disclosure of Larsen and confirmed that it taught “the illuminator being configured to uniformly illuminate a treatment surface of the patient via the light sources.” [October 25, 2021 Office Action ¶23 (citing Larsen ¶0072)].

202. As Figure 1 of Larsen clearly illustrates five panels, this description informs a POSITA that Larsen’s panels are configured to illuminate a treatment surface of a patient (in this case the back of a human) with light. Further, Larsen’s use of a scan system to achieve even and gap-free coverage [Larsen ¶0028] demonstrates that Larsen’s illumination is uniform.

203. For this reason, it is my opinion that this claim limitation is disclosed by Larsen.

204. In the alternative, Bansal teaches “The 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 mechanisms 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.” [Bansal ¶0010]. “This array of light sources 40 is a 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.” [Bansal ¶0025].

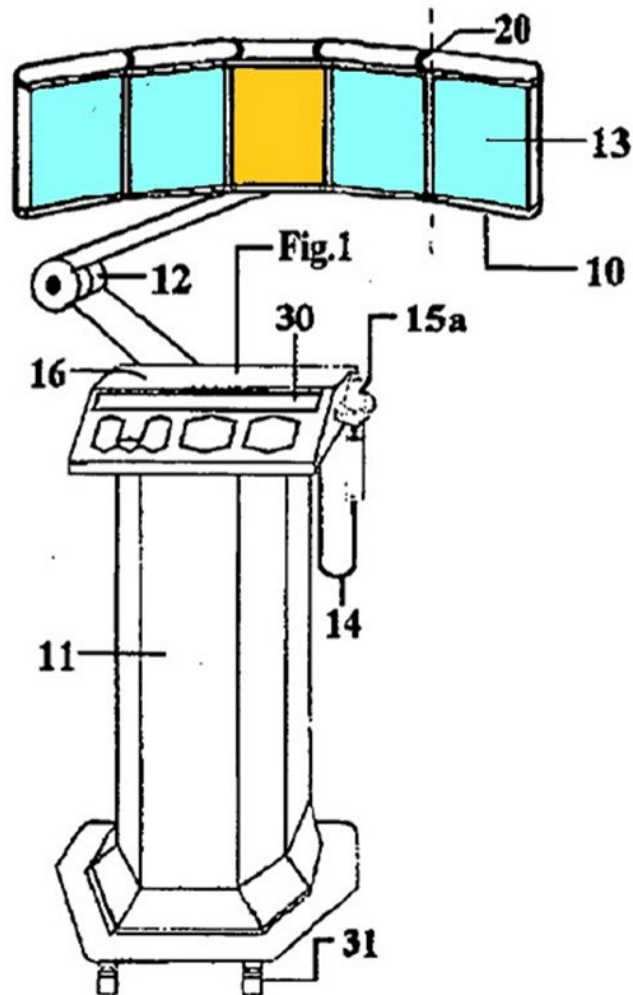
205. As Bansal explicitly states the goal of even (i.e., uniform) exposure on the subject's skin, it necessarily follows that Bansal teaches “the illuminator being configured to uniformly illuminate a treatment surface of the patient via the light sources”.

206. For these reasons, it is my opinion that Larsen in view of Bansal renders this claim limitation obvious. A POSITA would have found it obvious and would have been motivated with a reasonable expectation of success to incorporate the non-uniform light arrangement of Bansal into Larsen in order to uniformly illuminate a treatment surface of the patient, for all the reasons described above at Section IX.A.

207. Therefore, in my opinion, Larsen in view of Bansal renders this claim limitation obvious.

Claim 1(c): “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,”

208. The annotated version of Fig. 1 of Larsen reproduced below clearly shows a center panel (highlighted in orange) and two panels on each side (highlighted in blue) angled relative to the center panel.



209. Larsen teaches that light is emitted from the applicators on the panels, and that the panels are aimed at a treatment surface of the patient (such as the patient's back). [Larsen ¶¶0027, 0072].

210. I note that the Examiner agreed that Figure 1 in the Larsen '381 Patent (which is virtually identical to Figure 1 of Larsen) discloses this limitation. [Nov. 18, 2022 Office Action ¶13].

211. Therefore, in my opinion, Larsen discloses this claim limitation.

Claim 1(d): “wherein the five panels are positioned to allow treatment within approximately four inches of the treatment surface, and”

212. Larsen teaches that its jointed arm (12) “allows the positioning of the applicators 13 in front of, or above, a tissue area while maintaining a correct positioning distance.” [Larsen ¶0073]. Furthermore, Jones teaches “Further, a scale or other visual aid may be used to maintain a distance between the lamp modules and the treatment area between about 5 cm to 8 cm.” [Jones ¶0093]. “[T]he operator moves the lamp modules into the first position and positions the lamp head in a distance of 5-8 cm over a selected treatment area on the patient’s back/chest with the arrays of LEDs facing the treatment area”. [Jones ¶0095]. A person of ordinary skill in the art would have understood that a distance of about 5-8 cm, which converts to 2-3.15 inches is within approximately four inches. This is because a POSITA would have understood that in this context, to be “within approximately four inches” means to be equal to or less than approximately four inches. A distance of 5-8 cm is equal to or less than approximately four inches.

213. Further, a POSITA would know that where light is output from multiple panels in a concave configuration (as with Larsen), the light emitted by adjacent panels can overlap which improves uniformity. A POSITA would also be aware that the degree of overlap would increase with distance and thus be strongly motivated to increase the distance beyond 5-8 cm to further improve uniformity if necessary, including at a distance of approximately four inches.

214. Additionally, Jones also teaches “Then the operator simply has to run the alignment procedure (e.g. by pressing a button on the user interface and/or by selecting the alignment procedure from a menu) and, if there is a shadow visible on the patient’s back/chest, reposition the lamp until there is even illumination without a shadow.” [Jones ¶0095]. A POSITA would understand that shadows could result from the lamp panels being placed too close to the patient and that repositioning the panels further away from the patient (i.e., more than 5-8 cm) would reduce or eliminate shadows. Thus, a POSITA would understand that while Jones recommends a starting position that is about 5-8 cm from the patient, 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.

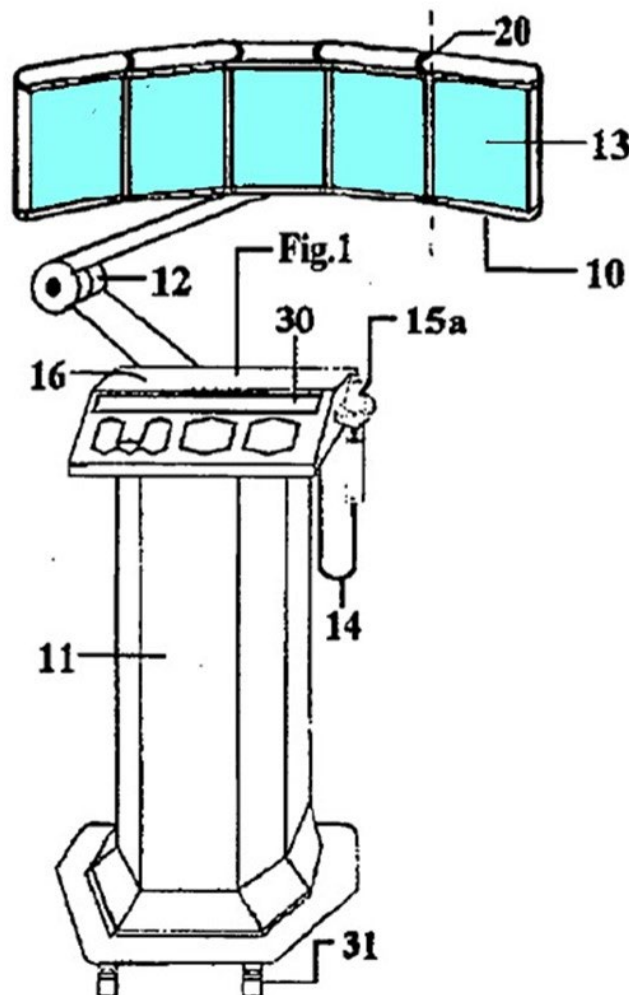
215. A POSITA would have found it obvious and would have been motivated with a reasonable expectation of success to incorporate the treatment distance described in Jones into Larsen, for all the reasons described above in Section IX.B.

216. Therefore, in my opinion Larsen in view of Jones renders obvious this claim element.

Claim 1(e): “wherein each of the five panels has two first edges and two second edges shorter than the two first edges, and”

217. A POSITA would understand that a panel with two first edges and two second edges shorter than the two first edges is a description of a rectangular panel.

218. By inspection, each of the panels (highlighted in blue) in the annotated reproduction of Figure 1 of Larsen below are rectangular. Hence a POSITA would understand that each of the five panels in this embodiment has two first edges and two second edges shorter than the two first edges.



Therefore, in my opinion, Larsen discloses this claim limitation.

Claim 1(f): “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.”

219. Bansal teaches “In 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 on the outer edges.” [Bansal ¶0025, Figure 9b]. Bansal also states “The 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.” [Bansal claim 10]. 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.

220. A POSITA would have found it obvious and would have been motivated with a reasonable expectation of success to incorporate the non-uniform

light arrangement of Bansal into Larsen to increase the intensity of light emitted from the second edges of the panels compared to regions of the panel not proximate to the second edges, for all the reasons described above Section IX.A.

221. Therefore, in my opinion, Larsen in view of Bansal renders obvious this claim limitation.

222. In summary, it is my opinion that claim 1 of the '028 Patent is obvious in view of the combination of Larsen, Bansal, and Jones.

Claim 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.*”

223. As discussed above, Larsen teaches use of sensors to ensure the proper amount of therapeutic energy reaches the tissue as measured in J/cm². “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.” [Larsen ¶0079]. Larsen’s applicators are configured to output red light: “devices are available for the photodynamic stimulation of human cell energy in the form of red and infrared radiation emitted by laser diodes and semiconductor diodes.” [Larsen ¶0024]. Larsen also teaches using light radiation within the wavelength of 300 – 2000 nm, which includes red light. [Larsen ¶¶0025, 0071-0076, 0083].

224. As discussed above, Jones teaches use of both blue light and red light. “According to an exemplary variant of the present invention each LED emits red

light, preferably red light at a nominal wavelength of approximately 632 nm $\pm$ 5 nm, and more preferably a nominal wavelength of 636 nm. According to another exemplary variant of the present invention each LED emits blue light, preferably blue light at a nominal wavelength of approximately 417 $\pm$ 5 nm. According to another exemplary variant of the present invention each array of LEDs consists of a subset of LEDs that emits red light and another subset of LEDs that emits blue light. Preferably, each subset contains the same number of LEDs.” [Jones ¶0032].

225. A POSITA would have found it obvious and would have been motivated with a reasonable expectation of success to adjust the controllable timer on Larsen’s applicator to increase the treatment time, and therefore increase the total light dose in a range of 30-150 J/cm², to destroy cancerous tissue. This would have involved nothing more than applying a known technique (increased irradiance over a longer period) to a known device (Larsen’s applicators) ready for improvement to yield predictable results (destroying cancerous tumors). Larsen teaches the importance of PDT that can stimulate “human cells of both surface *and underlying tissue*.” [Larsen ¶0026] (emphasis added). Jones teaches that “red light penetrates deeper into the skin than for instance blue light, thus being able to reach and treat deeper layers and structures in the skin.” [Jones ¶0080]. Jones also teaches “red light can be used to treat deeper layers and structures in the skin, e.g., the sebaceous glands in the case of an acne treatment.” [Jones ¶0080]. A POSITA would have

been motivated by this disclosure of Jones and Larsen to configure the applicators to increase the irradiance and/or treatment time of the red light from 30 to 150 J/cm², to more effectively treat deeper layers and structures of the skin. A POSITA would have understood that doses of 150 J/cm² would provide a permanent improvement in sebaceous gland disorders such as acne. [Anderson 9:6-21]. A POSITA would have had a reasonable expectation of success, since the unique benefits of red light for treatment purposes were well known. [Larsen ¶0083].

226. Second, Larsen teaches that “high-intensity treatments (higher doses of PDT substances and strong irradiation) are used where it is desired to destroy tissue, as in destroying tumor tissue to cure cancer, or in hair-removal where it is desired to destroy the hair follicle.” [Larsen ¶0112]. A POSITA would have had a reasonable expectation of success, since Larsen and Jones both describe PDT illuminators for treating skin conditions, and Larsen teaches that its light sources are adjustable “within a relatively large range with reference to duration, amplitude and frequency of surge of current,” which allows “the printed circuit boards can be equipped with a more intensive radiation effect.” [Larsen ¶0074]. A POSITA would have known that Larsen’s timer (29) could easily be set for a long enough duration to achieve any dose of red light.

227. Further, Jones teaches light doses in the range of about 1 to 99 J/cm². “According to an exemplary variant of the present invention a light dose of the array

of LEDs is from about 1 to 99 J/cm², more preferably from 5 to 80 J/cm² and most preferably from 10 to 99 J/cm².” [Jones ¶0034]. A person of ordinary skill in the art understands that Jones teaching of 1 to 99 J/cm² significantly overlaps the dosage in claim 2 of the ‘028 Patent (30 J/cm² to 150 J/cm²). Further, a POSITA would be strongly motivated to increase the dose delivered by either increasing the energy input to Jones’ LED array or by increasing the time duration of treatment to arrive at the upper limit of 150 J/cm². And a POSITA would have known that the total light dose (measured in J/cm²) is equal to irradiance (W/cm²) multiplied by time (in seconds). [Lundahl 30:7-10]. Larsen teaches that “[a]n increase of the registered amount of energy [measured in J/cm²] 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.” [Larsen ¶0079]. Larsen’s control mechanism (16) includes a timer (29) that can be used to adjust the duration of treatment. [Larsen ¶0074, Fig. 4].

228. Either change would be well within the capability of a POSITA as the goal a PDT/PT is to deliver an effective dose and that the dose delivered by Jones is not limited to a practical extent by the hardware design.

229. Moreover, Jones explicitly describes a cooling system for the LEDs [Jones ¶0082] which allows the LEDs to be operated indefinitely without degradation in output.

230. Finally, a POSITA would have known that the amount of energy used to radiate light is a result-effective variable, since it directly impacts the radiation received at the surface of the patient's skin (as well as below the surface). [Jones ¶¶0080-0082]. Configuring Larsen's applicators to output red light at a dose of 30 J/cm² to 150 J/cm² would have required nothing more than routine experimentation by POSITA. This operation would have involved nothing more than combining prior art elements according to known methods to yield predictable results. And POSITA would have had a reasonable expectation of success, given Jones and Larsen's similar design and purpose.² I am unaware of any unexpected results that the claimed range of 30-150 J/cm² achieves relative to the prior art.

²I also note that during prosecution of the '512 Patent, the Examiner found that this same limitation would have been obvious in view of a prior art reference (U.S. Publication No. 2003/0216795 to Harth) that described an illuminator configured to output red light at an intensity of only 20 J/cm². [October 25, 2021 Office Action ¶33 (finding that an illuminator configured to output red light at an intensity of about

231. Therefore, in my opinion, Larsen in view of Bansal and Jones renders claim 2 obvious.

Claim 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.”

232. Larsen teaches “The light sources 17 are adjustable and can radiate light in at least three wavelengths within the wavelength area 300-2000 nm.” [Larsen ¶0071]. A POSITA would readily note that the wavelength range of claim 4 of the ‘028 Patent is entirely within the explicit wavelength range taught by Larsen and thus easily be able to use the teachings of Larsen to design a system with a plurality of light sources configured to emit light having a wavelength in a range of 400 nm to 700 nm.

233. As further support for my opinion, during prosecution of the ’512 Patent, the Examiner found that this same limitation was disclosed by Larsen. [October 25, 2021 Office Action ¶25 (“Larsen discloses that a plurality of the light sources are configured to emit light having a wavelength in a range of 400 nm to 700 nm (see paragraph [0071]”)].

234. In the alternative, even if the Board determines that Larsen does not expressly or inherently disclose light sources configured to emit light having a

30 J/cm² to 150 J/cm² would have involved nothing more than “combining prior art elements according to known methods to yield predictable results”)].

wavelength in a range of 400 nm to 700 nm, this limitation would have been obvious to a POSITA. Larsen teaches applicators that emit light across a broad spectrum of wavelengths (between 300 and 2000 nm). [Larsen ¶0071]. Configuring Larsen's panels to emit light at wavelengths in a range of 400 nm to 700 nm would have involved nothing more than routine experimentation by a POSITA. And a POSITA would have been motivated to do so since the benefits of red and blue light (which span 400-700 nm) for PDT were well known, as described in Larsen itself. I am unaware of any unexpected results associated with the claimed range compared to the prior art.

235. Therefore, in my opinion, Larsen in view of Bansal and Jones renders claim 4 obvious.

'028 Patent: Claim 5

5. A method of photodynamically diagnosing or treating a patient, comprising:

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

[b] positioning an illuminator proximate to the patient, the illuminator comprising five panels connected by hinged structures on inner side surfaces of adjacent panels; and

[c] 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,

[d] wherein each of the five panels has two first edges and two second edges shorter than the two first edges, and

[e] 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.

Claim 5[preamble]: “*A method of photodynamically diagnosing or treating a patient, comprising:*”

236. As discussed above with respect to claim 1 of the ‘028 Patent, Larsen teaches a method of photodynamically diagnosing or treating a patient.

Claim 5(a): “*administering 5-aminolevulinic acid (ALA) to the patient;*”

237. Larsen teaches administering 5-aminolevulinic acid (ALA) to the patient. “ALA (5-Aminolavulinacid) is externally applied as a 10 to 20 percent mixture in an oil in water emulsion or in a cream. 4 to 6 hours is allowed for absorption, during which time the patient should remain in dim light. After treatment by irradiation from the invented device, the patient remains photosensitive for 24 to 48 hours”. [Larsen ¶0116, see also ¶0120].

238. Therefore, in my opinion, Larsen discloses this claim limitation.

Claim 5(b): “*positioning an illuminator proximate to the patient, the illuminator comprising five panels connected by hinged structures on inner side surfaces of adjacent panels; and*”

239. As discussed above in relation to claim limitation 1(a) of the ‘028 Patent, Larsen teaches an illuminator comprising five panels connect by hinged structures on inner side surfaces of adjacent panels. [Larsen ¶¶0070-0072]. Larsen also teaches that the illuminator is positioned proximate to the patient (such as over a patient’s back). [Larsen ¶¶0070-0072]. See discussion of claim 1(a).

240. Therefore, in my opinion, Larsen teaches, or renders obvious, this claim limitation.

Claim 5(c): “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,”

241. As discussed above in relation to claim limitations 1(b) and 1(d) of the ‘028 Patent, a POSITA would understand that Jones teaches positioning the panels within approximately four inches of the treatment surface. *See* discussion of claims 1(b) & 1(d).

242. Further, as also discussed above, Larsen, Bansal, and Jones all teach the importance of uniform illumination or irradiation for PDT/PT applications, and a POSITA would thus be highly motivated to combine the teachings of Larsen, Bansal, and Jones to achieve this claim limitation.

243. Therefore, in my opinion, this claim limitation is rendered obvious over the combination of Jones with Larsen and Bansal.

Claim 5(d): “wherein each of the five panels has two first edges and two second edges shorter than the two first edges, and”

244. As discussed above in relation to claim limitation 1(e) of the ‘028 Patent, a POSITA would understand that the panels of Larsen as illustrated in Fig. 1 of Larsen are rectangular and thus each of the five panels in the embodiment of

Larsen's Fig. 1 would have two first edges and two second edges shorter than the two first edges. *See* discussion of claims 1(e).

245. Therefore, in my opinion, Larsen discloses this claim limitation.

Claim 5(e): “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”

246. As discussed above in relation to claim limitation 1(f) of the '028 Patent, Bansal teaches light sources with a higher intensity of light emitted along the periphery as compared to the center via a higher density of LEDs, or higher driving current through LEDs along the periphery. [Bansal ¶0025, Figures 9a-9d]. *See* discussion of claims 1(f).

247. Therefore, in my opinion, Larsen in view of Bansal renders this claim limitation obvious.

248. In summary, it is my opinion that claim 5 of the '028 Patent is obvious over the combination of Larsen, Bansal, and Jones.

Claim 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.”

249. Larsen teaches use of light sources that emit in the wavelength range of 200-2000 nm. “Light sources 17 are adjustable and can radiate light in at least three wavelengths within the wavelength area 300-2000 nm.” [Larsen ¶0071]. A POSITA would understand that visible light spans the wavelength range of 360-830nm and

that thus Larsen's wavelength range spans the entire visible gamut and thus necessarily includes red light. [Larsen ¶¶0024-0025]. Larsen also teaches the desirability of red light for treatment. "The same can be said for existing devices for treatment with pulsating electromagnetic fields. Moreover, a combined treatment with both red/infrared and blue light together with electromagnetic fields is not possible with these devices for the stimulation of light sensitive substances." [Larsen ¶0024]. Therefore, in my opinion Larsen teaches this limitation.

250. Further, Jones teaches treatment with both red and blue light. "According to an exemplary variant of the present invention each LED emits red light, preferably red light at a nominal wavelength of approximately 632 nm $\pm$ 5 nm, and more preferably a nominal wavelength of 636 nm. According to another exemplary variant of the present invention each LED emits blue light, preferably blue light at a nominal wavelength of approximately 417 $\pm$ 5 nm. According to another exemplary variant of the present invention each array of LEDs consists of a subset of LEDs that emits red light and another subset of LEDs that emits blue light. Preferably, each subset contains the same number of LEDs." [Jones ¶0032]. Therefore, a POSITA would understand that Jones discloses this claim limitation.

251. Therefore, in my opinion, Larsen, in view of Jones and Bansal renders claim 6 obvious.

Claim 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.”

252. Larsen teaches the desirability of blue light for treatment. “Moreover, a combined treatment with both red/infrared and blue light together with electromagnetic fields is not possible with these devices for the stimulation of light sensitive substances.” [Larsen ¶0024]. Further, as discussed above with respect to claim 6 of the ‘028 Patent, Larsen teaches radiating light in at least three wavelengths within the range of 300-2000 nm, which include the entire visible spectrum and hence necessarily includes blue light. For this reason, a POSITA would understand that Larsen discloses this claim limitation.

253. I note that during prosecution of the ’028 Patent, the Examiner determined that this limitation was disclosed by the same text in the Larsen ’381 Patent. [Nov. 18, 2022 Office Action ¶14].

254. Further, as also discussed above in regards to claim 6 of the ‘028 Patent, Jones teaches use of both red light and blue light during treatment. [Jones ¶0032]. Therefore, a POSITA would understand that Jones discloses this claim limitation.

255. For these reasons, it is my opinion that Larsen, in view of Jones and Bansal renders claim 7 obvious.

Claim 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.”

256. Larsen teaches “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 optimize the therapy results.” [Larsen ¶0030]. “The applicators 13, according to the FIGS, 2a, 2b and 2c are equipped with sensors 32 arranged between the semiconductor and/or laser diodes 17. For therapeutic uses it is typically intended to apply a given amount of energy (joule/cm²) per irradiated surface of tissue, which can be adjusted at the control mechanism 16. Sensors 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.” [Larsen ¶0079].

257. Larsen’s applicators also include “[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.” [Larsen ¶0080].

258. A POSITA would understand that the human body has few if any flat surfaces and is instead bounded by curved surfaces. Therefore, a POSITA would

understand that Larsen’s description of sensors means that those sensors and the information they transmit relate to a curvature of the treatment surface and are used to control or regulate the intensity of light related to the curvature of the treatment surface. If a treatment surface curves away from the light source, then the portion of the surface further from the light source will radiate less energy and/or have a lower temperature, which would be detected by the sensors on Larsen’s applicators. My opinion is confirmed by the prosecution of the ’512 Patent. In an Office Action on October 25, 2021, the Examiner found that the limitation “changing intensities of 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,” was anticipated by Larsen. [October 25, 2021 Office Action ¶28]. The Examiner’s rejection relied on paragraphs [0030] and [0079] of Larsen. *Id.*³ Thus, Larsen discloses claim 8.

259. To the extent the Board determines that Larsen does not expressly or inherently teach claim 8, a POSITA would have found it obvious and would have

³ The Examiner mistakenly cited “Tobin,” but the context makes clear that the Examiner meant to cite Larsen, since the citation is part of a 102(a)(1) rejection of the claims over Larsen, and the specific paragraphs cited by the Examiner ([0030] and [0079]) disclose the sensor cited above.

been motivated with a reasonable expectation of success to modify Larsen to change 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. Larsen expressly discloses a controller that receives readings from sensors 32 (measuring radiated energy from the treatment surface) and 32a (measuring temperature of the treatment surface). [Larsen ¶¶0079-0080, Figs. 2a-2c]. The controller uses these readings to adjust the radiation parameters of the applicators, which would have motivated a POSITA to add sensors to measure the curvature of the treatment surface in order to more finely tune the radiation parameters of the applicators, and thus provide a more “even and gap-free radiation,” as taught by Larsen. [Larsen ¶0028]. This would have involved nothing more than applying a known technique (sensor that measured the curvature of the treatment surface) to a known device (Larsen’s applicators) ready for improvement to yield predictable results (more even and gap-free radiation). A POSITA would have had a reasonable expectation of success, since Larsen’s controller was already configured to adjust the radiation parameters based on sensor data.

260. Therefore, in my opinion, Larsen, in view of Bansal and Jones renders obvious claim 8.

’028 Patent: Claim 16

16.A system for photodynamically diagnosing or treating a patient, comprising:

- [a] a mobile base supported by at least four wheels;
- [b] a pillar perpendicular to the base;
- [c] a controller disposed to be supported by the pillar;
- [d] an arm mounted to a top portion of the pillar; and
- [e] 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:
 - [f] 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,
 - [g] 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,
 - [h] each of the five panels having two first edges and two second edges shorter than the two first edges,
 - [i] 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
 - [j] one or more fans mounted to at least one of the five panels.

Claim 16 [preamble]: *“A system for photodynamically diagnosing or treating a patient, comprising:”*

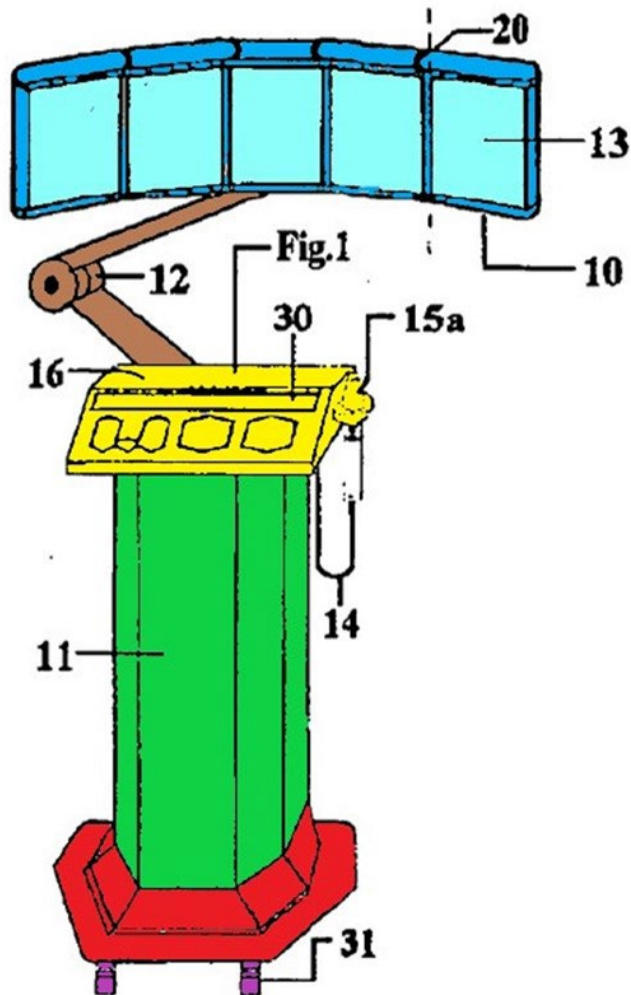
261. As discussed above in relation to claim 1 of the ‘028 Patent, Larsen teaches a system for photodynamically diagnosing or treating a patient. Therefore, in my opinion Larsen discloses this claim limitation.

Claim 16(a): *“a mobile base supported by at least four wheels;”*

262. Larsen's describes a system that is freely moveable on wheels. "The device consists of a stand, to which machine applicators are connected by means of a jointed arm. 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." [Larsen ¶0027].

263. Larsen also describes the embodiment of Fig.1. "As shown in FIG. 1, the invented device 10 for the stimulation of cells with the aid of (PDT) photodynamic light and electromagnetic fields combined with light sensitive substances 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 is also connected by an electric circuit 14 with a hand applicator 15. 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)." [Larsen ¶0069].

264. In the annotated version of Fig. 1 of Larsen reproduced below, I have highlighted the wheels in purple.



265. Although Figure 1 of Larsen only shows two wheels, a POSITA would understand that at least four wheels must necessarily be present in order for Larsen's system to be "freely moveable." 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

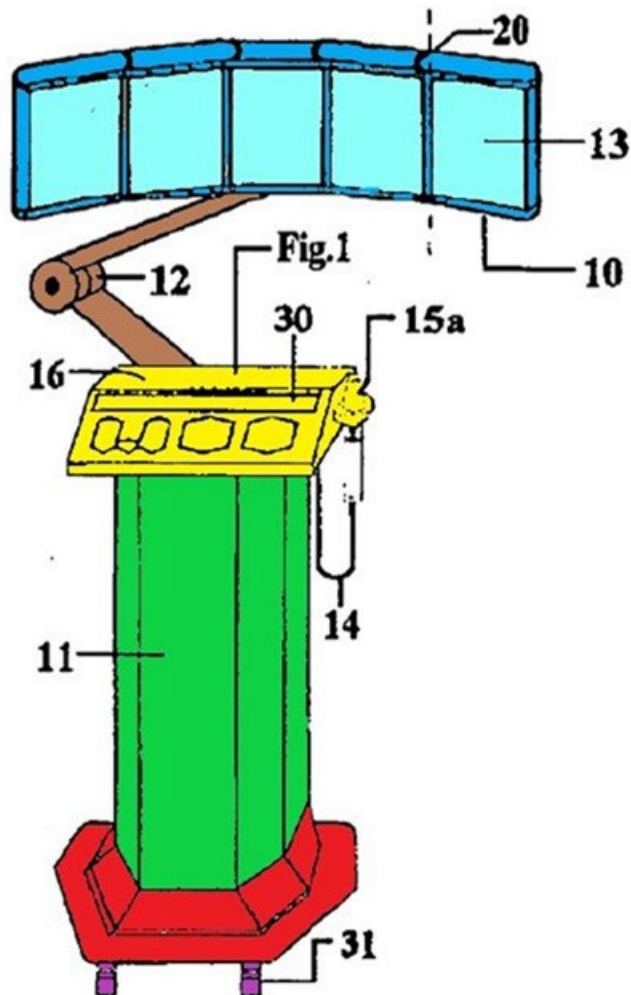
“freely moveable.” The Examiner found this to be the case with respect to the same disclosure in the Larsen ’381 Patent. [Nov. 18, 2022 Office Action, ¶12 (citing Figure 1 of Larsen ’381 Patent and stating “although only two wheels are shown, it is inherent that there are least two more wheels, for a total of 4, in order for the device to be stable”)].

266. Furthermore, using at least four wheels to support the stand was one of a finite number of known solutions to support a mobile stand, and would have been obvious to try with predictable results (more stability compared to only three wheels). A POSITA would have been motivated with a reasonable expectation of success to use four wheels, since the stability provided by four wheels was a well-known outcome.

267. For this reason, it is my opinion that Larsen discloses or renders obvious this claim limitation.

Claim 16(b): “*a pillar perpendicular to the base;*”

268. By inspection, a POSITA would understand that the (apparently) hexagonally shaped lower member to which Larsen’s wheels are attached forms a base and that element 11 of Larsen’s Fig. 1 comprises a pillar which is perpendicular to the base. [Larsen ¶0069]. In the annotated version of Fig. 1 of Larsen reproduced below, I have highlighted the base in red, and the pillar in green.



269. I note that during prosecution of the '028 Patent, the Examiner determined that this limitation was disclosed by the same “pillar 11” found in Figure 1 of the Larsen '381 Patent. [Nov. 18, 2022 Office Action ¶12].

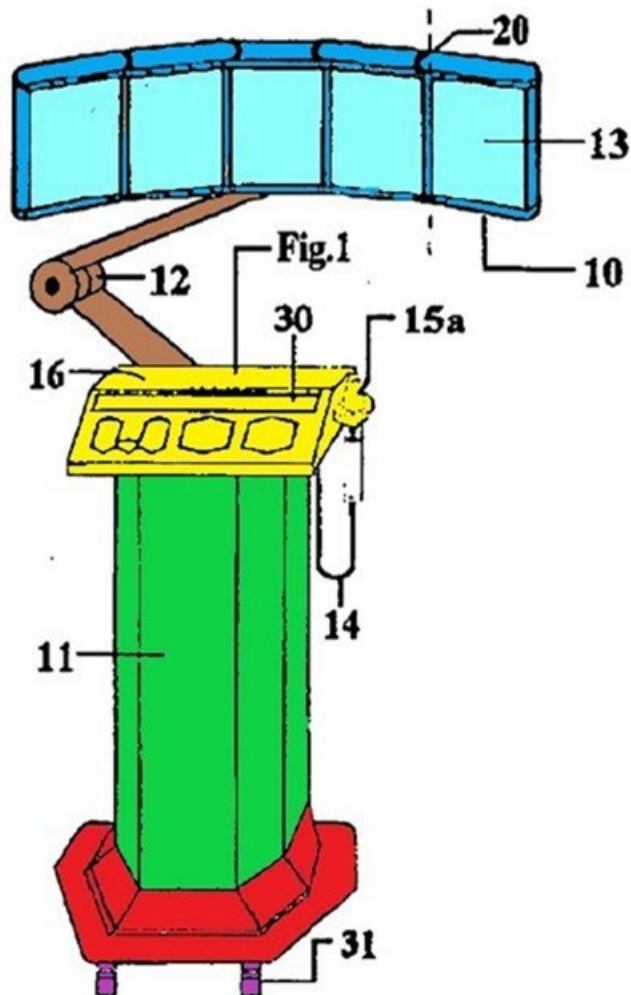
270. Therefore, in my opinion, Larsen discloses this claim limitation.

Claim 16(c): *a controller disposed to be supported by the pillar;*”

271. Larsen describes the embodiment of Fig. 1. “As shown in FIG. 1, the invented device 10 for the stimulation of cells with the aid of (PDT) photodynamic light and electromagnetic fields combined with light sensitive substances 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 is also connected by an electric circuit 14 with a hand applicator 15. 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).” [Larsen ¶0069].

272. In the annotated version of Fig. 1 of Larsen reproduced below, I have highlighted the control mechanism (i.e., controller) in yellow. [Larsen ¶0074]. By inspection, a POSITA would understand that Larsen’s controller is supported by the pillar.



273. I note that during prosecution of the '028 Patent, the Examiner determined that this limitation was disclosed by the same “controller 16” found in Figure 1 of the Larsen '381 Patent. [Nov. 18, 2022 Office Action ¶12].

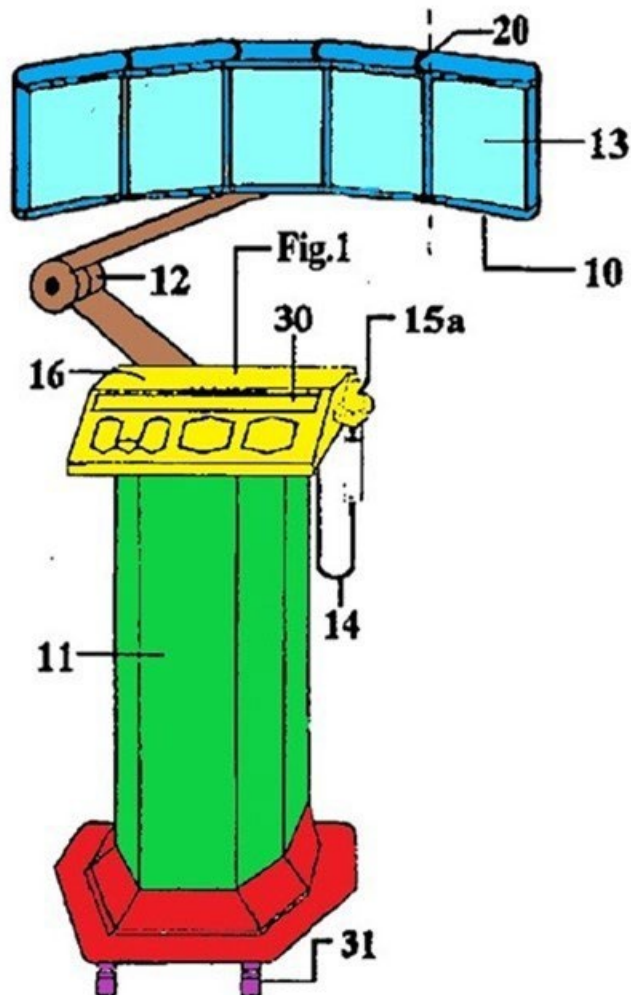
274. Therefore, in my opinion, Larsen discloses this claim limitation.

Claim 16(d): “an arm mounted to a top portion of the pillar; and”

275. Larsen teaches applicators (i.e., light panels) connected a stand by means of a jointed arm. “The device consists of a stand, to which machine applicators are connected by means of a jointed arm. 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.” [Larsen ¶0027]. “As shown in FIG. 1, the invented device 10 for the stimulation of cells with the aid of (PDT) photodynamic light and electromagnetic fields combined with light sensitive substances consists of a stand 11, with which machine applicators 13 (in the following just called applicators 13) are connected through a jointed arm 12.” [Larsen ¶0069].

276. In the annotated version of Fig. 1 of Larsen reproduced below, I have highlighted Larsen’s arm in brown.



277. By inspection, a POSITA would understand that Larsen's arm must necessarily be mounted on or connected to a top portion of the pillar as this would allow maximum flexibility or positioning capability for the light panels. [Larsen ¶0073]. If the arm were connected to the middle or lower portion of the pillar, then the pillar itself would impede movement of the arm and hence limit the ability of a user to position of the panels which would in turn limit the utility of the system.

278. I note that during prosecution of the '028 Patent, the Examiner determined that this limitation was disclosed by the same “arm 12” found in Figures 1 and 3 of the Larsen '381 Patent. [Nov. 18, 2022 Office Action ¶12].

279. Therefore, in my opinion, Larsen discloses this claim limitation.

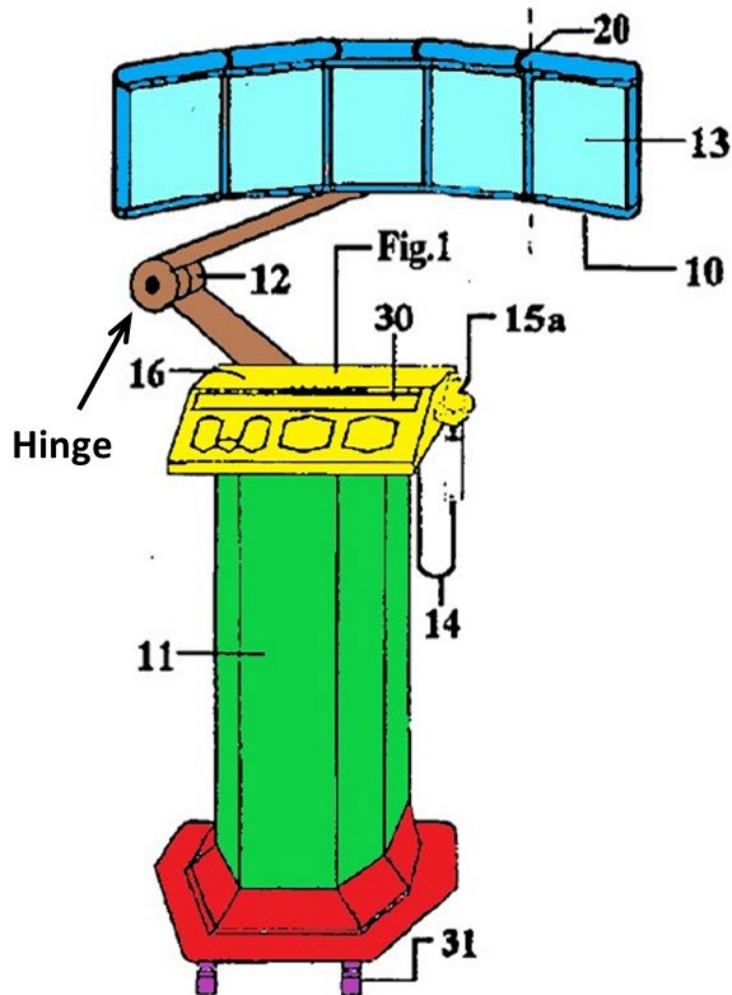
Claim 16(e): “an illuminator connected at an end of the arm, the arm being hinged to allow adjustment of a position of the illuminator relative to the base, the illuminator comprising:”

280. Larsen teaches 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. “As shown in FIG. 1, the invented device 10 for the stimulation of cells with the aid of (PDT) photodynamic light and electromagnetic fields combined with light sensitive substances consists of a stand 11, with which machine applicators 13 (in the following just called applicators 13) are connected through a jointed arm 12.” [Larsen ¶0069].

281. Larsen further describes the joint arm in paragraph 73. “The joint arm 12, shown in FIG. 3, connects one or more applicator(s) 13 with the stand 11. The jointed arm 12 has three joint carriers 21, 22, 23, where the joint carrier 21, together with the stand 11 and the joint carrier 23 are moveable at a free end through a fixing joint 24 connected with one or more applicators 13. Another fixing joint 25 connects the joint carrier 23 with 21, while the joint carrier 22 is connected with the joint carrier 21 with a hinge 26. The joint carrier 21 is connected with the stand 11 through

a joint 27 and one or more joints can also be produced as friction-adjustable ball-joints, which gives almost unlimited adjustment possibilities and user comfort. The jointed arm 12 thereby allows the positioning of the applicators 13 in front of, or above, a tissue area while maintaining a correct positioning distance.” [Larsen ¶0073].

282. This is also evident by inspection of Fig. 1 of Larsen. In the annotated version of Fig. 1 of Larsen reproduced below, I have highlighted the arm in brown and the applicators (i.e., illuminators) in blue and light blue.



283. I note that during prosecution of the '028 Patent, the Examiner determined that this limitation was disclosed by the same “hinged arm and joints/hinges 25/26/27” found in Figure 3 of the Larsen '381 Patent. [Nov. 18, 2022 Office Action ¶12].

284. Therefore, in my opinion, Larsen discloses this claim limitation.

Claim 16(f): *“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,”*

285. As discussed above in claim limitation 1(a), Larsen teaches an embodiment with five panels connected with hinge structures. *See* discussion of claim 1(a). Further, Larsen teaches individual control of each illuminator (i.e., panel). “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, 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.” [Larsen ¶0072]. Larsen’s panels allow for continuous illumination across the five panels to treat large surfaces on the patient (such as the patient’s back). [Larsen ¶¶0027, 0072].

286. Larsen also teaches that each of the applicators are individually configurable to control illumination from each of the five applicators. In 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.” [Larsen ¶0070] (emphasis added). Each of the applicators is connected

to a control mechanism 16, as shown in Larsen's Figures 1 and 3. Using 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." [Larsen ¶0074]. The 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." [Larsen ¶0074].

287. Moreover, Larsen teaches use of sensors to adjust the operating conditions of each panel to assure the delivery of the correct fluence over the target area which necessarily includes the ability to adjust or control the output of each panel. "The applicators 13, according to the FIGS. 2a, 2b and 2C are equipped with sensors 32 arranged between the semiconductor and/or laser diodes 17. For therapeutic use it is typically intended to apply a given amount of energy (Joule/cm²) per irradiated surface of tissue, which can be adjusted at the control mechanism 16. Sensors 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.” [Larsen ¶0079]. A POSITA would understand this to mean that each applicator is individually configurable, since each one can be adjusted based on feedback from its sensors.

288. Therefore, in my opinion, Larsen discloses this claim limitation.

Claim 16(g): “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,”

289. For the reasons discussed above in relation to claim limitation 1(b) of the ‘028 Patent, Larsen discloses this claim limitation. *See* discussion of claim 1(b).

290. Furthermore, Larsen discloses the light sources are configured to output light uniformly during at least part of a time when the treatment surface is illuminated. Larsen teaches that “[t]he semiconductor diodes and/or laser diodes useable in this invention emit a light radiation with either SPE (single photon emission), TPE (Two photon emission) and/or MTE (multiple photon emission) within the wavelength area of 300-2000 nanometers in order to correspond with available light sensitive substances (PDT).” [Larsen ¶0076, see also 0071 (showing

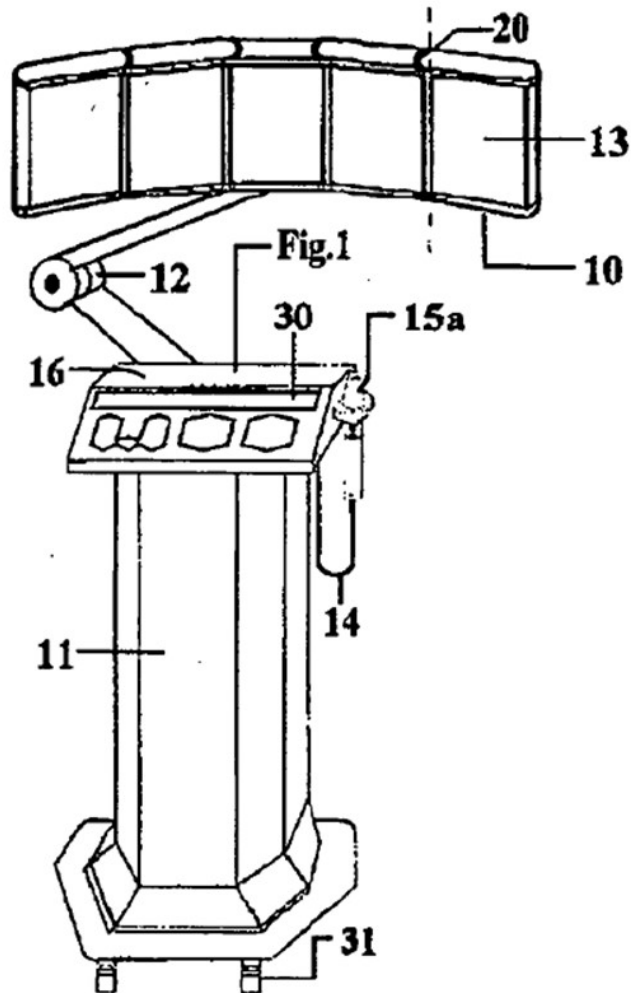
applicators can radiate light at different discrete wavelengths)]. Furthermore, “[i]n each applicator the printed circuit board carrying the light sources is connected to a small electrical scan engine 66, which can move the light sources with linear movements, whereby a correctly adjusted scan length and frequency gives the radiated surface a total radiation at the necessary wavelengths without leaving any unradiated gaps.” [Larsen ¶0072].

291. Therefore, in my opinion, Larsen, or Larsen in view of Bansal, discloses or renders obvious claim 16(g).

Claim 16(h): “*each of the five panels having two first edges and two second edges shorter than the two first edges,*”

292. As discussed above in relation to claim limitation 1(e) of the ‘028 Patent, Larsen clearly teaches use of rectangular panels. Rectangular panels necessarily have two first edges and two second edges shorter than the two first edges. *See* discussion of claim 1(e).

293. Additionally, by inspection, Fig. 1 of Larsen teaches use of five rectangular panels. I have reproduced Fig. 1 of Larsen below for reference.



294. Therefore, in my opinion, Larsen discloses this claim limitation.

Claim 16(i): *“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”*

295. As discussed above in relation to claim limitation 1(f) of the ‘028 Patent, Larsen in view of Bansal renders obvious this claim limitation. See discussion of claim 1(f).

Claim 16(j): *“one or more fans mounted to at least one of the five panels.”*

296. As discussed above (see Section VIII.c), Jones provides significant teachings on the desirability of cooling LEDs during operation and identifies many exemplary methods for cooling LEDs, including the use of fans to cool LED arrays. “According to an exemplary variant of the present invention, the cooling unit includes at least one fan, preferably a fan configured to provide forced-air cooling of the array of LEDs.” [Jones ¶0027]. “The lamp modules 21 may preferably include a cooling system to maintain the temperature of the LEDs for optimal performance. Preferably, the lamp modules 21 may be cooled by forced-air cooling. For example, each lamp module 21 may include heat sinks to which the LED arrays are directly mounted, and fans and associated ducts behind each array of LEDs that provide effective forced-air cooling.” [Jones ¶0083].

297. Figure 4D of Jones depicts one or more fans mounted to the panels.

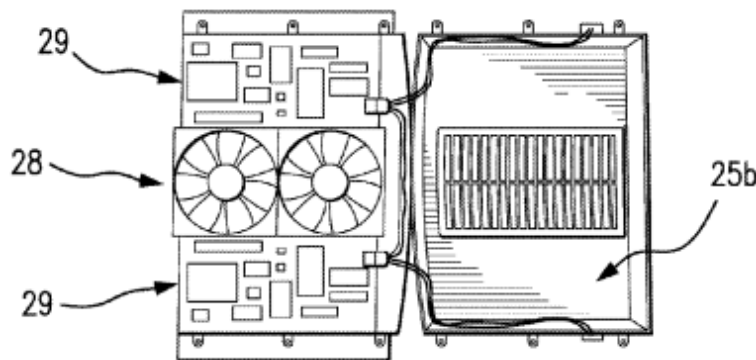


FIG. 4D

298. In Jones, “the support and/or heat sink of each lamp module 21 may be mounted to one or more cooling fans 28 and associated ducts for cooling, and one

or more driver modules 29 for control of the lamp module 21 as illustrated in FIG. 4D.” [Jones ¶0084].

299. Therefore, in my opinion, Jones discloses this claim limitation. A POSITA would have found it obvious and would have been motivated with a reasonable expectation of success to combine the cooling fans on Jones’ lamp modules with the device in Larsen, for all the reasons give above in Section IX.B.

300. For these reasons, in my opinion, claim 16 is obvious over the combination of Larsen, in view of Bansal, further in view of Jones.

Claim 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.*”

301. As discussed above in relation to claim limitation 1(c) of the ‘028 Patent, Larsen discloses this claim limitation. *See* discussion of claim 1(c).

302. For these reasons, it is my opinion that Larsen in view of Bansal, further in view of Jones renders obvious claim 17.

Claim 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.*”

303. As discussed above in relation to claim 7 of the ‘028 Patent, Larsen discloses this claim limitation. *See* discussion of claim 7.

304. For these reasons, it is my opinion that Larsen in view of Bansal, further in view of Jones renders obvious claim 18.

Claim 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.”*

305. As discussed above in relation to claim 6 of the ‘028 Patent, Larsen discloses this claim limitation. See discussion of claim 6.

306. For these reasons, it is my opinion that Larsen in view of Bansal, further in view of Jones renders obvious claim 19.

’028 Patent: Claim 20

20. A system for photodynamically diagnosing or treating a patient, comprising:

[a] 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

[b] 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,

[c] wherein the five panels are positioned to allow treatment within approximately four inches of the treatment surface, and

[d] wherein each of the five panels has two first edges and two second edges shorter than the two first edges, and

[e] 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.

Claim 20 [preamble]: *“A system for photodynamically diagnosing or treating a patient, comprising:”*

307. As discussed above in relation to the preamble of claim 1 of the ‘028 Patent, it is my opinion that each of Larsen, Bansal, and Jones teach this claim limitation.

Claim 20(a): “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”

308. For the reasons discussed above in relation to claim limitation 1(a) of the ‘028 Patent, it is my opinion that Larsen discloses (or renders obvious) an illuminator comprising five panels connected by hinged structures on inner side surfaces of adjacent panels. *See* discussion of claim 1(a). Larsen also discloses that its illuminator (applicators) are configured to output light at a variable irradiance density during treatment. In Larsen, the applicators can produce “an intensive light radiation with selective multiple wavelengths” in order to provide intensive photodynamic therapy to a patient. [Larsen, ¶¶0025-0026]. Larsen further teaches that the energy output from its applicators is adjustable “within a relatively large range with reference to duration, amplitude and frequency of surge of current, so that semiconductor diodes 17, 17a and 18 . . . can be used as light sources.” [Larsen, ¶0074]. Larsen’s applicators are connected to sensors measuring the amount of energy radiated away from the skin surface and the temperature of the skin surface. [Larsen, ¶¶0079-0080, Figs. 2a-2c]. In response to readings from the sensors, “[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.” [Larsen, ¶0079].

309. Therefore, Larsen discloses, or renders obvious, claim 20(a).

Claim 20(b): “*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.*”

310. For the reasons discussed above in relation to claim limitation 1(b) above, it is my opinion that Larsen discloses this claim limitation. *See* discussion of claim 1(b).

Claim 20(c): “*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,*”

311. For the reasons discussed above in relation to claim limitation 1(c) above, it is my opinion that Larsen discloses this claim limitation. *See* discussion of claim 1(c).

Claim 20(d): “*wherein the five panels are positioned to allow treatment within approximately four inches of the treatment surface, and*”

312. For the reasons discussed above in relation to claim limitation 1(d) above, it is my opinion that Larsen in view of Jones renders obvious this claim limitation. *See* discussion of claim 1(d).

Claim 20(e): “*wherein each of the five panels has two first edges and two second edges shorter than the two first edges, and*”

313. For the reasons discussed above in relation to claim limitation 1(e), it is my opinion that Larsen discloses this claim limitation. See discussion of claim 1(e).

Claim 20(f): “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.”

314. For the reasons discussed above in regards to claim limitation 1(f), it is my opinion that Larsen in view of Bansal renders obvious this claim limitation. See discussion of claim 1(f). Accordingly, in my opinion, claim 20 is obvious over Larsen in view of Bansal, further in view of Jones.

’028 Patent: Claim 21

21. A system for photodynamically diagnosing or treating a patient, comprising:

[a] an illuminator comprising five panels connected by hinged structures on inner side surfaces of adjacent panels; and

[b] 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,

[c] 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,

[d] wherein the five panels are positioned to allow treatment within approximately four inches of the treatment surface,

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

[f] wherein each of the five panels has two first edges and two second edges shorter than the two first edges, and

[g] 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.

Claim 21 [preamble]: “A system for photodynamically diagnosing or treating a patient, comprising:”

315. For the reasons discussed above regarding the preamble of claim 1, it is my opinion that Larsen discloses this claim limitation.

Claim 21(a): “an illuminator comprising five panels connected by hinged structures on inner side surfaces of adjacent panels; and”

316. For the reasons discussed above in relation to claim limitation 1(a), it is my opinion that Larsen discloses or renders obvious this claim limitation.

Claim 21(b): “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,”

317. For the reasons discussed above in relation to claim limitation 1(b), it is my opinion that Larsen in view of Bansal renders obvious this claim limitation.

Claim 21(c): “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,”

318. As discussed above with respect to claim limitation 1(c), it is my opinion that Larsen discloses this claim limitation.

Claim 21(d): “wherein the five panels are positioned to allow treatment within approximately four inches of the treatment surface,”

319. As discussed above in regards to claim limitation 1(d), it is my opinion that Larsen in view of Jones renders this limitation obvious.

Claim 21(e): “wherein the five panels are individually configurable to control illumination from each of the five panels, and”

320. As discussed above at claim 16(f), Larsen’s teaching of hinged control panels and the ability to adjust the position of panels for treatment is one method of allowing individual configuration. “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, 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.” [Larsen ¶0072].

321. A POSITA would understand that Larsen’s teaching of an “electrical scan engine” on the printed circuit board carrying light sources in each applicator (i.e., panel) is a clear description of individual control of illumination from each panel.

322. Bansal further teaches “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.” [Bansal ¶0080]. A person of ordinary skill in the art understands this is yet another example of individually configurable control, albeit automatic, at the panel level.

323. Therefore, in my opinion, Larsen discloses this claim limitation.

Claim 21(f): “*wherein each of the five panels has two first edges and two second edges shorter than the two first edges, and,*”

324. As discussed above in relation to claim element 1(e), it is my opinion that Larsen discloses this claim limitation.

Claim 21(g): “*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.*”

325. As discussed above in relation to claim limitation 1(f), the combination of Larsen and Bansal renders this limitation obvious.

326. Accordingly, in my opinion, claim 21 is obvious over Larsen, in view of Bansal, further in view of Jones.

B. Larsen in view of Bansal, further in view of Jones, further in view of Anderson renders obvious at least claims 2-4 of the ’028 Patent

Claim 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:*”

327. As discussed above, Anderson teaches specific treatment regimes for sebaceous gland disorders. As such, a POSITA would understand that the teachings of Anderson are guidelines for PDT/PT treatments. Anderson teaches “In preferred

embodiments, the energy source emits visible light, especially red visible light. Generally, the range of energy applied to the skin surface ranges from 1 J/cm² to about 200 J/cm², preferably from about 25 J/cm² to about 200 J/cm², and most preferably about 100 J/cm².” [Anderson 8:12-15]

328. The fluence range of claim 2 of the ‘028 Patent (30 J/cm² to 150 J/cm²) is entirely within the limits taught by Anderson.

329. A POSITA would have found it obvious and would have been motivated with a reasonable expectation of success to incorporate the red light doses of Anderson into the combination of Larsen, Bansal, and Jones, for all the reasons given above at Section IX.C.

330. Therefore, in my opinion, the combination of Larsen, in view of Bansal, in view of Jones, further in view of Anderson renders this claim limitation obvious.

Claim 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.”

331. As discussed above (see Section VIII.d), Anderson teaches a wide range of fluences ranging from 1 J/cm² to about 200 J/cm². Anderson further teaches “In another aspect, the invention includes the combination of ALA with UVA and/or UVB absorbing substances. The combination can be applied topically and is useful in the treatment of sebaceous gland disorders, such as acne. Application of the ALA with the UVA and/or UVB absorbing substance followed by PDT causes the converted ALA to eradicate bacteria associated with acne. Generally, sunlight is the

energy source for PDT stimulation and the total fluence energy is between about 1 and about 100 J/cm², preferably between about 1 and about 50 J/cm² and most preferably between about 10 and about 40 J/cm².” [Anderson 11:1-8].

332. Furthermore, Anderson describes PDT illuminators that provide “lower average irradiance exposures given over longer exposure time would be appropriate for example approximately **10-100 mW/cm²** delivered for about 100-2000 seconds (total fluence, 1-200 J/ cm²).” [Anderson 20:23-25 (emphasis added)]. This range of irradiance densities fully brackets the irradiance range of claim 3 of the ‘028 Patent.

333. A POSITA would have found it obvious and would have been motivated with a reasonable expectation of success to incorporate the irradiance densities of Anderson into the combination of Larsen, Bansal, and Jones, for all the reasons given above at Section IX.C.

334. Therefore, in my opinion, the combination of Larsen, in view of Bansal, in view of Jones, further in view of Anderson renders this claim limitation obvious.

Claim 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.”

335. Anderson teaches “[i]n general, the wavelength range for therapeutic treatment is from about 320 nm to about 700 nm, preferably from about 550 to about 700 nm, more preferably from about 550 to about 600 nm.” [Anderson 8:16-18]. This range of light wavelengths fully brackets the range of claim 4 of the ‘028 Patent.

336. A POSITA would have found it obvious and would have been motivated with a reasonable expectation of success to incorporate the light wavelengths of Anderson into the combination of Larsen, Bansal, and Jones, for all the reasons given above at Section IX.C.

337. Therefore, in my opinion, the combination of Larsen, in view of Bansal, in view of Jones, further in view of Anderson renders this claim limitation obvious.

C. Larsen in view of Bansal, further in view of Jones, further in view of Mackinnon renders obvious at least claims 10, 11, 13, and 14 of the '028 Patent

Claim 10: “*The method of claim 5, further comprising determining a size of the treatment surface of the patient using a sensor.*”

338. As discussed above, Larsen in view of Bansal and Jones render obvious the method of claim 5. Furthermore, Mackinnon describes that its system “may match the shape and size of the illumination area to correspond to the shape and size of a target region discerned by an imaging system, for example an imaging sensor and image processing system of an endoscope or surgical microscope, such as those discussed herein.” [Mackinnon 21:23-27]. Mackinnon provides an example where the imaging system can identify a skin lesion on the treatment surface, then control the shape of the illumination light to match the size and shape of the lesion. [Mackinnon 21:27-22:6, 34:18-25]. Thus, Mackinnon discloses determining the size and shape of the treatment surface using a sensor.

339. A POSITA would have found it obvious and would have been motivated with a reasonable expectation of success to incorporate the imaging sensor and system of Mackinnon into the combination of Larsen, Bansal, and Jones, for all the reasons given above at Section IX.D.

340. Therefore, in my opinion, the combination of Larsen, in view of Bansal, in view of Jones, further in view of Mackinnon renders this claim limitation obvious.

Claim 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.”

341. Mackinnon’s system “receives the data from the sensor and uses the data to coordinate the tunable light source and the processor such that the programming varies the selected spectral output and wavelength dependent intensity distribution of the illumination light.” [Mackinnon 34:29-35:4, 21:23-22:6].

342. A POSITA would have found it obvious and would have been motivated with a reasonable expectation of success to configure the controller in the combination of Larsen, Bansal, and Jones to adjust the light dose using data from the image sensor of Mackinnon related to the size and shape of the treatment surface, for all the reasons given above at Section IX.D.

343. Therefore, in my opinion, the combination of Larsen, in view of Bansal, in view of Jones, further in view of Mackinnon renders this claim limitation obvious.

Claim 13: “The method of claim 5, further comprising determining a shape of the treatment surface of the patient using a sensor.”

344. As discussed above, Larsen in view of Bansal and Jones render obvious the method of claim 5. Furthermore, Mackinnon describes that its system “may match the shape and size of the illumination area to correspond to the shape and size of a target region discerned by an imaging system, for example an imaging sensor and image processing system of an endoscope or surgical microscope, such as those discussed herein.” [Mackinnon 21:23-27]. Mackinnon provides an example where

the imaging system can identify a skin lesion on the treatment surface, then control the shape of the illumination light to match the size and shape of the lesion. [Mackinnon 21:27-22:6, 34:18-25]. Thus, Mackinnon discloses determining the size and shape of the treatment surface using a sensor.

345. A POSITA would have found it obvious and would have been motivated with a reasonable expectation of success to incorporate the imaging sensor and system of Mackinnon into the combination of Larsen, Bansal, and Jones, for all the reasons given above at Section IX.D.

346. Therefore, in my opinion, the combination of Larsen, in view of Bansal, in view of Jones, further in view of Mackinnon renders this claim limitation obvious.

Claim 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.*”

347. Mackinnon’s system “receives data from the sensor and uses the data to coordinate the tunable light source and the processor such that the programming varies the selected spectral output and wavelength dependent intensity distribution of the illumination light.” [Mackinnon 34:30-35:4, 21:23-22:6].

348. A POSITA would have found it obvious and would have been motivated with a reasonable expectation of success to configure the controller in the combination of Larsen, Bansal, and Jones to adjust the light dose using data from the image sensor of Mackinnon related to the size and shape of the treatment surface, for all the reasons given above at Section IX.D.

349. Therefore, in my opinion, the combination of Larsen, in view of Bansal, in view of Jones, further in view of Mackinnon renders this claim limitation obvious.

IX. CONCLUSION

350. In my opinion, claims 1-8, 10, 11, 13, 14, and 16-21 of the '028 Patent are invalid for at least the reasons stated above.

351. I reserve the right to supplement my opinions in the future to respond to any arguments raised by the owner of the '028 Patent and to take into account new information that becomes available to me.

352. I declare under penalty of perjury that all statements made herein are of my own knowledge and are true and correct. I further understand that willful false statements and the like are punishable by fine or imprisonment, or both. Signed on this 30 day of April, 2024, in Flower Mound, TX.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Eric Bretschneider", written over a horizontal line.

Eric Bretschneider, Ph.D.

APPENDIX A MATERIALS CONSIDERED

All Materials Referenced in this Declaration, and other Relevant Materials, Including the Following:

- U.S. Patent No. 11,697,028
- File History for U.S. Patent No. 11,697,028
- U.S. Patent Publication No. 2005/0075703
- U.S. Patent Publication No. 2004/0068305
- U.S. Patent Publication No. 2014/0067024
- WO 02/013788
- U.S. Patent No. 7,033,381
- WO 99/056827
- WO 05/030328
- U.S. Patent No. 11,179,574
- U.S. Patent Publication No. 2004/0127961
- U.S. Patent Application No. 09/815,348
- U.S. Patent No. 7,517,101
- Office Action dated March 23, 2021, from file history of Application No. 17/009,871
- Office Action dated October 25, 2021, from file history of Application No. 16/791,004
- McGraw-Hill Dictionary of Scientific and Technical Terms (5th Ed.) (1994)
- Cooksey et al., *Reference Data Set and Variability Study for Human Skin Reflectance*, presented at Proceedings of the 29th CIE Session, June 14-22, 2019
- Luxeon 1-Watt Star Technical Data DS23 (2002)
- Military Handbook Reliability Prediction of Electronic Equipment, MIL-HDBK-217F (December 2, 1991)
- Expert Declaration of Irving J. Bigio, Ph.D., for *Inter Partes* Review of U.S. Patent No. 8,216,289
- Petition for *Inter Partes* Review of U.S. Patent No. 8,216,289

APPENDIX B

Eric Bretschneider, Ph.D.

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Flower Mound, TX 75022

Phone: +1 (248) 766-4665
E-mail: eric@led.expert

Skills Summary

- Successful Management and Team building with personnel at levels ranging from Sr. Scientists and Engineers to Technicians/Operators. Maximum Department size >100; Budget >\$25 million/yr.
- Strong New Product Development background; over 100 new SSL products taken from concept to manufacturing, including regulatory, Energy Star certification and DLC certification.
- Excellent communication skills sales and sale support experience as evidenced by development of new 8+ figure accounts for LED die, packages and applications. Proven ability to match customer demands/needs/desires with existing products.
- Comprehensive technical background in the full range of LED production technologies including MOCVD hardware/process, fabrication, LED chip/package test/reliability, optical design, thermal management, color conversion, SSL fixture/lamp design/integration and reliability.
- Direct Design and Development experience of LEDs (structures, die, packages) and SSL fixtures/components using TracePro and SolidWorks.
- Extensive experience in development of industry test and measurement standards.

Employment

CTO; EB Designs & Technology Flower Mound, TX

2014 –

- Design and development of innovative solid-state lighting technology and designs, with a primary focus on optical design, thermal design and production/assembly technologies.
- Manage technology roadmap and draft IP disclosures/patent filings.
- Provide technical support and conduct research/technology development for clients in the field of solid-state lighting. This work additionally includes serving as an expert witness.
- Developed the first method able to predict chromaticity shift of LED products over time. Method is being used as the basis for a new industry standard: IES TM-35-19 "Projecting Long-Term Chromaticity Coordinate Shift of LED Packages, Arrays and Modules."
- Developed the method for interpolating between drive currents for flux maintenance lifetime for LED based products that is being implemented in IES TM-21-19 "Projecting Long Term Lumen, Photon and Radiant Flux Maintenance of LED Light Sources."

CTO; QuarkStar, LLC Las Vegas, NV

2016 – 2023

- Manage technology roadmap and draft IP disclosures/patent filings.
- Developed technology to stabilize color shift over time of LED lighting products.
- Negotiated first IP licensing technology with a major European lighting company. Technology was used to develop a premium downlight product line.
- Managed transition from R&D to manufacturing. Products provided the majority of artificial lighting for a \$500 million expansion at the Museum of Fine Art Houston.
- Developed technology and oversaw product design for L-Prize concept phase. Resulting design was one of four winners at this stage of the L-Prize competition.

Director of Engineering; HeathCo, LLC Bowling Green, KY

2013 – 2014

- Managed Engineering Department Staff (11 domestic, 14 international); Responsibilities included preparation and administration of the department budget (\$3.5 million annual). The department was charged with developed advanced technology/products related to: Solid State Lighting, Sensors, Notifications and Control Products and included regulatory/certifications for UL, FCC, Energy Star and DLC.
- Developed technology, IP and product roadmaps for all three business units (Lighting, Sensors, Notifications). Provided solid state lighting technology support for The Chamberlain Group.
- Additional responsibilities included establishing career development paths and training goals for all members of the department.
- Key accomplishments:

- Led team for product recall issue dating back to 2006. Reduced recall scope (# units) by >80% and financial exposure by >85% through detailed investigation and analysis of production records and analysis of excess and obsolete inventory.
- Completed review for entire product portfolio to comply with new cUL bi-lingual language requirements. Project required warning requirement changes to physical components (tooling), warning labels, documents and packaging on >400 products.

Elec Tech International Zhuhai, Guangdong Province, P.R. China

Chief Engineer ETi Lighting Research Institute

VP Research & Development ETi Solid State Lighting

2011 – 2013

- Managed Engineering and R&D staff for newly formed vertically integrated LED company (107 Engineering, Scientists, Designers); responsibilities included preparation and administration of the department budget (>\$25 million annual)
- Worked directly with President and CEO of the company to develop IP and product roadmaps for all LED based lighting products/projects for markets in the US, Europe, Japan and China.
- Key accomplishments:
 - Developed capability for fast turn functional prototypes (<2 weeks from concept to operating units). This was an improvement over the prior process that required 6+ weeks for a working prototype. Prior to this the company lost ~50% of all opportunities that required functional prototypes.
 - Supported product development and production ramps that enabled the company to increase sales from ~\$10 million to >\$40 million in one year.
 - Developed proprietary linear lamp technology capable of >1000 lumens/ft with a wall plug efficacy >100 lm/W, CRI>80 and L70>50,000 hrs (Ta = 25°C). Technology allows the same base units to be installed in fixtures as a replacement tube or used as individual luminaires with transverse spacing criteria ranging from 1.6 – 2.9.

Lighting Science Group Corporation Satellite Beach, FL

2010 - 2011 VP of Research

- Assembled and managed research and development teams for projects related to solid state lighting.
- Direct responsibility for design/development of customized photometric and radiometric characterization equipment.
- Direct responsibility for modeling and determining product and component lifetimes based on optical, thermal, mechanical and electrical analysis with respect to intended operating environments.
- Served as company representative on industry standards committees related to SSL technology (LM79, LM80, TM21, etc.)
- Key accomplishments:
 - Developed advanced LED models for product development and production control; including advanced color control schemes for multi-color applications. Methods capable of predicting average chromaticity to within a combined $\Delta xy \leq 0.02$; production variation < 2 step MacAdam ellipse.
 - Developed and characterized wavelength conversion materials, methods and technology. Work included development of optics and materials for L-Prize entry.

2008 – 2010 Product Development Manager

- Tasked with developing Solid State Lighting products including: optical, mechanical and thermal design, design and process FMEA, oversight of initial production, development of quality system documents and requirements for internal production and out-sourced components. Projects ranged from individual efforts to team of 10+ employees
- Served as the primary technical resource for all OEM customers.
- Managed group responsible for all product certifications and standards requirements including UL, FCC, CE, Energy Star and DLC as well as IES lighting requirements for outdoor products.
- Responsible for development, calibration and maintenance of photometric equipment in development and production areas.
- Key accomplishments:
 - Completed fast track development and launch of OEM SSL acorn retrofit product (<5 months). Product exceeded all customer requirements including: lumen output, efficacy, thermal resistance and size. Developed second generation product with >100% increase in light output with now cost increase.

- Completed design of Streetlight family (4 products) in 4 month time span. Products achieved >90 lumens/Watt efficacy at thermal stability with projected L₇₀ lifetimes >80,000 hours at T_a=40°C (continuous).
- Development replacement lamp family line (6 primary lamp types, 100+ variations). Product family included the first replacement LED lamps to achieve Energy Star certification. Product variations developed for LSG brand name and 3 OEM customers. Altogether the family accounted for >50% of the Energy Star certified LED lamps as of December 2011.

2004 - 2008 Toyoda Gosei North America Troy, MI

Sales Manager

- Primary responsibility for developing new and managing existing LED die and package customers for the Eastern region of North America. This required extensive communications with existing and potential customers to determine best fit products for their applications/requirements.
- Additional responsibility for search for and identifying new market opportunities for existing or newly developed products.
- Served as the primary technical resource for all customers in North/South America and Europe; provide engineering support for customers developing LED packages and LED lighting products.
- Key accomplishments:
 - Secured two new 8 figure accounts in a new market niche. These customers designated as the only two priority customers for Toyoda Gosei world-wide. Sales ramped from \$0 to >\$100 million/yr in less than 18 months.
 - Secured sole supplier status for LED backlights in Apple - 9.9" (iPad), 15.4", 17" and 22" displays. This was the culmination of an 18 month campaign with the Apple Display group to find the best fit product for their requirement and to train Apple personnel on potential technical barriers/issues with their application.
 - Addressed Microsoft concerns about blue light hazards related to development of a next generation optical mouse. After three months, I was able to conclusively show to Microsoft that it would be impossible for 14mil die products to present a photo-biological hazard under both IEC 62471 and IEC 60825.
 - Awarded business for all passenger lighting on the B787 Dreamliner. This award was made by Diehl which controls all lighting for Boeing, Airbus and Embraer and was achieved within 4 months of first contact with Diehl. At the time of first contact Diehl had no knowledge of Toyoda Gosei and had been working with 4 LED companies for over 12 months on the project.

2003 – 2004 Beeman Lighting Sarasota, FL

Director of Solid-State Lighting Engineering

- Tasked with leading development of solid-state lighting systems and materials with primary focus on chip on board applications and devices. Product lines included RGB landscape lighting and minimal environmental impact fixtures and novel display/artwork fixtures.
- Managed all IP issues (competitor analysis, IP roadmap, patentability analysis).
- Worked with existing and potential customers to ensure new products meet or exceed requirements and expectations.
- Key accomplishment
 - Developed RGB LED based landscape light with minimal environmental impact. This was accomplished by establishing a research project with FAU and included studies that conclusively showed the products had no impact on the behavior of sea turtle hatchlings.

2003 University of South Florida Tampa, FL

Intellectual Property Manager

- Managed IP portfolio of over 100 active patents and applications for University faculty/staff. Key portfolio items included: anti-cancer bioactive compounds, dendrimer synthesis and application technology, and spectral analysis of biological materials (blood analysis, surface and soluble protein analysis).
- Tasked with enhancing University reputation and revenue through negotiation of licensing agreements for IP
- Key accomplishments:
 - Negotiated license agreement for evaluation of new anti-cancer compounds derived from cold water tunicates.

- Assembled team that included 3 corporate and 2 academic partners for the DARPA SUVOS program. This task was completed in one month and the resulting proposal was ranked 2nd overall out of a field of 34 entries and was noted by the reviewers as the only proposal to address each and every portion of the RFP.

1998 – 2003 Uniroyal Optoelectronics Tampa, FL

Director of Intellectual Property, University Relations & Government Contracts (2001 – 2003)

- Concurrent assignment as Sr. Epi Scientist.
- Tasked with establishing IP roadmap and track patent landscape related to MOCVD growth, chip/package design and applications for LED technology.
- Reviewed all production and R&D activities to identify potential IP. This included drafting initial disclosures and working with external counsel for patent filings and responses to office actions. Activities with external counsel further included development of opinions of non-infringement.
- Oversight and management of a \$3.4 million multi-campus research program.
- Monitor and track RFP notices for externally funded research related to the company's core technology development roadmap.
- Key accomplishments:
 - Developed opinions of non-infringement with external counsel for 10 LED patents that had been the subject of numerous infringement suits against Tier 1 LED companies.
 - Assembled team that included 3 corporate and 2 academic partners for the DARPA SUVOS program. This task was completed in one month and the resulting proposal was ranked 2nd overall out of a field of 34 entries and was noted by the reviewers as the only proposal to address each and every portion of the RFP.

Team Leader, Epitaxial Materials & Characterization (1999 – 2001)

- Concurrent assignment as Sr. Epi Scientist.
- Oversaw start up and qualification of Epitaxial Growth & Characterization areas; role included training of Sr. Scientists, Engineers and Technicians for both areas in theory, application, process and maintenance procedures.
- Managed Epitaxial Growth & Characterization areas for production of InGaN and AlInGaP LED wafers. This included preparation and administration of the department budget (~\$25 million annual) as well as setting department performance goals (total good wafers, wafer yield, performance improvements and unit production costs).
- Coordinate inventory levels with purchasing department to minimize value of inventory necessary to support production plan. Additionally, negotiated key raw material specifications and prices.
- Served as Sr. member of Quality Team responsible for ISO9001 certification. Certification was achieved within a 12 month time span.
- Key accomplishments:
 - Completed process qualifications for all MOCVD systems within 3 months of CapEx delivery and established initial production yields 15% higher than the benchmark process transferred to UOE.
 - Managed departmental expansion and quality system efforts that allowed >250% increase in production capacity.
- Managed start up and qualification of Epitaxial Growth & Characterization areas; role included training of Engineers and technicians for both areas in theory, application, process and maintenance procedures.

Sr. Epi Scientist (1999 – 2003)

- Primary responsibility for MOCVD hardware and process modifications necessary to support performance improvements, yield enhancements and cost reductions.
- Served as primary technology liaison with customers and investors. Provided support to customers on package and fixture design and integration.
- Tasked with technical oversight of all photometric/radiometric characterization.
- Responsible for LED chip and package optical/thermal design including wavelength conversion materials.
- Key accomplishments:
 - Resolved gold corrosion issue in Fab area. Also eliminated transparent contact failure mechanism. Combined efforts increased fabrication yield by >30%.
 - Modified hardware and epitaxial growth process to increase throughput of Epitaxial Growth & Characterization areas by 80% (9 hour to 5 hour cycle time), while cutting unit cost by >30%. Also reduced

- surface and interfacial roughness by a factor of >3x while improving thickness uniformity from 4% to <2%, using DOE methods. Additional hardware modification increased throughput by another 20%.
- Developed new test methods to verify performance of LED structures prior to Fabrication. Methods allowed verification of optical power to within 15% and wavelength within 2 nm prior to beginning of fabrication.

Staff Engineer (1998 – 1999)

- Designed/specified Epitaxial Growth & Characterization areas. This responsibility included specification and selection of all CapEx equipment for the Epitaxial Growth and Characterization areas and managing the construction, CapEx equipment installation and start up.
- Additional responsibilities included determining initial product cost and throughput based on installed CapEx tool base.
- Key accomplishments:
 - Implemented and validated new ammonia delivery system that allowed multiple MOCVD systems to draw from the same cylinder and eliminated downtime for cylinder changes. Implemented new exhaust management process for arsine/phosphine waste stream, extending maintenance interval by >300%.
 - Developed zero assumption cost and throughput models for LED facility. Cost estimate for 18 months post-start up proved accurate to within 10% of actual costs.

1996 – 1998 Emcore Corporation Somerset, NJ

Process Engineer

- Responsible for installation, materials demonstration and production process qualification and transition into manufacturing of MOCVD systems in an ISO9000 manufacturing environment (6 systems in 18 months).
- Tasked with identifying cost reduction and throughput/yield enhancements for epitaxial growth processes.
- Member of internal Quality System audit team.
- Key accomplishments:
 - Developed MOCVD Tool Qualification Procedure for benchmarking and qualifying all MOCVD systems installed for internal corporate use as well as at customer locations world-wide.
 - Completed Manufacturing Readiness Review for AlGaAs/Ge solar cell process in ~25% of standard time. Resulted in 3 year, \$15 million supply contract for company.
 - Scaled up and transferred of InSb magneto resistor process to a higher throughput system (single wafer D-180 to five wafer E-300). Increased wafer yield by from 65% to >95%.
 - Developed industry's first comprehensive cost and throughput model for epitaxial growth processes. The model typically allowed cost reductions of 10-20% and throughput increases of >10%.

1990 AT&T Bell Labs

Holmdel, NJ

Visiting Researcher

- Designed and built custom MOCVD/Mass spec system. System allowed tracking of precursor molecules, reaction intermediates and products over 12+ orders of magnitude of concentration.
- Implemented program to evaluate novel precursors for use in growth and doping of III-V and II-VI compound semiconductors. Data used to determine reaction and decomposition mechanisms for metal-organic sources. Successfully identified grow conditions for novel carbon doping source (norbornadiene) for III-V materials.

1989 Shell Oil Norco, LA

Process Engineer

- Developed and implemented new system for determining optimal time to clean heat exchangers on crude oil distillation column based on global economic metrics of unit and detailed process simulations.
- System exceeded system cost savings target of \$50,000/year by ~3 orders of magnitude. Project resulted in corporate-wide savings of >\$100 million/year. Cumulative corporate savings exceed \$1 billion.

Education

Ph.D. in Chemical Engineering

University of Florida 1997

BSE in Chemical Engineering

Tulane University 1989

- Graduate work focused on development of optoelectronic devices, including novel silicon based visible LEDs and sulfide based TFELD structures.

- Developed the world's first crystalline silicon based visible light LED. Utilized DOE methods to identify process conditions to allow first growth of epitaxial silicon on ZnS epi layers.
- Tested and verified efficacy of novel precursors for p-type doping of ZnSe materials in LED structures.
- Responsible for modification, operation and maintenance of MOCVD system for growth of wide bandgap compound semiconductor materials.
- Trained incoming post docs and graduate students in theory, operation and maintenance of MOCVD systems. Group comprised ~20 students and 6 post docs.

References **Available on request**

Curricula Vitae

University of Florida, Department of Chemical Engineering Advisory Board

Member 1998 – 2023

Chair 2007 – 2009, 2017 – 2023

University of Florida, Dean's Advisory Board, College of Engineering

Member 2007 – 2009, 2017 - 2023

Professional Societies:

- SPIE
- OSA
- Materials Research Society
- Illuminating Engineering Society (Member of Science Advisory Panel, Member of Executive Board of Test Procedures Committee, Chair of Projection and Reliability Sub-Committee, Member of Light Sources Committee, Secretary of Color Committee)
- American Society of Horticultural Science (ASHS)
- American Society of Agricultural and Biological Engineers (ASABE)

Testing and Standards Development:

- 30+ years experience testing LED components and fixtures
- 16 years experience developing LED testing standards, technical coordinator ANSI/IES LM-86: Measuring Luminous Flux and Color Maintenance of Remote Phosphor components; technical coordinator: ANSI/IES TM-21: Projecting Long-Term Lumen, Photon, and Radiant Flux Maintenance of LED Light Sources; technical coordinator ANSI/IES TM-28: Projecting Long-Term Luminous Flux Maintenance of LED Lamps and Luminaires ; co-technical coordinator ANSI/IES LM-79: Optical and Electrical Measurements of Solid-State Lighting Products
- Developed the modeling method that enabled prediction of color shift of LED based products that is used in ANSI/IES TM-35: Projecting Long-Term Chromaticity Shift of LED Packages, Arrays, and Modules
- Work Group member on over a dozen ANSI/IES Test standards (Test Procedures Committee, Color Committee, Photobiology Committee, Light Sources Committee)

Conference Chair

LED Measurement and Standards, San Diego, CA October 2-3 (2008).

Patents (Granted)

1 US Patent 7,093,956 "Method of Lighting for Protecting Sea Turtles." D. Miller, E. Bretschneider, issued August 22, 2006.

2 US Patent D650,519 "Pole for a Street Light Luminaire." F. Maxik, D. Henderson, E. Bretschneider, A. Widjaja, K. Bowen, J. Sundin, E. Peiniger, issued December 13, 2011.

3 US Patent 8,157,413 "Light Fixture and Associated LED Board and Monolithic Optic." F. Maxik, Z. Gibler, E. Bretschneider, D. Henderson, A. Widjaja, issued April 17, 2012.

- 4 US Patent D673,323 "Light Fixture." F. Maxik, D. Henderson, E. Bretschneider, A. Widjaja, K. Bowen, J. Sundin, E. Peiniger, issued December 25, 2012.
- 5 US Patent 8,360,607 "Lighting Unit with Heat Dissipating Chimney." E. Bretschneider, Z. Berkowitz, R. Sosnick, L. Pattison, P. Pattison, issued January 29, 2013.
- 6 US Patent 8,408,725 "Remote Wavelength Conversion Device and Associated Methods." F. Maxik, E. Bretschneider, R. Soler, D. Bartine, issued April 2, 2013.
- 7 US Patent D681,874 "Light Fixture." F. Maxik, D. Henderson, E. Bretschneider, A. Widjaja, K. Bowen, J. Sundin, E. Peiniger, issued May 7, 2013.
- 8 US Patent 8,439,515 "Remote Lighting Device and Associated Methods." F. Maxik, R. Soler, D. Bartine, E. Bretschneider, issued May 14, 2013.
- 9 US Patent 8,465,167 "Color Conversion Occlusion and Associated Methods." F. Maxik, E. Bretschneider, R. Soler, D. Bartine, issued June 18, 2013.
- 10 US Patent 8,491,165 "Lighting Unit Having Lighting Strips with Light Emitting Elements and a Remote Luminescent Material." E. Bretschneider, Z. Berkowitz, R. Sosnick, L. Pattison, P. Pattison, issued July 23, 2013.
- 11 US Patent 8,492,995 "Wavelength Sensing Lighting System and Associated Methods." F. Maxik, E. Bretschneider, P. Medelius, D. Bartine, R. Soler, G. Flickinger, issued July 23, 2013.
- 12 US Patent 8,506,118 "Light Fixture and Associated LED Board and Monolithic Optic." F. Maxik, Z. Gibler, E. Bretschneider, D. Henderson, A. Widjaja, issued August 13, 2013.
- 13 US Patent 8,515,289 "Wavelength Sensing Lighting System and Associated Methods for National Security Application." F. Maxik, D. Bartine, P. Medelius, E. Bretschneider, issued August 20, 2013.
- 14 US Patent 8,547,391 "High Efficacy Lighting Signal Converter and Associated Methods." F. Maxik, R. Soler, D. Bartine, R. Zhou, V. Bastien, M. Regan, E. Grove, E. Bretschneider, issued October 1, 2013.
- 15 US Patent 8,616,715 "Remote Light Wavelength Conversion Device and Associated Methods." F. Maxik, E. Bretschneider, P. Medelius, D. Bartine, R. Soler, G. Flickinger, issued December 31, 2013.
- 16 US Patent 8,680,457 "Motion Detection System and Associated Methods Having at Least One LED of a Second Set of LEDs to Vary Its Voltage." F. Maxik, issued March 25, 2014.
- 17 US Patent 8,686,641 "Tunable LED Lamp for Producing Biologically Adjusted Light." F. Maxik, D. Bartine, R. Soler, E. Grove, E. Bretschneider, issued April 1, 2014.
- 18 US Patent 8,684,566 "Light Emitting Unit With Indirect Light Source." E. Bretschneider, Z. Berkowitz, R. Sosnick, L. Pattison, M. Pattison, issued April 1, 2014.
- 19 US Patent 8,702,259 "Color Conversion Occlusion and Associated Methods." F. Maxik, E. Bretschneider, R. Soler, D. Bartine, issued April 22, 2014.
- 20 US Patent 8,818,202 "Wavelength Sensing Lighting System and Associated Methods for National Security Applications." F. Maxik, D. Bartine, P. Medelius, E. Bretschneider, issued August 26, 2014.
- 21 US D715467 "LED Linear Replacement Lamp Design." E. Bretschneider, Z. Berkowitz, R. Sosnick, issued October 14, 2014.

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Patents (Pending)

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