

**EXPERT DECLARATION OF ROBERT E. GROVE, PH.D., FOR INTER PARTES
REVIEW OF U.S. PATENT NO. 11,446,512**

I. INTRODUCTION

1. I, Robert E. Grove, submit this declaration in support of a Petition for *Inter Partes* Review of United States Patent No. 11,446,512 (“the ’512 Patent”), owned by DUSA Pharmaceuticals, Inc., (“DUSA” or “Patent Owner”). I have been retained in this matter by Polsinelli (“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 my 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. 11,446,512 by Thomas Boyajian et al. entitled “Adjustable Illuminator for Photodynamic Therapy and Diagnosis” (“the ’512 Patent”);
- File History for U.S. Patent No. 11,446,512;
- U.S. Patent No. 11,697,028 by Thomas Boyajian et al. entitled “Adjustable Illuminator for Photodynamic Therapy and Diagnosis” (“the ’028 Patent”);
- File History for U.S. Patent No. 11,697,028;
- U.S. Patent No. 6,223,071 by Scott Lundahl et al. entitled “Illuminator For Photodynamic Therapy and Diagnosis Which Produces Substantially Uniform Intensity Visible Light” (“Lundahl”);
- U.S. Patent Publication No. 2005/0075703 by Eric Larsen entitled “Photodynamic Stimulation Device and Methods” (“Larsen”);
- U.S. Patent No. 5,079,262 by James C. Kennedy et al. entitled “Method Of Detection and Treatment Of Malignant and Non-Malignant Lesions Utilizing 5-Aminolevulinic Acid” (“Kennedy”);
- U.S. Patent Publication No. 2010/0118522 by Dirk Hente entitled “Light Emitting Device Using Oled Panels In Folded or Deployed Configuration” (“Hente”);

- U.S. Patent No. 4,823,858 by Simon G. A. Perutz entitled “Portable display panel and hinge system” (“Perutz”);
- Levulan® Label, 2010; and
- Declaration of Michael Ehrenreich, MD.

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 Rubin Anders Scientific, Inc. (“RAS”), and that RAS is being compensated at a rate of \$1,000 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 lasers and LEDs for photodynamic therapy (PDT) and other medical applications, which may be used individually or in multi-LED panels. 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 been involved with PDT since its inception over forty years ago. This professional relationship began with conversations and collaboration with Thomas J. Dougherty Ph.D., following the publication of his pivotal work on PDT treatment of cancer in 1978. Dr. Dougherty is considered the founder of modern PDT. In 1981, I started and led a medical laser company and was directly responsible for the commercial sale of the first gold vapor laser for PDT to Leon Goldman, MD. Dr. Goldman is now universally acknowledged as the father of laser medicine. I have remained actively involved in the design, development, clinical research, and commercialization of lasers and LED medical devices, primarily for skin conditions. My expertise focuses on LED and laser usage to diagnose and treat dermatologic conditions for both medical and aesthetic applications. I have a B.S. in Engineering Physics from Cornell University, an M.S. in Aeronautics and Astronautics from MIT, and a Ph.D. in Instrumentation from MIT, specifically in the field of laser applications. I was the founding CEO of a company in 2003 that developed a ~650-nm LED panel for wrinkle reduction and a 412-nm handheld LED device for acne treatment. I have also served as an advisor to the leading company in photobiomodulation for red-IR vaginal rejuvenation and other feminine wellness issues. I have extensive industry experience as set forth in my CV attached as Appendix B to this report, and I am a named inventor on over 30 patents and

publications, including a phototherapy device patent relating to a thermal control apparatus and method.

8. I have over forty years of experience in the medical laser industry, including a comprehensive background on a full range of laser technologies and LEDs, including short-pulse lasers, lower-cost diode lasers, over-the-counter laser devices, consumer laser devices for hair removal and LED devices for acne, as well as laser devices for burn-depth diagnosis.

9. I founded a start-up Intellectual Light, Inc. and served as President and CEO from 2012-2017 to develop and patent a novel low-cost laser diode source for over-the-counter devices for medical and other applications, with an emphasis on the patent portfolio. I also served as Executive Chairman of ON Light Sciences, Inc. from 2013-2016 to direct the development of transparent gel patches for accelerated tattoo removal with short-pulse lasers. Prior to these positions, I founded a start-up Once Again Me, Inc. and served as President and CEO in 2011 to develop an innovative over-the-counter laser beauty device and associated patent applications. I also founded a start-up TRIA Beauty Inc. and served as CEO from 2003-2008 and CTO from 2009-2010 to develop, manufacture, and market consumer laser devices for permanent hair removal, acne, and facial wrinkle treatment at home. Additionally, I co-founded a start-up Star Medical Technologies, Inc. and served as President and CEO from 1993-1999 to develop, manufacture, and market the first successful office-based laser hair removal system (*LightSheerTM*) that remains the gold standard today. I negotiated the acquisition of Star Medical Technologies, Inc. in 1999 by Coherent, Inc. I served as President of Coherent Star from 1999-2001 and expanded the *LightSheerTM* business as part of Coherent Medical.

10. I also co-founded one of the first laser med-spas in the US, DermaCare, Inc., and served as President and CEO from 1987-1990 to direct operations of two clinics in southern

California with over 400 patients a month. Additionally, I served as President of the Laser Products Division of Cooper LaserSonics, Inc. from 1984-1987 to integrate copper and gold lasers into a newly formed division, and identify research clinicians to spur product development of laser treatment of port-wine hemangiomas. As noted earlier, I also co-founded the world's first commercial copper vapor laser company, Plasma Kinetics, Inc., and served as President and CEO from 1981-1984 to raise funding, establish manufacturing operations, and lead global marketing. Additionally, I served as Project Leader of Lawrence Livermore National Laboratory from 1976-1981 to direct Copper Laser Development for the Atomic Vapor Laser Isotope Separation Program, where I managed Ph.D. scientists and engineers developing the world's largest laser pump source for pulsed dye laser uranium enrichment.

11. I also have extensive experience as a global consultant to diverse clients including private equity, law firms, and medical device companies on a full range of light technologies, including high-power diode laser manufacturing, UVB-LED home-use devices, a home-use ultrasound device for enhanced application of topicals, and lasers.

12. Most recently, I was a business and technical consultant for QPC, Inc. in 2024, a high-power diode laser manufacturer exploring opportunities for 1726-nm acne treatment systems. Prior to this experience, I was a technical consultant for Zerigo Health, Inc. from 2021-2023, an innovative UVB-LED home-use device company specializing in devices for the treatment of psoriasis, eczema, and vitiligo. I also was a consultant for Arbonne International LLC from 2014-2018 to conceive, design, and develop, with an outside firm, a novel home-use ultrasound device for enhanced penetration of topical skincare products. Additionally, I was a consultant for Apax Partners, LLP in 2017, a private equity firm evaluating Syneron-Candela prior to its acquisition by Apax Partners. I was also a consultant for JLE Associates from 1990-1993 to work with two other

laser experts in formulating a plan for a new laser business to be founded and owned by Hoya Corporation of Japan.

13. I also have experience on independent corporate boards. I joined the Compensation Committee and Audit Committee for IRIDEX Corporation, an industry-leading ophthalmic laser manufacturer, in 2018 and presently serve as Independent Director. I also served as Independent Director for Candesant Corporation from March 2019 to March 2023, a venture-funded biotechnology company developing a safe, in-office, non-drug solution to excessive sweating. Additionally, I served as Independent Director for Ellman International, Inc. from December 2013 to September 2014, a manufacturer of advanced radio-frequency products utilized around the world for precision surgical and aesthetic procedures.

14. I also have experience on corporate advisor/advisory boards. I am currently an advisor to the CEO of Joylux, Inc., a position I have held since 2017. The company develops and markets through physicians the world's first home-use dual-wavelength LED apparatus for women's intimate wellness. The device incorporates photobiomodulation and thermal energy and has been shown to be safe and effective in clinical trials. I also have served on various committees and in various positions for the American Society for Laser Medicine and Surgery, Inc. (ASLMS), including being appointed to the Membership Committee (2020 and 2021) and the Nominating Committee by the ASLMS president (2018), elected to the position of Industry Research and Development Representative for two terms (1995-1998 and 2008-2011), and appointed Exhibits Chairperson (1994-1998). I have also received two Presidential Citations from ASLMS, in 2019 and again in 2024, for my contributions and leadership.

15. 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.

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

17. 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.

18. 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.

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

III. PERSON OF ORDINARY SKILL IN THE ART

20. 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.

21. I understand that the '512 Patent, filed on February 14, 2020, 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 '512 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).

22. In addition to my testimony as an expert, I am prepared to testify as someone who actually practiced in the field from 1976 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.

23. 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.

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

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

IV. LEGAL UNDERSTANDING

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

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

27. 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.

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

29. 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.

30. 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.

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

32. 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.

33. 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.

34. 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.

35. 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.

36. 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.

37. 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.

38. 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.

39. I understand that a claim may recite a range or otherwise to cover several compositions. Additionally, I understand that when a prior art reference recites a range overlapping or touching the claimed range, the claim is anticipated if the range of the prior art reference discloses the claimed range with “sufficient specificity”. Further, I understand that what constitutes “sufficient specificity” is fact dependent and may depend on, for example, the size of the range(s) in question. Additionally, I understand that when a prior art reference teaches a value or range that is close to, but does not overlap or touch, the claimed range, the claim is not anticipated but may still be found to be obvious. I further understand that, when a range of values taught by the prior art overlaps or lies inside a claimed range, the claimed range is considered obvious so long as the claimed range is not shown to provide surprising or unexpected results, and that the prior art literature did not “teach away” from the specifically claimed range.

40. I understand that Lundahl incorporates Kennedy by reference. Thus, I understand that the text presented in Kennedy is treated as much a part of Lundahl as filed as if the text was repeated in Lundahl, and should be treated as part of the text of Lundahl.

41. I have been informed there is a requirement that patent claims must particularly point out and distinctly claim the subject matter which the inventors regard as the invention and that this is referred to as the “definiteness” requirement.

42. I have been informed that, as part of the definiteness requirement, a claim must be precise enough to provide clear notice of what is claimed, and to inform the public of what is still available to them.

43. I have been informed that claims must also provide a person of ordinary skill in the art with objective boundaries, and when a claim term might mean several different things and no informed and confident choice is among the contending definitions, that term fails to comply with the definiteness requirement.

44. I have been informed that, as part of the definiteness requirement, a claim must not contradict itself since a person of ordinary skill in the art will not know which portion of the claim must be met to be considered infringing.

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

45. *Phototherapy* is the use of light - either ultraviolet, visible or infrared – for the treatment of disease. *Photodynamic Therapy* (PDT) is a subgroup of phototherapy that utilizes light to activate a chemical on or within the body to achieve a beneficial therapeutic effect. In the text below, phototherapy is briefly discussed, followed by a more detailed explanation of PDT.

46. At least two-thousand years ago, sunlight was known to have beneficial health effects. Today, red and infrared light at low levels are employed to treat cold sores, reduce acne breakouts, and stimulate muscle recovery; while ultraviolet light is routinely used to treat skin disorders such as psoriasis and eczema, through a process called photobiomodulation. The prime targets of medicine, however, are pre-cancers and cancers of all types; and the cure rather than the mitigation of disease. To achieve these goals, the more potent *photodynamic* therapy is utilized.

47. Photodynamic therapy is based on the local or systemic application of a photosensitive compound – a photosensitizer – which preferentially accumulates in pre-cancerous and cancerous tissues. The photosensitizer molecules absorb light of the appropriate wavelength, initiating an activation process that leads to the destruction of the undesired cells. The photocytotoxic reactions therefore occur only within the pathological tissues, in the area of photosensitizer distribution and light illumination; thereby selectively destroying the pre-cancerous or cancerous tissue.¹

48. To perform PDT, a light source with sufficient irradiance within a narrow wavelength band is typically required. The invention of the laser in 1960 provided an apparently ideal source and sparked renewed interest in PDT, shifting the challenge to identifying an

¹ Agostinis, P et al. Photodynamic Therapy of Cancer: An Update. CA Cancer J Clin.2011; 61(4): 250-281.

appropriate photosensitizer; that is, one which is easily administered either intravenously or topically, has high selectivity for accumulation in target tumors or lesions, becomes sufficiently toxic to host cells when illuminated, and clears the body soon after treatment. Thomas Dougherty successfully conducted the first controlled PDT clinical trials in 1978. The photosensitizer he developed, called Photofrin, was approved by the US Food and Drug Administration in 1994 and is still in use today to treat esophageal cancer, lung cancer, and many other forms.

49. While the lasers of the 1990's had the requisite power and in some cases even wavelength tunability to precisely match photosensitizer absorption bands, the cost and size of these light sources impeded progress in PDT. Fortunately, concurrent development of solid-state light-emitting diodes (LEDs) and laser diodes (or diode lasers) quite effectively removed this limitation. With low cost, long lifetimes and adequate power, LEDs became the obvious replacement for previous illumination sources, including fluorescent tubes. For PDT, LEDs with output wavelengths in the blue (~400-450 nm) and/or in the red (~600-690 nm) were rapidly being designed in to relatively inexpensive, compact illumination sources for PDT.

50. In the years since the introduction of Photofrin, newer topical photosensitizers such as 5-aminolevulinic acid (ALA) have been utilized successfully for both the effective treatment of actinic keratosis (AK) and off-label treatment of severe acne.² For either application, the response of the AK or acne lesion depends on the uptake of the photosensitizer as well as the irradiance (in W/cm² or mW/cm², the rate at which energy is delivered per unit area of skin) and the wavelength of the light source. Assuming that the drug uptake by individual lesions is similar, uniform efficacy

² In the U.S., 5-ALA is approved and marketed as several different products, including Levulan® Kerastick® (DUSA Pharmaceuticals, Wilmington, MA) and Ameluz® gel (Biofrontera Bioscience GmbH, Woburn, MA) for the treatment of actinic keratosis.

then depends on the uniformity of the irradiance on the skin surface and the wavelength of the light source.

51. The design of the light source plays an important role in achieving an irradiance that is as uniform as possible. To visualize this, imagine a square-shaped lamp pointed directly at a white wall, at a close distance; and that further, the output surface of the lamp emits light with the same color (wavelength) and intensity across the entire surface of the lamp. Despite this consistent light output, the wall surface directly in front of the lamp (corresponding with the middle of the square) will naturally be “brighter” than the rest of the wall (corresponding with the edges of the square); that is, it will receive a greater irradiance. To at least partially compensate for this non-uniform illumination, the lamp can be designed to be “brighter” (i.e., to emit light at a greater intensity) near its four edges than from its central region. In this case the region of the wall with more uniform illumination would be significantly increased.

52. If the lamp is made up of, for example, horizontal fluorescent tubes, the spacing between tubes could be reduced near the top and bottom of the lamp; or extra tubes added. If the lamp consists of a rectangular panel or panels of many LEDs, the number or density of LEDs could be increased near the upper and lower edges of the panel(s).

53. For illumination of the face as an example, a U-shaped collection of fluorescent tubes (as in the DUSA Blu-U, described in Lundahl) or an array of hinged, rectangular panels with numerous LEDs (described, e.g., by Larsen²) can be utilized. Each approach requires appropriate placement of the individual light sources, either tubes or LEDs, to minimize the variation in irradiance on the face. For the Blu-U, this is accomplished by adding additional U-shaped fluorescent tubes near the upper and lower edges of the apparatus, since the light source length in

² US Patent Application Publication No. 2005/0075703 A1.

this dimension is substantially less than the light source length completely around the U-shaped apparatus. Uniformity is more easily achieved for an apparatus consisting of LED-populated panels, by simply placing more LEDs along the upper and lower edges of a horizontal array of panels, achieving adequate uniformity.

VI. THE '512 PATENT

A. Priority Dates

54. I note that the '512 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. '512 Patent, 1:8-13.

55. 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 '512 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.

56. I have reviewed the '512 Patent.

57. I understand that Sun has alleged that Biofrontera has infringed the '512 Patent.

58. I understand that Biofrontera is submitting my declaration in support of a Petition for Inter Partes Review that the '512 Patent is invalid.

B. The '512 Patent's Specification

59. The '512 Patent uses the acronyms "PDT" and "PD" for the terms "photodynamic therapy" and "photodynamic diagnosis" respectively. The '512 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." '512 Patent, 1:34-43.

60. The '512 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." '512 Patent, 1:48-49.

61. The '512 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." '512 Patent, 3:12-19.

62. The '512 Patent also teaches that light exposure will decrease with increased distance from the light source (i.e., panel). "In addition, 'fall off' increases as the distance between the light source and the point on the surface increases." '512 Patent, 6:6-8.

63. In order to compensate for intensity fall off and improve uniformity, the '512 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." '512 Patent, 6:16-21.

64. Specifically, the '512 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.” ’512 Patent, 6:30-38.

65. Exemplary embodiments of the ’512 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.” ’512 Patent, 8:54-63.

66. The ’512 Patent includes 20 claims. I have been informed by counsel that Claims 1, 3, 5, 8, 17, 18, and 20 are the subject of the *Inter Partes* Review petition.

C. The ’512 Patent’s Prosecution History

67. The ’512 Patent was filed on February 14, 2020, as application number 16/791,004. The ’512 patent is a divisional application of Application No. 15/292,731, filed on October 13, 2016, now granted as U.S. Patent No. 10,589,122, which claims the benefit of priority to U.S. Provisional Application No. 62/241,902, filed October 15, 2015.

68. I summarize here the actions most relevant to the grounds of unpatentability set forth in the present Petition. In a non-final office action mailed on October 25, 2021, the claims were rejected as followed: (i) claims 1-20 under §112 as being indefinite for failing to particularly point out and distinctly claim the subject matter regarded as the invention; (ii) claims 1, 2, 6, 7, 13, 18, and 19 under §102 as being anticipated by U.S. Application Publication No. 2007/0283655 (Tobin); (iii) claims 1, 2, 5-7, and 18 under §102 as being anticipated by U.S. Application Publication No. 2005/0075703 (Larsen); (iv) claims 3-5 under §103 as being unpatentable over

Tobin in view of U.S. Application Publication No. 2003/0216795 (Harth); (v) claims 11, 12, and 14-17 under §103 as being unpatentable over Tobin in view of U.S. Application Publication No. 2013/0066404 (Tapper); (vi) claims 3 and 4 under §103 as being unpatentable over Larsen in view of Harth; (vii) claims 11, 12, and 14-17 under §103 as being unpatentable over Larsen in view of Tapper; and (viii) claim 20 under §103 as being unpatentable over Larsen. Additionally, the disclosure was objected to for informalities.

69. A response was filed February 25, 2022, in which claims 1, 3, 6, and 18-20 were amended, claims 7-10 were cancelled, and claims 21-24 were newly added. Additionally, paragraph [0001] of the specification was revised. The claims were amended as described below.

70. Independent claim 1, directed to a system for photodynamically diagnosing or treating a patient, was amended to include: the nested hinges connecting the at least five panels of the illuminator being “on inner side surfaces of adjacent panels”; the light sources being disposed on “surfaces of the at least five panels”; and “wherein each of the at least five panels has two first edges and two second edges shorter than the two first edges, and the light sources are arranged such that a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges”.

71. Independent claim 6, directed to a method of photodynamically diagnosing or treating a patient, was amended to include the above listed recitations of amended claim 1. Additionally, claim 6 was amended to include a method step of “administering 5-aminolevulinic acid (ALA) to the patient” as the first step of the claimed method.

72. The response asserts that the added limitation of “wherein each of the at least five panels has two first edges and two second edges shorter than the two first edges, and the light sources are arranged such that a higher intensity of light is emitted proximate the second edges

compared to the intensity of light emitted not proximate the second edges” overcomes the §102 rejections over Tobin and Larsen. Specifically, the response indicates that neither Tobin or Larsen discloses or teaches an illuminator with light sources arranged so as to provide a higher intensity of light emitted proximate second edges of the panels, which are shorter than first edges of the panels, as compared to the intensity of light emitted not proximate the second edges. Additionally, the response asserts that claims 1 and 6 as amended, and the claims depending therefrom, overcome the §103 rejections over Tobin and Larsen in view of Harth and Tapper.

73. A notice of allowability was mailed on May 16, 2022, allowing claims 1-6 and 11-24. In the reasons for allowance, the examiner indicated that the art of record neither anticipates nor renders obvious “nested hinges on inner side surfaces of adjacent panels” and “wherein each of the at least five panels has two first edges and two second edges shorter than the two first edges, and the light sources are arranged such that a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges” in combination with the rest of the claimed limitations set forth in the independent claim.

VII. CLAIM CONSTRUCTION

74. 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 '512 Patent.

75. I have applied this standard in forming my opinions offered below. In particular, it is my opinion that the term “recess” recited in claims 17 and 18 of the '512 Patent is properly construed to have its plain and ordinary meaning of “an indentation in a surface.” This understanding of the plain and ordinary meaning of the term is consistent with known dictionary definitions: (i) the American Heritage Dictionary (2006 and 2022) definition of “an indentation or small hollow”; (ii) the Merriam-Webster Collegiate Dictionary (2005) and the Merriam-Webster Dictionary (2024) definition of “indentation, cleft”; (iii) the Oxford Dictionary of Construction, Surveying, and Civil Engineering (2012) definition of “an indent in a wall or surface”; and (iv) the Oxford Dictionary (2024) definition of “a space set back in a wall; a niche or alcove”.

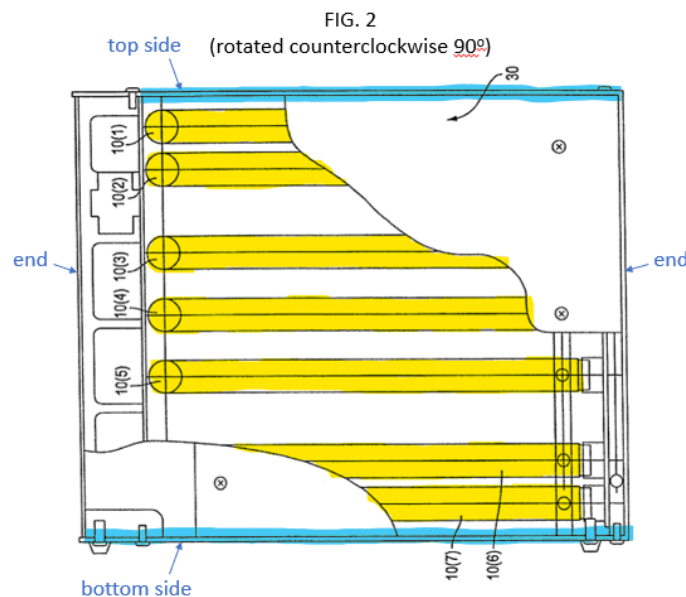
VIII. SUMMARY OF REFERENCES RELIED ON FOR UNPATENTABILITY

A. Lundahl (Ex. 1014)

76. U.S. Patent No. 6,223,071 (hereinafter referred to as “Lundahl”) was filed on May 1, 1998. I understand that Lundahl qualifies as prior art because it was published before the earliest effective filing date of the ’512 Patent.

77. Lundahl teaches an apparatus and method for photodynamic therapy or photodynamic diagnosis using an illuminator comprising a plurality of light sources. Lundahl Abstract. “The present invention is directed to photodynamic therapy using an illuminator that provides a uniform distribution of visible light.” Lundahl, 1:9-11.

78. To achieve this uniformity, Lundahl utilizes the light distribution pattern illustrated in Figure 2 (which has been highlighted, labeled, and rotated 90° to better illustrate):



Lundahl, Fig. 2.

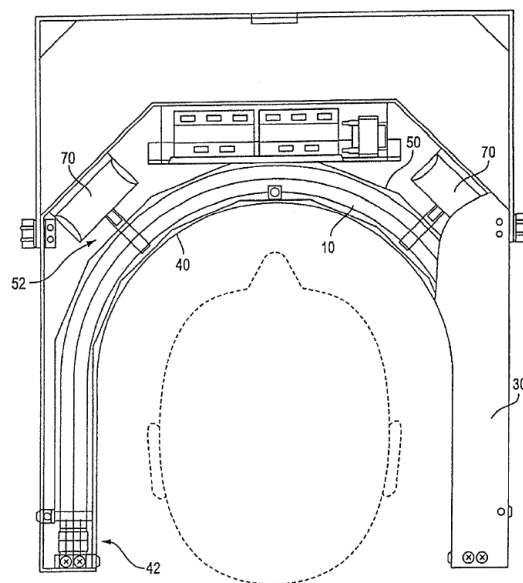
79. Lundahl explains that “[t]o avoid uniformity problems, one embodiment, of the present invention utilizes a plurality of U-shaped tubes 10(1)-10(7) [An] advantage of the arrangement is that uniformity can also be adjusted by varying the lateral spacing of the tubes

(relative vertical spacing as shown in Figure 2). This is important since it is necessary to compensate for the fact that the output from a flat plane emitting light source drops near the edges. Varying the lateral spacing of the tubes creates the same effect as folding the edges of a larger illuminator in on itself, thus emulating an infinite plane emitter with a compact unit.” Lundahl, 6:16-30.

80. Lundahl states that the spacing of lights and greater density of lighting near the top and bottom of the panel provide for uniform illumination, stating “[t]he number of tubes used and the spacing between them were chosen to achieve desired uniformity and power output specifications... The present invention provides a highly uniform output irradiance without the use of an additional diffusing element.” Lundahl, 6:43-57.

81. Lundahl teaches the position of the PDT device to allow treatment within approximately four inches of the treatment surface. Lundahl states “the present invention uses a U-shaped emitting surface that more closely follows the contours of the human face and scalp, and minimizes lamp to target distance variations which in turn minimizes irradiance variations at the target.” Lundahl, 4:34-38. Lundahl illustrates this positioning on the PDT device in Figure 1, showing the positioning of the patient’s head and nose within the device.

FIG. 1



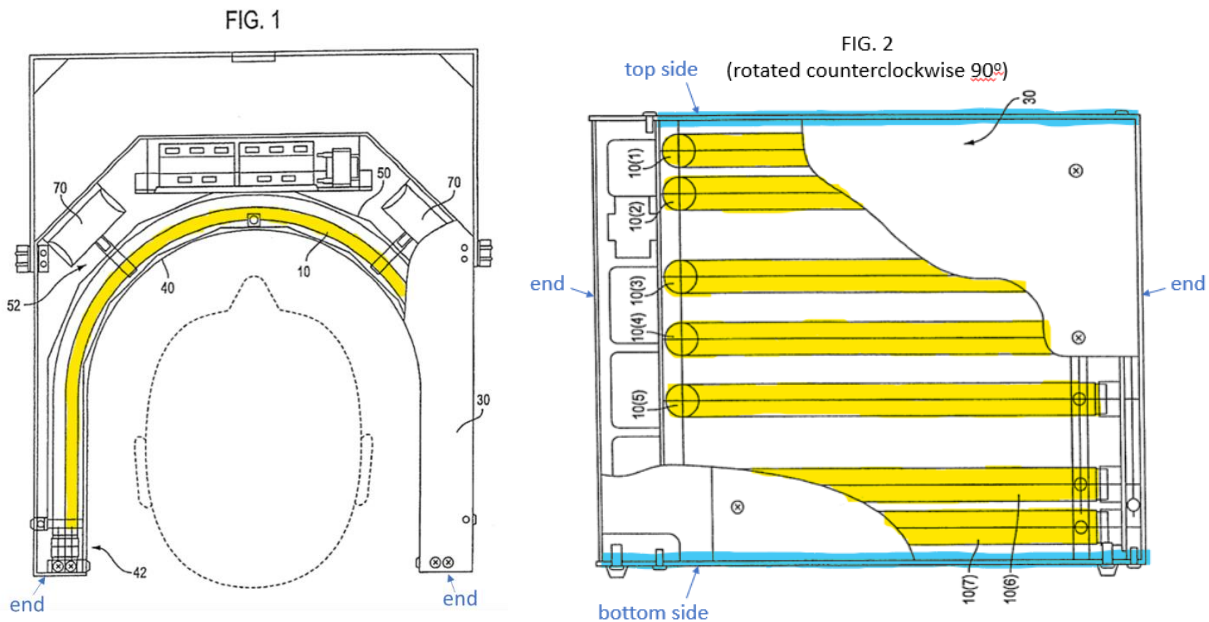
Lundahl, Fig. 1.

82. Lundahl explains that the U-shape of the PDT device helps to maintain the proper distance between the light-emitting panel and the patient head, stating “[t]he U-shape minimizes the variations in distance between the emitter and the target, providing a uniform visible light distribution to the face or scalp of the patient; the tube dimensions were chosen based on the average dimensions of the adult human head.” Lundahl, 6:31-35.

83. Lundahl further teaches that the light-emitting surface of the PDT device is positioned at distances of 2” and 4” from the treatment surface (i.e., the skin on the patient’s head), stating that “according to a preferred embodiment of the present invention, the measured output over the active emitting area is within 70% of the measured maximum when measured with a cosine response detector at distances of 4” and 2””. Lundahl, 15:22-26.

84. Lundahl teaches that “[t]he number of tubes used and the spacing between them were chosen to achieve desired uniformity and power output specifications.” Lundahl, 6:43-45. As shown in the annotated Figures 1 and 2 of Lundahl below (with the light tubes highlighted yellow,

the top and bottom sides highlighted blue, and Figure 2 rotated to show the apparatus as oriented during operation), “[o]ptimum output distribution has been found to occur when seven tubes 10(1)-10(7) are placed in the chassis in a symmetric pattern with respect to opposite edges of the unit”. Lundahl, 6:45-48.



85. Lundahl includes the “following approximate lateral spacing: 7 cm between the center tube 10(4) and each of the two tubes 10(3),10(5) adjacent to the center tube 10(4); 5 cm between the tubes 10(3),10(2) and 10(5),10(6), i.e., the next pairs of tubes out from the center; and 3.5 cm between tubes 10(2),10(1) and 10(6),10(7), i.e., the outermost pairs of tubes at the sides of the unit.” Lundahl, 6:48-54. Lundahl also states that “[t]he outermost tubes 10(1),10(7) are approximately 2.5 cm from the edges of the housing” and “[t]he present invention provides a highly uniform output irradiance without the use of an additional diffusing element.” Lundahl, 6:54-57. A POSITA would have understood that the tubes of Lundahl are spaced to emit a higher intensity of light proximate the top and bottom sides compared to the intensity of light emitted not proximate the top and bottom sides.

86. Lundahl teaches that “[s]ince total light Dose (J/cm^2) = Irradiance (W/cm^2) $\times$ Time (sec), the only additional parameter that needs to be controlled for delivery of the correct treatment light dose is exposure time”, which is “accomplished in a preferred embodiment of the present invention by the timer which controls electrical power to the ballasts and which can be set by the physician.” Lundahl, 15:55-61.

87. Additionally, in its discussion of the background on PDT treatment, Lundahl states “[g]eneral background information on PDT using 5-aminolevulinic acid (“ALA”) as the precursor of a photoactivatable agent can be found in U.S. Pat. No. 5,079,262, entitled “Method of Detection and Treatment of Malignant and Non-Malignant Lesions Utilizing 5-Aminolevulinic Acid,” issued to James C. Kennedy et al. on Jan. 7, 1992, and U.S. Pat. No. 5,211,938, entitled “Method of Detection of Malignant and Non-Malignant Lesions by Photochemotherapy of Protoporphyrin IX Precursors,” issued to James C. Kennedy et al. on May 18, 1993. The contents of these patents are incorporated herein by reference.” Lundahl expressly incorporates all teachings of U.S. Patent No. 5,079,262 to Kennedy et al. (“Kennedy”).

88. Lundahl teaches that “[a]ccording to one preferred embodiment of the present invention, blue light having wavelengths exceeding 400 nm (nanometers) is particularly advantageous for certain diagnostic purposes and treatments, especially when ALA is the photoactivatable agent used for PD and PDT of actinic keratosis” and that “visible light in other ranges of the spectrum, particularly in the green and red ranges between 400 and 700 nm, may also be used.” Lundahl, 2:18-26.

89. Lundahl teaches that “[a]ccording to one preferred embodiment of the present invention, blue light having wavelengths exceeding 400 nm (nanometers) is particularly advantageous for certain diagnostic purposes and treatments, especially when ALA is the

photoactivatable agent used for PD and PDT of actinic keratosis” and that “visible light in other ranges of the spectrum, particularly in the green and red ranges between 400 and 700 nm, may also be used.” Lundahl, 2:18-26. Lundahl describes applying ALA to a patient for the treatment of actinic keratosis, stating “One example of a treatment method for precancerous lesions, such as actinic keratosis, by PDT utilizing an illuminator described above in conjunction with 5-aminolevulinic acid (ALA) will now be described. Essentially anhydrous ALA is admixed with a liquid diluent just prior to its use. The ALA admixture is topically applied to the lesions using a point applicator to control dispersion of the ALA admixture.” Lundahl, 15:30-37.

90. Lundahl teaches that “[a]ccording to a preferred embodiment of the present invention, an electronic control system 110 consists of six functional blocks. A microcontroller 200 is the central processing unit; it contains firmware which reads the system sensors, determines the system status, controls the ballast voltage (and tube output), and provides user information by way of a system status LED 112 (the firmware is described in detail below). To achieve output irradiance in the specified range, the microcontroller 200 monitors the tube output via a visible light sensor 120 which is located behind the tube reflector 50.” Lundahl, 11:19-29. Additionally, Lundahl teaches a cooling system incorporating fans. Lundahl states “a cooling system is provided to ensure proper bulb operation. According to an embodiment of the present invention, the cooling system comprises vents in the polycarbonate shield 40, the reflector 50 and the housing 30, as well as fans 70 to displace cooling air.” Lundahl, 9:14-18.

91. Lundahl is from the same field of endeavor as the ’512 Patent, which also describes illuminators for PDT. ’512 Patent, 1:24-2:4. Lundahl is also directed to the same problem as the ’512 Patent, namely, a PDT device for the treatment of actinic keratosis of the face and scalp, as

well as other parts of the body (arms, legs, etc.). Lundahl, 1:12-17. Therefore, Lundahl is analogous art to the '512 Patent.

B. Larsen (Ex. 1004)

92. 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 '512 Patent.

93. 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].

94. “Treatments have included the application of substances such as photoflim, 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].

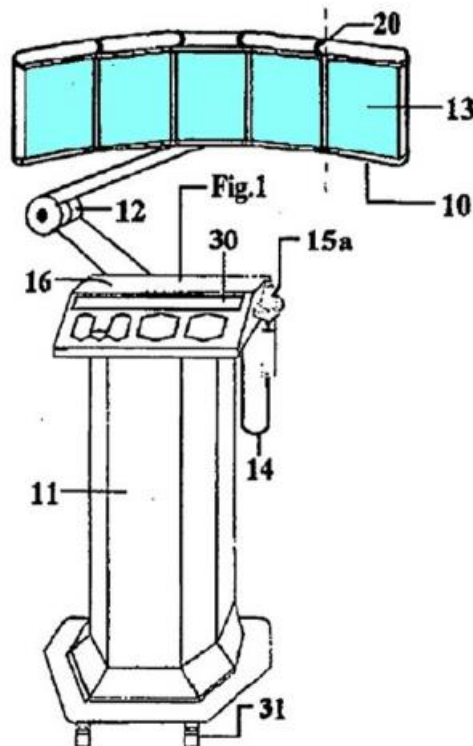
95. Larsen teaches the desirability and use of phototherapy equipment that can emit light over a large range of wavelengths from 300 nm to 2000 nm. “A device able to deliver an intensive light radiation with selective multiple wavelengths within the wavelength area of 300-2000 nm and electromagnetic 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.

96. 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].

97. 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 Figure 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].

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



99. 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 dose 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, [0008].

100. Larsen’s sensors are further able to compensate for patient-to-patient variations and ensure the desired 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 variations 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].

101. Larsen is from the same field of endeavor as the '512 Patent, which also describes illuminators for PDT. '512 Patent, 1:24-2:4. Larsen is also directed to the same problem as the '512 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 '512 Patent.

C. Kennedy (Ex. 1017)

102. U.S. Patent No. 5,079,262 (hereinafter referred to as “Kennedy”) was filed on July 28, 1989. I understand that Kennedy qualifies as prior art because it was published before the earliest effective filing date of the '512 Patent.

103. Lundahl expressly incorporates all teachings of Kennedy. Lundahl, 1:38-48.

104. Kennedy teaches that red light was preferred for PDT, as it penetrates more deeply into the skin, as compared to blue light, and PpIX (the compound produced by topical application of ALA) strongly absorbs red light. Kennedy states “[a] method of detecting and treating malignant and non-malignant tissue abnormalities and lesions of the skin” in which “5-aminolevulinic acid is administered to the patient.” Kennedy, Abstract. Kennedy states that “[i]n preferred aspects of

this invention the preferred precursor of protoporphyrin IX is 5-amino-4-oxo-pentanoic acid, otherwise known as 5-aminolevulinic acid, and a preferred wavelength of the photoactivating light is in the range 350-640 nm, more preferably a red light of about 610-630 nm.” Kennedy, 4:3-8. Kennedy also states that “[t]he wavelength of the photoactivating light is of some importance, as it has been shown that between 1 and 10 percent of incident red light (600-700 nm) can pass through a slab of human tissue 1 cm thick, whereas only 0.001 percent or less of blue light (about 400 nm) can pass through the same thickness of human tissue. The photosensitizer will, therefore, be more successful if it strongly absorbs red light. PpIX does strongly absorb red light.” Kennedy, 4:60-68.

D. Hente (Ex. 1026)

105. U.S. Patent Publication No. 2010/0118522 (hereinafter referred to as “Hente”) was filed on October 26, 2009, as a §371(c) national stage filing of PCT/IB08/51629 filed on April 28, 2009. I understand that Hente qualifies as prior art because it was published before the earliest effective filing date of the ’512 Patent.

106. Hente is directed to light emitting devices comprising organic light emitting diodes (i.e., organic LEDs or OLEDs) that allow for adjustable and foldable orientations. Hente, Title, Abstract. Hente explains that a number of illumination devices were known in the art, but that such light emitting devices were generally inefficient (in the case of gas discharged lamps) and did not have the desired flexibility to adjust for different sizes of areas to be illuminated. Hente, [0002]-[0004].

107. Hente teaches light emitting devices that have the flexibility to “illuminate large and point-like limited areas.” Hente, [0005]. Specifically, Hente discloses lighting devices with at least one first section and at least one second section. Hente, Abstract. Hente explains that the light emitting device can be expanded to provide a flat illumination surface, stating “In Figure

2 the light emitting device 10 is shown in an expanded position 100...In the expanded position 100 the first section 20 and the second section 30 are arranged in such a way, that they form a longish stretched sheet like light emitting device 10. The artificial light 45 is primarily emitted through the bottom sides 21, 31 of each section 20, 30. In this position 100 the light emitting device 10 can be used to illuminate large areas....” Hente [0036]. Figure 2 is illustrated below.

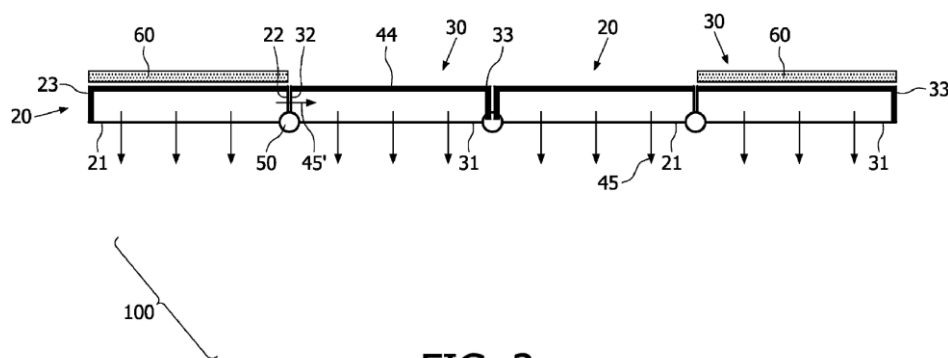
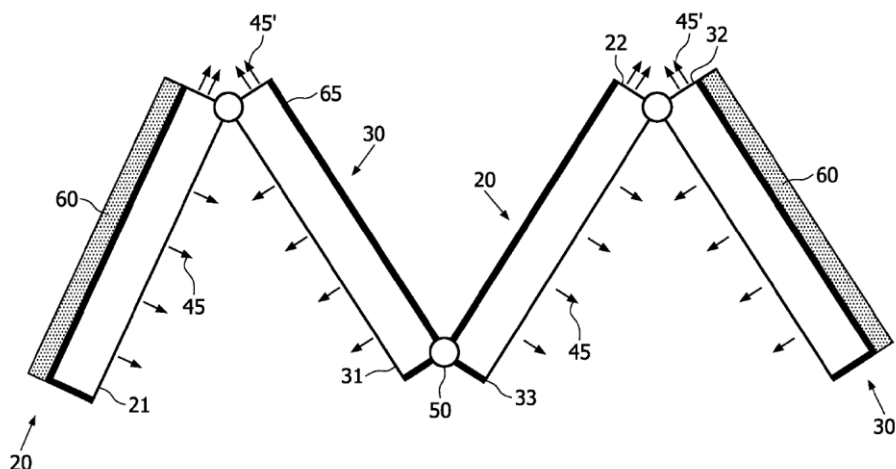


FIG. 2

Hente, Fig. 2.

108. Hente also teaches that the light emitting device may be adjusted or folded into a smaller, “compact” position, stating “[t]o enable the light emitting device to be converted from the expanded position 100 into the compact position 110 the sections 20, 30 are connected through a connection mean 50. As shown in Figure 3 the connection mean may be a hinges, being located at the outer ends of each section 20, 30.” Hente, [0037]. Figure 3 is illustrated below.



Hente, Fig. 3.

109. Hente is from the same field of endeavor as the '512 Patent, which also describes illuminators. '512 Patent, 1:24-2:4. A POSITA would be well aware of the potential benefits related to maintaining close proximity between illuminator panels to minimize the distance between, and thereby emit a maximum amount of light from, the panels.

110. Furthermore, Hente teaches that at least one panel includes a recess configured to receive a flange of one of the nested hinges. Based on a construction of the term "a recess" as the plain and ordinary meaning of "an indentation in a surface," Hente discloses at least one panel including an indentation in a surface to receive a flange of one of the nested hinges. As shown below, at least one panel includes an indentation in a surface to receive a nested hinge and the indentation in the surface is positioned at an inner side surface of the panel.

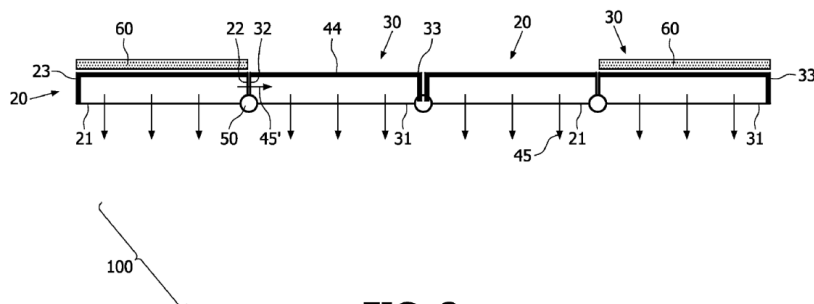


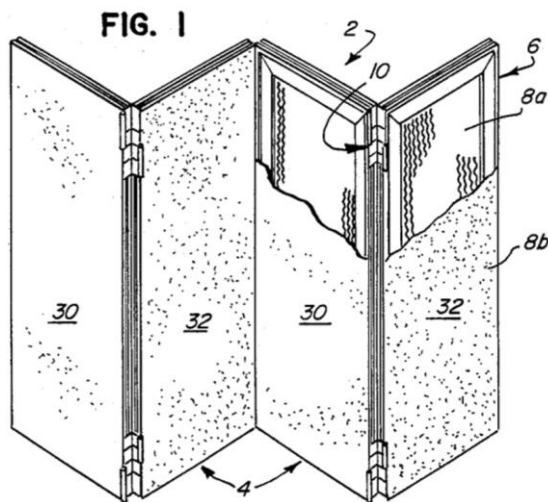
FIG. 2

111. Given this knowledge, a POSITA would be motivated to combine the hinge system of Hente with the panels of Larsen.

E. Perutz (Ex. 1027)

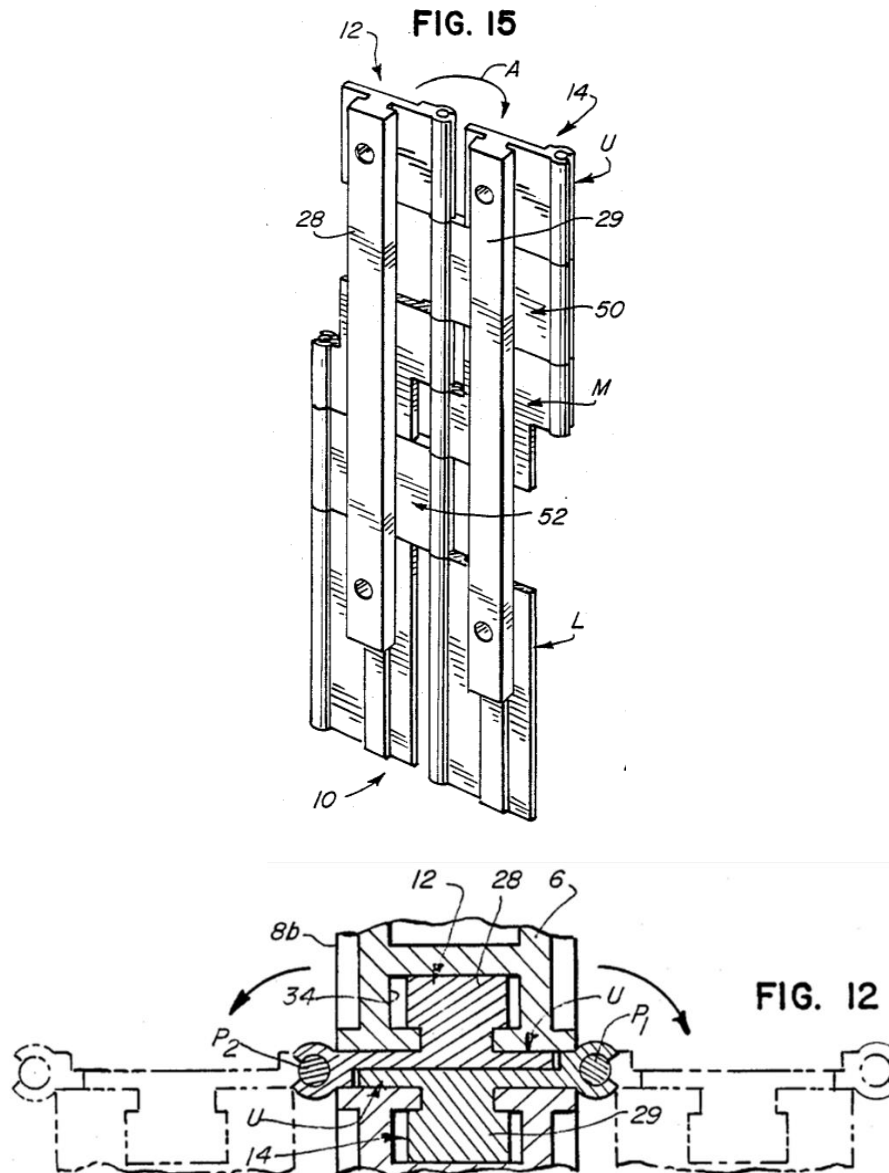
112. U.S. Patent No. 4,823,858 (hereinafter referred to as “Perutz”) was filed on June 02, 1987. Perutz was filed before the earliest effective filing date of the ’512 Patent.

113. Perutz teaches a display panel and hinge system having “a plurality of display panels arranged in side by side relation and hingedly interconnected whereby one of the panels is capable of being selectively rotated relative to the other panel through a maximum arc of substantially 360°.” Perutz, Abstract. Perutz teaches connecting adjoining display panels 30, 32 with hinges 10, the display panels 30, 32 having a frame 6. Perutz, 3:54-66.



Perutz, Fig. 1.

114. Perutz states that the segments of the hinge 10 “are maintained in vertically spaced alignment by an elongated rib or strut 28, 29,” with the ribs 28, 29 being received within slots 34 “formed in the corners of the frame 6 of the adjacent display panels.” Perutz, 4:16-20 and 33-38.



Perutz, Figs. 12 and 15.

115. As shown in Figures 12 and 15, reproduced above, the side-mounted hinges of Perutz are received in an indentation in the side surface (e.g., slot 34) to reduce space between adjoining display panels.

116. A POSITA would be well aware of the potential benefits related to maintaining close proximity between panels, whether the panels are light panels of an illuminator or adjacent

panels of a display panel assembly, to minimize the distance between, and improve the alignment of, the panels.

117. Thus, Perutz teaches that at least one panel includes an indentation in a side surface configured to receive a flange (such as the upper, middle, and/or lower hinge portions of hinge segments 12, 14) of one of the hinge structures. Based on a construction of the term “a recess” as the plain and ordinary meaning of “an indentation in a surface,” Perutz discloses at least one display panel including an indentation in a surface. Based on a construction of the term “a recess” as the plain and ordinary meaning of “an indentation in a surface,” Perutz discloses at least one display panel including an indentation in a surface. As shown in Figures 12 and 15 above, at least one panel of Perutz includes an indentation in a surface, slot 34 in frame 6, to receive a flange, the ribs 28, 29, of the hinge, hinge 10.

118. Given this knowledge, a POSITA would be motivated to combine the hinge system of Perutz with the panels of Larsen, and would have had a reasonable expectation of success in doing so.

IX. MOTIVATIONS TO COMBINE PRIOR ART REFERENCES

A. Motivations to Combine Lundahl with Larsen

119. A POSITA would be motivated to combine the teachings of Lundahl and Larsen to incorporate the hinged panel LED displays of Larsen into the PDT device of Lundahl. In coming to this conclusion, I have reviewed the expert declaration of Michael Ehrenreich, M.D. Based on my understanding that a POSITA would represent a team of individuals, some with engineering expertise (like myself), and some with expertise in the medical treatment of patients with AK (like Dr. Ehrenreich), it is my opinion that the combined opinions and experiences of Dr. Ehrenreich and myself are the appropriate POSITA combination from which the motivation to combine and modify the prior art should be judged.

120. In paragraphs 38-45, Dr. Ehrenreich explains that he sees patients diagnosed with AK nearly every day, and routinely treats these patients with PDT, including treatment using the combination of LEVULAN and Sun Pharmaceuticals' BLU-U lamp device. Ehrenreich at ¶40. Dr. Ehrenreich states that the BLU-U lamp device he uses often in his practice, including the years preceding 2015, resembles the lamp device described in Lundahl. *Id.* at ¶41. Comparing the known pictures and disclosure of the BLU-U lamp with the disclosure provided in Lundahl, I agree that the Lundahl patent appears to disclose the BLU-U device, particularly given the fact that Lundahl is assigned on its face to DUSA Pharmaceuticals, Inc., the manufacturer of BLU-U. Consequently, Dr. Ehrenreich's comments regarding his experience with BLU-U are equally applicable to the device described in Lundahl, as the two appear to be the same.

121. Moreover, in paragraphs 67-74 of his declaration, Dr. Ehrenreich explains that there were known issues and flaws with the BLU-U/Lundahl design. Dr. Ehrenreich rightly points out that Lundahl discloses a fixed U-shape, that this fixed U-shape was developed based on "the average dimensions of the human head," and, because of this, the Lundahl design may not be ideal

given the variety of sizes and shapes of patients' heads. *Id.* at ¶¶67. Dr. Ehrenreich also states that the fixed U-shape design of Lundahl did not provide the flexibility needed to treat other parts of the patients' bodies that would typically have AK lesions, including the arms, back, chest, and hands, particularly in view of the need to maintain a distance of 2-4" from the treatment surface (skin) to the lighting surface. *Id.* at ¶¶42-43 and 70.

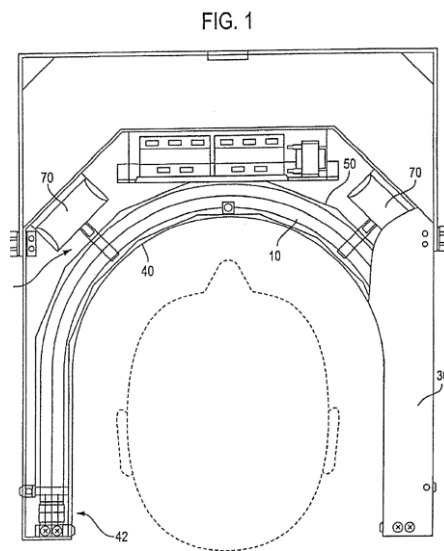
122. In addition, Dr. Ehrenreich notes known problems with the fluorescent tubes utilized in the Lundahl design. Dr. Ehrenreich correctly notes that the uniformity of light from fluorescent tubes varies across the length of the tube, and the uniformity of lighting can also be affected by heat and the ability to cool the Lundahl device. *Id.* at ¶¶68-69.

123. Consequently, as discussed in his expert declaration, Dr. Ehrenreich identifies the problems associated with the Lundahl device design, as Dr. Ehrenreich experienced these problems first-hand in his use of the BLU-U device. The known problems outlined in Dr. Ehrenreich's declaration include: (1) the inflexibility of the fixed U-shape of Lundahl not only created issues ensuring the proper 2-4" treatment distance for the wide variety of patient head sizes and shapes, but also would not allow for proper treatment of other parts of the anatomy requiring AK treatment, including the arms, back, chest, and hands; and, (2) the fluorescent tubes utilized in Lundahl had inherent shortcomings due to the lack of uniform light output across the length of the tube and sensitivity to temperature. These issues (and others) represent known problems for which the POSITA team member with a background in engineering (like myself) would have been motivated to find solutions.

a. Increasing the Flexibility of the Lundahl Device For Use with All Head Sizes and Shapes, As Well as Varying Anatomies

124. As discussed in the declaration of Dr. Ehrenreich, the PDT device and design of Lundahl appears to be the same design utilized for BLU-U, a device publicly known and used in

the treatment of AK lesions from 1999-2015. Lundahl teaches that “[t]he U-shape minimizes the variations in distance between the emitter and the target, providing a uniform visible light distribution to the face or scalp of the patient; the tube dimensions were chosen based on the average dimensions of the adult human head. The mounting of the tubes minimizes the impact of the non-emitting area at their ends. This allows the present invention to be more compact and permits easier centering of the patient's head within the visible light sources. Moreover, the “U” shape provides the desired irradiance and irradiance uniformity for scalp and facial irradiation, and thus ensures that the proper visible light dosage is applied to all target areas during PDT.” Lundahl, 6:31-42.³ Lundahl illustrates the “U” shape design in Figure 1:



Lundahl, Fig. 1.

125. As can be seen from Figure 1, the various points of the treatment surface (i.e., the various points on the patient's skin) will have varying distances from the light surface (e.g., the nose will be closer to the light surface than the point where the nose meets the cheek). As noted in

³ Unless otherwise indicated, all emphasis added.

the declaration of Dr. Ehrenreich, the FDA approved indication for the treatment of AK using LEVULAN and BLU-U requires that the light surface be 2-4” from all points on the treatment surface (i.e., all points on the patient’s nose, cheeks, chin, ears, etc.). While is it possible that a patient having head dimensions similar to “the average dimensions of the adult human head” would allow for positioning within the Lundahl device similar to Figure 1; a POSITA would also envision many scenarios where the shape and dimensions of the patient would not allow for the required 2-4” distance required by the FDA approved indication.

126. A POSITA considering Lundahl would have been motivated to increase the flexibility of the device to ensure the light surface could be maintained at a distance of 2-4” of the entire treatment surface of the patient (i.e., face, nose, forehead, ears, sides of head, etc.), particularly given the wide variety of head shapes and sizes. Additionally, a POSITA would have understood that there are other bodily anatomies that could use treatment for AK lesions, such as the arms, back, and other body parts. In fact, Lundahl expressly contemplates the treatment of other parts of the body, stating that “[t]he present invention is directed to photodynamic therapy using an illuminator that provides a uniform distribution of visible light. In particular, the present invention is directed to an apparatus and method for photodynamic treatment (PDT) or diagnosis (PD) of actinic keratosis of the scalp or facial areas of a patient. The present invention is also directed to an apparatus and method for PDT and PD of other indications (e.g., acne) **and other areas of the patient (e.g., arms, legs, etc.).**” Lundahl, 1:9-17.

127. Consequently, a POSITA would have been motivated to change the design of the system of Lundahl to allow for adjustment of the light surface to ensure a 2-4” distance from the face and from other varying anatomies. A POSITA would have understood that the easiest way to modify the fixed, curved U-shape of Lundahl would be to incorporate hinged panels that could be

individually adjusted to account for variations in head shape/size or other anatomy selected for treatment.

128. Larsen teaches that “[f]or the treatment of large-area tissues according to Figure 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]. These teachings would have motivated a POSITA to incorporate Larsen’s solution of connecting light applicators by hinges, to allow for adjustability of Lundahl’s device to provide the desired irradiance and irradiance uniformity to all target areas during PDT.

129. A POSITA would have had a reasonable expectation of success in combining Lundahl with Larsen, because both references describe similar illuminators for using light to treat conditions on a patient’s skin.

b. Increasing Light Output Consistency by Changing the Light Source from Fluorescent Tubes to LEDs

130. A POSITA was also motivated to modify Lundahl to incorporate LEDs as taught by Larsen, rather than the fluorescent tubes. Lundahl discloses horizontally oriented fluorescent tube lights. However, by the late 2000’s and early 2010’s, a POSITA would have been motivated to use solid-state light-emitting diodes (LEDs) as the illumination source for at least four reasons. First, LEDs have a lower cost and a longer lifetime than fluorescent tubes. Second, fluorescent tubes are known to have inconsistent light output within the tube itself, as acknowledged in Lundahl (the tubes have “non-emitting area at their ends” (6:31-42) and that “tube output may vary over its length” (4:41-42)). Third, by moving to adjustable panels connected by hinges to increase flexibility, the use of LEDs would be more practical to reduce spacing between light sources and

the edges of the panels, as opposed to the bulky metal couplings at the end of fluorescent tubes, to reduce optical dead space across the light surface. Fourth, the relatively narrow output spectrum of LEDs allows for an illuminator with an output wavelength ideally matched to an absorption band of the photosensitizer

131. Larsen teaches that light sources are disposed on the surfaces of five applicators, the light sources being “semiconductor diodes (LED) and/or laser diodes.” Larsen, [0070]. The state of illumination technology as described in the previous paragraph along with this teaching of Larsen would have motivated a POSITA to incorporate Larsen’s solution of disposing light sources, specifically LEDs, on the surface of the light applicators to Lundahl’s device.

132. A POSITA would have had a reasonable expectation of success in combining Lundahl with Larsen, because both references describe similar illuminators and the conversion from fluorescent tubes to LEDs was a routine practice prior to 2015.

c. Increasing Light Absorption at Deeper Skin Depths by Emitting Red Light

133. Moreover, a POSITA was motivated to utilize red light wavelengths in the PDT device rendered obvious by Lundahl and Larsen. In its discussion of the background on PDT treatment, Lundahl states “[g]eneral background information on PDT using 5-aminolevulinic acid (“ALA”) as the precursor of a photoactivatable agent can be found in U.S. Pat. No. 5,079,262, entitled “Method of Detection and Treatment of Malignant and Non-Malignant Lesions Utilizing 5-Aminolevulinic Acid,” issued to James C. Kennedy et al. on Jan. 7, 1992, and U.S. Pat. No. 5,211,938, entitled “Method of Detection of Malignant and Non-Malignant Lesions by Photochemotherapy of Protoporphyrin IX Precursors,” issued to James C. Kennedy et al. on May 18, 1993. The contents of these patents are incorporated herein by reference.” Thus, Lundahl expressly incorporates all teachings of U.S. Patent No. 5,079,262 to Kennedy et al. (“Kennedy”).

134. Kennedy teaches that red light was preferred for PDT, as it penetrates deeper into the skin, as compared to blue light, and PpIX (the compound produced by topical application of ALA) strongly absorbs red light. Kennedy states “[a] method of detecting and treating malignant and non-malignant tissue abnormalities and lesions of the skin” in which “5-aminolevulinic acid is administered to the patient.” Kennedy, Abstract. Kennedy states that “[i]n preferred aspects of this invention the preferred precursor of protoporphyrin IX is 5-amino-4-oxo-pentanoic acid, otherwise known as 5-aminolevulinic acid, and a preferred wavelength of the photoactivating light is in the range 350-640 nm, more preferably a red light of about 610-630 nm.” Kennedy, 4:3-8. Kennedy also states that “[t]he wavelength of the photoactivating light is of some importance, as it has been shown that between 1 and 10 percent of incident red light (600-700 nm) can pass through a slab of human tissue 1 cm thick, whereas only 0.001 percent or less of blue light (about 400 nm) can pass through the same thickness of human tissue. The photosensitizer will, therefore, be more successful if it strongly absorbs red light. PpIX does strongly absorb red light.” Kennedy, 4:60-69. Based on the teachings of Kennedy, a POSITA would have expected red light (preferably at wavelengths of about 610-630) to more effectively penetrate skin tissue, and for PpIX to more effectively absorb the red light, resulting in greater activation of the photosensitizer. These enhancements in the penetration of light and absorption by the photosensitizer would have led a POSITA to reasonably expect enhanced efficacy of the PDT device.

135. Additionally, Larsen teaches that its 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 . . .” Larsen, [0024]. Larsen also teaches using light radiation within the wavelength of 300 – 2000 nm, which includes red light. *Id.*, [0025], [0071]-[0076], and [0083].

136. Based on the expectation of enhanced light penetration and absorption by the photosensitizer, a POSITA was motivated to combine the teachings of Lundahl, incorporating Kennedy, and Larsen to use red light for PDT.

137. Additionally, Kennedy reports in Examples 1-4 that patients were administered PDT with a light source that was “filtered to remove both infrared (heat filter) and wavelengths below 600 nm,” meaning red light, likely with wavelengths of 600-700 nm was utilized. Kennedy, 5:47 to 6:47. Kennedy reports that PDT with this red light demonstrated clearance of treated lesions. *Id.* In view of this, a POSITA had at least a reasonable expectation that red light could be utilized in the device rendered obvious by Lundahl (incorporating Kennedy) and Larsen.

138. For these reasons, claims 1, 8, and 20, and each of the claims that depend from them, are obvious over Lundahl in view of Larsen.

B. Motivation to Combine Lundahl, Larsen, and Hente

139. As discussed herein, Larsen teaches an illuminator comprising at least five panels connected by hinges on inner side surfaces of adjacent panels. To the extent that Larsen does not expressly or implicitly disclose or render obvious that the panels are connected by “nested hinges” on inner side surfaces, this limitation is disclosed by Hente. As an initial matter, for all the reasons noted above, Lundahl and Larsen disclose and render obvious the inclusion of hinged panels (as taught by Larsen) in the illumination device taught by Lundahl via attachment to the inner side surface of adjacent panels, as doing so would allow for flexibility in the arrangement of panels to allow for adjustment based on the variations in size/dimensions of patient heads, and also would allow for treatment of other parts of the body (e.g., chest, arms, etc.). However, based on the teachings of Lundahl and Larsen, uniformity of illumination is still a key design motivation, as a POSITA would want to minimize gaps between the adjacent panels (appreciable gaps between panels might impact the ability to produce uniform illumination). Hente teaches hinges that allow

for movement and adjustment of adjacent panels/sections, while also minimizing the gap between the adjacent panels/sections.

140. Hente is directed to light emitting devices comprising organic light emitting diodes (i.e., organic LEDs or OLEDs) that allow for adjustable and foldable orientations. Hente, Title, Abstract. Hente teaches light emitting devices that have the flexibility to “illuminate large and point-like limited areas.” Hente, [0005]. Specifically, Hente discloses lighting devices with at least one first section and at least one second section. Hente, Abstract. Hente explains that the light emitting device can be expanded to provide a flat illumination surface, stating “In FIG. 2 the light emitting device 10 is shown in an expanded position 100...In the expanded position 100 the first section 20 and the second section 30 are arranged in such a way, that they form a longish stretched sheet like light emitting device 10. The artificial light 45 is primarily emitted through the bottom sides 21, 31 of each section 20, 30. In this position 100 the light emitting device 10 can be used to illuminate large areas” Hente, [0036]. Figure 2 is illustrated below.

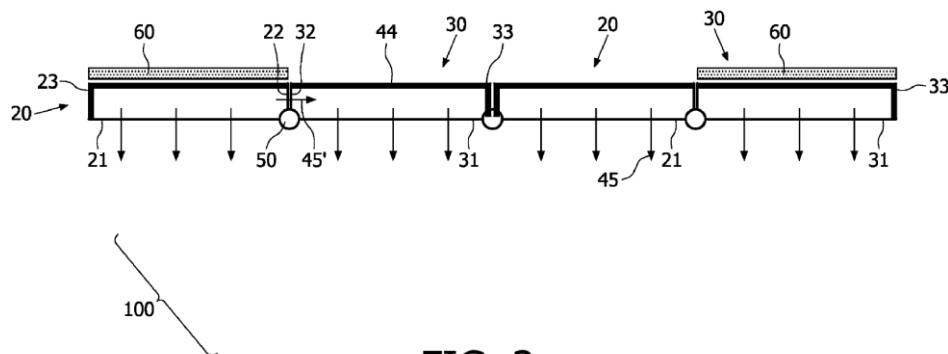
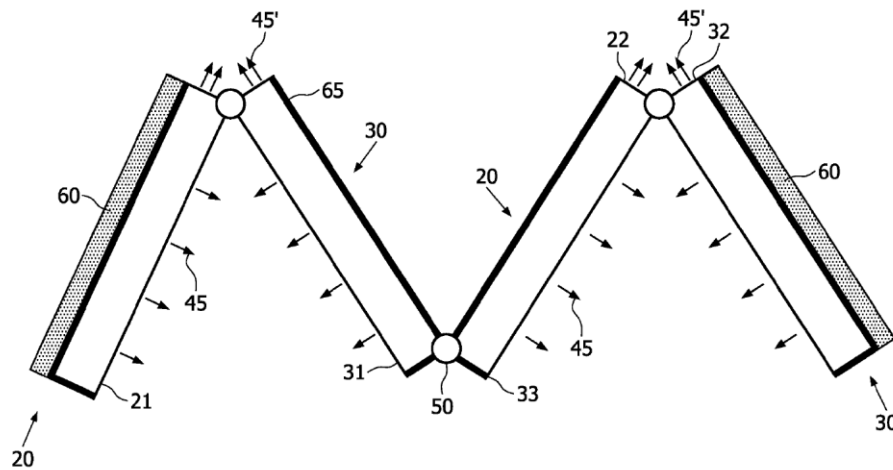


FIG. 2

Hente, Fig. 2.

141. Hente also teaches that the light emitting device may be adjusted or folded into a smaller, “compact” position, stating “[t]o enable the light emitting device to be converted from the expanded position 100 into the compact position 110 the sections 20, 30 are connected through a

connection mean 50. As shown in Figure 3, the connection mean may be a hinges [sic], being located at the outer ends of each section 20, 30.” Hente, [0037]. Figure 3 is illustrated below.



Hente, Fig. 3.

142. Hente is from the same field of endeavor as the '512 Patent, which also describes illuminators having multiple adjacent sections/panels incorporating light emitting diodes, that can be rotated relative to each other. '512 Patent, 1:24-2:4. A POSITA would be well aware of the potential benefits related to maintaining close proximity between illuminator panels to minimize the distance between the panels, enhancing the uniformity of illumination (by reducing spaces or zones with no light). Consequently, to the extent that the hinges present in the Larsen 5-panel device are not attached to inner side surfaces of the adjacent panels, a POSITA was motivated to utilize hinges similar to those described in Hente, attached to inner side surfaces of adjacent sections/panels.

143. Furthermore, Hente teaches that at least one panel includes a recess configured to receive a flange of one of the “nested hinges.” Based on a construction of the term “a recess” as the plain and ordinary meaning of “an indentation in a surface,” Hente teaches at least one panel

including an indentation in a surface to receive a flange of one of the “nested hinges” and that the indentation in the surface is positioned at an inner side surface of the panel.

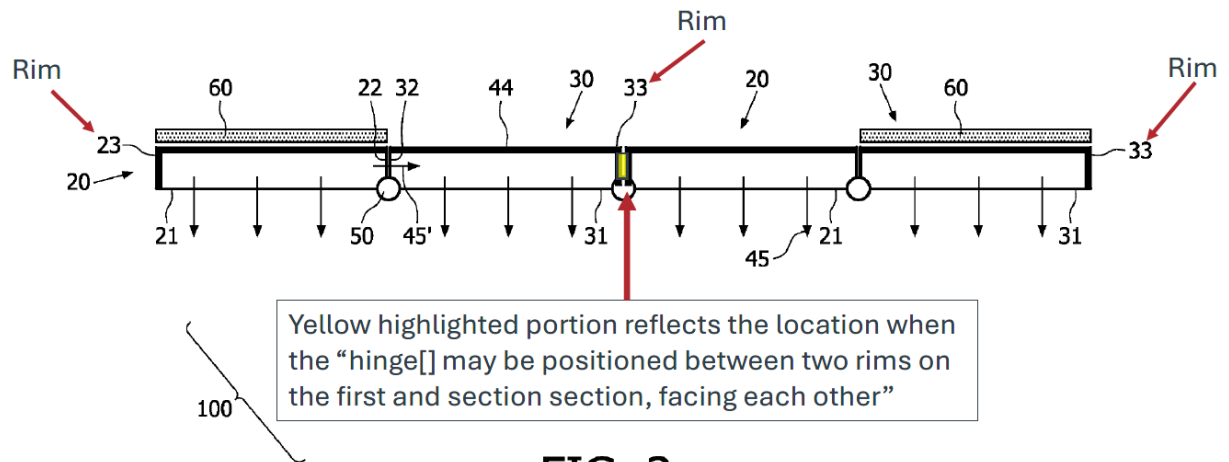
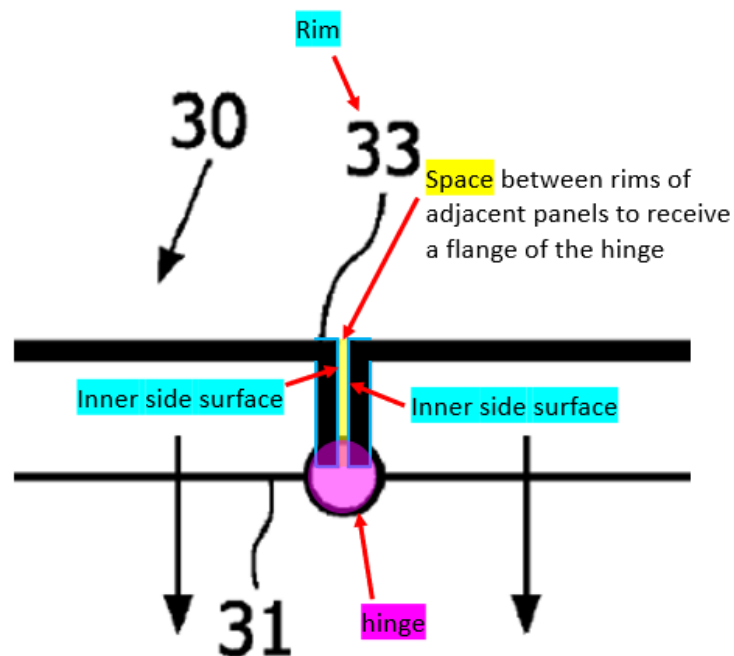


FIG. 2

144. As shown in the enlarged annotated figure below, there is a space between the rims of adjacent panels of Hente to receive a flange of the hinge.

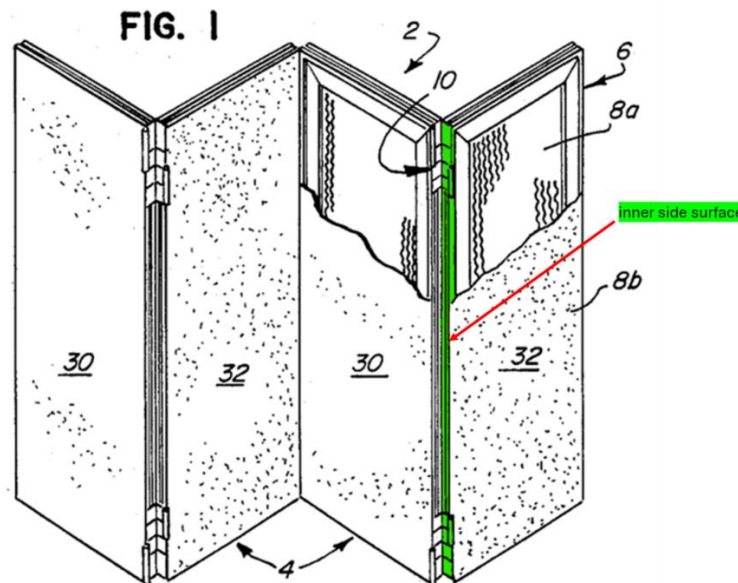


145. Given this knowledge, a POSITA would be motivated to combine the hinge system of Hente with the panels of Larsen, and would have a reasonable expectation that the hinges of Hente could be successfully utilized in the device rendered obvious by Lundahl and Larsen.

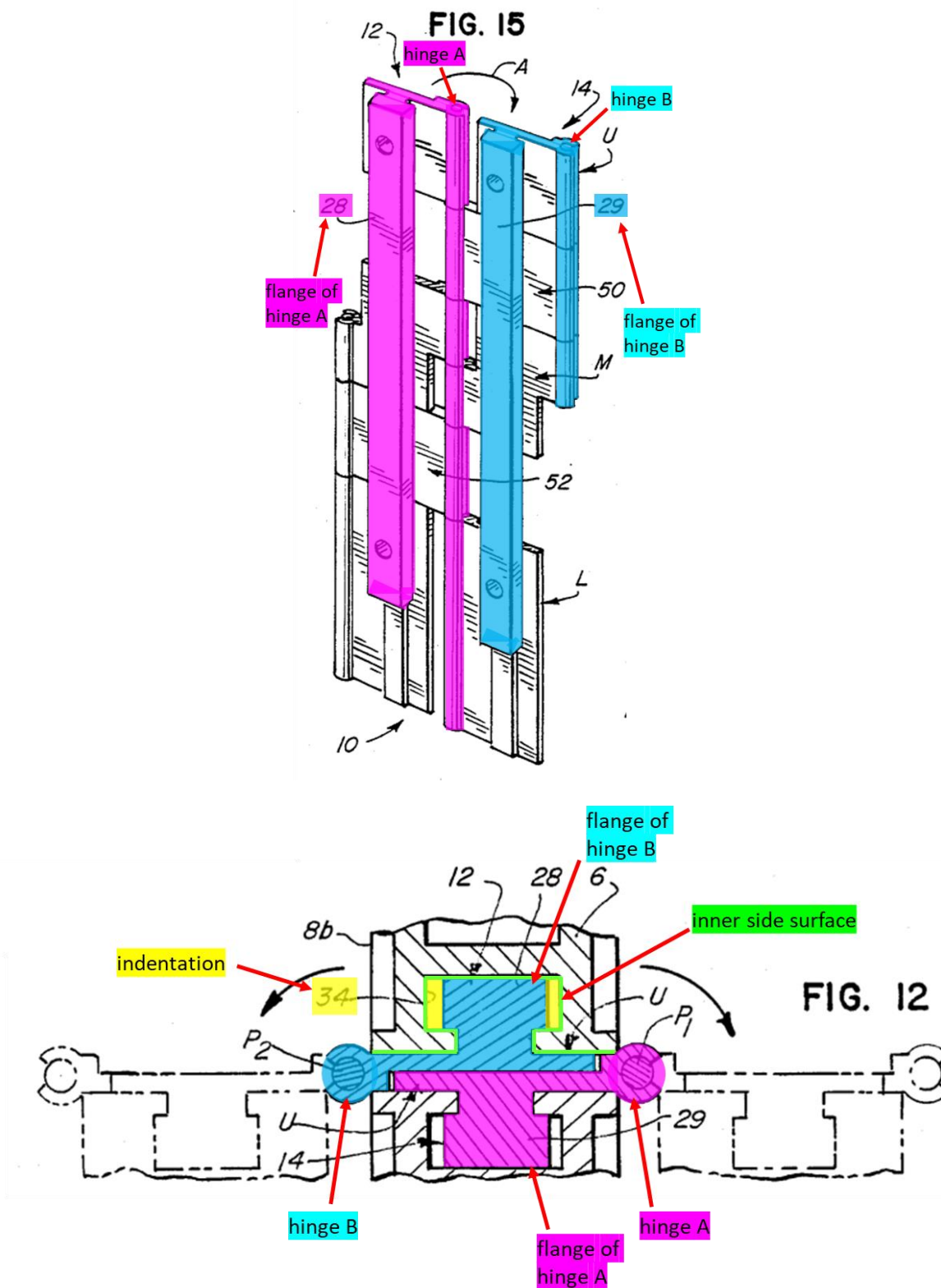
C. Motivation to Combine Lundahl, Larsen, Hente, and Perutz

146. As discussed herein, a motivation existed to combine the teachings of Lundahl, Larsen, and Hente. To the extent that Lundahl, Larsen, and Hente do not expressly or implicitly disclose or render obvious at least one panel including a recess configured to receive a flange of one of the nested hinges, the recess being positioned at an inner side surface of the at least one panel, as recited in claims 17 and 18, respectively, these limitations are disclosed by Perutz. Based on the teachings of Lundahl, Larsen, and Hente, uniformity of illumination is still a key design motivation, as a POSITA would want to minimize gaps between the adjacent panels (appreciable gaps between panels might impact the ability to produce uniform illumination). Perutz teaches minimizing the gap between the adjacent panels/sections.

147. Perutz teaches a display panel and hinge system having “a plurality of display panels arranged in side by side relation and hingedly interconnected whereby one of the panels is capable of being selectively rotated relative to the other panel through a maximum arc of substantially 360°.” Perutz, Abstract. Perutz teaches connecting adjoining display panels 30, 32 with hinges 10, the display panels 30, 32 having a frame 6. Perutz, 3:54-66. As shown in annotated Figure 1 below, the hinges 10 connect adjoining display panels 30, 32 at an inner side surface of the display panels 30, 32.



148. Perutz states that the segments of the hinge 10 “are maintained in vertically spaced alignment by an elongated rib or strut 28, 29,” with the ribs 28, 29 being received within slots 34 “formed in the corners of the frame 6 of the adjacent display panels.” Perutz, 4:16-20 and 33-38. As shown in annotated Figures 12 and 15 below, the side surface of adjoining display panels includes an indentation in a surface (e.g., slot 34 in frame 6) to receive the side-mounted hinges, specifically a flange (e.g., ribs 28, 29) of the hinges 10, to reduce space between adjoining display panels.



149. A POSITA would be well aware of the potential benefits related to maintaining close proximity between panels, whether the panels are light panels of an illuminator or adjacent

panels of a display panel assembly, to minimize the distance between, and improve the alignment of, the panels.

150. Thus, Perutz teaches that at least one panel includes a recess configured to receive a flange of one of the hinge structures. Based on a construction of the term “a recess” as the plain and ordinary meaning of “an indentation in a surface,” Perutz discloses at least one display panel including an indentation in a surface. As shown in annotated Figures 12 and 15 above, at least one panel of Perutz includes an indentation in a surface (slot 34 in frame 6) to receive a flange (ribs 28, 29) of the hinge (hinge 10).

151. Given this knowledge, a POSITA would be motivated to combine the hinge system of Perutz with the panels of Larsen, and would have a reasonable expectation that the hinges of Perutz could be successfully utilized in the device rendered obvious by Lundahl and Larsen.

X. GROUNDS OF UNPATENTABILITY

152. Ground 1: Lundahl in view of Larsen renders obvious at least claims 1, 3, 5, 8, and 20 of the '512 Patent for at least the reasons described herein.

153. Ground 2: Lundahl in view of Larsen further in view of Hente renders obvious at least claims 1, 3, 5, 8, 17, 18, and 20 of the '512 Patent for at least the reasons described herein.

154. Ground 3: Lundahl in view of Larsen, further in view of Hente, and further in view of Perutz renders obvious at least claims 17 and 18 of the '512 Patent for at least the reasons described herein.

155. I am unaware of any secondary considerations that would support a finding of non-obviousness with respect to claims 1, 3, 5, 8, 17, 18, and 20 of the '512 Patent.

A. Lundahl in view of Larsen renders obvious at least claims 1, 3, 5, 8, and 20 of the '512 Patent

'512 Patent: Claim 1

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

- [a] an illuminator comprising at least five panels connected by nested hinges on inner side surfaces of adjacent panels,
- [b] light sources disposed on surfaces of the at least five panels,
- [c] the illuminator being configured to uniformly illuminate a treatment surface of the patient via the light sources,
- [d] one of the at least five panels positioned as a center panel configured to face the treatment surface, and two or more of the at least five panels being configured to be angled relative to the center panel,
- [e] wherein each of the at least 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:”

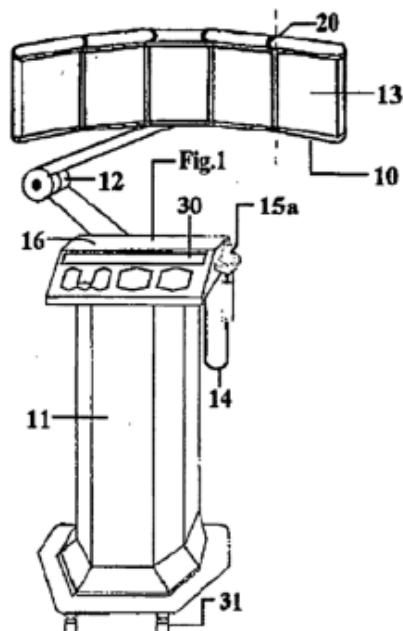
156. Lundahl discloses an “invention...directed to photodynamic therapy using an illuminator that provides a uniform distribution of visible light. In particular, the present invention is directed to an apparatus and method for photodynamic treatment (PDT) or diagnosis (PD) of actinic keratosis of the scalp or facial areas of a patient.” Lundahl, 1:9-17.

157. Larsen similarly discloses an “invention relat[ing] 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]. Larsen further states its device “provides multiple wavelength stimulation that is also effective in conjunction with photodynamic therapy (PDT) chemicals.” Larsen, [0037].

158. Therefore, in my opinion, Lundahl and Larsen each disclose this claim limitation.

Claim 1(a): “an illuminator comprising at least five panels connected by nested hinges on inner side surfaces of adjacent panels,”

159. Larsen’s illuminator has at least five hinged panels (13):



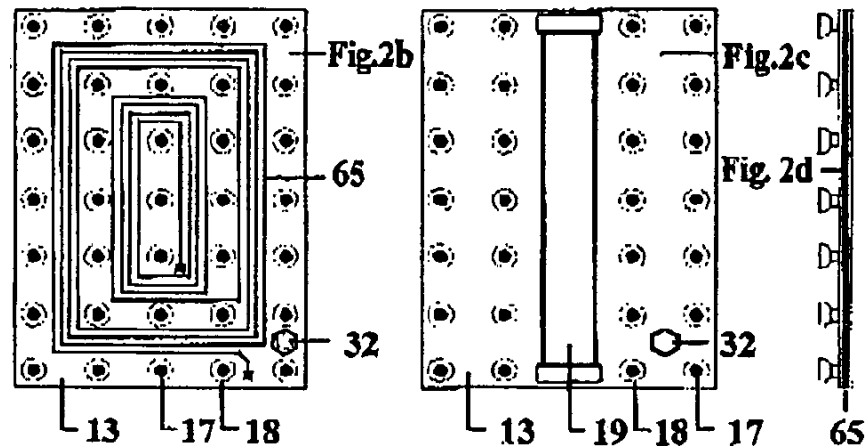
Larsen, Fig. 1.

160. Larsen teaches that “[f]or the treatment of large-area tissues according to Fig. 1, several applicators 13 are flexibly connected to each other through hinges 10, respectively connecting one edge with the other, whereby the applicators are suitable for the treatment of for example, the backs of humans and so become adjustable for an equidistant positioning of the applicators 13 above the skin.” Larsen, [0072]. While this passage refers to “hinges 10,” it is clear from the disclosure of Larsen that this is a labeling error, and that the “10” illustrated in Figure 1 refers to the device as a whole, while the hinge component is illustrated by the dotted line labeled as “20.” Larsen states “[a]s 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] (emphasis added). In view of this express statement from Larsen, it is clear to a POSITA that the “10” designation of Figure 1 is referencing the device as a whole.

161. Additionally, the passage from Larsen above notes that the several applicators 13 (i.e., the panels) “are flexibly connected to each other through hinges...*connecting one edge with the other.*” (Emphasis added) The connecting of edges of adjacent applicators (panels) indicates that the hinge structure is located between the inner side surfaces of the adjacent applicators, which is exactly where dotted line 20 is illustrated in Figure 1.

162. Further, during the prosecution of Application No. 17/009,871 (which is a continuation application of the ’512 patent), the Examiner reviewed Larsen and similarly determined that it taught “five panels connected by a plurality of hinges 20 . . . on inner side surfaces of adjacent panels that connect panels together . . .” Ex.1009, ¶4 (citing Larsen, Figs. 1-3, [0069], [0072], lines 1-4).

163. Moreover, feature “20” of the device is only referenced once throughout the disclosure of Larsen. Larsen states “According to FIGS. 2 b and 2 c the light sources 17 are placed in regular row arrangements, i.e., 20 equidistant from each other, whereby, according to FIG. 2 c, one applicator 13, in addition to the diodes 17, has a light source 19.” Larsen [0071]. Figures 2b and 2c are provided below:

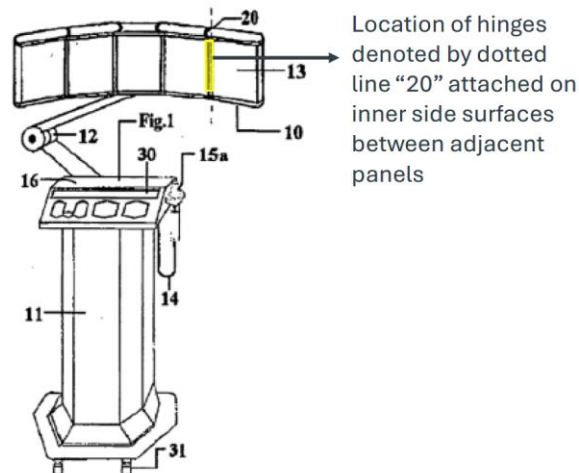


Larsen, Figs. 2b and 2c. As shown above, there is no feature “20” illustrated in either Figure 2b or 2c.

164. I am aware that the '512 patent owner filed a preliminary patent owner response in IPR2024-00874 (filed against related U.S. Patent No. 11,697,028, a continuation of the '512 patent), and argued that another Larsen patent application (AU 2001/43869) includes a similar figure to Figure 1 of the '512 patent, including feature “27” which similarly points to the bottom of the panel arrangement, and is referred to in claim 19 as “individual [sic] hinged (27) flat elements.” As an initial matter, it is my understanding that AU 2001/43869 is not related to the '512 patent, and, in fact, appears to be focused on an entirely different device (see Figures 1a-1c). As I have stated herein, the express disclosure provided in the '512 patent itself indicates that feature “10” is directed to “the invented device” as a whole. Consequently, the disclosure of AU

2001/43869 does not impact my conclusion regarding the typographical error in Figure 1 of Larsen.

165. For these reasons, a POSITA would understand that the passage from Larsen above, referencing “hinges 10” is a typographical error, and that the hinges described in the specification of Larsen are illustrated as “20” in Figure 1.⁴ Based on this understanding, Larsen discloses an illuminator comprising at least five panels connected by hinges on inner side surfaces of adjacent panels. The figure below illustrates this arrangement:



166. Even if the Board determines that Larsen’s hinges are not expressly (or inherently) disclosed on the inner side surfaces of the panels, a POSITA would have found it obvious and would have been motivated with a reasonable expectation of success to locate Larsen’s hinges on the inner side surfaces of adjacent panels. First, Figure 1 of Larsen shows that the inner edges of each of the panels (13) are nearly flush with each other. This disclosure would have motivated a POSITA to place the hinges on the inner side surfaces of Larsen’s panels in order to facilitate this nearly flush arrangement. Such a modification would have involved nothing more than the use of

⁴ This determination is also consistent with my experience reviewing device patents, whereby the first number illustrated in the figures typically refers to the device as a whole.

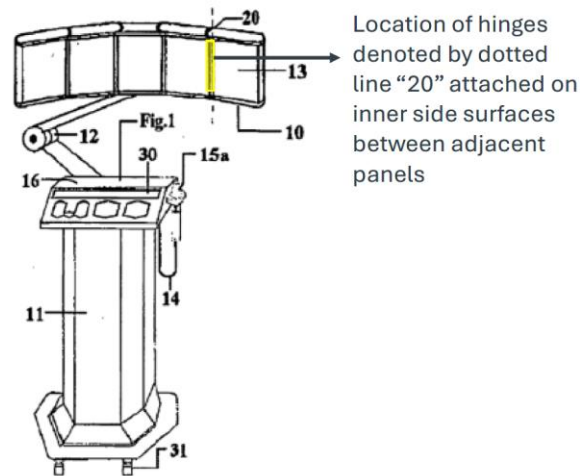
a known prior art element according to known methods to yield predictable results. Second, there were finite number of known, predictable solutions for Larsen's panels to be "flexibly connected to each other through hinges." Specifically, from a practical perspective, there are only three options for locations where the hinges can be connected: (1) on the inner side surfaces of the adjacent panels; (2) on the top and bottom of the adjacent panels; and (3) on the rear surface of the panels.⁵ Based on this limited number of design options, a POSITA would have found it obvious to try placing the hinges on the inner side surfaces of the panels. And a POSITA would have had 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 nearly flush arrangement as shown in Figure 1.

167. Regarding the requirement that the at least five panels are connected by "nested" hinges on inner side surfaces of adjacent panels, I first note that it is my opinion that the "nested hinges" term is indefinite, as the '512 patent specification does not define what is meant or required by this term. However, I am aware that the owner of the '512 patent (Sun Pharmaceuticals) has asserted in the public version of its opening claim construction brief that "nested hinges on inner side surfaces of adjacent panels" should be construed as "hinges that fit on inner side surfaces of adjacent panels." Sun Opening Brief, 21.

168. Again, I reiterate my opinion that the "nested hinges" term is indefinite, but using the '512 patent owner's assertions of what is required by "nested hinges on inner side surfaces of adjacent panels," (i.e., hinges that fit on inner side surfaces of adjacent panels), Larsen discloses this limitation. Larsen discloses or renders obvious an illuminator comprising at least five panels

⁵ A POSITA would not have connected the hinges on the front surface of the panels, as that would block the light produced by the device, inhibiting the function of the device.

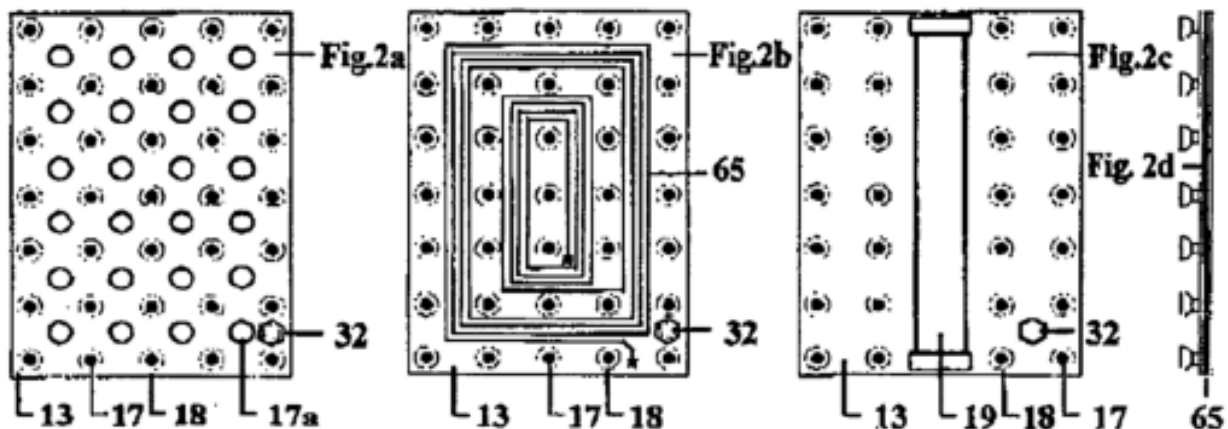
connected by hinges that fit on inner side surfaces of adjacent panels, as I discussed previously, and as illustrated in the annotated figure below:



169. Therefore, in my opinion, Larsen discloses or renders obvious, claim 1(a).

Claim 1(b): "light sources disposed on surfaces of the at least five panels,"

170. Larsen discloses that light sources are disposed on the surfaces of at least five applicators. Figures 2a-2c of Larsen show "plain surfaced printed circuit boards with light sources mounted in the applicators 13." Larsen, [0070].



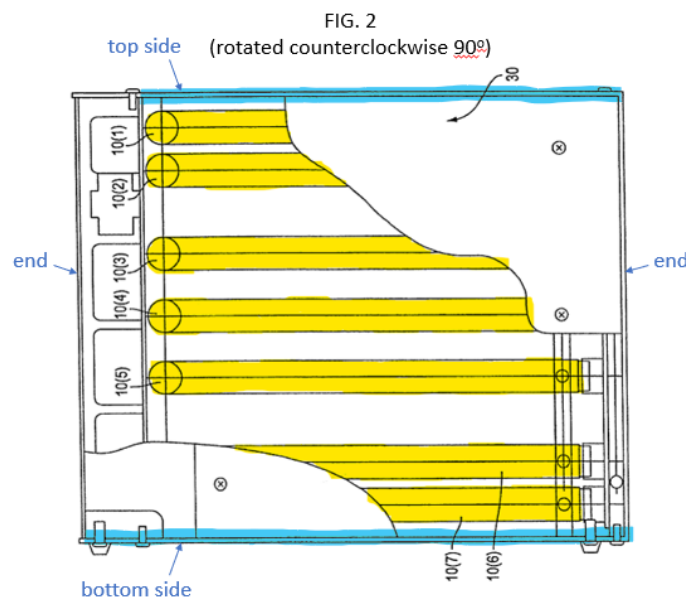
171. The applicators are mounted in a shifting order "with semiconductor diodes (LED) and/or laser diodes 17 and 17a (in the following called light sources), whereby shifting the order of the light sources 17 means, that the respective light source 17a of one row is placed at the point

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].⁶

172. Thus, Larsen discloses this claim limitation.

Claim 1(c): “the illuminator being configured to uniformly illuminate a treatment surface of the patient via the light sources,”

173. Lundahl teaches uniform illumination of the head of a patient via photodynamic therapy. Lundahl states “[t]he present invention is directed to photodynamic therapy using an illuminator that provides a uniform distribution of visible light.” Lundahl, 1:9-11. To achieve this uniformity, Lundahl utilizes the light distribution pattern illustrated in Figure 2 (which has been highlighted, annotated, and rotated 90° to better illustrate):



Lundahl, Fig. 2.

⁶ One embodiment of Larsen shows that the lights are inside of flattened oval tubes. Larsen, [0102], Fig. 17b. This is just one of many embodiments, and the light sources themselves are still individually controllable just like other light sources. Larsen, [0106].

174. Lundahl explains that “[t]o avoid uniformity problems, one embodiment, of the present invention utilizes a plurality of U-shaped tubes 10(1)-10(7)...[An] advantage of the arrangement is that uniformity can also be adjusted by varying the lateral spacing of the tubes (relative vertical spacing as shown in the rotated FIG. 2). This is important since it is necessary to compensate for the fact that the output from a flat plane emitting light source drops near the edges. Varying the lateral spacing of the tubes creates the same effect as folding the edges of a larger illuminator in on itself, thus emulating an infinite plane emitter with a compact unit.” Lundahl, 6:16-30.

175. Lundahl states that the spacing of lights and greater density of lighting near the top and bottom of the panel provide for uniform illumination, stating “[t]he number of tubes used and the spacing between them were chosen to achieve desired uniformity and power output specifications...The present invention provides a highly uniform output irradiance without the use of an additional diffusing element.” Lundahl, 6:43-57.

176. Furthermore, in addition to Lundahl’s express disclosure that the device described therein provides uniform illumination of the patient’s head, it is my understanding that the patent owner (Sun Pharmaceuticals Industries, Inc.) and Petitioner (Biofrontera) have agreed that the terms “uniformly illuminate a treatment surface”/ “uniformly illuminating a treatment surface” are to be construed as “irradiating light over the active emitting area such that the measured irradiance at a treatment surface of the patient is at least within 60% of the measured maximum.” Sun’s Claim Construction Brief (public version), 9-10. Lundahl discloses this limitation, stating “[i]t has been found that, according to a preferred embodiment of the present invention, the measured output over the active emitting area is within 70% of the measured maximum when measured with a cosine response detector at distances of 4” and 2”, and within 60% of the measured maximum over

all operation distances.” Lundahl, 15:22-26. Consequently, in addition to routinely stating that the devices described therein provide “uniform” illumination, Lundahl discloses that the measured output over the active emitting area is within 70% of the measured maximum at distances of 4” and 2”, and within 60% of the measured maximum over all operation distances, meeting the construed requirement “irradiating light over the active emitting area such that the measured irradiance at a treatment surface of the patient is at least within 60% of the measured maximum.”

177. Larsen teaches that its panels (applicators) are configured to uniformly illuminate a treatment surface of the patient via the light sources. Larsen teaches that “[i]n each applicator the printed circuit board carrying the light sources is connected to a small electrical scan engine 66, which can move the light sources with linear movements, 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]. During prosecution of Application No. 16/791,004 (the “’004 Application”), which was granted as the ’512 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.” Ex.1010, ¶23 (citing Larsen, [0072]).

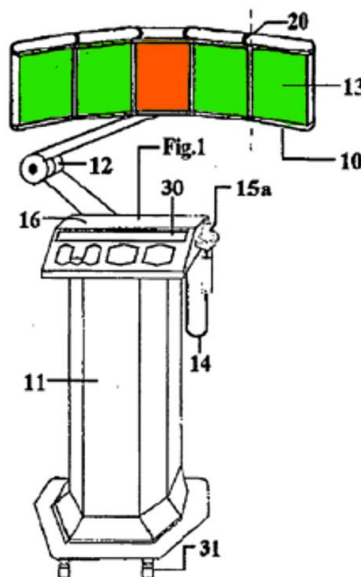
178. Larsen also teaches that its applicators “*permit[] an even and gap-free radiation* of the surface with multiple wavelengths of light.” Larsen, [0028]. An “even and gap-free radiation of the surface” would uniformly illuminate the treatment surface. Larsen also describes measurements taken by sensors 32 that measure “the amount of energy radiated away from the skin surface, which is indicative of the total energy penetrating into the tissue.” Larsen, [0079]. Larsen teaches that “[t]aking 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]. A POSITA would have understood that Larsen’s applicator is configured to uniformly illuminate a treatment surface of the patient.

179. Thus, Lundahl and Larsen disclose (or Lundahl in view of Larsen renders obvious) this claim limitation.

Claim 1(d): “one of the at least five panels positioned as a center panel configured to face the treatment surface, and two or more of the at least five panels being configured to be angled relative to the center panel,”

180. As shown in Figure 1 of Larsen, one of the at least five panels is positioned as the center panel, with two or more of the remaining panels configured to be angled relative to the center panel.



Larsen, Fig. 1.

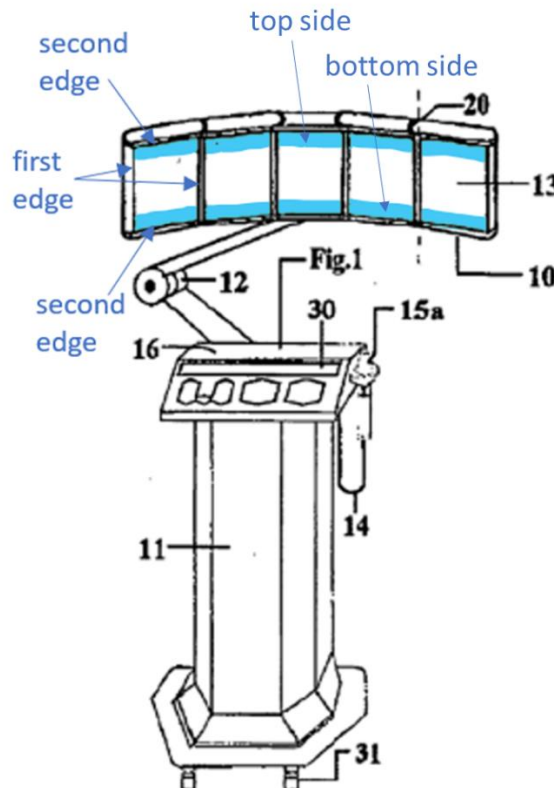
181. Larsen teaches that “the applicators are suitable for the treatment of, for example, the backs of humans and so become adjustable for an equidistant positioning of the applicators 13 above the skin.” Larsen, [0072]. As shown above, the center panel (annotated in orange) is positioned to illuminate the center of the patient’s back, with each adjacent side panel (annotated

in green) angled relative to the center panel to accomplish the equidistant positioning described in Larsen. Larsen, [0072]; *see also* Ex.1034, ¶330 (finding this limitation disclosed by Figure 1 in the Larsen '381 Patent).

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

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

183. As shown in the annotated Figure 1 of Larsen below, each of the at least five panels (13) has two first edges (vertical sides) and two second edges (horizontal edges on the top and bottom of the panels that extend along the top and bottom sides of the panel arrangement). The two second edges of each panel are shorter than the two first edges. Larsen, Fig. 1.



184. 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.”

185. Regarding the requirement that “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,” I first note that it is my opinion that this claim language is indefinite, as the ’512 patent specification does not define what is meant or required by this term, or, for example, how a POSITA is to determine what is “proximate” vs. “not proximate.” However, I am aware that the owner of the ’512 patent (Sun Pharmaceutical Industries, Inc.) has asserted that Biofrontera’s RhodoLED® XL allegedly meets this claim limitation, stating “The BF-RhodoLED XL’s LEDs each have ‘a fixed LED light intensity.’ The LEDs are arranged such that a higher intensity of light is emitted proximate the second edges (i.e., the shorter edges) compared to the intensity of light emitted not proximate the second edges. For example, the ‘LEDs are distributed on each panel in a specific way (see Figure 1), such that they are more densely packed towards the upper and lower edges than in the center region of each panel.’” Sun Infringement Claim Chart for U.S. Patent No. 11,445,512 (the “’512 Patent”), Ex. 4 to District Court Complaint at pp. 14-15.



Ex. 13, Fig. 14.

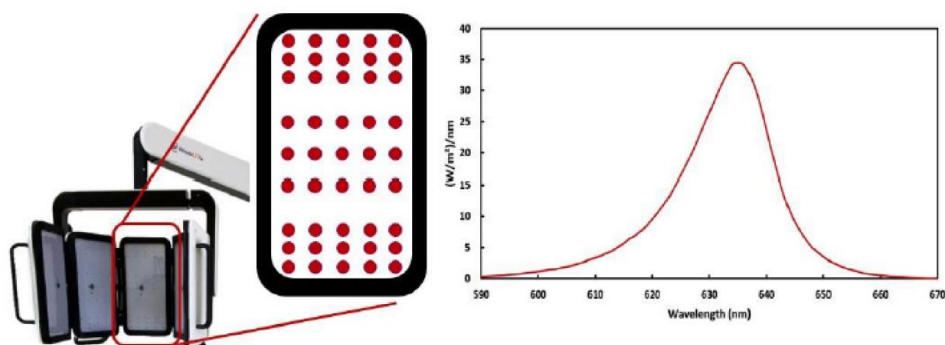


Figure 1: LED panels with LED distribution and emission spectrum of RhodoLED® XL LEDs.

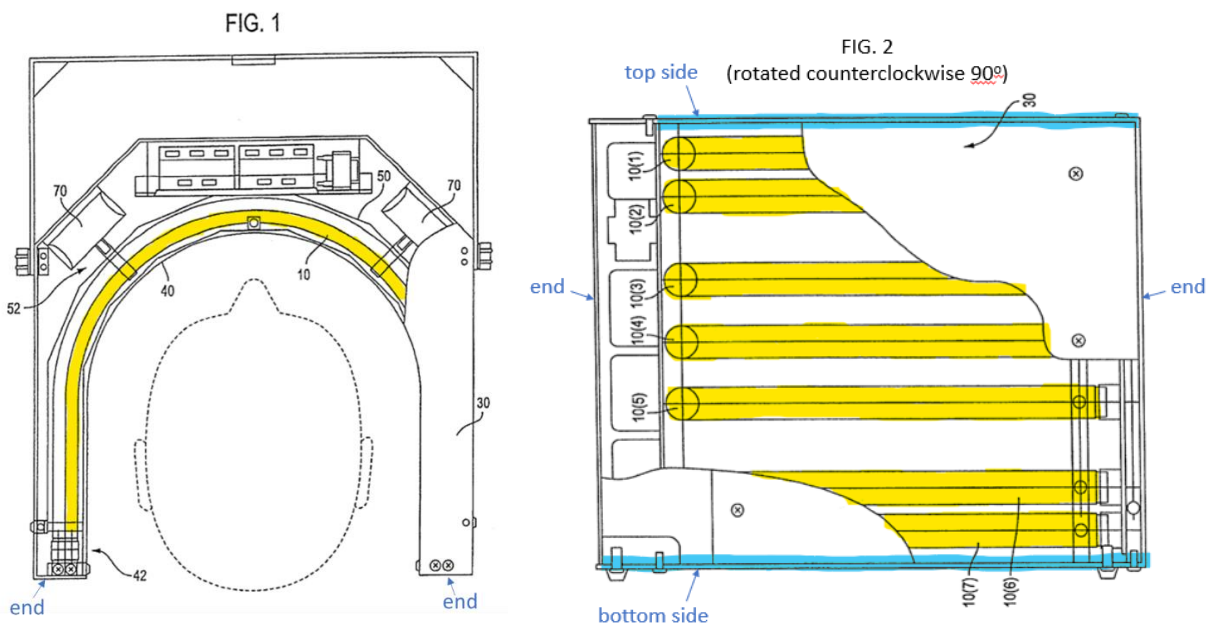
Id.

186. Based on the above, the '512 patent owner has not provided any guidance regarding the meaning of the claimed “higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges” limitation, but has asserted that the light arrangement present in the BF-RhodoLED XL panels meets the claim requirement, as illustrated in the picture and illustration of BF-RhodoLED XL above.

187. Again, I reiterate my opinion that the “higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges” term

is indefinite. However, using the '512 patent owner's assertions of what is required by this claim language, Lundahl discloses this limitation.

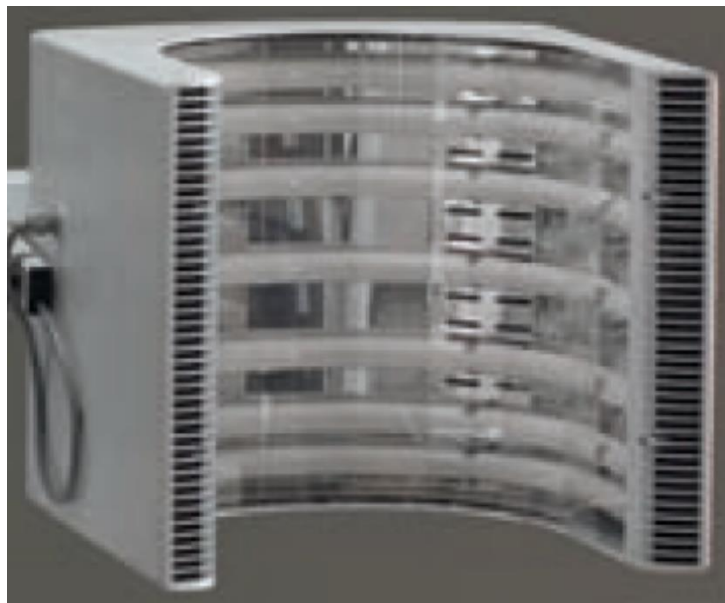
188. Lundahl teaches that “[t]he number of tubes used and the spacing between them were chosen to achieve desired uniformity and power output specifications.” Lundahl, 6:43-45. As shown in the annotated Figures 1 and 2 of Lundahl below (with the light tubes highlighted yellow, the top and bottom sides highlighted blue, and Figure 2 rotated to show the apparatus as oriented during operation), “[o]ptimum output distribution has been found to occur when seven tubes 10(1)-10(7) are placed in the chassis in a symmetric pattern with respect to opposite edges of the unit” Lundahl, 6:45-48.



189. Lundahl includes the “following approximate lateral spacing: 7 cm between the center tube 10(4) and each of the two tubes 10(3),10(5) adjacent to the center tube 10(4); 5 cm between the tubes 10(3),10(2) and 10(5),10(6), i.e., the next pairs of tubes out from the center; and 3.5 cm between tubes 10(2),10(1) and 10(6),10(7), i.e., the outermost pairs of tubes at the sides of the unit.” Lundahl, 6:48-54. Lundahl also states that “[t]he outermost tubes 10(1),10(7) are

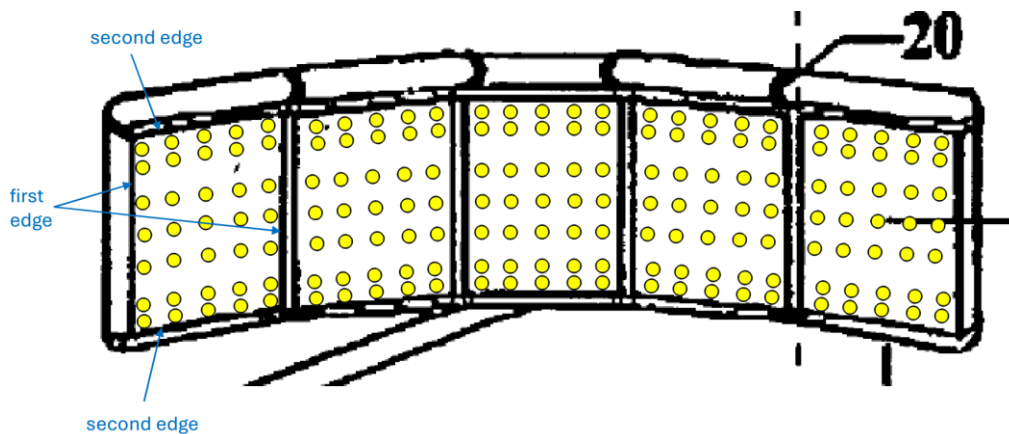
approximately 2.5 cm from the edges of the housing” and “[t]he present invention provides a highly uniform output irradiance without the use of an additional diffusing element.” Lundahl, 6:54-57. A POSITA would have understood that the tubes of Lundahl are spaced to emit a higher intensity of light proximate the top and bottom sides compared to the intensity of light emitted not proximate the top and bottom sides.

190. Lundahl discloses a single-panel fixed U-shape device. A POSITA would know from the Lundahl disclosure (including the combined disclosure of Figures 1 and 2 above), that these curved tubes extend from one side of the “U” shape to the other. While not part of the Lundahl disclosure, the picture below illustrates this understanding, and how a POSITA would expect to view the Lundahl device if viewed from the front, instead of the top (as in Figure 1 of Lundahl):



See M. Gold, “Lasers and Light Treatments for Acne Vulgaris, Promising Therapies,” J. of Clinical Aesthetic Dermatology, Vol. 1, No. 3, pp. 28-34, at 29 (Sept. 2008). One can see that the tubes in the illustration above are situated in the same distribution pattern illustrated in Figure 2 of Lundahl, but with a perspective that allows one to visualize the three-dimensional shape of the fixed “U” shape of Lundahl.

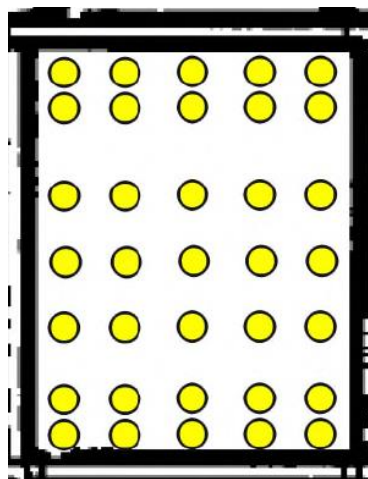
191. As discussed in the motivation to combine section, a motivation existed to combine the teachings of Lundahl and Larsen to: (1) incorporate the hinged panels of Larsen into the PDT device of Lundahl to increase the adaptability of the device; and (2) replace the fluorescent bulbs of Lundahl with LEDs. By combining the design principles of Larsen related to hinged panels and LED lights with the PDT device and light distribution of Lundahl, a POSITA would expect the resulting device to have a design similar to the below (yellow circles representing LEDs):



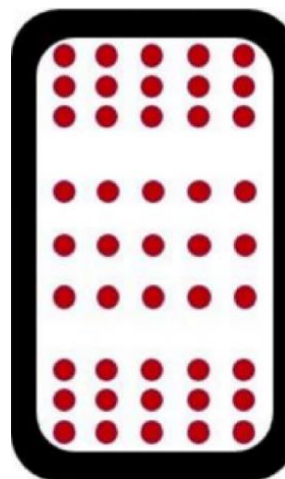
192. The annotated figure above demonstrates a rendering whereby the hinged panels and LEDs taught by Larsen are incorporated into the device of Lundahl, while maintaining the same light distribution pattern Lundahl utilized for the fluorescent bulbs, as shown in Figure 2 above and the accompanying disclosure.

193. The light distribution illustrated in the annotated figure above is nearly identical to the light distribution in BF-RhodoLED XL, which Sun has asserted to meet the claimed requirement of “higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges.” To illustrate, below is a side-by-side comparison of the light distribution/arrangement rendered obvious Lundahl and Larsen, and the light distribution/arrangement in BF-RhodoLED XL:

Lundahl and Larsen:



BF-RhodoLED XL:



194. Thus, while it is my opinion that the “higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges” claim language is indefinite, the light arrangement/distribution rendered obvious by Lundahl and Larsen (shown above) is very similar to what Sun has asserted to meet the “higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges” limitation in the BF-RhodoLED XL.

195. A POSITA would have found it obvious and would have been motivated with a reasonable expectation of success to incorporate the uneven spacing of light sources of Lundahl to increase the intensity of light emitted from the second edges (e.g., extending along the top and bottom sides of the panel arrangement) of the panels of Larsen compared to regions not proximate to the second edges.

196. Therefore, in my opinion, Lundahl in view of Larsen renders obvious this claim limitation.

197. For these reasons, in my opinion, claim 1 is obvious over Lundahl in view of Larsen.

Claim 3: “The system of claim 1, wherein the illuminator is configured to output red light at a dose of about 30 J/cm² to about 150 J/cm².”

198. The combination of Lundahl in view of Larsen renders obvious the system of claim 1, for all the reasons given above. Lundahl also teaches and renders obvious the use of red light at a dose of 30 J/cm² to 150 J/cm². Lundahl, 15:55-61 (incorporating Kennedy, 4:3-8, 4:60-65, 5:54-56.

199. Lundahl teaches that “[s]ince total light Dose (J/cm²) = Irradiance (W/cm²) × Time (sec), the only additional parameter that needs to be controlled for delivery of the correct treatment light dose is exposure time”, which is “accomplished in a preferred embodiment of the present invention by the timer which controls electrical power to the ballasts and which can be set by the physician.” Lundahl, 15:55-61.

200. Additionally, in its discussion of the background on PDT treatment, Lundahl states “[g]eneral background information on PDT using 5-aminolevulinic acid (“ALA”) as the precursor of a photoactivatable agent can be found in U.S. Pat. No. 5,079,262, entitled “Method of Detection and Treatment of Malignant and Non-Malignant Lesions Utilizing 5-Aminolevulinic Acid,” issued to James C. Kennedy et al. on Jan. 7, 1992, and U.S. Pat. No. 5,211,938, entitled “Method of Detection of Malignant and Non-Malignant Lesions by Photochemotherapy of Protoporphyrin IX Precursors,” issued to James C. Kennedy et al. on May 18, 1993. The contents of these patents are incorporated herein by reference.” Lundahl expressly incorporates all teachings of U.S. Patent No. 5,079,262 to Kennedy et al. (“Kennedy”).

201. Kennedy teaches that red light was preferred for PDT, as it penetrates deeper into the skin, as compared to blue light, and PpIX (the compound produced by topical application of ALA) strongly absorbs red light. Kennedy states “[a] method of detecting and treating malignant and non-malignant tissue abnormalities and lesions of the skin” in which “5-aminolevulinic acid

is administered to the patient.” Kennedy, Abstract. Kennedy states that “[i]n preferred aspects of this invention the preferred precursor of protoporphyrin IX is 5-amino-4-oxo-pentanoic acid, otherwise known as 5-aminolevulinic acid, and a preferred wavelength of the photoactivating light is in the range 350-640 nm, more preferably a red light of about 610-630 nm.” Kennedy, 4:3-8. Kennedy also states that “[t]he wavelength of the photoactivating light is of some importance, as it has been shown that between 1 and 10 percent of incident red light (600-700 nm) can pass through a slab of human tissue 1 cm thick, whereas only 0.001 percent or less of blue light (about 400 nm) can pass through the same thickness of human tissue. The photosensitizer will, therefore, be more successful if it strongly absorbs red light. PpIX does strongly absorb red light.” Kennedy, 4:60-69.

202. Further, Kennedy teaches and renders obvious a red light dose of 30 J/cm² to 150 J/cm². Kennedy, 6:5-37, 5:54-56, 5:47-6:47 (Examples); Ex. 1016, ¶¶55-56. Examples 1-4 of Kennedy provide PDT treatment of patients with various skin conditions and disease states, including specific light doses 52.5 mWhr/cm² (Example 1); 26 mWhr/cm² (Example 2); 17, 26, and 50 mWhr/cm² (Example 3); and 37 mWhr/cm² (Example 4). Kennedy, 5:47-6:47 (Examples); Ex. 1016, ¶¶55-56. In all cases, treatment was found to effectively resolve the treated lesions. Kennedy, 5:47-6:47 (Examples); Ex. 1016, ¶¶55-56. As 1 mWhr/cm² = 3.6 J/cm², examples 1-4 of Kennedy provide PDT treatment with red light doses ranging from approximately 61 J/cm² to 189 J/cm². It has been explained to me that a prior art disclosure of a single value within a claimed range is considered to disclose or anticipate that range.⁷ Therefore, Kennedy’s teaching of red light

⁷ “[W]hen, as by a recitation of ranges or otherwise, a claim covers several compositions, the claim is ‘anticipated’ if one of them is in the prior art.” *Titanium Metals Corp. v. Banner*, 778 F.2d 775,

doses ranging from 61 J/cm² to 189 J/cm², including specific values of 61.2 J/cm² (Example 3), 93.6 J/cm² (Example 2), and 133.2 J/cm² (Example 4), disclose the claimed range of 30 J/cm² to 150 J/cm².

203. Further, as noted above, total light Dose (J/cm²) = Irradiance (W/cm²) × Time (sec), meaning the dose is simply a function of the amount of time the patient is exposed to the light at the specific irradiance. Consequently, a POSITA knew and understood that any of the doses reported in Examples 1-4, that is, 52.5 mWhr/cm² (Example 1); 26 mWhr/cm² (Example 2); 17, 26, and 50 mWhr/cm² (Example 3); and 37 mWhr/cm² (Example 4) could be changed to a different light dose of any value in the range from 30 J/cm² to 150 J/cm² simply by increasing or decreasing the light exposure time. Because of this ability to routinely optimize the light dose, the claimed range of 30 J/cm² to 150 J/cm² is also rendered obvious by Kennedy.⁸

204. Additionally, Larsen teaches that its applicators are configured to output red light, stating “devices are available for the photodynamic stimulation of human cell energy in the form of red and infrared radiation” Larsen, [0024]. Larsen also teaches using light radiation within the wavelength of 300 – 2000 nm, which includes red light. Larsen, [0025], [0071]-[0076], [0083]. As such, Larsen also renders obvious the use of red light at a dose of about 30 J/cm² to about 150 J/cm².

205. Therefore, in my opinion, claim 3 is obvious over Lundahl in view of Larsen.

782, 227 USPQ 773 (Fed. Cir. 1985) (citing *In re Petering*, 301 F.2d 676, 682, 133 USPQ 275, 280 (CCPA 1962)).

⁸ “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

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

206. The combination of Lundahl in view of Larsen renders obvious the system of claim 1, for all the reasons given above. Lundahl teaches that “[a]ccording to one preferred embodiment of the present invention, blue light having wavelengths exceeding 400 nm (nanometers) is particularly advantageous for certain diagnostic purposes and treatments, especially when ALA is the photoactivatable agent used for PD and PDT of actinic keratosis” and that “visible light in other ranges of the spectrum, particularly in the green and red ranges between 400 and 700 nm, may also be used.” Lundahl, 2:18-26. Lundahl further states that, in certain embodiments, “the visible light has a nominal wavelength of 417 nm.” Lundahl, 15:53-54. Thus, Lundahl discloses the claimed requirement that “a plurality of the light sources are configured to emit light having a wavelength in a range of 400 nm to 700 nm.”

207. Therefore, in my opinion, claim 5 is obvious over Lundahl in view of Larsen.

'512 Patent: Claim 8

8. 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,
 - [c] the illuminator comprising at least five panels connected by nested hinges on inner side surfaces of adjacent panels; and
 - [d] uniformly illuminating a treatment surface of the patient
 - [e] with light sources disposed on the at least five panels of the illuminator,
 - [f] wherein each of the at least 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 8[preamble]: “A method of photodynamically diagnosing or treating a patient, comprising:”

208. Lundahl discloses a “method for photodynamic treatment (PDT) or diagnosis (PD) of actinic keratosis of the scalp or facial areas of a patient” and “PDT and PD of other indications (e.g., acne) and other areas of the patient (e.g., arms, legs, etc.).” Lundahl, 1:9-17. Larsen similarly discloses a method for photodynamically diagnosing or treating a patient: “[t]he 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].

209. Therefore, in my opinion, Lundahl and Larsen each disclose this claim limitation.

Claim 8(a): “administering 5-aminolevulinic acid (ALA) to the patient;”

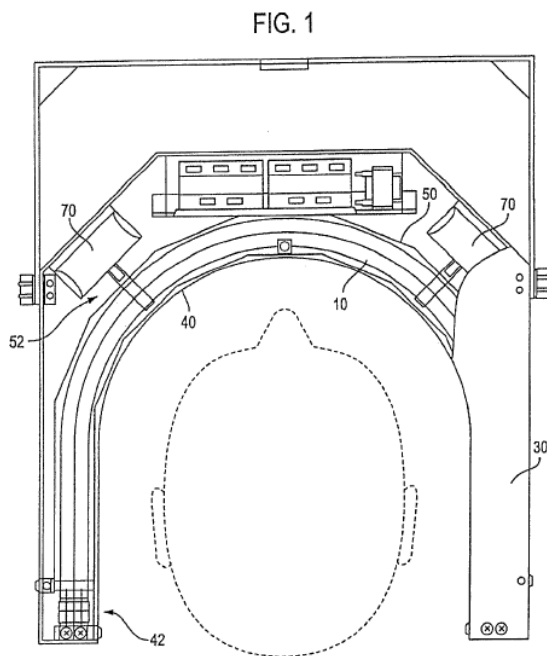
210. Lundahl teaches that “[a]ccording to one preferred embodiment of the present invention, blue light having wavelengths exceeding 400 nm (nanometers) is particularly advantageous for certain diagnostic purposes and treatments, especially when ALA is the photoactivatable agent used for PD and PDT of actinic keratosis” and that “visible light in other ranges of the spectrum, particularly in the green and red ranges between 400 and 700 nm, may also be used.” Lundahl, 2:18-26. Lundahl describes applying ALA to a patient for the treatment of actinic keratosis, stating “[o]ne example of a treatment method for precancerous lesions, such as actinic keratosis, by PDT utilizing an illuminator described above in conjunction with 5-aminolevulinic acid (ALA) will now be described. Essentially anhydrous ALA is admixed with a liquid diluent just prior to its use. The ALA admixture is topically applied to the lesions using a point applicator to control dispersion of the ALA admixture.” Lundahl, 15:30-37.

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

Claim 8(b): “positioning an illuminator proximate to the patient,”

212. Lundahl teaches positioning the PDT device proximate to the patient's head for treatment. Lundahl states "the present invention uses a U-shaped emitting surface that more closely follows the contours of the human face and scalp, and minimizes lamp to target distance variations which in turn minimizes irradiance variations at the target." Lundahl, 4:33-38.

213. Additionally, Lundahl illustrates the positioning of the PDT device proximate to the patient's head in Figure 1:



Lundahl, Fig. 1.

214. Therefore, in my opinion, Lundahl discloses this claim limitation.

Claim 8(c): "the illuminator comprising at least five panels connected by nested hinges on inner side surfaces of adjacent panels; and"

215. As discussed in my analysis for claim 1(a), it is my opinion that the "nested hinges" term is indefinite, but using the '512 patent owner's assertions of what is required by "nested hinges on inner side surfaces of adjacent panels," (i.e., hinges that fit on inner side surfaces of adjacent panels), Larsen discloses this limitation. Larsen discloses or renders obvious an

illuminator comprising at least five panels connected by hinges that fit on inner side surfaces of adjacent panels, for the same reasons given for claim 1(a) above.

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

Claim 8(d): “uniformly illuminating a treatment surface of the patient”

217. In my opinion, Lundahl and Larsen disclose this claim limitation for the same reasons given for claim 1(c) above.

Claim 8(e): “with light sources disposed on the at least five panels of the illuminator,”

218. In my opinion, Larsen discloses this claim limitation for the same reasons given for claim 1(b) above.

Claim 8(f): “wherein each of the at least five panels has two first edges and two second edges shorter than the two first edges, and”

219. In my opinion, Larsen discloses this claim limitation for the same reasons given for claim 1(e) above.

Claim 8(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.”

220. In my opinion, this claim limitation is obvious over Lundahl in view of Larsen for the same reasons given for claim 1(f) above.

221. Accordingly, in my opinion, claim 8 is obvious over Lundahl in view of Larsen.

’512 Patent: Claim 20

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

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

[b] light sources disposed on surfaces of the at least five panels,

[c] the illuminator being configured to uniformly illuminate a treatment surface of the patient via the light sources,

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

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

[f] 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.

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

222. In my opinion, Lundahl and Larsen disclose this claim limitation, for all the reasons given above with respect to the preamble of claim 1.

Claim 20(a): “an illuminator comprising at least five panels connected by nested hinges on inner side surfaces of adjacent panels,

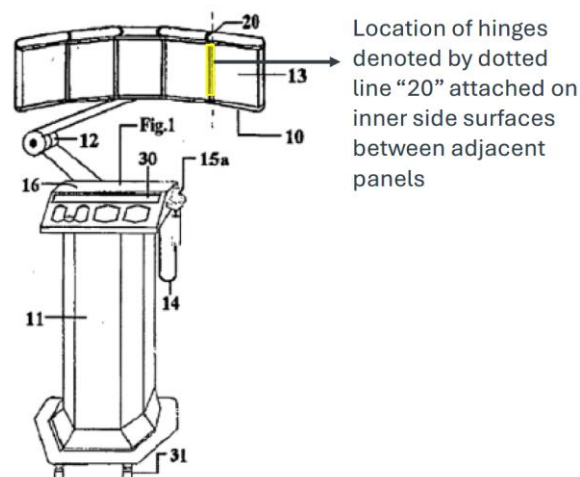
223. As discussed in my analysis for claim 1(a), it is my opinion that the “nested hinges” term is indefinite, but using the ’512 patent owner’s assertions of what is required by “nested hinges on inner side surfaces of adjacent panels,” (i.e., hinges that fit on inner side surfaces of adjacent panels), Larsen discloses this limitation. Larsen discloses or renders obvious an illuminator comprising at least five panels connected by hinges that fit on inner side surfaces of adjacent panels, for the same reasons given for claim 1(a) above.

Claim 20(b): “the nested hinges being configured so as to allow continuous illumination across the at least five panels,”

224. As an initial matter, the ’512 patent does not state or define what is meant by “continuous illumination” across the at least five panels. However, it is my understanding that the “continuous illumination across the at least five panels” is the result of the configuration of the “nested hinges,” which the ’512 patent owner alleges to simply be “hinges that fit on inner side surfaces of adjacent panels.” In view of this, it is my understanding that “nested hinges” configured

in a way to minimize the gap between adjacent panels would “allow continuous illumination across the at least five panels.” Larsen discloses or renders obvious this limitation.

225. As an initial matter, Figure 1 of Larsen illustrates that the adjacent panels are connected by “nested hinges” fit on the inner side surfaces of the adjacent panels, as illustrated below:



The orientation of adjacent panels illustrated in Figure 1, with “nested” hinges that fit on the inner side surfaces between adjacent panels demonstrates minimal/no gap between the adjacent panels, which is a configuration that would “allow continuous illumination across the at least five panels.”

226. Additionally, Larsen teaches that “[i]n each applicator the printed circuit board carrying the light sources is connected to a small electrical scan engine 66, which can move the light sources with linear movements, 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]. Emphasis added. By preventing any “unradiated gaps” on the radiated surface (i.e., the treatment surface), Larsen teaches that the “nested hinges” connected to the inner side surfaces of the adjacent panels (as illustrated in Figure 1) are “configured so as to allow continuous illumination across the at least five panels.”

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

Claim 20(c): “light sources disposed on surfaces of the at least five panels,”

228. In my opinion, Larsen discloses this claim limitation, for all the reasons given above with respect to claim 1(b).

Claim 20(d): “the illuminator being configured to uniformly illuminate a treatment surface of the patient via the light sources,”

229. In my opinion, Lundahl and Larsen disclose (or Lundahl in view of Larsen renders obvious) this claim limitation, for all the reasons given above with respect to claim 1(c).

Claim 20(e): “one of the at least five panels positioned as a center panel configured to face the treatment surface, and two or more of the at least five panels being configured to be angled relative to the center panel,”

230. In my opinion, Larsen discloses this claim limitation, for all the reasons given above with respect to claim 1(d).

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

231. In my opinion, Larsen discloses this claim limitation, for all the reasons given above with respect to claim 1(e).

Claim 20(g): “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.”

232. In my opinion, this claim limitation is obvious over Lundahl in view of Larsen, for all the reasons given above with respect to claim 1(f).

233. Therefore, in my opinion, this claim is obvious over the combination of Lundahl in view of Larsen.

B. Lundahl in view of Larsen further in view of Hente renders obvious at least claims 1, 3, 5, 8, 17, 18, and 20 of the '512 Patent

234. My previous analysis provided in Ground 1, outlining the obviousness of claims 1, 3, 5, 8, and 20 over Lundahl in view of Larsen, is incorporated herein in its entirety. Additionally, limitations 1(a), 8(b), and 20(a) recite the requirement of an “illuminator comprising at least five panels connected by nested hinges on inner side surfaces of adjacent panels.” ’512 Patent, 10:24-26 (claim 1), 10:65-67 (claim 8), and 12:19-21 (claim 20). For these limitations, Hente’s teachings are in addition to what Lundahl and Larsen already teach as discussed in Ground 1.

Claim 1(a), 8(b), and 20(a): “an illuminator comprising at least five panels connected by nested hinges on inner side surfaces of adjacent panels”

235. As discussed in my analysis for claim 1(a), it is my opinion that the “nested hinges” term is indefinite, but using the ’512 patent owner’s assertions of what is required by “nested hinges on inner side surfaces of adjacent panels,” (i.e., hinges that fit on inner side surfaces of adjacent panels), Hente discloses this limitation.

236. Hente teaches a light emitting device with at least one first section and at least one second section. Hente, Abstract. Hente states that the lighting device can be used in multiple orientations, including flat and angled (folded) orientations, stating “the disclosed light emitting device possesses two different positions, each resulting in a different type of illumination. In the expanded position the light emitting device forms a longish stretched large area illumination device. In this context the longish stretched arrangement is not limited to a rectangular form but can also include slightly curved or spherically bent arrangements. The sections of the light emitting device may also be arranged in a V- or a W-form, depending on the type of use.” Hente, [0011]. “To achieve the object of the invention the light emitting device 10 can either be used as a large area illumination device or as a small point like light source. In FIG. 2 the light emitting device 10 is shown in an expanded position 100...In the expanded position 100 the first section 20 and the second section 30 are arranged in such a way, that they form a longish stretched sheet like light

emitting device 10...To enable the light emitting device to be converted from the expanded position 100 into the compact position 110 the sections 20, 30 are connected through a connection mean 50.” Hente, [0036]-[0037]. Figure 2 is provided below, and represents the arrangement described by Hente that “can include slightly curved spherically bent arrangements,” as well a “V-form”:

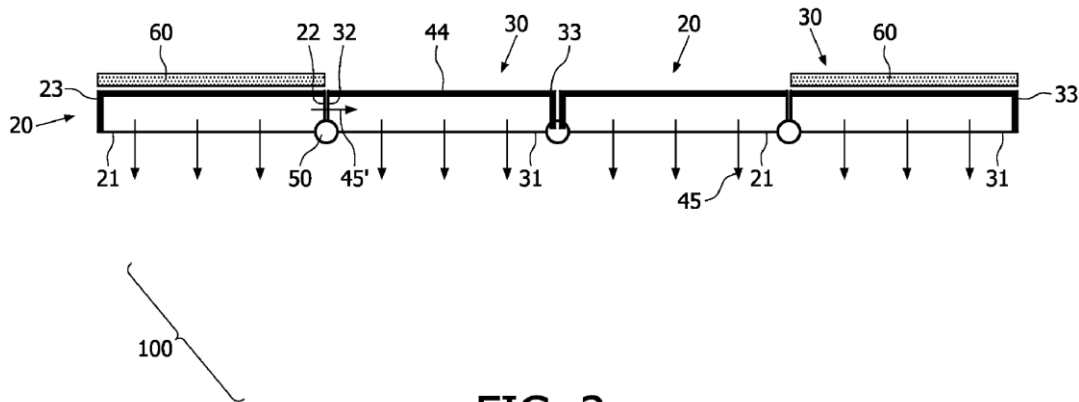
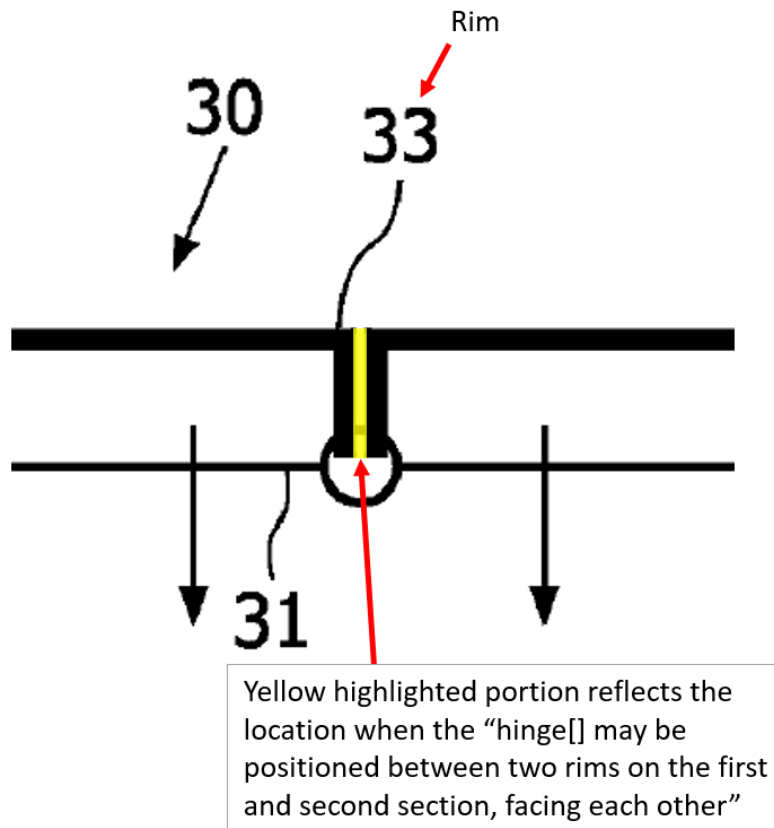


FIG. 2

Hente, Fig. 2.

237. Hente further explains that connection mean 50 may be a hinge, stating “[i]n a preferred embodiment the connection mean may be a hinges [sic], being positioned at the outer rims of the light emitting device respectively sections. Depending on the position of the side surfaces, *the hinges may be positioned between two rims of the first and the second section, facing each other.*” Hente, [0015] (emphasis added). The “first and second section” referenced in the passage above is understood to represent the first section 20 and the second section 30 illustrated in Figure 2. Additionally, Hente explains that the “rim” components are represented by 23 and 33 in the figures. Hente, [0048], [0052]. Consequently, the annotated version of Figure 2 below illustrates the location of the rims and the hinge “positioned between two rims of the first and second section, facing each other”:



238. As shown in annotated Figure 2 above, Hente discloses the placement of a hinge between two rims of the first and second section, facing each other, meeting the requirement of a “hinge[] that fits on inner side surfaces of adjacent panels,” which Sun alleges to meet the claimed “nested hinge.”

239. A POSITA would have found it obvious and would have been motivated with a reasonable expectation of success to place Hente’s hinges in a location that fits on the inner side surfaces of adjacent sections. First, Figure 2 of Hente illustrates that the inner edges of adjacent sections 20 and 30 are nearly flush with each other. This disclosure would have motivated a POSITA to fit the hinges on the inner side surfaces of Larsen’s panels in order to facilitate this nearly flush arrangement. In my opinion, this is nothing more than applying a known prior art

design element to a known device (i.e., the panels of Larsen) to predictably decrease the space between the adjacent panels. There is nothing novel or non-obvious about this design process.

240. Hente is from the same field of endeavor as the '512 Patent, which also describes illuminators. '512 Patent, 1:24-2:4. A POSITA would be well aware of the potential benefits related to maintaining close proximity between illuminator panels to minimize the distance between, and thereby improve the uniformity of light from, the panels. Hente describes a number of “folding” orientations whereby certain examples (e.g., Figure 2) involve the folding of adjacent light surfaces/sections toward one another, and certain other orientations whereby adjacent light surfaces/sections fold away from one another (e.g., Figure 3). Regardless, the principles associated with the placement of hinges on inner side surfaces of adjacent sections/panels apply to the panels of the Larsen display, as a POSITA was motivated to enhance adjustability of the illuminator rendered obvious by Lundahl and Larsen. Given this knowledge, a POSITA was motivated to combine the hinge system of Hente (i.e., hinges that fit and attach on inner side surfaces of adjacent panels) with the panels of Larsen. Thus, Larsen in view of Hente renders obvious this requirement of a “nested” hinge, and the claim limitation requiring “an illuminator comprising at least five panels connected by nested hinges on inner side surfaces of adjacent panels” is taught and rendered obvious by the prior art.

241. Therefore, in my opinion, Larsen in view of Hente discloses or renders obvious claims 1(a), 8(b), and 20(a).

242. Consequently, Lundahl in view of Larsen further in view of Hente renders obvious claims 1, 3, 5, 8, and 20 of the '512 Patent.

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

243. My previous analysis outlining the obviousness of claim 8 over Lundahl in view of Larsen further in view of Hente is incorporated herein in its entirety.

244. Hente renders obvious the requirement that “at least one panel includes a recess configured to receive a flange of one of the nested hinges,” as required by claim 17. As I have noted in the Claim Construction section, it is my opinion that the term “a recess” should be construed consistent with its plain and ordinary meaning of “an indentation in a surface.” Based on this construction, claim 17 requires “an indentation in a surface configured to receive a flange of one of the nested hinges.”

245. As shown in the annotated figure below, Hente discloses the placement of a hinge in a location that fits on the inner side surfaces between adjacent sections.

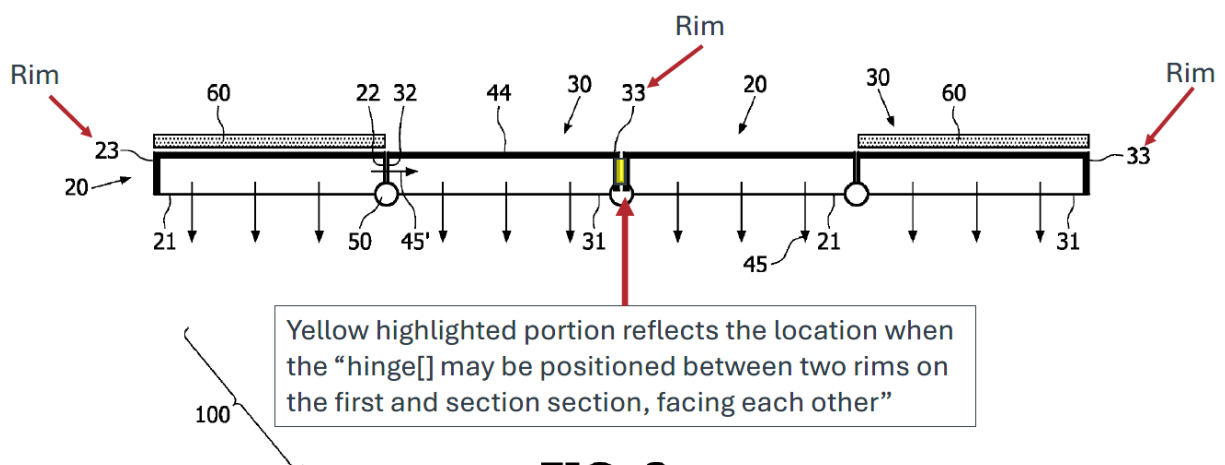
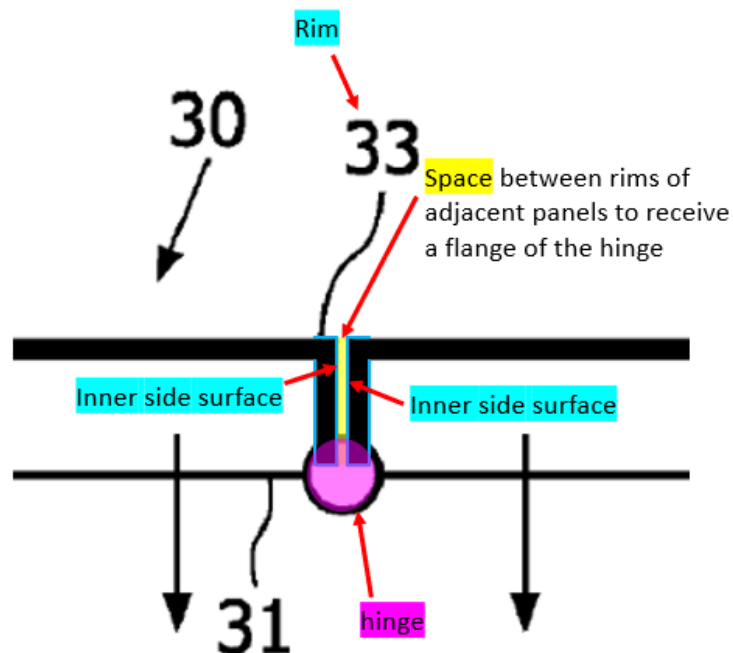
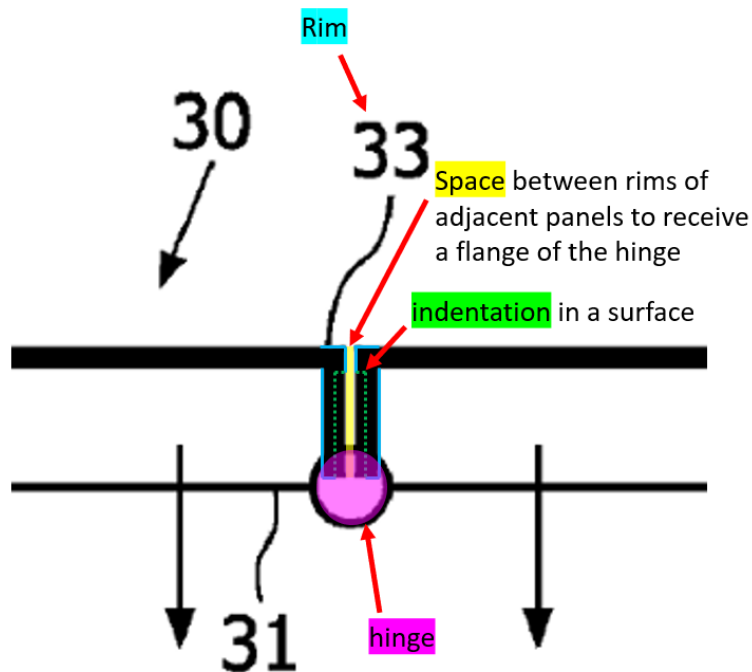


FIG. 2

246. As shown in the enlarged annotated figure below, there is a space between the rims of adjacent panels of Hente to receive a flange of the hinge.



247. A POSITA would have found it obvious and would have been motivated with a reasonable expectation of success to include an indentation at the inner side surfaces between adjacent sections to receive a flange of a hinge, as shown in the annotated figure below.



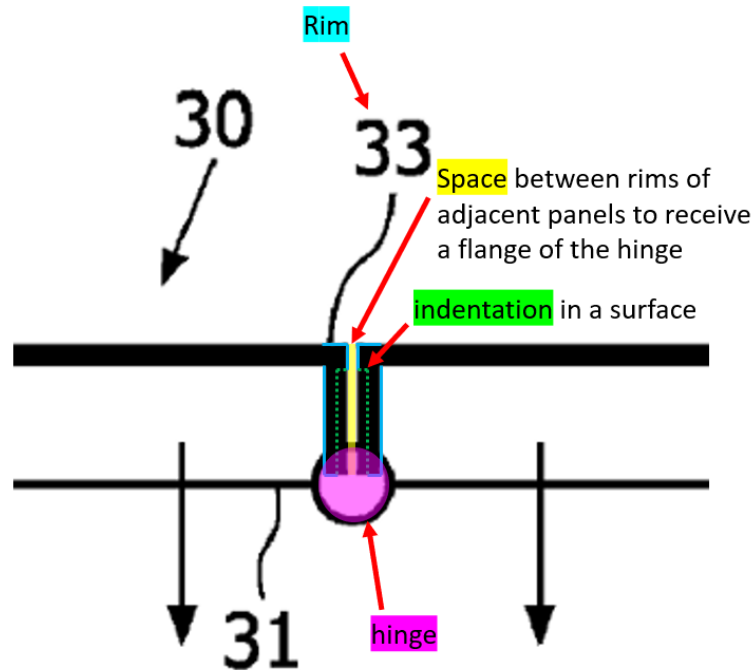
248. As illustrated in Figure 2 of Hente, the inner edges of adjacent sections 20 and 30 are nearly flush with each other. This disclosure would have motivated a POSITA to place the flange of the hinges in an indentation at the inner side surfaces of Larsen's panels in order to facilitate this nearly flush arrangement, and to minimize the space between the adjacent sections, which was a well-established design motivation from the teachings of Hente and Larsen. Again, this is nothing more than applying known design elements and strategies to a known device (i.e., the panels of Larsen) to predictably decrease the space between the adjacent panels.

249. Therefore, in my opinion, Lundahl in view of Larsen further in view of Hente renders obvious claim 17.

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

250. My previous analysis outlining the obviousness of claim 17 over Lundahl in view of Larsen further in view of Hente is incorporated herein in its entirety.

251. As I discussed previously, A POSITA would have found it obvious and would have been motivated with a reasonable expectation of success to include an indentation at the inner side surfaces between adjacent sections to receive a flange of a hinge, as shown in the annotated figure below.



252. As shown in the annotated figure above, Hente renders obvious the placement of the indentations at the inner side surfaces of the adjacent section, meeting the claimed requirement that “the recess is positioned at an inner side surface of the at least one panel.”

253. Therefore, in my opinion, Lundahl in view of Larsen further in view of Hente renders obvious claim 18.

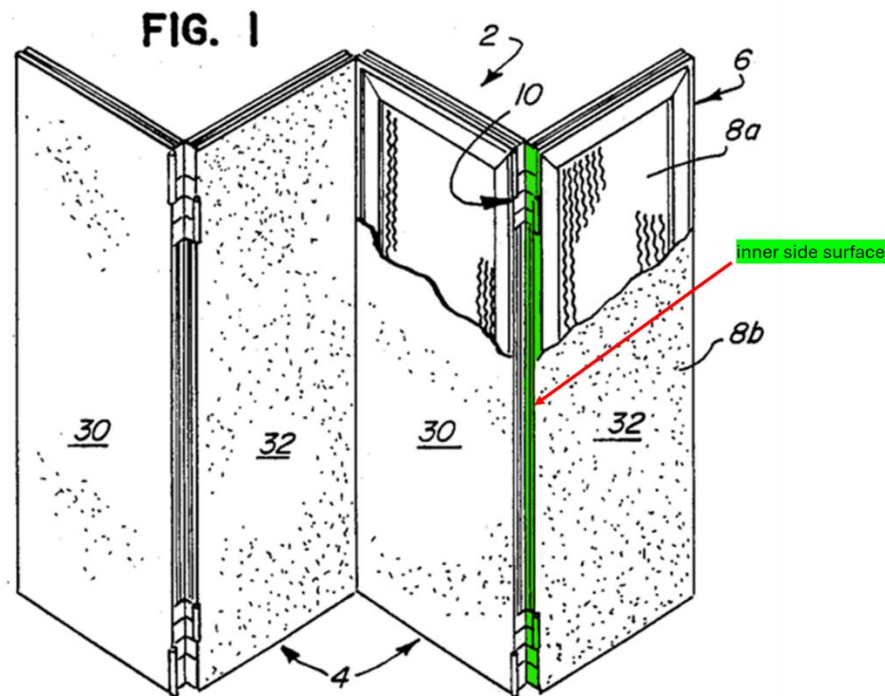
C. Lundahl in view of Larsen, further in view of Hente, and further in view of Perutz, renders obvious at least claims 17 and 18 of the '512 Patent

254. Claims 17 and 18 depend from independent claim 8. My discussion outlining the obviousness of claim 8 over Lundahl in view of Larsen further in view of Hente in Ground 2 is incorporated herein in its entirety.

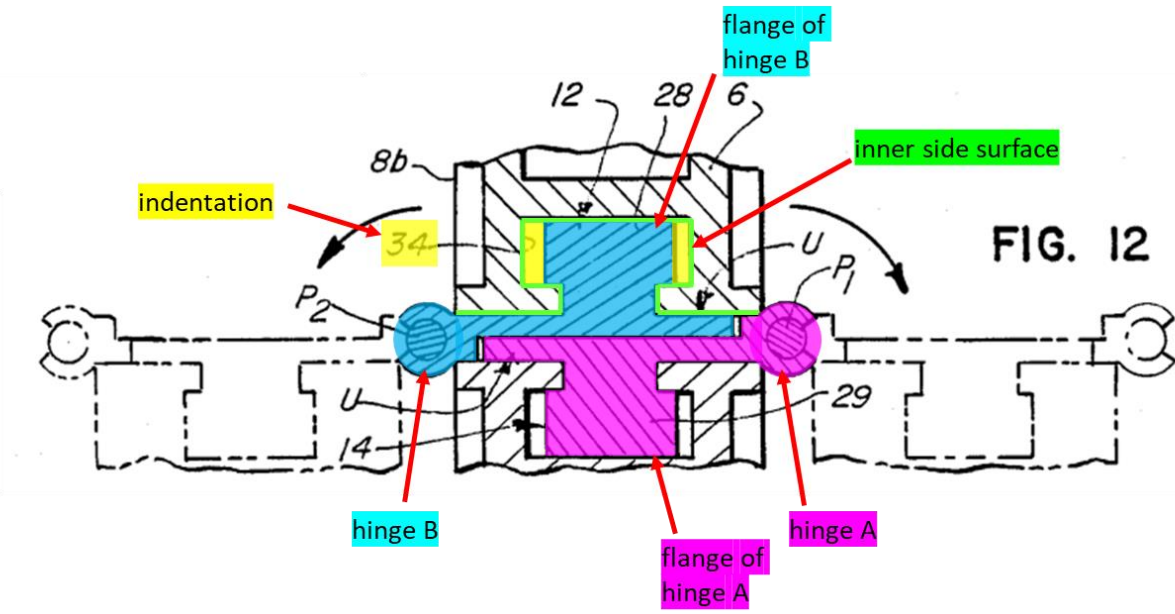
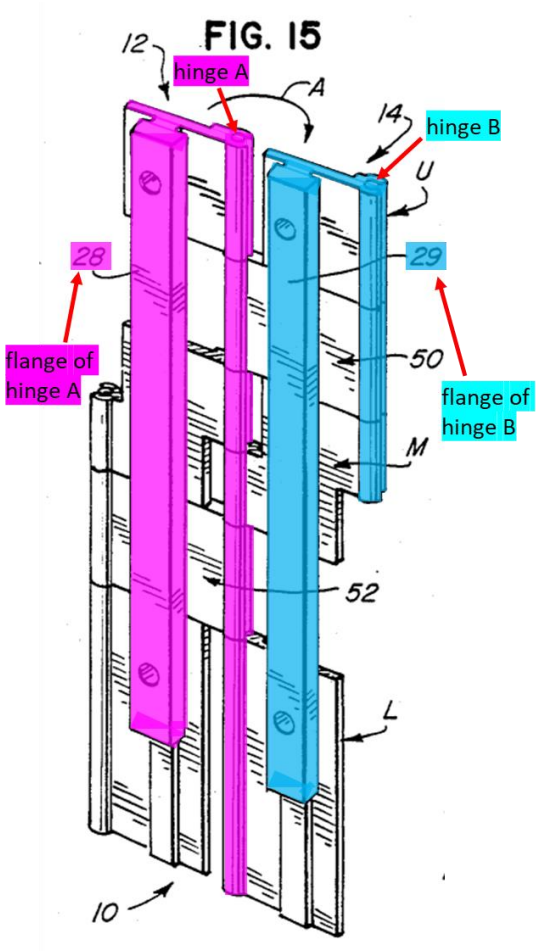
Claim 17: “The method of claim 8, wherein at least one panel includes a recess configured to receive a flange of one of the nested hinges.”

255. Perutz teaches a display panel and hinge system having “a plurality of display panels arranged in side by side relation and hingedly interconnected whereby one of the panels is capable of being selectively rotated relative to the other panel through a maximum arc of

substantially 360°.” Perutz, Abstract. Perutz teaches connecting adjoining display panels 30, 32 with hinges 10, the display panels 30, 32 having a frame 6. Perutz, 3:54-66. As shown in annotated Figure 1 below, the hinges 10 connect adjoining display panels 30, 32 at an inner side surface of the display panels 30, 32.



256. Perutz states that the segments of the hinge 10 “are maintained in vertically spaced alignment by an elongated rib or strut 28, 29,” with the ribs 28, 29 being received within slots 34 “formed in the corners of the frame 6 of the adjacent display panels.” Perutz, 4:16-20 and 33-38. As shown in annotated Figures 12 and 15 below, the side surface of adjoining display panels includes an indentation in a surface (e.g., slot 34 in frame 6) to receive the side-mounted hinges, specifically a flange (e.g., ribs 28, 29) of the hinges 10, to reduce space between adjoining display panels.



257. A POSITA would be well aware of the potential benefits related to maintaining close proximity between panels, whether the panels are light panels of an illuminator or adjacent panels of a display panel assembly, to minimize the distance between, and improve the alignment of, the panels.

258. Thus, Perutz teaches that at least one panel includes a recess configured to receive a flange of one of the hinge structures. Based on a construction of the term “a recess” as the plain and ordinary meaning of “an indentation in a surface,” Perutz discloses at least one display panel including an indentation in a surface. As shown in annotated Figures 12 and 15 above, at least one panel of Perutz includes an indentation in a surface (slot 34 in frame 6) to receive a flange (ribs 28, 29) of the hinge (hinge 10).

259. For these reasons, in my opinion, claim 17 is obvious over Lundahl in view of Larsen, further in view of Hente, and further in view of Perutz.

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

260. The combination of Lundahl in view of Larsen, further in view of Hente, and further in view of Perutz, renders obvious the method of claim 17, for all the reasons given above. Additionally, as demonstrated in annotated Figures 1, 12, and 15 above (Figure 12 being a top view of Figure 1), the indentations in the surfaces of the adjacent panels of Perutz (i.e., the “recesses” of the adjacent panels) are located on the inner side surfaces of the adjacent panels, meeting the claimed requirement that “the recess is positioned at an inner side surface of the at least one panel.”

261. For these reasons, in my opinion, claim 18 is obvious over Lundahl in view of Larsen, further in view of Hente, and further in view of Perutz.

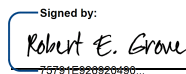
XI. CONCLUSION

262. In my opinion, claims 1, 3, 5, 8, 17, 18, and 20 of the '512 Patent are invalid for at least the reasons stated above.

263. I reserve the right to supplement my opinions in the future to respond to any arguments raised by the owner of the '512 Patent and to take into account new information that becomes available to me.

264. I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code. Signed on this 18th day of December, 2024.

Respectfully submitted,

Signed by:

75791E920920490...
Robert E. Grove, Ph.D.

APPENDIX A
MATERIALS CONSIDERED

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

- U.S. Patent No. 11,446,512
- File History for U.S. Patent No. 11,446,512
- U.S. Patent No. 11,697,028
- File History for U.S. Patent No. 11,697,028
- Levulan® Kerastick® (aminolevulinic acid HCl) for Topical Solution, 20%, Initial U.S. Approval: 1999, Revised 3/2010
- U.S. Patent No. 5,079,262
- U.S. Patent No. 6,223,071
- U.S. Patent No. 7,033,381
- File history for Application No. 17/009,871
- File history for Application No. 16/791,004
- U.S. Patent Publication No. 2005/0075703
- U.S. Patent Publication No. 2010/0118522
- U.S. Patent No. 4,823,858
- Declaration of Michael Ehrenreich, MD
- Agostinis, P et al. Photodynamic Therapy of Cancer: An Update. CA Cancer J Clin.2011; 61(4): 250-281
- M. Gold, “Lasers and Light Treatments for Acne Vulgaris, Promising Therapies,” J. of Clinical Aesthetic Dermatology, Vol. 1, No. 3, pp. 28-34, at 29 (Sept. 2008)
- Petition for *Inter Partes* Review of U.S. Patent No. 11,446,512
- American Heritage Dictionary Entry- Recess
- Merriam-Webster Collegiate Dictionary (2005)- Recess
- Merriam-Webster Dictionary (2024)- Recess
- Oxford Dictionary of Construction, Surveying, and Civil Engineering (2012)- Recess
- Oxford Dictionary (2024)- Recess
- Complainant’s Opening Claim Construction Brief (Oct. 31, 2024)
- Complainant’s Responsive Claim Construction Brief (Nov. 15, 2024)
- Complainant’s Infringement Claim Chart for U.S. Patent No. 11,445,512

Robert Grove, Ph.D.

Background

- Extensive experience with photodynamic therapies since its inception forty years ago
- Involved in the design, development, clinical research, and commercialization of photodynamic or photobiomodulatory medical devices for various applications, but mostly skin conditions
- Expertise focuses on LED and laser usage to treat and diagnose dermatologic conditions
- Reviewed the patents-in-suit and states that he is very well-qualified in the described technologies
- In 2003, was the founding CEO of a company that developed a ~650nm panel for wrinkle reduction and a 412nm handheld device for acne treatment
- Served as an advisor to the leading company in photobiomodulation for red-IR vaginal rejuvenation and other feminine wellness issues
- Named inventor on over 30 patents
- B.S. in Engineering Physics from Cornell University, M.S. in Aeronautics and Astronautics from MIT, and Ph.D. in Instrumentation, specifically in the field of laser applications

Litigation

- Served as an expert witness in five patent matters
- Deposed 2-3 times
- Has not testified in court but notes that while he prepared to testify on one matter, the case was settled as he was waiting outside the courtroom

Patents

- US 10,342,617 "Phototherapy device thermal control apparatus and method."

CURRICULUM VITAE

ROBERT E. GROVE, PH.D.

28 GREY EAGLE CT.
PLEASANTON, CA 94566

EXECUTIVE SUMMARY

Business executive and entrepreneur with a career of over forty years in the medical laser industry. Proven ability to build successful companies from concept through acquisition. Exceptionally strong technical background combined with CEO-level business management experience. Global consultant to diverse clients including private equity, law firms and medical device companies. Particular expertise in implementing recent trends in the med-device space toward recurring revenues with both Rx and OTC dermatologic devices. Public and private Board experience as well as IP litigation and deposition.

PROFESSIONAL CORPORATE EXPERIENCE

ON Light Sciences, Inc. (2013 – 2016)

Executive Chairman

Directed start-up developing transparent gel patches for accelerated tattoo removal with short-pulse lasers. Raised seed-round funding and recruited world-renowned dermatologists for clinical trials. Acquired by Merz North America in August of 2016.

Intellectual Light, Inc. (2012 – 2017)

President and CEO

Founded start-up to develop and patent a novel low-cost laser diode source for OTC devices for medical and other applications, with emphasis on patent portfolio.

Once Again Me, Inc. (2011)

President and CEO

Founded start-up, raised \$300k in seed capital, developed an innovative OTC laser beauty device and associated patent applications. Acquired by TRIA Beauty, Inc. in Dec. 2011.

TRIA Beauty Inc. (2003 – 2010)**CEO '03-'08; CTO '09-'10**

Co-founded start-up to develop, manufacture and market consumer laser devices for permanent hair removal, acne and facial wrinkle treatment at home. Directed venture capital raise, grew worldwide sales to ~\$20M while CEO.

Coherent Star, Inc. (1999 – 2001)**President**

Expanded *LightSheer™* business as part of Coherent Medical. Managed over 100 employees with revenues in excess of \$50 million.

Star Medical Technologies, Inc. (1993 – 1999)**President and CEO**

Co-founded start-up to develop, manufacture and market the first successful Rx laser hair removal system (*LightSheer™*) that remains the gold standard today. Negotiated acquisition by Coherent in 1999 for \$65 million.

DermaCare, Inc. (1987 – 1990)**President and CEO**

Co-founded one of the first laser med-spas in the US; over \$2.5 million in domestic and foreign investment. Directed operation of two clinics in S. CA with over 400 patients/month.

Cooper LaserSonics, Inc. (1984 – 1987)**President, Laser Products Division**

Integrated copper lasers into newly formed Scientific and Industrial Division; identified research clinicians to spur new product development (e.g., laser treatment of port-wine hemangiomas).

Plasma Kinetics, Inc. (1981 – 1984)**President and CEO**

Co-founded world's first commercial copper vapor laser company. Raised funding, established manufacturing operations and led global marketing effort. Negotiated acquisition by Cooper LaserSonics in 1984.

Lawrence Livermore National Laboratory (1976 – 1981)**Project Leader**

Directed Copper Laser Development for the Atomic Vapor Laser Isotope Separation Program. Managed Ph.D. scientists and engineers developing world's largest laser pump source for pulsed dye laser uranium enrichment efforts at LLNL.

CONSULTING EXPERIENCE

QPC, Inc. (2024)

Business and technical consultant for high-power diode laser manufacturer, exploring opportunities for 1726-nm acne treatment systems.

Zerigo Health, Inc. (2021 - 2023)

Technical consultant for company with innovative UVB-LED home-use devices for treatment of psoriasis, eczema and vitiligo.

Arbonne International LLC (2014 – 2018)

Conceived, designed and developed, with outside firm, a novel home-use ultrasound device for enhanced application of topicals. Achieved over \$50 million in revenues during first two years on the market with \$2.5 M investment.

Apax Partners, LLP (2017)

Assisted private equity firm in evaluation of Syneron-Candela prior to its acquisition by Apax Partners.

JLE Associates (1990 – 1993)

Worked with two other laser experts to formulate plan for new laser business to be founded and owned by Hoya Corporation of Japan.

EXPERT WITNESS/DEPOSITION EXPERIENCE

Solta Medical, Inc. v. Lumenis Ltd. and Lumenis, Inc., 19-11600 (D. Mass 2021)

Served as technical expert witness in patent infringement litigation relating to aesthetic laser technologies, including providing deposition testimony, formal written opinions on claim construction, in-depth inspections of implicated laser systems and non-infringement and invalidity analyses regarding the same.

Lumenis LTD. and Pollogen LTD. (2019)

IPR2019-01180 and -01181. IPR proceedings before the Patent Trial and Appeal Board at the U.S. Patent and Trademark Office involving patents related to RF energy skin treatment apparatus and method.

Lutronic, Inc. (2018)

ITC Investigation 337-TA-1112. Certain Radio Frequency Micro-Needle Dermatological Treatment Devices and Components Thereof. Lead technical witness for company. Consulted on all aspects of invalidity and non-infringement, including developing theories of anticipation based on inherency and developing strategies related to obviousness.

Lumenis LTD. (2013)

Labor File 30125-07-10 (Tel Aviv – Jaffa), *Lumenis Ltd. vs. Karni et al.* Suit involved alleged theft of trade secrets relating to IPL devices for dermatology.

TRIA Beauty, Inc. (2009)

Deposed during litigation between Palomar Medical Technologies and TRIA Beauty alleging infringement of Palomar/MGH hair removal patents.

INDEPENDENT CORPORATE BOARD EXPERIENCE

Candesant Corporation (March 2019 – March 2023)

Independent Director for a venture-funded biotech company developing a safe, in-office, non-drug solution to excessive sweating.

IRIDEX Corporation [NASDAQ: IRIX] (Oct. 2018 – present)

Independent Director for an industry-leading ophthalmic laser manufacturer.
Member of Compensation Committee and Audit Committee.

Ellman International, Inc. (Dec. 2013 – Sept. 2014 acquisition by Cynosure, Inc.)

Independent Director for manufacturer of advanced radio-frequency products utilized around the world for precision surgical and aesthetic procedures.

CORPORATE ADVISOR/ADVISORY BOARD EXPERIENCE

American Society for Laser Medicine and Surgery, Inc.

Appointed to the Membership Committee (*2020 and 2021*). Appointed to the Nominating Committee by the ASLMS president, Eric Bernstein, MD (*2018*).

Elected to position of Industry Research and Development Representative (*1995 – 1998*); Elected to second term (*2008 – 2011*)

Appointed Exhibits Chairperson (*1994 – 1998*).

Joylux, Inc. (2017 – present)

Advisor to the CEO, shareholder of company developing and marketing through physicians the world's first home-use device for women's intimate wellness incorporating photobiomodulation and thermal energy.

RECENT PRESENTATIONS AND AWARDS AT PROFESSIONAL MEETINGS

American Society for Laser Medicine and Surgery Annual Meeting, Baltimore, April, 2024.

Recipient of the *Presidential Citation Award*, presented at the 2024 Annual Meeting.

American Society for Laser Medicine and Surgery Annual Meeting, Denver, February 2019.
Recipient of the *Presidential Citation Award*, presented at the 2019 Annual Meeting.

9th 5-Continent Congress, Lasers and Aesthetic Medicine, Barcelona, August 2018. “Will Vaginal Rejuvenation become the Largest Home-Use Device Market?”.

American Academy of Dermatology Annual Meeting, San Diego, February 2018. “Lessons in Entrepreneurship: What I’ve Learned as Founder or Co-founder of Seven Companies”.

EDUCATION

Postdoctoral training:

Head research associate, Research laboratory of Prof. Shaoul Ezekiel; MIT, 1976.

University: Ph.D. in Instrumentation (Field of laser applications); MIT, 1975.

M.S. in Aeronautics and Astronautics; MIT, 1971.

B.S. With Distinction in Engineering Physics; Cornell University, 1970. Graduated as salutatorian of engineering class (all EP, EE, ME, ChemE, CivE students).

PUBLICATIONS

1. R. E. Grove, F. Y. Wu, L. A. Hackel, D. G. Youmans and S. Ezekiel, “Jet-stream CW Dye Laser for High Resolution Spectroscopy”, *Appl. Phys. Lett.* 23, 442 (1973).

2. F. Y. Wu, R. E. Grove and S. Ezekiel, “CW Dye Laser for Ultra-High Resolution Spectroscopy”, *Appl. Phys. Lett.* 25, 73 (1974).

3. R. E. Grove, F. Y. Wu, and S. Ezekiel, “Frequency Stabilization of a CW Dye Laser”, *Opt. Engr.* 13, 531 (1974).

4. F. Y. Wu, R. E. Grove and S. Ezekiel, “Measurement of the Resonance Fluorescence Spectrum under Monochromatic Excitation”, *Phys. Rev. Lett.* 35, 1426 (1975).

5. R. E. Grove, F. Y. Wu, and S. Ezekiel, “Measurement of the Spectrum of Resonance Fluorescence from a Two-level Atom in an Intense Monochromatic Field”, *Phys. Rev. A* 15, 227 (1977).

6. R.S. Hargrove, R. E. Grove and T. Kan, "Copper Vapor Laser Unstable Resonator Oscillator and Oscillator-Amplifier Characteristics", IEEE J. Quantum E. QE-15, 1228 (1979).
7. B. E. Warner, R. S. Anderson and R. E. Grove, "Large Bore Copper Vapor Laser", Digest of Technical Papers, Opt. Soc. of America, CLEOS Conf., 90, Feb. (1980).
8. R. E. Grove, "Copper Lasers Come of Age", Laser Focus 18, 45 (1982). Reprinted in Frontiers of Laser Technology, PennWell, Tulsa, OK (1985).

PATENTS

	Patent No.	Patent Title	Issue Date
1.	10,342,618	Self-contained, eye-safe hair-regrowth-inhibition apparatus and method	July 9, 2019
2.	10,342,617	Phototherapy device thermal control apparatus and method	July 9, 2019
3.	D794,784	Skin care device	August 15, 2017
4.	9,687,671	Optical sensor and method for identifying the presence of skin and the pigmentation of skin	June 27, 2017
5.	9,302,118	Phototherapy device thermal control apparatus and method	April 5, 2016
6.	9,172,210	Mount for semiconductor devices using conformable conductive layers, and method	October 27, 2015
7.	8,965,214	Manufacturing system and method using IR communications link	February 24, 2015
8.	8,792,527	Mount for semiconductor devices using conformable conductive layers, and method	July 29, 2014
9.	8,777,935	Optical sensor and method for identifying the presence of skin	July 15, 2014
10.	8,755,420	Failure protection apparatus and system	June 17, 2014
11.	8,728,063	Antimicrobial layer for optical output window	May 20, 2014
12.	8,681,829	Compression mount for semiconductor devices, and method	March 25, 2014
13.	8,551,104	Self-contained, diode-laser-based dermatologic treatment apparatus	October 8, 2013

14.	8,518,027	Phototherapy device thermal control apparatus and method	August 27, 2013
15.	8,512,322	Antimicrobial layer for optical output window	August 20, 2013
16.	8,340,144	Compression mount for semiconductor devices, and method	December 25, 2012
17.	7,981,111	Method and apparatus for the treatment of benign pigmented lesions	July 19, 2011
18.	7,452,356	Eye-safe dermatologic treatment apparatus	November 18, 2008
19.	7,413,567	Optical sensor and method for identifying the presence of skin	August 19, 2008
20.	7,250,045	Self-contained, eye-safe hair-regrowth-inhibition apparatus and method	July 31, 2007
21.	D535,746	Portable hair removal device	January 23, 2007
22.	7,118,563	Self-contained, diode-laser-based dermatologic treatment apparatus	October 10, 2006
23.	6,758,845	Automatic firing apparatus and methods for laser skin treatment over large areas	July 6, 2004
24.	5,835,518	Laser diode array packaging	November 10, 1998
25.	5,743,901	High fluence diode laser device and method for the fabrication and use thereof	April 28, 1998
26.	5,707,403	Method for the laser treatment of subsurface blood vessels	January 13, 1998
27.	5,527,350	Pulsed infrared laser treatment of psoriasis	June 18, 1996