

**UNITED STATES INTERNATIONAL TRADE COMMISSION
WASHINGTON, DC**

**Before the Honorable Bryan F. Moore
Administrative Law Judge**

In the Matter of

**CERTAIN PHOTODYNAMIC THERAPY
SYSTEMS, COMPONENTS THEREOF,
AND PHARMACEUTICAL PRODUCTS
USED IN COMBINATION WITH THE
SAME**

Investigation No. 337-TA-1411

EXPERT REPORT OF DR. ROBERT E. GROVE, PH.D.



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B. Lack of Enablement Under 35 U.S.C. § 112(a)

1. The Asserted Patents Do Not Enable a POSA to Make and Use a Device that “Uniformly Illuminates” a Treatment Surface

183. It is my opinion that the Asserted Claims are not enabled because a POSA would not know how to make and use an illuminator that provides “uniform illumination” of all of the various body parts disclosed by the Asserted Patents (i.e., not just the face and scalp, but also the torso (chest and back), arms, legs, etc.), and given the variations in distances from the illuminator to those regions of the body. It would require a POSA to perform undue experimentation to determine if and how “uniform illumination” may be achieved for all of these different anatomies. For reference, the language of claims 1 and 8 of the ’512 Patent (which I believe to be exemplary of the Asserted Claims) is provided below:

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

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

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

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

wherein each of the at least five panels has two 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.

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

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

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

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

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.

184. As highlighted in the exemplary claims above, the Asserted Claims require that the claimed illuminator “uniformly illuminate a treatment surface” (for the system claims) and/or “uniformly illuminating a treatment surface” (for the method claims), which I will collectively refer to as the “uniformly illuminate” limitation. While I have provided claims 1 and 8 of the ’512 Patent for reference, these same limitations are present in all Asserted Claims.

185. As an initial matter, it is my understanding that Complainant and patent owner (Sun Pharmaceuticals Industries, Inc.) and Respondent (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

[REDACTED]

treatment surface of the patient is at least within 60% of the measured maximum.” Sun’s Claim Construction Brief (public version), 9-10. Consequently, I understand that the “uniformly illuminate” limitation requires that the measured irradiance for all points on the treatment surface must be at least within 60% of the point on the treatment surface that provides the maximum measured irradiance.

186. Additionally, I understand that an invention must be enabled, meaning that the patentee is required to provide guidance and teach a POSA how to practice the full scope of the claims without undue experimentation. I understand that the relevant statutory requirement is that “[t]he specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains . . . to make and use the same.” It is also my understanding that factors considered in determining whether a disclosure would require “undue experimentation” to make and use the claims include the following: (1) breadth of the claims; (2) the quantity of experimentation necessary, (3) the amount of direction or guidance presented, (4) the presence or absence of working examples, (5) the nature of the invention, (6) the state of the prior art, (7) the relative skill of those in the art, and (8) the predictability or unpredictability of the art. Importantly, it is further my understanding that the scope of enablement must be commensurate with the full scope of the claims. I have considered these factors, and it is my opinion that a POSA would be required to perform undue experimentation to make and use an illuminator that provides “uniform illumination” over the full scope of the claims.

a) The Scope of the Asserted Claims is Broad, Encompassing Illumination of All Parts of the Body and a Broad Range of Treatment Distances

187. As illustrated in the exemplary claim language I provided above, the Asserted Claims do not recite or limit the claims to specific types of anatomies that are to be illuminated. Rather, the claims simply recite “a system for photodynamically diagnosing or treating a patient” and “a method for photodynamically diagnosing or treating a patient.” Nowhere in any of the Asserted Claims does it state that the illuminator is limited to “uniform illumination” of a specific part of the anatomy such as the face and scalp. Consequently, a POSA would understand the Asserted Claims as encompassing illumination of all parts of the patient’s body. This understanding is consistent with the specification of the Asserted Patents, which state “it is an object of some embodiments of the present invention to provide an infinitely adjustable illuminator that can effectively deliver a uniformity of light across various areas of a patient’s body, such as a patient’s extremities (*e.g.*, arms and legs) or torso, in addition to a patient’s face and scalp.” ’512 Patent, at 2:54-59; ’028 Patent, at 2:56-61. Additionally, the specification provides that “the adjustable illuminator may also be easily positioned to deliver a uniform light intensity to larger treatment areas, such as the back or chest.” ’512 Patent, at 7:64-67; ’028 Patent, at 7:66-8:2. The Asserted Patents further state “[t]hus, a uniform light may be delivered to a targeted treatment area regardless of the shape and location of the contoured surface of the patient’s body.” ’512 Patent, at 2:59-62; ’028 Patent, at 2:61-64.

188. In view of this disclosure, and the fact that the Asserted Claims do not recite illumination of a specific part of the anatomy, a POSA would understand that the Asserted Claims broadly encompass illumination of all parts of a patient’s body, including at least the extremities (*e.g.*, hands, feet, arms and legs), torso (*e.g.*, stomach, chest, and back), and the face/scalp of the patient.

189. Additionally, I note that the Asserted Claims recite uniform illumination over a broad range of treatment distances (*i.e.*, the distance from the light source to the treatment surface). None of the Asserted Claims of the '512 Patent (*i.e.*, claims 1, 3, 5, 8, 17, 18, and 20) or claims 16, 17, and 19 of the '028 Patent limit the distance from which the illuminator is to be positioned from the treatment surface, meaning that a POSA would understand the claims to encompass any potential treatment distance (*e.g.*, 1 inch, 3 inches, 5 inches, one foot, etc.). The remainder of the Asserted Claims of the '028 Patent (*i.e.*, claims 1-2, 4-6, and 20-21), require that the panels of the illuminator are positioned at a treatment distance of “within approximately four inches” of the treatment surface. It is my understanding that Biofrontera has construed “within approximately four inches” as “less than or equal to four inches from the treatment surface,” while Sun Pharma has proposed the term be construed to have its “plain and ordinary meaning” (but does not provide what the “plain and ordinary meaning” of the term would be). Sun’s Claim Construction Brief (public version), at 16. Under Biofrontera’s construction, for these specific claims, a POSA would understand that the claims must enable uniform illumination over the full range of 0-4 inches, while under Sun Pharma’s proposed construction, the range of treatment distances is even broader, presumably encompassing treatment distances greater than 4 inches. Under either construction, my opinions laid out herein are the same.

190. Consequently, a POSA would understand that the Asserted Claims are very broad, encompassing illumination of all parts of the patient’s anatomy (including at least the extremities, torso, and face/scalp), and encompassing illumination over a broad range of treatment distances, with presumably no upper limit for the treatment distance of claims 1, 3, 5, 8, 17, 18, and 20 of the '512 Patent and claims 16, 17, and 19 of the '028 Patent, and zero inches to four inches (or presumably greater than four inches if Sun Pharma’s “plain and ordinary meaning” construction

is adopted) for claims 1-2, 4-6, and 20-21 of the '028 Patent. Thus, it is my understanding that the Asserted Patents must enable “uniform illumination” of the full scope of the Asserted Claims, including the broad variety of patient body parts (including the extremities and torso, in addition to the face/scalp) and broad range of treatment distances.

b) The Field of Optics and Illumination is Complex the Amount of Experimentation Necessary is Very High, and the Asserted Patents Provide Limited Guidance and Working Examples for How to Achieve “Uniform Illumination” Over the Broad Scope of the Claims

191. It is well-known that the field of optics and illumination is complex, and in some cases requires extensive measurement and experimentation. A POSA will expect that the amount of experimentation and testing necessary to achieve a specific design goal increases where the treatment surface is not flat, a challenge further compounded by the fact that the shape of the illuminator does not follow the contours of a face or other treatment area. Moreover, there is a range of distances between the illuminator and the treatment surface, and this variation can dramatically affect irradiance of the skin. And, finally, much of the targeted skin area is not in the same plane as the emitting source; the irradiance falls off rapidly if the treatment surface is not orthogonal to the light emitted from the illuminator.

192. In view of this complexity and the high degree of testing and experimentation necessary, it is my opinion that the Asserted Patents fail to provide adequate guidance regarding how a POSA would make and use an illuminator that: (1) can provide uniform illumination to the extremities and torso; and (3) can provide uniform illumination across all of the varying treatment distances encompassed by the claims.

193. As an initial matter, the illuminator display may be positioned in an “infinite amount of configurations” to illuminate different portions of the patient’s body, complicating the assessment of whether a device can achieve “uniform illumination.” The Asserted Patents state:



The adjustable illuminator of the present invention allows for an infinite amount of configurations that can be adapted for the targeted treatment area. The configurations may range from a flat-plane emitter (as shown in FIGS. 1B and 2B) to a substantially U-shaped configuration (as shown in FIGS. 1A and 2A). The adjustable illuminator may also be configured such that the two end panels 10 a, 10 e can be pulled back relative to the three middle panels 10 b, 10 c, 10 d, such that a smaller U-shaped configuration may be created by the middle panels. Thus, the adjustable illuminator allows for the treatment of additional areas of a patient's body. In other words, not only can the adjustable illuminator effectively deliver a uniform light intensity to traditional surfaces such as the face or scalp, but the adjustable illuminator can also provide a device that can easily be configured to treat other portions of a patient's body, in particular, those having smaller curved surfaces, such as the arms and legs. Moreover, the adjustable illuminator may also be easily positioned to deliver a uniform light intensity to larger treatment areas, such as the back or chest.

'512 Patent, at 7:48-67; '028 Patent, at 7:50-8:2.

194. Each of the “infinite” different configurations will result in a different percentage variation in irradiance on each specific area of skin, and would in fact be different for each patient. The Asserted Patents explain that the illuminator can be configured in various orientations ranging from a flat-plane emitter to a substantially U-shaped configuration, which allow for “uniform” illumination of “traditional surfaces such as the face or scalp,” as well as other parts of the body including arms, legs, and torso. '512 Patent, at 7:60-67; '028 Patent, at 7:62-8:2. Importantly, there is considerable variation in the different areas of the body that may be treated and even across individuals for treatment of the same body part. There are dimensional differences based on what body part is being treated (*e.g.*, treatment of face vs. treatment of arm vs. treatment of back). All of these factors complicate the task of developing “uniform illumination,” particularly in view of the fact that the illuminator may be configured in an “infinite” number of positions based on the contours of the body part being treated. For example, an illuminator that provides “uniform illumination” when the panels are collectively positioned in a “flat” orientation will provide a

substantially different percentage of uniform illumination when the panels are angled relative to one another to produce a U-shape, as described in the passage above. The adjustability and configurability of the illuminator significantly adds to the amount of development and testing that would be required to develop an illuminator providing uniform illumination for the various body parts disclosed by the Asserted Patents.

195. Additionally, I note that, in addition to the “uniform illumination” claim requirement, the Asserted Patents all recite 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.” As I have discussed in other parts of this declaration, it is my opinion that the claim language requiring “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” is indefinite, as a POSA does not have reasonable certainty as to what is required by the claims (i.e., primarily, how does a POSA determine what is “proximate” vs. “not proximate;” how is the intensity to be measured; etc.). As I discussed in the indefiniteness section, Sun Pharma has asserted that the claim term should be construed to require “a higher intensity of light is emitted close the second edges compared to the intensity of light emitted not close to the second edges,” which does nothing to resolve the indefiniteness of the claims, as “close” suffers from the same ambiguity and imprecision as “proximate.”

196. Regardless, when attempting to manufacture an illuminator that meets the claimed requirements, a POSA must develop an illuminator that simultaneously (1) provides “uniform illumination” of all the various parts of the body encompassed by the claims (including the extremities and torso) and (2) has a higher intensity of light “proximate” the second edge as compared to the intensity “not proximate” the second edge. This additional requirement further

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complicates the task of developing an illuminator providing “uniform illumination.” While the “higher intensity of light proximate the second edge” may help establish uniform illumination for treatment areas such as the face, as described in Figure 8 of the Asserted Patents, it may complicate the task of developing “uniform illumination” of other parts of the body (e.g., the extremities and torso) that have significantly different shapes and contours than that of the face and scalp.. Consequently, given the requirement that the illuminator has a higher intensity of light proximate the second edge, and given the broad scope of patient anatomies encompassed by the claims (not just the face and scalp, but also the extremities (hands, feet, arms, legs, etc.) and torso (stomach, chest, back, etc.)), these requirements further add to the amount and complexity of experimentation that must be performed to make an illuminator meeting the claim requirements.

197. In fact, while the Asserted Patents clearly contemplate illumination of various parts of the patient’s anatomy, the disclosure is focused primarily on illumination of the face and scalp, and the goal of producing “uniform illumination” for the face and scalp. Indeed, the one instance where the specification appears to provide some discussion and assessment of “uniform illumination” is with regard to Figs. 7 and 8, where light uniformity for a “conventional” illuminator is illustrated in Fig. 7, while the light uniformity achieved with an illuminator made in accordance with the Asserted Patents is provided in Fig. 8. The Asserted Patents state:

The effects of this configuration can be best seen in a comparison of FIGS. 7 and 8. FIG. 7 illustrates the light uniformity produced by a conventional illuminator, measured with a cosine response detector, which mimics the response of a patient’s skin to the incident of light as described above, at a distance of two inches. Total light dose, in terms of J/cm^2 , was measured based on emitted irradiance (W/cm^2) over time (in seconds). The targeted treatment area shown is a patient’s head, where height is shown as the y-axis and rotation angle from the center of the emitting surface is shown as the x-axis. As can be seen in FIG. 7, higher light doses of about $10 \text{ J}/\text{cm}^2$ occur at the center of the face (for example, at region A), near the patient’s



nose, where the patient is facing closest to, and substantially perpendicular to, the middle-most panel. Total light dose then begins to drop as movement away from the center of the face occurs where the effects of cosine “fall-off” and optical dead spaces are more prevalent. For example, light dose is reduced by about 20% at the patient's cheek areas (for example, at region B), and by about 80% toward the outer boundaries of the patient's face (for example, at region E), such as the ears and forehead. Thus, as shown in FIG. 7, conventional adjustable illuminators utilizing equally-sized panels operating at the same power output level produce a varying field of light uniformity, making it undesirable and ineffective for those treatments requiring highly specific light uniformity.

FIG. 8, on the other hand, illustrates the light uniformity produced by an embodiment of the present invention. The targeted treatment area is the same as that measured in FIG. 7. However, compared to FIG. 7, the light output uniformity produced by the illuminator is greatly enhanced across the patient's face and exhibits little to no deviation from the light output measured in the center of the patient's face to the light output measured at the edges of the patient's face. For example, as shown in FIG. 8, total light doses of about 10 J/cm^2 (for example, at region A') occur across all regions of the face, including the center of the face (for example, the patient's nose), the patient's cheek areas, and the outer boundaries of the patient's cheek areas, such as the ears and forehead. Moreover, total light dose drops off minimally (for example, at region B') at the extreme outer boundaries of the patient's face.

'512 Patent at 8:12-54.

198. As noted in the passage above, “[t]he targeted treatment area shown is a patient's head,” meaning the testing was only performed to assess uniformity of illumination for a patient's head/face (the passage focuses on illumination of areas meant to replicate a patient's nose, cheeks, forehead, and ears). But, the claims of the Asserted Patents encompass treatment of a broad variety of other patient treatment areas, including the extremities (arms and legs) and torso (stomach, chest, and back). The discussion of Fig. 8 does not provide any guidance as to how to achieve the uniform illumination for other parts of the patient's body that will have different shapes and

contours, meaning that a POSA would be left with a substantial amount of development and testing to assess how to achieve uniform illumination for other parts of the patient's anatomy.

199. Additionally, the passage states that light uniformity was “measured with a cosine response detector, which mimics the response of a patient's skin to the incident of light as described above, at a distance of two inches.” The light uniformity measurement was assessed at a specific treatment distance of *two* inches, but the Asserted Claims encompass a broad treatment distance range of less than or equal to four inches for claims 1-2, 4-6, and 20-21 of the '028 Patent (including treatment distances presumably greater than four inches if Sun Pharma's “plain and ordinary meaning” construction for “within approximately four inches” is adopted), and an even broader range of treatment distances for claims 1, 3, 5, 8, 17, 18, and 20 of the '512 Patent and claims 16, 17, and 19 of the '028 Patent, which include no upper limit of treatment distances (encompassing treatment at 4 inches, 6 inches, 12 inches, etc.). Even assuming that the discussion of Fig. 8 provides meaningful guidance to a POSA (which I do not believe it does), the results were only reported at a treatment distance of two inches. This one treatment distance does not provide a POSA with any guidance or suggestion that similar results can be achieved at treatment distances of, for example, four inches, eight inches, twelve inches, etc. Again, in my opinion, the limited nature of the discussion for Fig. 8 means that a POSA would be left with a substantial amount of development and testing to assess how to achieve uniform illumination for all of the treatment distances encompassed by the Asserted Claims.

200. I have also reviewed the prosecution history for the Asserted Patents, but there is no meaningful guidance provided during prosecution that would allow a POSA like myself to develop the claimed illuminator meeting the requirement for “uniform illumination” without significant and complex experimentation that would require manufacturing various illuminators,

incorporating various LED designs, and testing the illuminators on various treatment surfaces (not just the face and scalp, but also the extremities and torso), and testing at various treatment distances including one inch, two inches, four inches, six inches, eight inches, etc.

c) Sum of the Factors

201. Having read the claims and specifications of the Asserted Patents in view of the factors I have described above, it is my opinion that all Asserted Claims of the '512 and '028 are invalid for lacking enablement over the full scope of the claims. The scope of the claims is overly broad, encompassing illuminators that can “uniformly illuminate” various parts of the patient’s anatomy (including not just the face/scalp, but also the extremities and torso), and encompassing illumination over a broad range of treatment distances, with presumably no upper limit for the treatment distance of claims 1, 3, 5, 8, 17, 18, and 20 of the '512 Patent and claims 16, 17, and 19 of the '028 Patent, and zero inches to four inches (or presumably greater than four inches if Sun Pharma’s “plain and ordinary meaning” construction is adopted) for claims 1-2, 4-6, and 20-21 of the '028 Patent. Furthermore, the field of optics, while useful given a specific source design, target distance and curvature, cannot determine or predict uniformity over the full range of body parts and distances without significant experimentation and actual, quantitative measurements. The Asserted Patents fail to provide sufficient guidance or working examples across the full scope of the Asserted Claims to inform a POSA like myself how to develop the claimed illuminator that can provide “uniform illumination” for the torso and extremities. A POSA would be forced to manufacture various illuminators, incorporating various LED designs, and testing the illuminators on various treatment surfaces of the extremities and torso (e.g., hands, feet, legs, arms, stomach, chest, back, etc.), and at various treatment distances including one inch, two inches, four inches, six inches, eight inches, etc., to assess which designs are capable of providing “uniform

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illumination” over the full scope of treatment areas and distances. In my opinion, this significant level of experimentation is undue, and it is my opinion that the Asserted Claims lack enablement.

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D. Obviousness Under 35 U.S.C. § 103

206. As set forth above, it is my opinion that the Asserted Claims are indefinite, lack proper enablement, and/or lack proper written description. However, alternatively, to the extent that the any or all of Asserted Claims are found to be definite, enabled, and supported by proper written description, it is my opinion that these claims are obvious over the prior art.

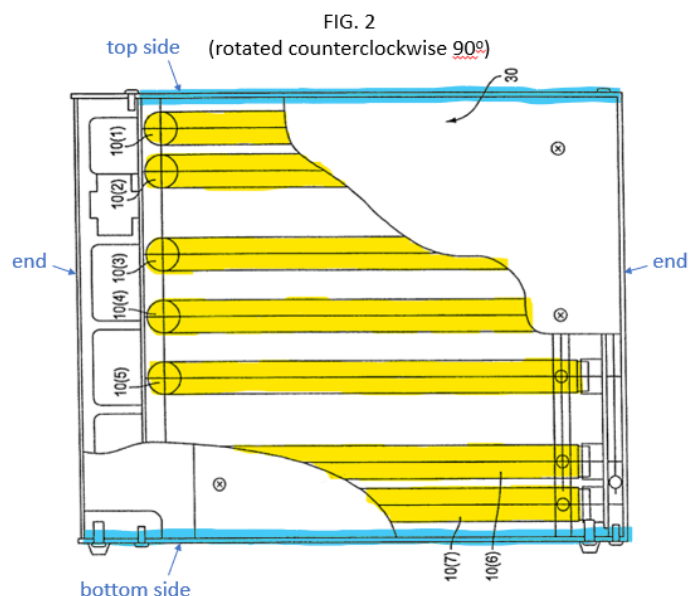
1. Summary of References Relied on for Obviousness

a) Lundahl

207. 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 '028 and '512 Patents.

208. 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.

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

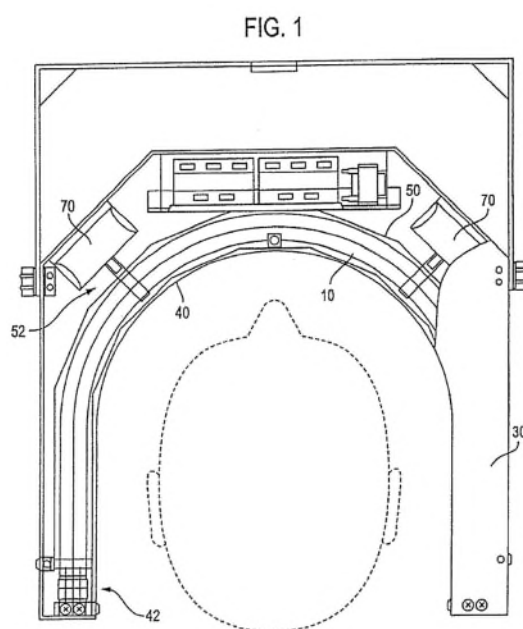


Lundahl, Fig. 2.

210. 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 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.

211. 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.

212. 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 Fig. 1, showing the positioning of the patient’s head and nose within the device.

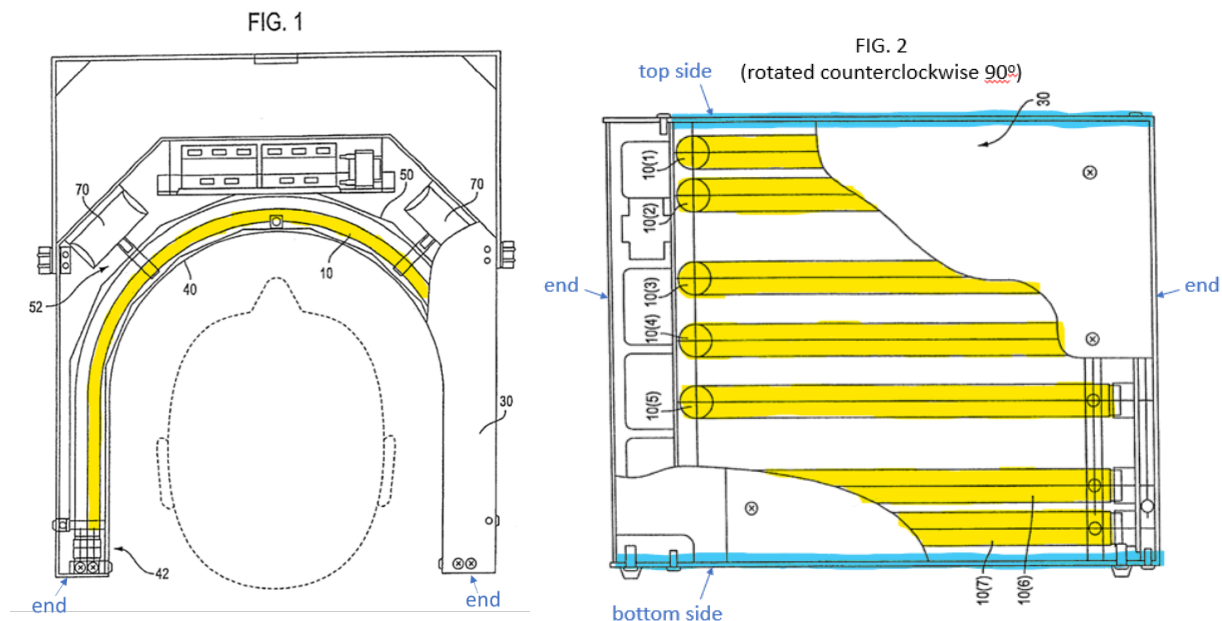


213. Lundahl explains that the U-shape of the PDT device helps to maintain the proper distance between the light-emitting panel and the patient head, stating “[t]he U-shape minimizes the variations in distance between the emitter and the target, providing a uniform visible light distribution to the face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

214. 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, 15:22-27.

215. 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.



216. 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. POSA 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.

217. 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.

218. 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”).

219. 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.

220. 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, 2:14-26. 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, 15:29-37.

221. 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.

222. Lundahl is from the same field of endeavor as the '028 and '512 Patents, which also describe illuminators for PDT. '028 Patent, 1:26-2:6; '512 Patent, 1:24-2:4. Lundahl is also directed to the same problem as the '028 and '512 Patents, 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 at 1:12-17. Therefore, Lundahl is analogous art to the '028 and '512 Patents.

b) Larsen

223. U.S. Patent Application No. 2005/0075703 (hereinafter referred to as “Larsen”) was published on April 7, 2005, and claims priority to a foreign patent application filed on January 22, 2001. I understand that Larsen qualifies as prior art because it was published before the earliest effective filing date of the '028 and '512 Patents.

224. 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].

225. “Treatments have included the application of substances such as photoflim [sic], 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].

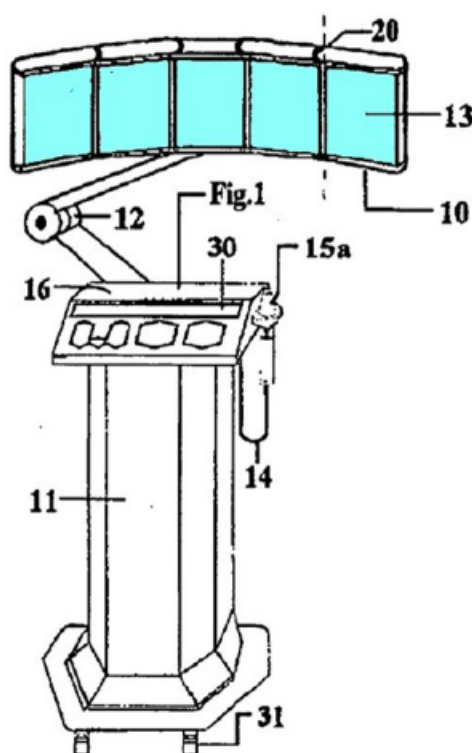
226. Larsen teaches the desirability and use of phototherapy equipment that can emit light over a large range of wavelengths from 300 nm to 2000 nm. “A device able to deliver an intensive light radiation with selective multiple wavelengths within the wavelength area of 300-2000 nm and electromagnetic 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 POSA would have understood that this range of wavelengths includes ultraviolet light, visible light, and infrared light.

227. 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].

228. 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].

229. 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.



230. 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].

231. 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].

232. Larsen is from the same field of endeavor as the '028 and '512 Patents, which also describes illuminators for PDT. '028 Patent, 1:26-2:6; '512 Patent, 1:24-2:4. Larsen is also directed to the same problem as the '028 and '512 Patents, namely, an illuminator that can provide an "even and gap-free radiation of the surface with multiple wavelengths of light." Larsen, ¶0028. Therefore, Larsen is analogous art to the '028 and '512 Patents.

c) Kennedy

233. 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 ’028 and ’512 Patents.

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

235. 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

236. 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.

237. 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].

238. 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.

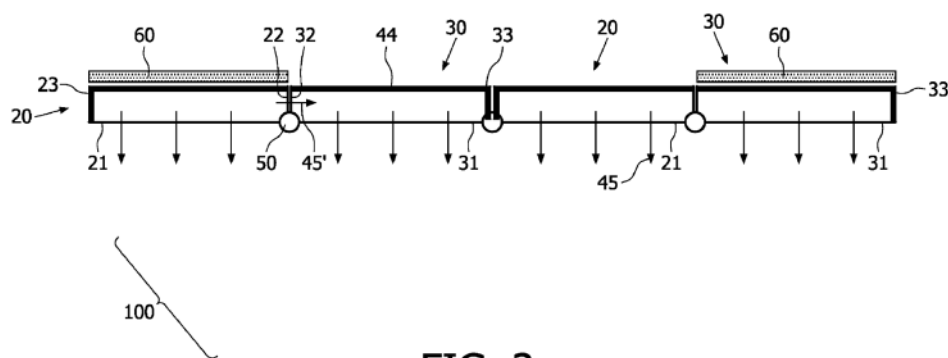
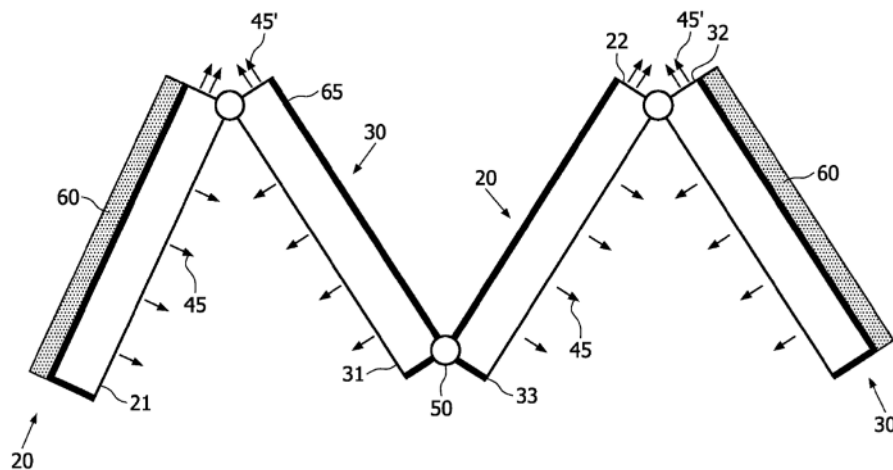


FIG. 2

Hente, Fig. 2.

239. 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.

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

241. Furthermore, Hente teaches that at least one panel includes a recess configured to receive a flange of one of the 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.

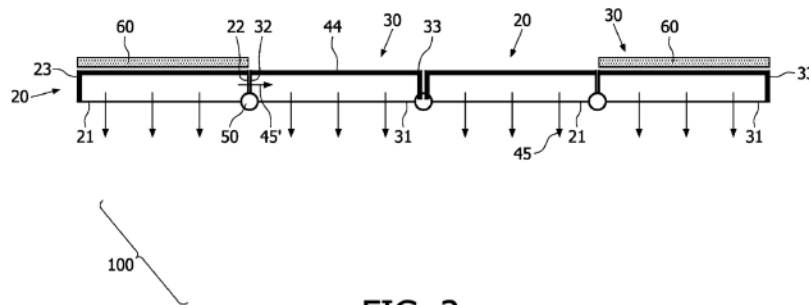


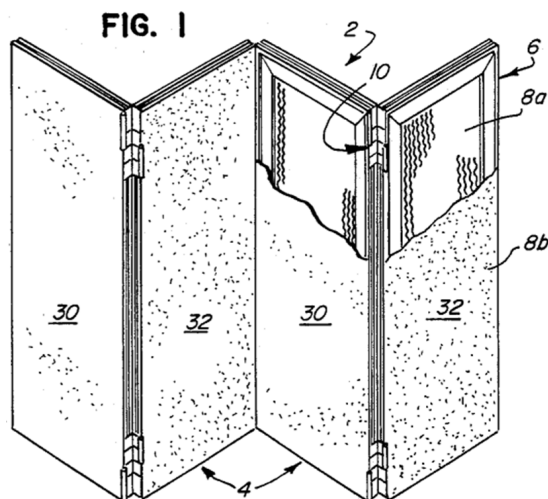
FIG. 2

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

e) Perutz

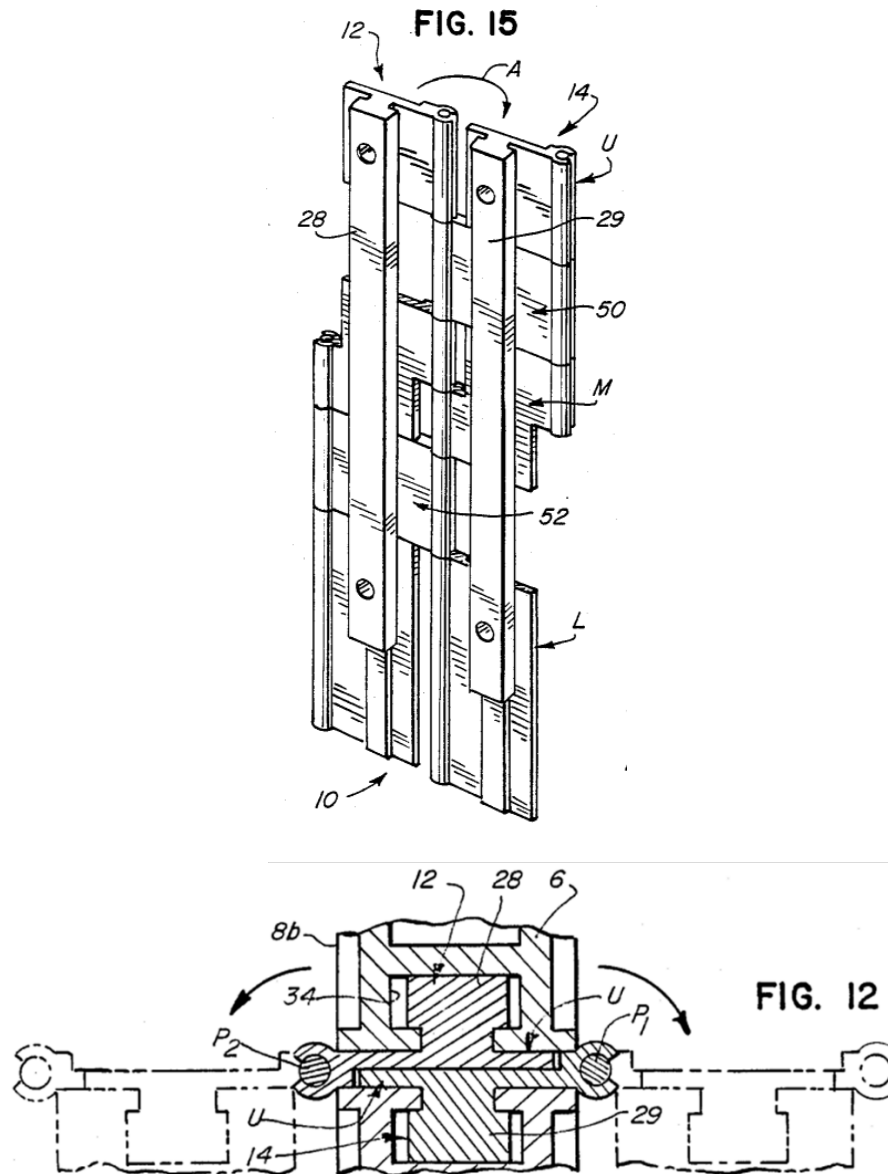
243. U.S. Patent No. 4,823,858 (hereinafter referred to as “Perutz”) was filed on June 02, 1987. Perutz was filed before the earliest effective filing date of the ’512 Patent.

244. 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.

245. 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.



246. 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.

247. A POSA 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.

248. 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.

249. Given this knowledge, a POSA 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.

2. Motivations to Combine Lundahl with Larsen

250. A POSA 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 report of Michael Ehrenreich, M.D. Based on my

[REDACTED]

understanding that a POSA 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 POSA combination from which the motivation to combine and modify the prior art should be judged.

251. In paragraphs 36-41, 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 ¶38. 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 ¶39. 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.

252. Moreover, in paragraphs 151-156 of the Expert Report of Dr. Ehrenreich (January 22, 2025), 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 ¶151. 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 ¶¶ 40-41.

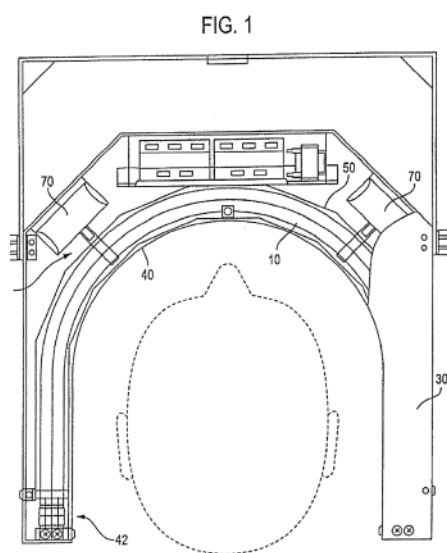
253. In addition, Dr. Ehrenreich notes known problems with the fluorescent tubes utilized in the Lundahl design. Dr. Ehrenreich correctly notes that the uniformity of light from fluorescent tubes varies across the length of the tube, and the uniformity of lighting can also be affected by heat and the ability to cool the Lundahl device. *Id.* at ¶¶ 152-153.

254. 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 POSA 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

255. As discussed in the expert report 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. *See* Expert Report of Dr. Ehrenreich (January 22, 2025), at ¶¶38-39. 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.” Lundahl, 6:31-35. Mr. Lundahl confirmed in his deposition that “the ’071 patent was a design that eventually became the BLU-U fluorescent product that was on the market.” See Lundahl Tr. at 37:6-9. 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.

256. 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 POSA 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.

257. A POSA 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” from 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 POSA 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 (emphasis added).

258. Consequently, a POSA 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 POSA 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

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

259. 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] (emphasis added). These teachings would have motivated a POSA 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.

260. A POSA 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. Specifically, Lundahl expressly states that the invention is directed to “an illuminator for PDT or PD of a contoured surface. The illuminator comprises a plurality of light sources generally conforming to the contoured surface and irradiating the contoured surface with substantially uniform intensity visible light, and a housing supporting the plurality of light sources with respect to the contoured surface.” Lundahl at 2:61-67. Similarly, as I discuss herein, Larsen is directed to devices for PDT therapy that incorporate five flexibly connected hinged panels that may be angled relative to one another so that panels can be positioned equidistant above the skin (treatment surface). *See* Larsen, ¶¶ [0037], [0072], claim 11. Consequently, the subject matter of Lundahl and Larsen is very similar, as both are directed to illumination devices that can provide PDT to different parts of the patient’s anatomy. The incorporation of Larsen’s hinged panels into the Lundahl device, and the replacement of Lundahl’s fluorescent tubes with Larsen’s

LEDs would both be considered straightforward design changes by the filing of the Asserted Patents, meaning a POSA would reasonably expect that these design changes could be successfully incorporated into the Lundahl device.

261. I am aware that Sun Pharma has asserted in its contentions that there was not a motivation to combine the teachings of Lundahl and Larsen because Lundahl's U-shaped device already resolved issues associated with PDT by "provid[ing] 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." Sun's Suppl. Resp. to Biofrontera's First and Second Set of ROGs, Att. A (Dec. 18, 2024) at 22. However, this is simply not the case. As I noted before (and as supported by the expert report 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 this might be possible for treatment of the face and scalp using Lundahl's fixed U-shape (though I suspect that is not always the case given the variability in shape and dimensions of patients' heads), it is simply not possible to ensure the 2-4" treatment distance for other parts of the body, including the arms, legs, chest, back, etc. without modifying the Lundahl U-shaped design to allow for adjustability of the illuminator.

262. Sun Pharma also asserts that a POSA would have been discouraged from modifying Lundahl's U-shape, because doing so would introduce unwanted corners and gaps, and that Lundahl "expressly criticizes 'flat emitting surface[s]' that 'would not deliver a uniform light dose to all contours of the face simultaneously.'" *Id.* at 23. Sun further states that "[i]n view of Lundahl's express criticism, a POSA would not have looked to Larsen's flat emitting surfaces with gaps that would not deliver a uniform light dose." *Id.* However, Sun's position overlooks the fundamental

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design aspects of Larsen. As I discuss herein, Larsen is directed to a hinged-panel illuminator, meaning that the illuminator may be positioned in a “flat” orientation, or may also be positioned in an orientation where the adjacent panels are angled toward one another, creating a curved orientation (approximating a U-shape depending on the desired shape of the treatment surface). Larsen expressly states the illuminator “comprises several single applicators hinged together so as to be adjustable *at angles with respect to one another.*” Larsen, cl. 11. (emphasis added). By positioning the panels of the Larsen illuminator at angles with respect to one another (e.g., in a bent/curved orientation), any gaps between panels will also be minimized or eliminated. Consequently, Larsen is not just a “flat emitting surface,” and Sun’s assertions that a POSA would not have combined Lundahl and Larsen based on Lundahl’s alleged criticism of flat emitting surfaces is not accurate and does not impact my opinion that a motivation existed to combine the references.

263. Moreover, Sun Pharma further argues that a POSA would have been discouraged from modifying Lundahl’s U-shape configuration to incorporate Larsen’s five panels because of the possibility that the cables leading from panel to panel could result in burdensome assembly of the device. *Id.* at 23-24. This is a very minor design consideration, as a POSA like myself would look for ways to minimize difficulties associated with assembly. Additionally, even if any cables between panels result in more difficult assembly, that would be an acceptable design choice in developing an illuminator that provides the desired uniform illumination and functionality. Consequently, this does not change my opinion that a motivation existed to combine Lundahl and Larsen.

264. Sun continues, asserting that Biofrontera “fails to show that the combined modified device with bits and pieces of disparate fluorescent tube and LED systems is configured to

uniformly illuminate at treatment surface, as required by the claims.” *Id.* at 24. However, as noted in my analysis herein (see ¶¶ 260-262 *supra*), the resulting combination of Lundahl and Larsen (incorporating the same light spacing orientation taught by Lundahl) would be expected to provide uniform illumination of the face/scalp in the same manner that Lundahl’s device provided uniform illumination of the face and scalp. Consequently, Sun’s assertions are without merit, and it is my opinion that a motivation existed to combine Lundahl and Larsen.

265. Finally, Sun Pharma asserts that a POSA would have been discouraged from incorporating the five-panel design of Larsen into the device of Lundahl, because Lundahl describes the use of a reflector with nine segments (not five), with the nine segments conforming to the U-shaped configuration of the tubes. *Id.* at 24-25. But these assertions overlook the fundamental design characteristics of Larsen. As I explain in the following section, Larsen teaches the inclusion of LEDs, which, by the time of filing of the Asserted Patents (i.e., October 2015), were widely replacing the use of fluorescent tubes in illumination devices. Consequently, because it was obvious (based on the teachings of Larsen) to replace the fluorescent tubes of Lundahl (which was filed in May 1998 when the use of fluorescent tubes was still a prominent design choice) with LEDs, a POSA would not seek to replicate the design of the reflector of Lundahl with nine sections conforming to the shape of the U-shaped fluorescent tubes. In other words, once the fluorescent tubes of Lundahl are replaced with LED panels (as taught by Larsen), to the extent that a POSA sought to include reflectors in the resulting device, he or she would simply include five reflectors, matching the number of panels disclosed by Larsen. In fact, Larsen even states that “[t]he applicators contain printed circuit boards mounted with semiconductor diodes and/or laser diodes (in large numbers), and the diodes are mounted with reflectors, which collect the radiation and bundle them in front of the applicator.” Larsen at ¶[0028]. To the extent a POSA elected to

include reflectors in the device rendered obvious by Lundahl and Larsen, the reflectors would be incorporated into each of the applicators (i.e., panels), meaning a POSA would simply include a reflector for each of the five panels in the Larsen device. Thus, these assertions by Sun do not impact my opinion that a motivation existed to combine the teachings of Lundahl and Larsen.

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

266. A POSA 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 POSA 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.

267. 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 POSA to incorporate Larsen's solution of disposing light sources, specifically LEDs, on the surface of the light applicators to Lundahl's device.

268. A POSA would have had a reasonable expectation of success in combining Lundahl with Larsen, because, again, both references describe similar illuminators and the conversion from fluorescent tubes to LEDs was a routine practice prior to 2015. Specifically, while the electrical needs and design of Lundahl's system for operating fluorescent tubes would need to be changed to accommodate the electrical needs and design of Larsen's LED panels, this would have been considered a relatively straight-forward and routine design process for a POSA by the time of filing of the Asserted Patents.

269. I am again aware that Sun Pharma has asserted in its contentions that there was not a motivation to modify Lundahl's device to incorporate LEDs as taught by Larsen, because "Biofrontera cherry-picks Larsen's LEDs (together with the five panels) and purports to arrange them according to "the uneven spacing" of Lundahl's fluorescent tubes." Sun's Suppl. Resp. to Biofrontera's First and Second Set of ROGs, Att. A (Dec. 18, 2024) at 27. However, as I note herein, Lundahl states "[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, at 6:43-57. See ¶312 *infra*) based on Lundahl's disclosure that the spacing of lights achieved the desired uniformity and highly uniform output irradiance, the decision to arrange the LEDs taught by Larsen in the same uneven spacing disclosed by Lundahl would have been based on the desire to maintain the desired uniformity and highly uniform output. Based on Lundahl's disclosure that uniformity was achieved for the face and scalp (see Lundahl, 6:39-42, "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"), a motivation existed to modify Lundahl's device to incorporate LEDs as taught by Larsen (as LEDs were a

superior technology by 2015 for the reasons I note above), while maintaining the spacing taught by Lundahl.

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

270. Moreover, a POSA 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”).

271. 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

[REDACTED]

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 POSA 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 POSA to reasonably expect enhanced efficacy of the PDT device.

272. 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].

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

274. 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 POSA had at least a reasonable expectation that red light could be utilized in the device rendered obvious by Lundahl (incorporating Kennedy) and Larsen.

3. Motivation to Combine Lundahl, Larsen, and Hente

275. As discussed herein, Larsen teaches an illuminator comprising at least five panels connected by hinges on inner side surfaces of adjacent panels. 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 POSA 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.

276. 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.

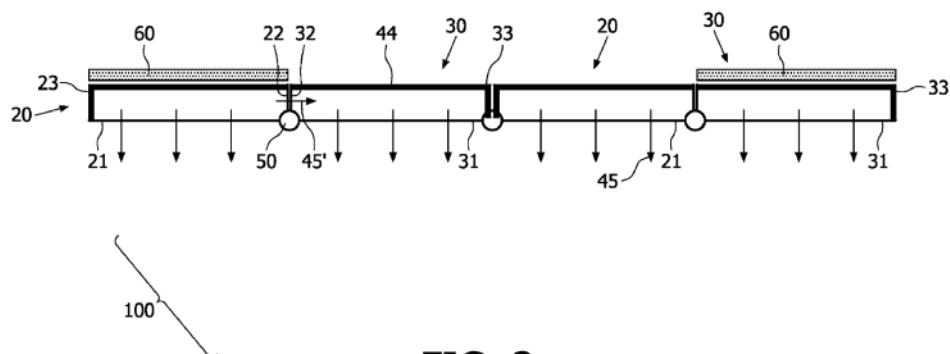
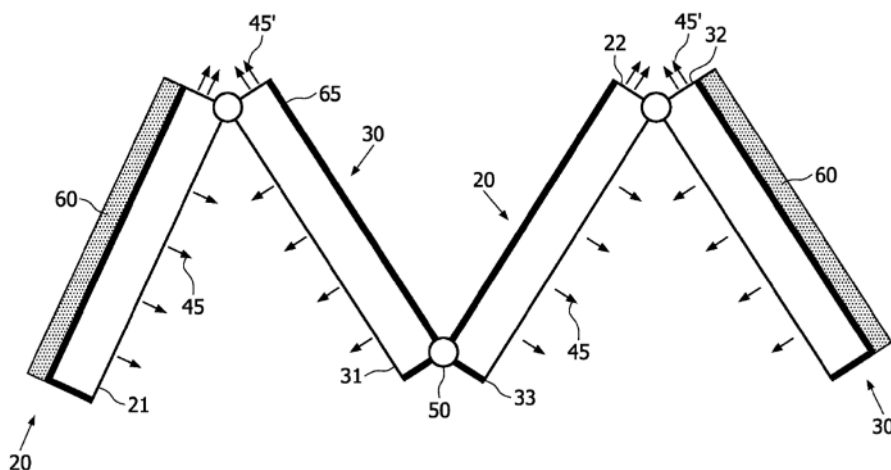


FIG. 2

Hente, Fig. 2.

277. 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.

278. Hente is from the same field of endeavor as the Asserted Patents, 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 POSA 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 POSA was motivated to utilize hinges similar to those described in Hente, attached to inner side surfaces of adjacent sections/panels.

279. 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, which Hente refers to as the panel “rim.”

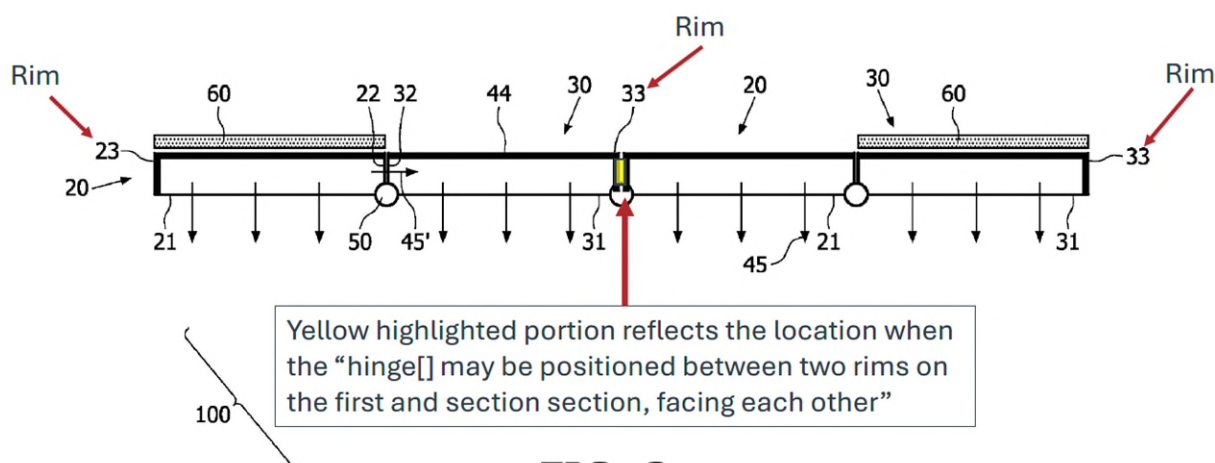
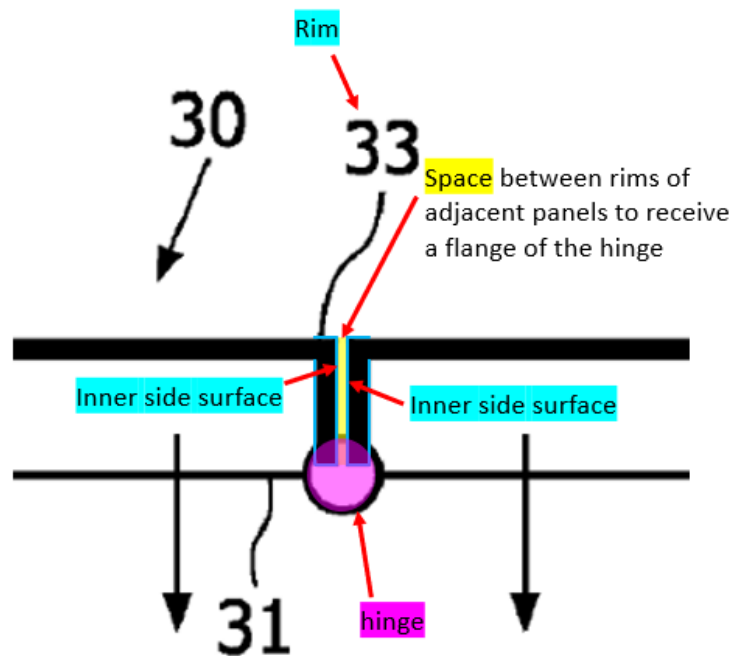


FIG. 2

280. 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.



281. Given this knowledge, a POSA 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. Specifically, while the end use of the illumination devices described by Hente and Larsen may be different (Hente is directed to illuminating work areas, whereas Larsen is primarily directed to PDT), the overarching design of the two devices is similar – both are directed to adjacent sections/panels housing LEDs, where the adjacent sections/panels are attached by hinges. Given this similarity in illuminator design, a POSA would not hesitate or be dissuaded from looking to the hinge design of Hente when considering potential hinge designs for Larsen.

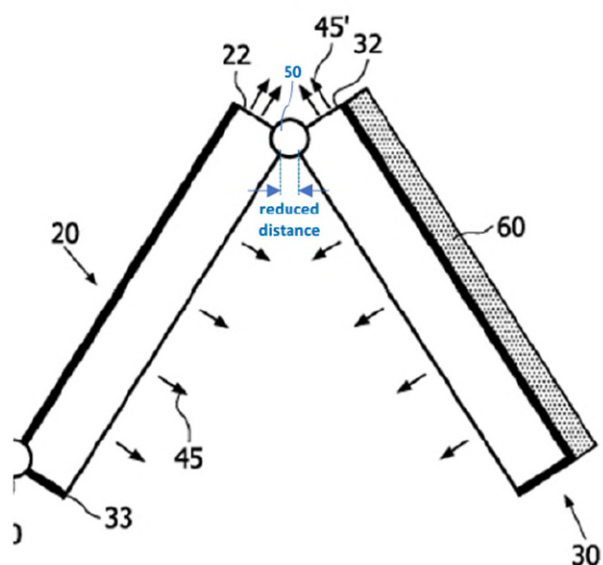
282. Again, it is my opinion that Larsen discloses panels connected by hinges on the inner side surface of the adjacent panels of Larsen, and the discussion of Hente does not change this opinion. However, as I noted above, uniformity of illumination is still a key design motivation, as a POSA would want to minimize gaps between the adjacent panels (appreciable gaps between



panels might impact the ability to produce uniform illumination). Hente provide a design strategy via hinges that allow for movement and adjustment of adjacent panels/sections, while also minimizing the gap between the adjacent panels/sections. Consequently, despite Larsen's teaching of hinges, a POSA would nonetheless be motivated to further look to the teachings of Hente related to the use of hinges that might minimize gaps/space between adjacent panels/section.

283. Additionally, the modification of hinges between panels would be a routine design process for a POSA, such that any POSA would reasonably expect that the hinges of Hente could be successfully incorporated into the illuminator rendered obvious by Lundahl and Larsen.

284. I am aware that Sun Pharma has asserted that, because "the hinges are 'positioned at the outer rims of the light emitting device respectively sections[,] ...the hinges at the outer rims of the sections protrude from the front of the light-emitting sections, which in the alleged modified combinations could interfere with the irradiance.'" Sun's Suppl. Resp. to Biofrontera's First and Second Set of ROGs, Att. A (Dec. 18, 2024) at 35. However, the possibility of the hinges protruding beyond the front of the light-emitting panels is not a design characteristic that would prevent a POSA from utilizing the hinge design of Hente. Specifically, as I describe in the sections that follow, even with the hinge potentially protruding beyond the front of the panels, the distance or "gap" between panels will nonetheless be minimized or eliminated when the panels are angled toward each other (as would be the case, e.g., when the panels are angled to surround the face/scalp of a patient), as illustrated below in the annotated version of Fig. 3 from Hente:

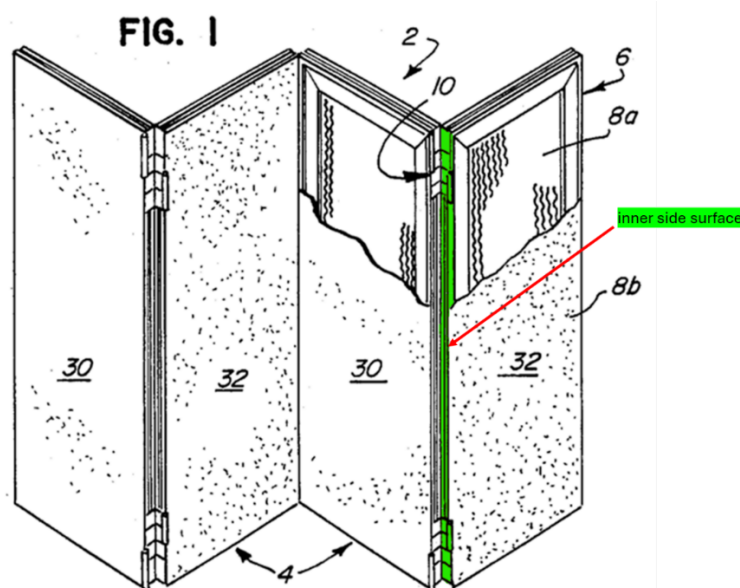


285. Consequently, the possibility that the hinges of Hente may protrude beyond the front surface of the adjacent sections/panels does not change my opinion that a motivation existed to combine the teachings of Hente's hinges with the illuminator rendered obvious by Lundahl and Larsen.

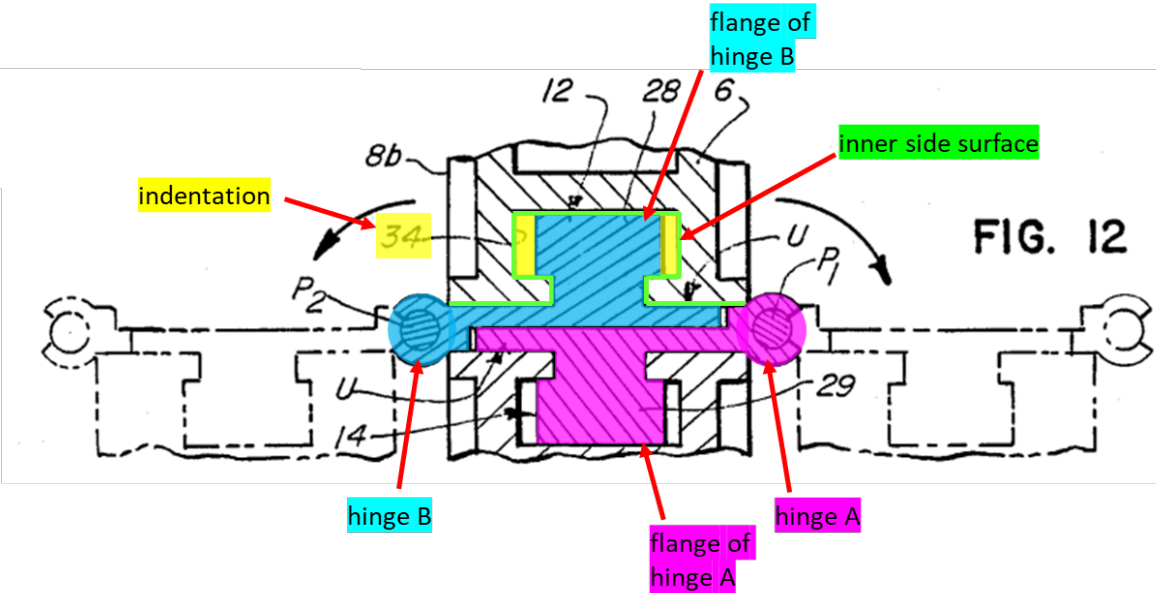
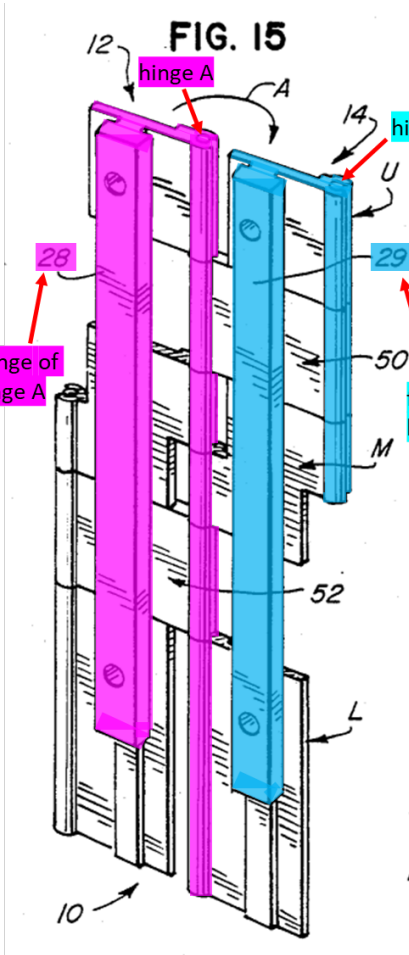
4. Motivation to Combine Lundahl, Larsen, Hente, and Perutz

286. As discussed herein, a motivation existed to combine the teachings of Lundahl, Larsen, and Hente. As discussed in the sections that follow, it is my opinion that Hente discloses and renders obvious the inclusion of the claimed “recess configured to receive a flange of one or the hinges. However, 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 hinges, the recess being positioned at an inner side surface of the at least one panel, these limitations are disclosed by Perutz. Based on the teachings of Lundahl, Larsen, and Hente, uniformity of illumination was a key design motivation, as a POSA 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.

287. 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.



288. 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.



[REDACTED]

289. A POSA 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.

290. 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).

291. Given this knowledge, a POSA would understand that Hente discloses hinges attached to inner side surfaces that would function to reduce the space/gap between adjacent panels/sections. Perutz adds to the teachings of Hente, further disclosing that the flange of the hinge may be placed within an indentation in the side surface (i.e., a “recess”), which would further minimize the space between adjacent panels (the width of the flange being housed within the indentation on the side surface reduces the amount of space necessary between the adjacent panels). Consequently, the subject matter of Hente and Perutz is similar (both directed to hinge designs that eliminate space between adjacent section) and a POSA would be motivated to combine disclosure of Perutz with the teachings of Lundahl, Larsen, and Hente, and would have a reasonable expectation that the teachings of Perutz could be successfully utilized in the device rendered obvious by Lundahl and Larsen, including the teachings of Hente related to hinges.

[REDACTED]

**Pages 120-169 Are
Redacted**

6. Unpatentability of the '512 Patent

436. It is my opinion that 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.

437. It is my opinion that 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.

438. It is my opinion that 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.

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

Claim 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:"

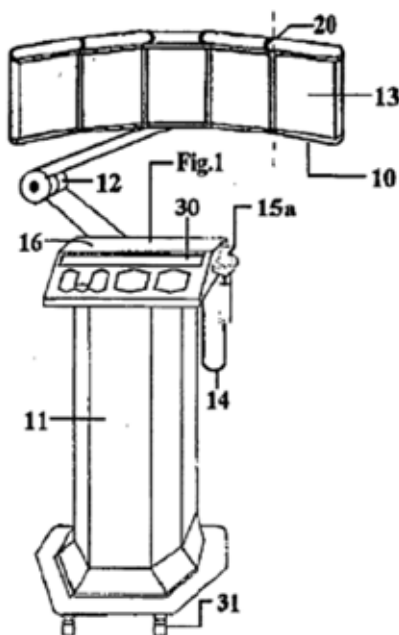
439. Lundahl discloses an “invention...directed to photodynamic therapy using an illuminator that provides a uniform distribution of visible light. In particular, the present invention is directed to an apparatus and method for photodynamic treatment (PDT) or diagnosis (PD) of actinic keratosis of the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

440. 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].

441. 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,”

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



Larsen, Fig. 1.

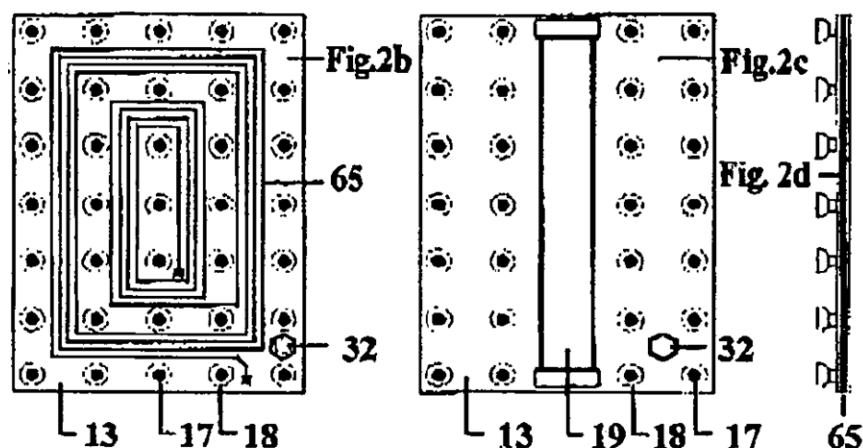
443. Larsen teaches that “[f]or the treatment of large-area tissues according to Fig. 1, several applicators 13 are flexibly connected to each other through hinges 10, respectively connecting one edge with the other, whereby the applicators are suitable for the treatment of for example, the backs of 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 POSA that the “10” designation of Figure 1 is referencing the device as a whole.

444. 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.

445. 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 . . .” March 23, 2021 Office Action from

file history of Application No. 17/009,871, at ¶4 (citing Larsen, Figs. 1-3, [0069], [0072], lines 1-4).

446. 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:

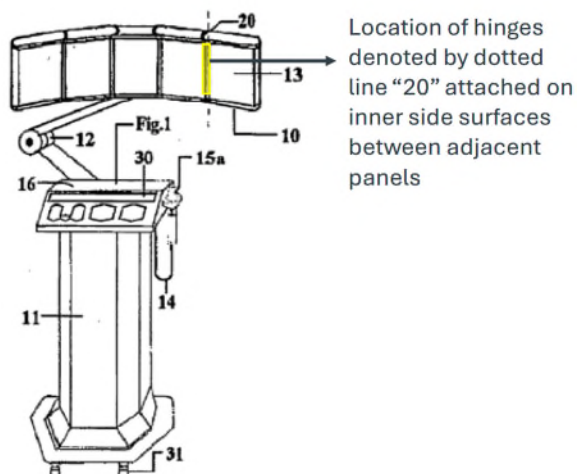


Larsen, Figs. 2b and 2c. As shown above, there is no feature “20” illustrated in either Figure 2b or 2c.

447. 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.

448. For these reasons, a POSA 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 1.¹¹ 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:



449. Even if Larsen’s hinges are not expressly (or inherently) disclosed on the inner side surfaces of the panels, a POSA 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 POSA to place the hinges on the inner side surfaces of Larsen’s panels in order to facilitate this nearly flush arrangement. Such a

¹¹ 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.



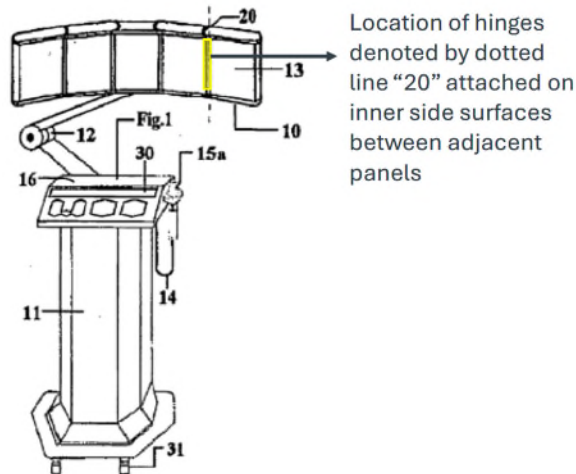
modification would have involved nothing more than the use of a known prior art element according to known methods to yield predictable results. Second, there were finite number of known, predictable solutions for Larsen's panels to be "flexibly connected to each other through hinges." Specifically, 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.¹² Based on this limited number of design options, a POSA would have found it obvious to try placing the hinges on the inner side surfaces of the panels. And a POSA would have had a reasonable expectation of success, since a POSA 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.

450. 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." Complainant's Opening Claim Construction Brief, at 21.

451. Again, I reiterate my opinion that the "nested hinges" term is indefinite, but even if Sun's construction for "nested hinges on inner side surfaces of adjacent panels" is adopted (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

¹² A POSA 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.

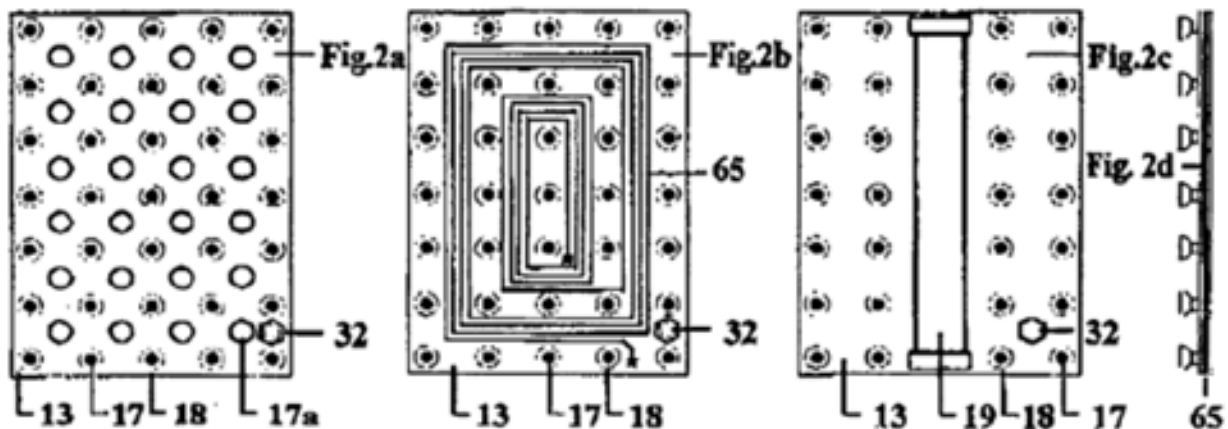
that fit on inner side surfaces of adjacent panels, as I discussed previously, and as illustrated in the annotated figure below:



452. 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,"

453. 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].



454. 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

[REDACTED]

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].

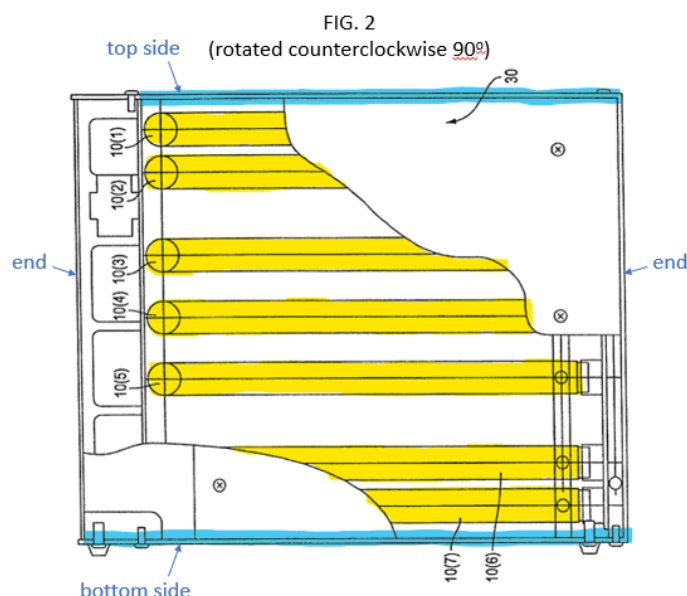
455. Thus, Larsen discloses this claim limitation.

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

456. As an initial matter, as I addressed previously, it is my opinion that the Asserted Claims lack enablement and written description support, based on the “uniformly illuminate” term, as the Asserted Patents have not enabled a POSA to make and use the claimed illuminator device to “uniformly illuminate” the full scope of patient anatomies encompassed by the claims (i.e., uniform illumination of areas other than the face/scalp, such as the extremities and torso) without undue experimentation. Additionally, the Asserted Claims have not established that the applicants were in possession of a device capable of uniformly illuminating areas of the patient’s body other than the face and scalp. However, the Asserted Patents provide what appears to be an enabling disclosure of the uniform illumination of a patient’s face and scalp. Consequently, while it is my opinion that the Asserted Patents fail to enable and support uniform illumination of body parts other than the face and scalp, the prior art discloses and renders obvious uniform illumination of a patient’s head and scalp (which is covered by the claims).

457. It is my understanding that the patent owner (Sun Pharmaceuticals Industries, Inc.) and 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.

458. 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 at 1:9-11. To achieve this uniformity, Lundahl utilizes the light distribution pattern illustrated in Fig. 2 (which has been highlighted, annotated, and rotated 90° to better illustrate):



Lundahl, Fig. 2.

459. 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, at 6:16-30.

460. 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, at 6:43-57.

461. Additionally, Lundahl states “[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 of “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.

462. 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 is the direct parent of the ‘028 Patent, the Examiner reviewed this same disclosure of Larsen and confirmed that it taught “the illuminator being configured to

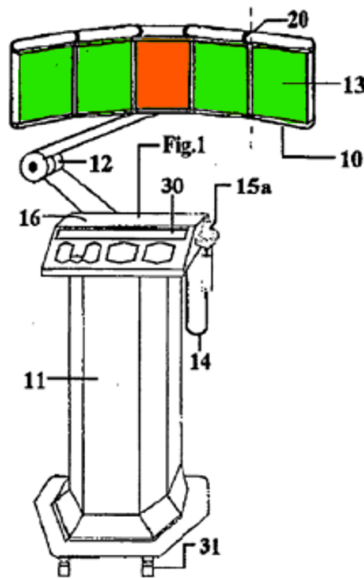
uniformly illuminate a treatment surface of the patient via the light sources.” Ex.1010, ¶23 (citing Larsen, [0072]).

463. 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, ¶202. 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]. POSA would have understood that Larsen’s applicator is configured to uniformly illuminate a treatment surface of the patient.

464. Thus, Lundahl and Larsen disclose (or Lundahl in view of Larson 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,”

465. 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.



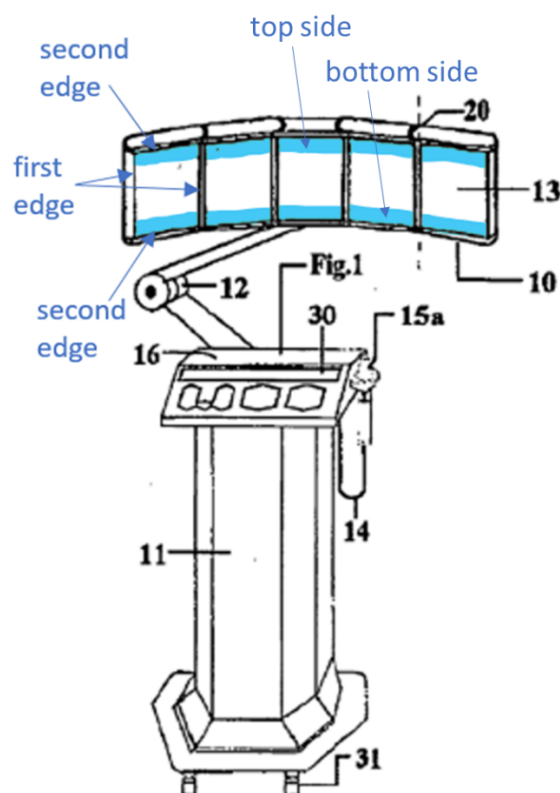
Larsen, Fig. 1.

466. 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* ’028 Patent File History at 328 (finding this limitation disclosed by Figure 1 in the Larsen ’381 Patent).

467. 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”

468. 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.



469. 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.”

470. As an initial matter, as noted in my previous analysis (see ¶¶122-149 *supra*) it is my opinion that the “a 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, as a POSA does not have reasonable certainty as to what is required by the claims (e.g., how to determine what is “proximate” vs. what is “not proximate”). I further note that Sun’s has proposed a construction for the term “a higher intensity of light is emitted close to the second shorter edges compared to the intensity of light emitted not close to the second shorter edges.” While the introduction of the term “close” for “proximate” does nothing to resolve the indefiniteness of the claim term, it is my

assumption that if the term is not deemed to be indefinite, Sun's construction will be adopted. Consequently, the analysis provided herein is based on Sun's construction of the proximate light limitation.

471. 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's Fifth Suppl. Resp. to Biofrontera's First Set of ROGs (Dec. 4, 2024) at 69.



Ex. 13, Fig. 14.

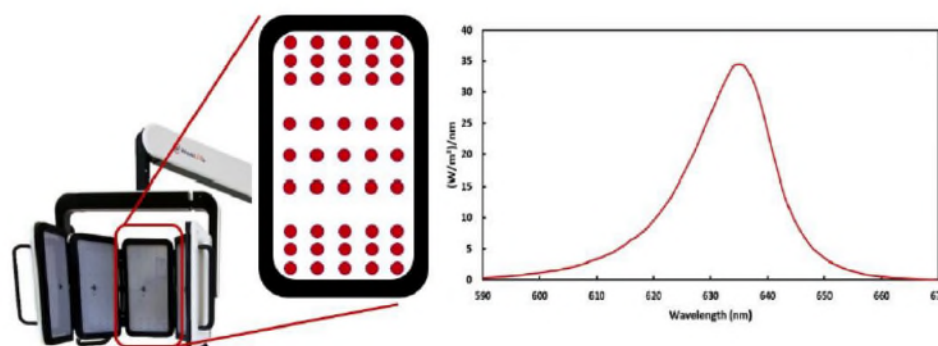
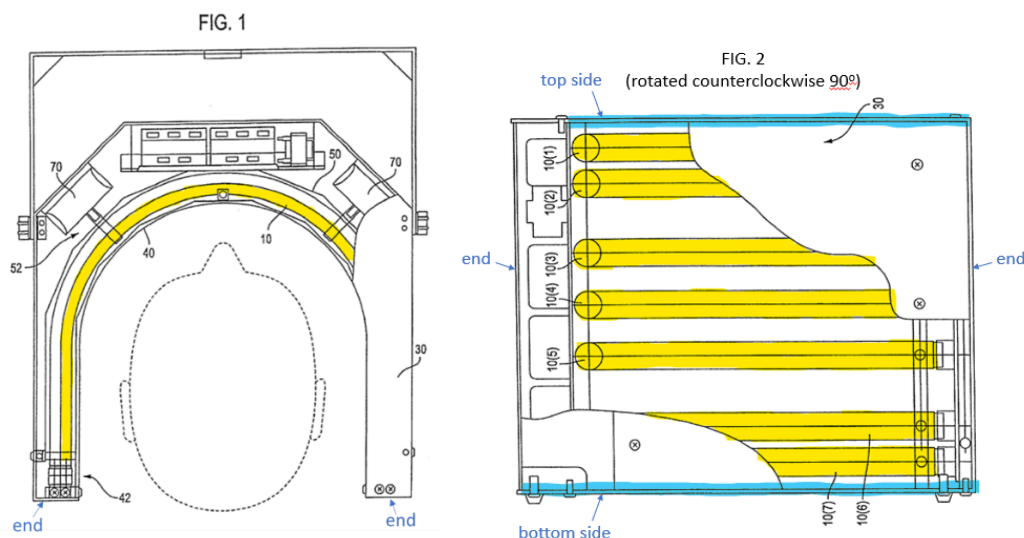


Figure 1: LED panels with LED distribution and emission spectrum of RhodoLED® XL LEDs.

Id.

472. 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, and presumably meet’s Sun’s construction of the proximate light limitation.

473. Using the '512 patent owner’s assertions of what is required by this claim language, Lundahl discloses this limitation. 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.



474. 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 POSA 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.

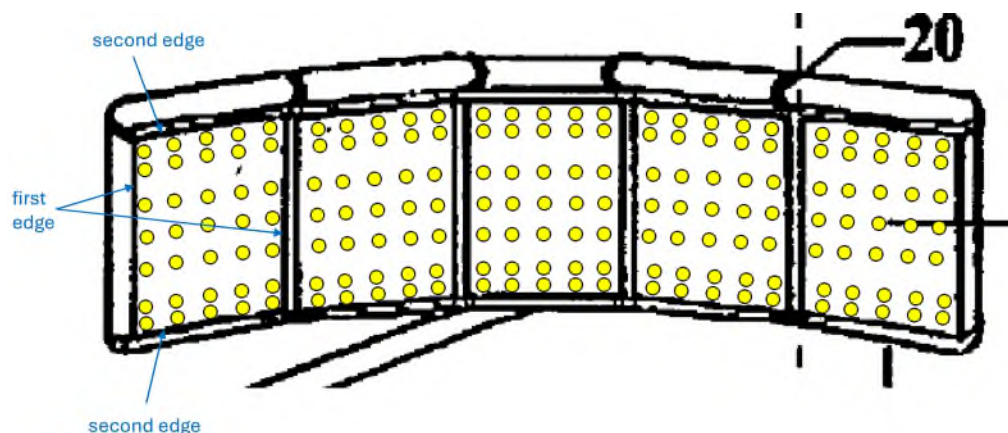
475. Lundahl discloses a single-panel fixed U-shape device. A POSA would know from the Lundahl disclosure (including the combined disclosure of Figures 1 and 2 above), that these curved tubes extend from one side of the “U” shape to the other. While not part of the Lundahl

disclosure, the picture below illustrates this understanding, and how a POSA 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.

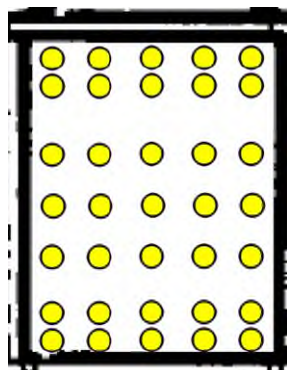
476. As discussed in the motivation to combine section, a motivation existed to combine the teachings of Lundahl and Larsen to: (1) incorporate the hinged panels of Larsen into the PDT device of Lundahl to increase the adaptability of the device; and (2) replace the fluorescent bulbs of Lundahl with 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 POSA would expect the resulting device to have a design similar to the below (yellow circles representing LEDs):



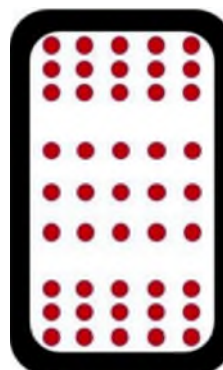
477. The annotated figure above demonstrates a rendering whereby the hinged panels and LEDs taught by Larsen are incorporated into the device of Lundahl, while maintaining the same light distribution pattern Lundahl utilized for the fluorescent bulbs, as shown in Figure 2 above and the accompanying disclosure.

478. 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 close to the second shorter edges compared to the intensity of light emitted not close to the second shorter 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:



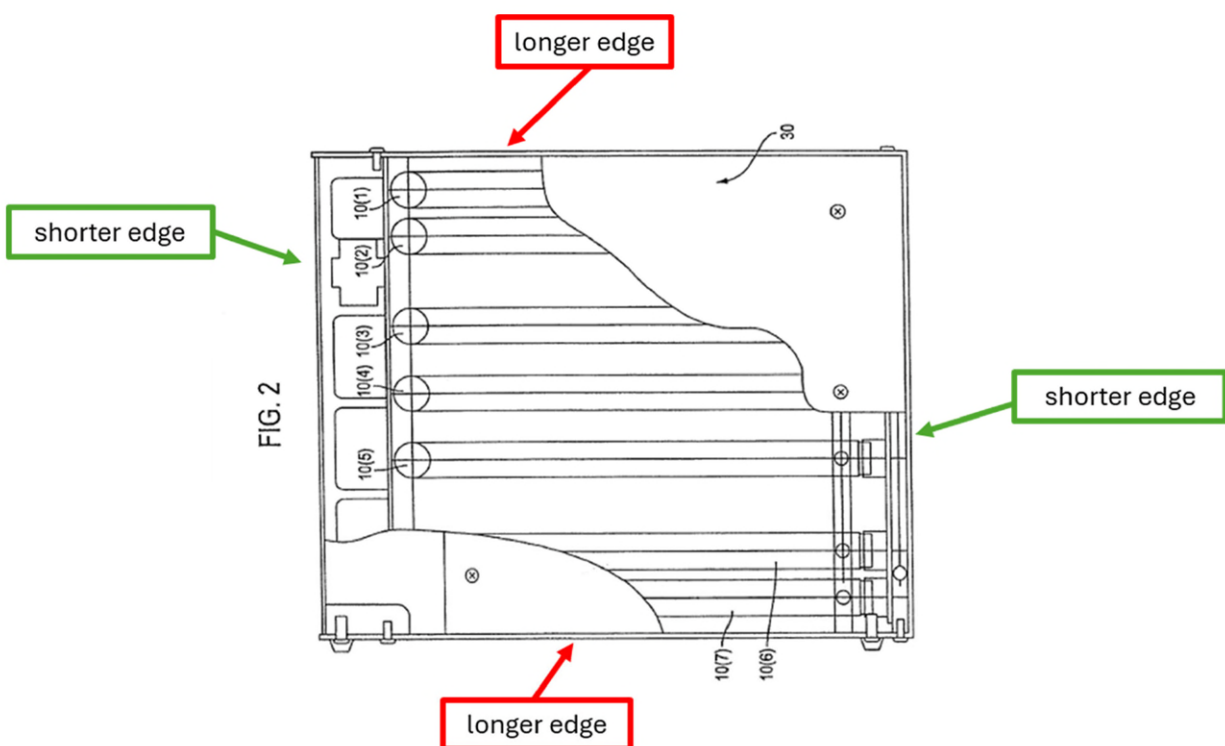
BF-RhodoLED XL:



479. 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, if the claim is found to be definite, and Sun’s construction for the term is adopted, the light arrangement/distribution rendered obvious by Lundahl and Larsen meets the requirement of “higher intensity of light is emitted close to the second shorter edges compared to the intensity of light emitted not close to the second shorter edges.”

480. A POSA 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.

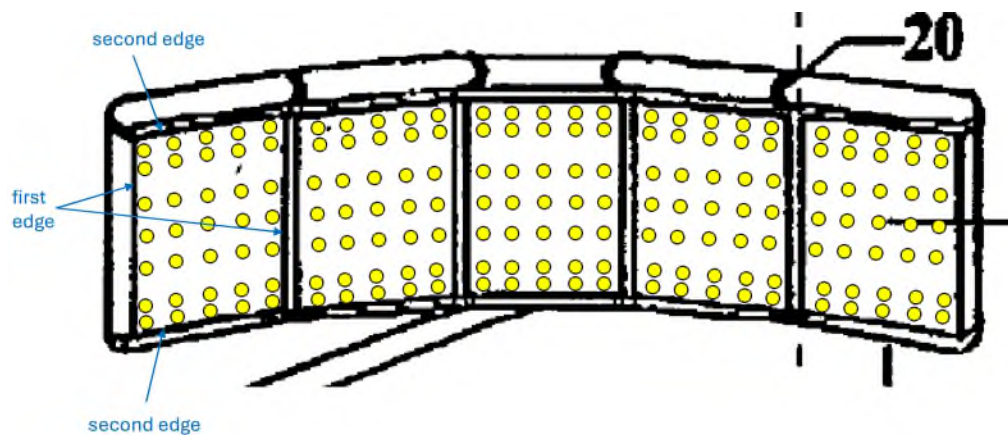
481. I am aware that Sun Pharma has asserted that this claim limitation is not rendered obvious because the “top and bottom sides” of Lundahl’s device that I reference above are “the longer edges, not the shorter edges,” as shown by the illustration Sun provides below:



482. Sun's Suppl. Resp. to Biofrontera's First and Second Set of ROGs, Att. A (Dec. 18, 2024) at 46-48. Sun argues that the Lundahl device, which is one single U-shaped panel stretching from end to end, includes a shorter edge that is the end of the U-shape, and a longer edge that is the top and bottom of the U-shape. However, Sun's comments entirely overlook the fact (as I have described above) that incorporating the five panel design of Larsen into the Lundahl device (effectively taking the single, long U-shaped panel of Lundahl and dividing it into five sections, as illustrated in Larsen) results in a device with a design similar to the below (yellow circles

representing

LEDs).



483. Clearly from the illustration above, the device has a shorter second edge at the top and bottom, and a longer first edge on the side, and the device also has a higher intensity of light emitted close to the second shorter edges compared to the intensity of light emitted not close to the second shorter edges, based on what Sun has asserted to meet the claimed requirement.

484. Additionally, Sun argues that the combination of Lundahl and Larsen renders obvious the proximate light limitation because the Lundahl fluorescent tubes would be expected to have areas of reduced emission near the cathodes of the U-shaped tubes, and submits the following illustrations:

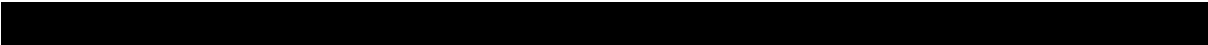


FIG. 1

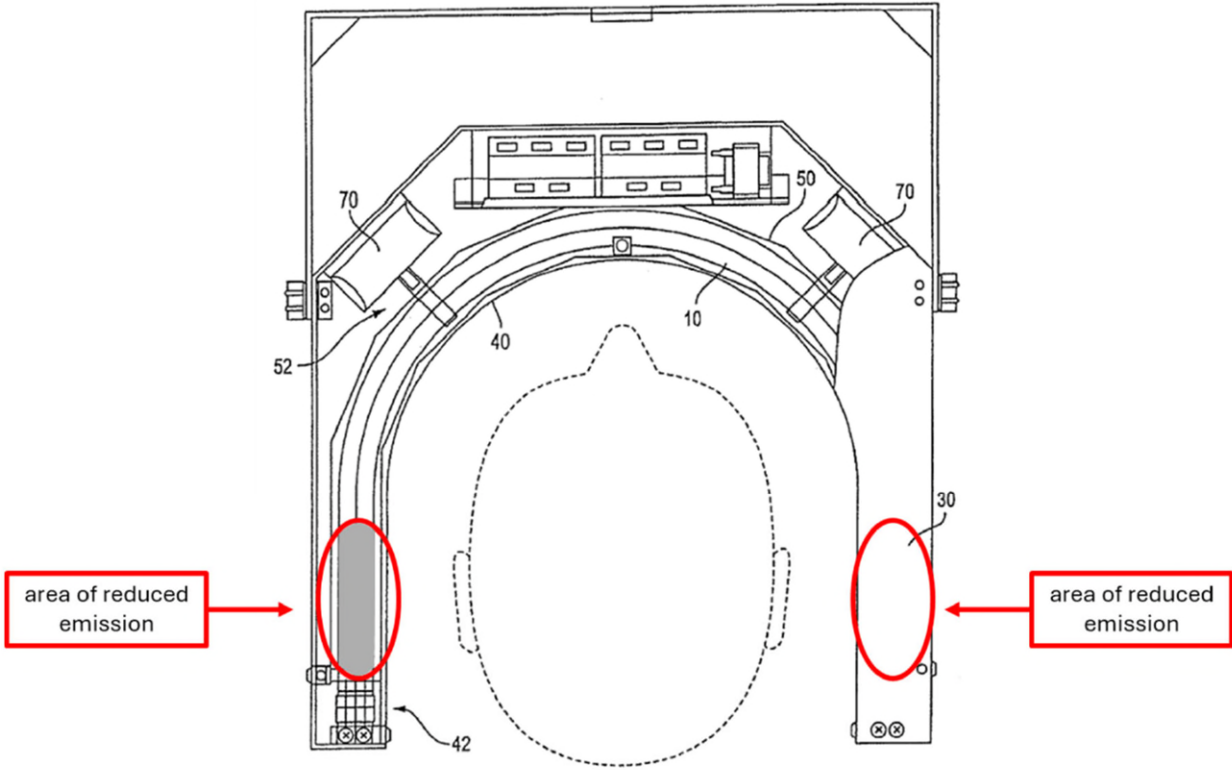
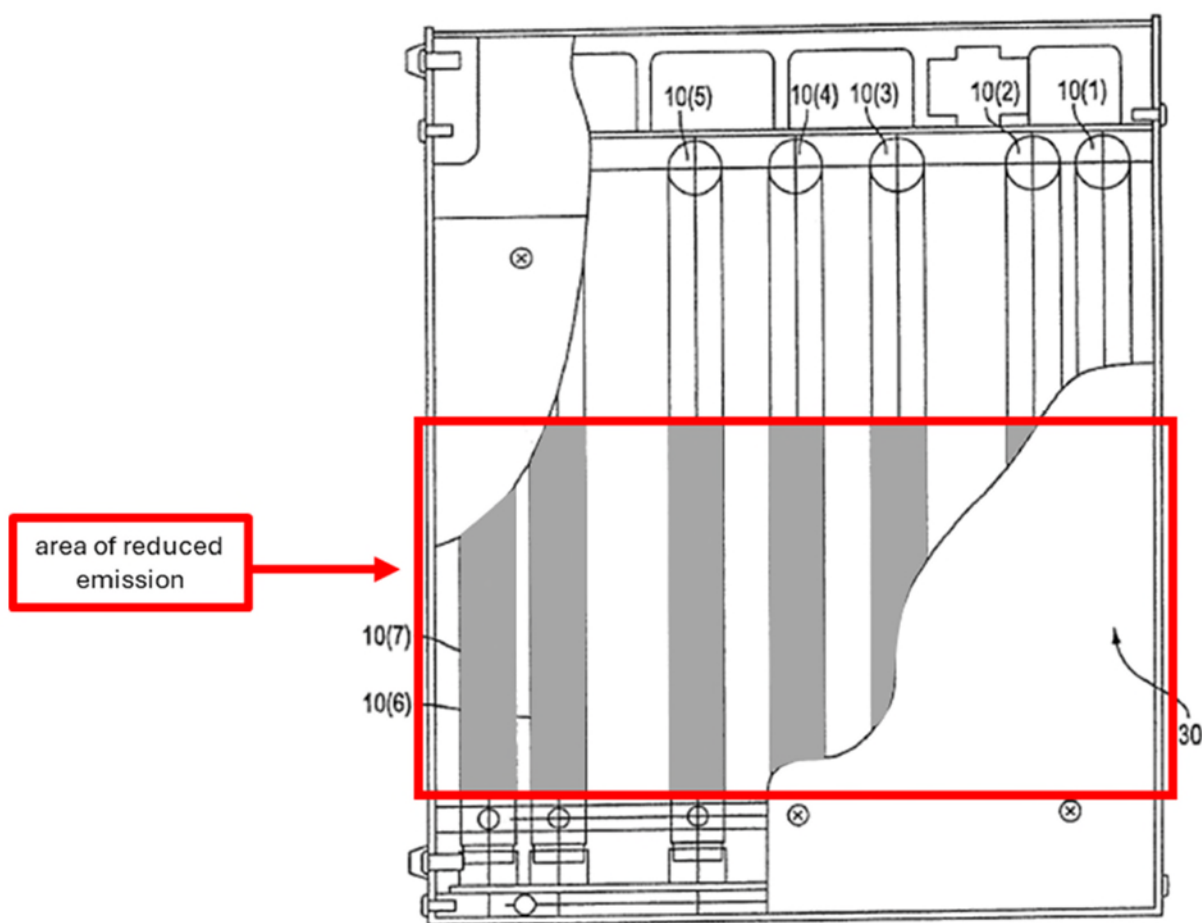


FIG. 2



Sun's Suppl. Resp. to Biofrontera's First and Second Set of ROGs, Att. A (Dec. 18, 2024) at 49-50.

485. Based on the illustrations above, Sun states that "contrary to Biofrontera's assertions, a POSA applying Lundahl's teachings of 'light distribution' would have understood that some of the panels of the alleged resulting device...would have had 'area[s] of reduced emission' as illustrated above in Figs. 1 and 2...In other words, the light emitted proximate the second edges of each panel would not be higher intensity than the light emitted not proximate the second edges, because of the 'low output area[s]' on at least the outer panels." *Id.* at 51.

486. As an initial matter, a POSA would not expect that the area of reduced emission would be as large as what is illustrated by Sun in annotated Figure 2 above. At most, the area of reduced emission would be a small area next to the cathode. Regardless, as I discuss in the section related to motivation to combine Lundahl and Larsen based on the desire to increase light output consistency by changing the light source from fluorescent tubes to LEDs (see ¶¶266-269 supra), this was one of the very problems with the design of Lundahl that a POSA would have sought to fix, and incorporating the LED panels of Larsen would have corrected this issue. As I noted, 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)). LEDs did not suffer from this inconsistent lighting (e.g., “non-emitting areas at their ends”), meaning that incorporating the five panel LED design of Larsen into the Lundahl device (as I illustrated above) would have eliminated this concern.

487. Consequently, Sun’s arguments that Lundahl and Larsen fail to render obvious the claimed requirement of “a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges” is without merit.

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

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.”

489. 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.

490. 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.

491. 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”).

492. 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.

493. 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); Ehrenreich Report at ¶¶139-140. 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); Ehrenreich Report at ¶¶139-140. In all cases, treatment was found to effectively resolve the treated lesions. Kennedy, 5:47-6:47 (Examples); Ehrenreich Report at ¶¶139-140. 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.¹³ Therefore, Kennedy’s teaching of red light 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.

494. 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

¹³ As I understand from Counsel, “when, 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, 782, 227 USPQ 773 (Fed. Cir. 1985) (citing *In re Petering*, 301 F.2d 676, 682, 133 USPQ 275, 280 (CCPA 1962)).

[REDACTED]

the specific irradiance. Consequently, a POSA 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.¹⁴

495. 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.

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

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.”

497. 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,

¹⁴ As I understand from Counsel, “where 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).

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.”

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

Claim 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:”

499. 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].

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

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

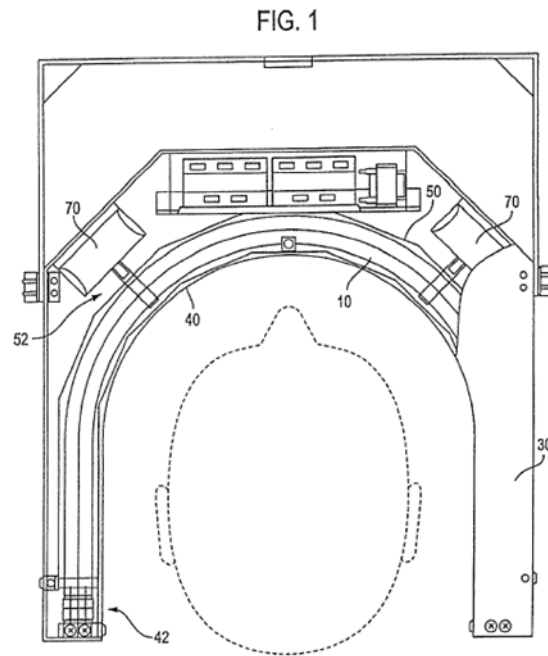
501. Lundahl teaches that “[a]ccording to one preferred embodiment of the present invention, blue light having wavelengths exceeding 400 nm (nanometers) is particularly advantageous for certain diagnostic purposes and treatments, especially when ALA is the photoactivatable agent used for PD and PDT of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

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

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

503. 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.

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



Lundahl, Fig. 1.

505. 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”

506. 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.

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

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

508. 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,”

509. 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”

510. 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.”

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

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

Claim 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:”

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

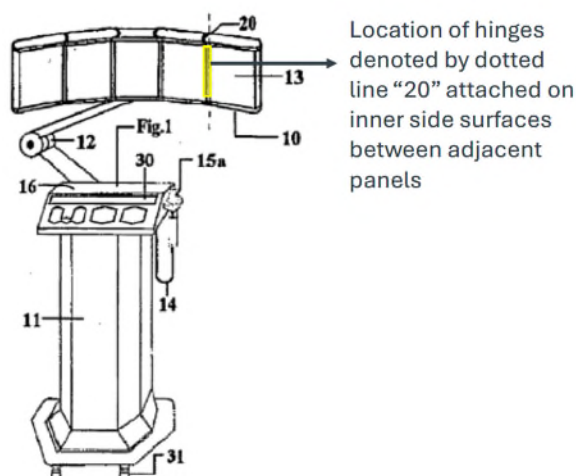
Claim 20(a): “an illuminator comprising at least five panels connected by nested hinges on inner side surfaces of adjacent panels,”

514. 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,”

515. 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 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.

516. 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."

517. 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."

518. 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,"

519. 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,”

520. 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,”

521. 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,”

522. 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.”

523. 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).

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

a. 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

525. My previous analysis provided above, 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-

[REDACTED]

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 above.

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”

526. 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 construction for “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.

527. 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”:

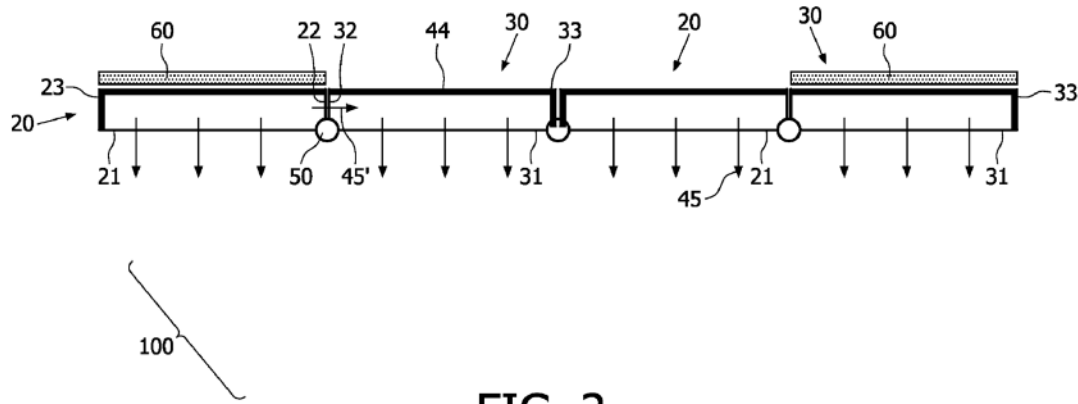
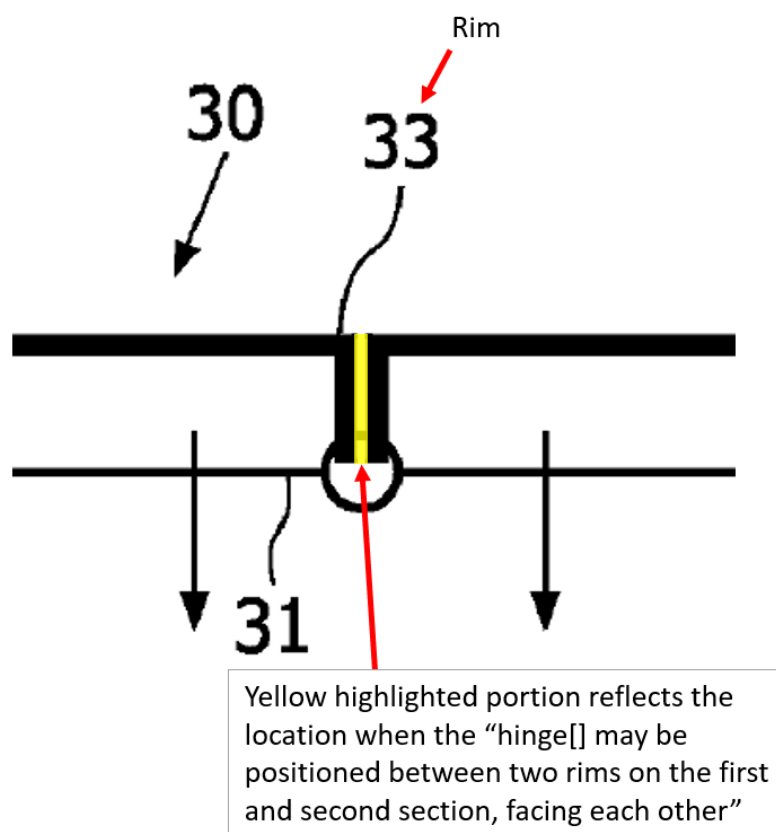


FIG. 2

Hente, Fig. 2.

528. 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”:



529. 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."

530. A POSA 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 POSA 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

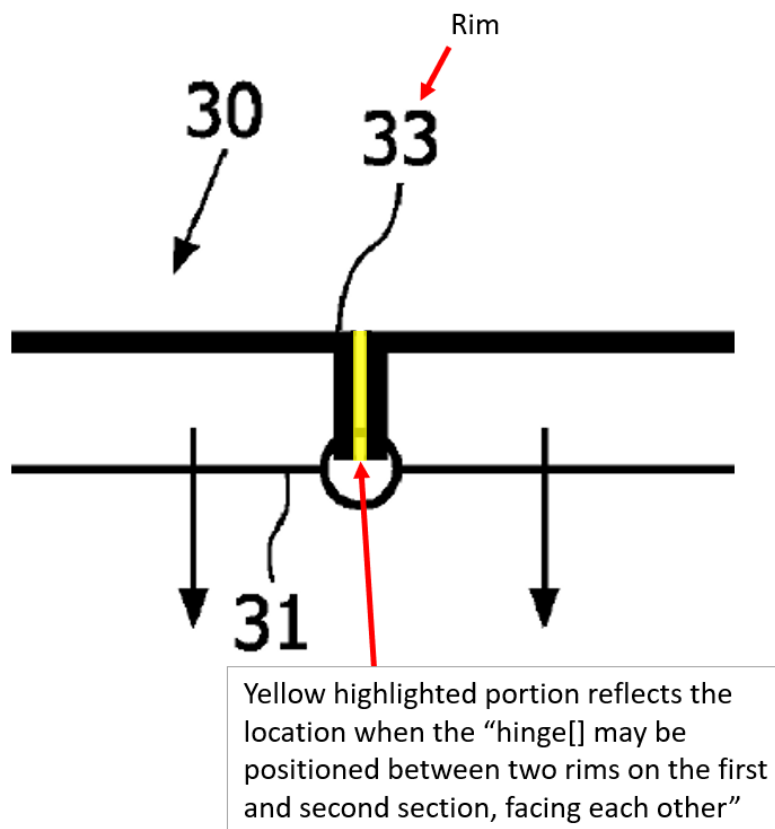
[REDACTED]

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.

531. Hente is from the same field of endeavor as the '512 Patent, which also describes illuminators. '512 Patent, 1:24-2:4. A POSA 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 POSA was motivated to enhance adjustability of the illuminator rendered obvious by Lundahl and Larsen. Given this knowledge, a POSA 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.

532. I am aware that Sun Pharma has asserted that Hente does not disclose “nested hinges on inner side surfaces of adjacent panels” because Hente discloses hinges “being positioned at the outer rims of the light emitting device respectively positions,” and that “the hinges 50 are located at the corners of the outer rims, and do not fit on the inner side surfaces between adjacent sections.” Sun’s Suppl. Resp. to Biofrontera’s First and Second Set of ROGs, Att. A (Dec. 18, 2024) at 86-87. As I illustrated above, and reproduced below, it is my opinion that a POSA would

locate the flange for the hinge in the yellow highlighted area between adjacent sections (i.e., at the outer rim):



533. The location illustrated above (highlighted yellow) is “on the inner side surfaces” between the adjacent panels. Additionally, while Sun argues that the hinge is “located at the corners of the outer rims,” it is clear from the illustration above that part of the hinge is attached to the inner side surface between the rims.

534. Sun further asserts that Biofrontera has not shown that a POSA was motivated to locate Hente’s hinges on inner side surfaces of adjacent panels because Figs. 3 and 4 of Hente illustrate embodiments whereby the sections are in “partially expanded” and “compact” positions. Sun’s Suppl. Resp. to Biofrontera’s First and Second Set of ROGs, Att. A (Dec. 18, 2024) at 87-88. However, Hente provides guidance for multiple orientations of the adjacent sections of the



illumination device. As I discussed above, the disclosure provided in the text of Hente and the illustration of Fig. 2 (representing a “nearly flush” orientation) would nonetheless motivate a POSA to locate the hinges on inner side surfaces of adjacent sections. Hente’s disclosure of other orientations (i.e., the “partially expanded” and “compact” orientations) would not change this motivation.

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

536. 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.”

537. 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.

538. 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. It is my understanding that Biofrontera has proposed that term “a recess” be construed as having its plain and ordinary meaning of an indentation in a surface. Respondents’ Opening Claim Construction Brief, at 19-20. Alternatively, Sun has construed the term as having its “plain and ordinary” meaning, but has not specified what the “plain and ordinary” meaning is. For purposes of this analysis I am using Biofrontera’s construction of “an indentation in a surface” as the construction for the term, but even if Sun’s proposed “plain and ordinary” construction is adopted (without specifying what is meant by “plain and ordinary”) it is nonetheless my opinion that Hente discloses and renders obvious “a recess configured to receive a flange of one of the nested hinges,” as it is

my opinion that the “plain and ordinary” meaning of “a recess” is, in fact, an indentation in a surface.

539. 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.

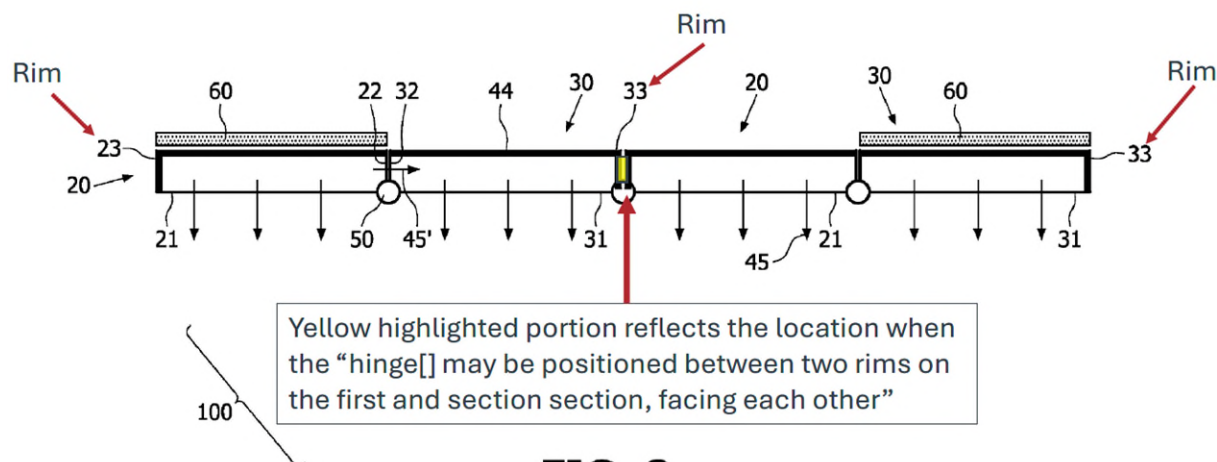
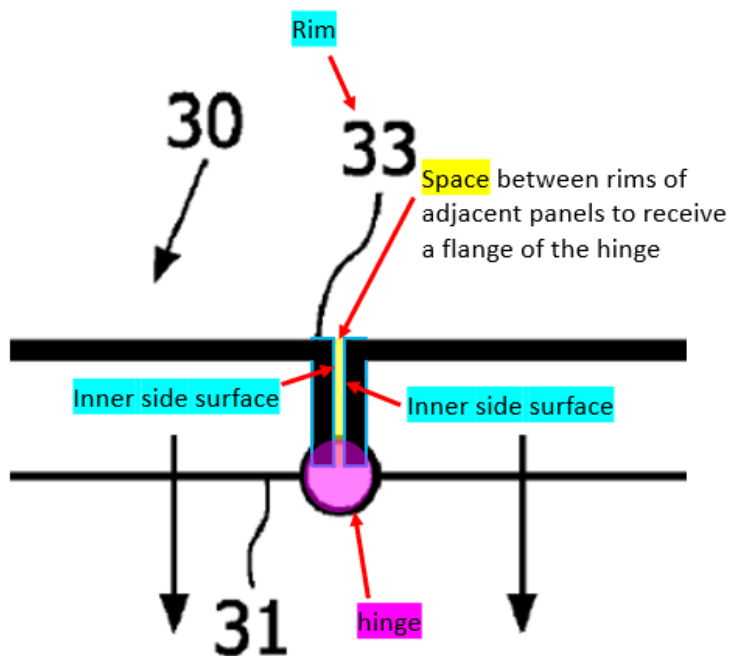
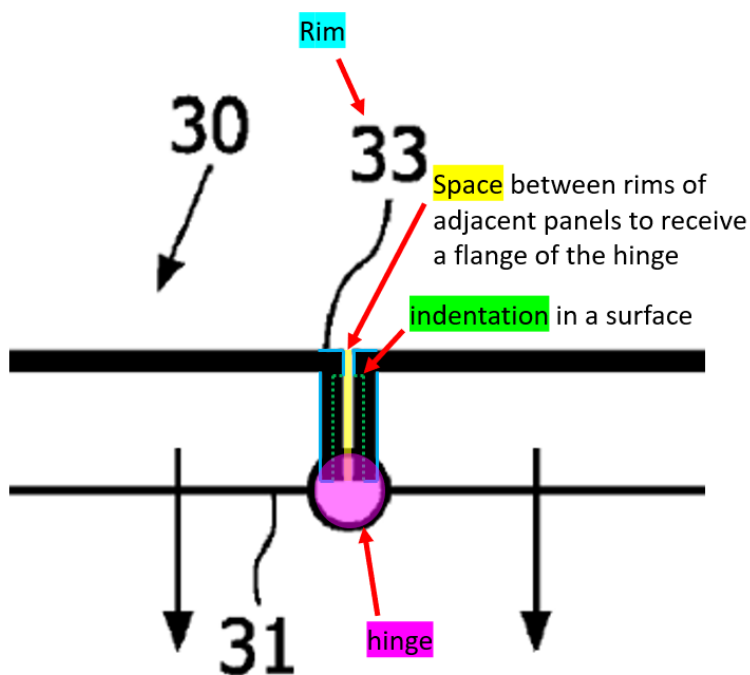


FIG. 2

540. 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.



541. A POSA 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.



542. 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 POSA 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.

543. I am aware that Sun Pharma has asserted that Lundahl in view of Larsen further in view of Hente fails to render obvious this limitation because Hente does not mention flange when describing Fig. 2 above. Sun's Suppl. Resp. to Biofrontera's First and Second Set of ROGs, Att.



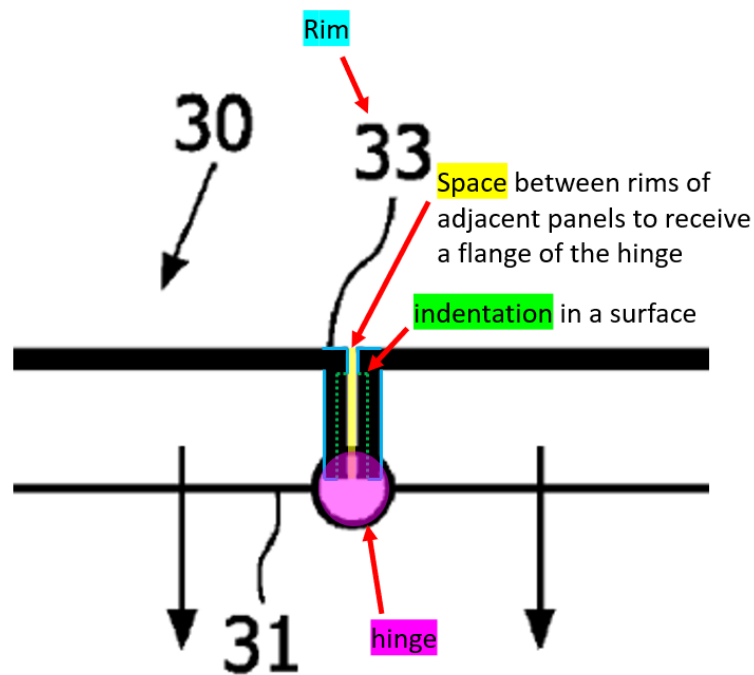
A (Dec. 18, 2024) at 92-93. However, it is well-known to a POSA that flanges are the most common mechanism by which a hinge is attached to an adjacent surface. Consequently, by disclosing that Hente incorporates “hinge 50,” a POSA would assume that the hinge is attached to the adjacent sections by means of a flange. In view of this understanding, a POSA would consider the space between the adjacent rims as the logical place to locate the flanges that attach hinge 50 to adjacent sections 30 and 20 described in Fig. 2. From there, it then logically flows that a POSA would be motivated to place the flanges of the hinge 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, again, was a well-established design motivation from the teachings of Hente and Larsen.

544. 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.”

545. 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.

546. As I discussed previously, A POSA 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.



547. 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.”

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

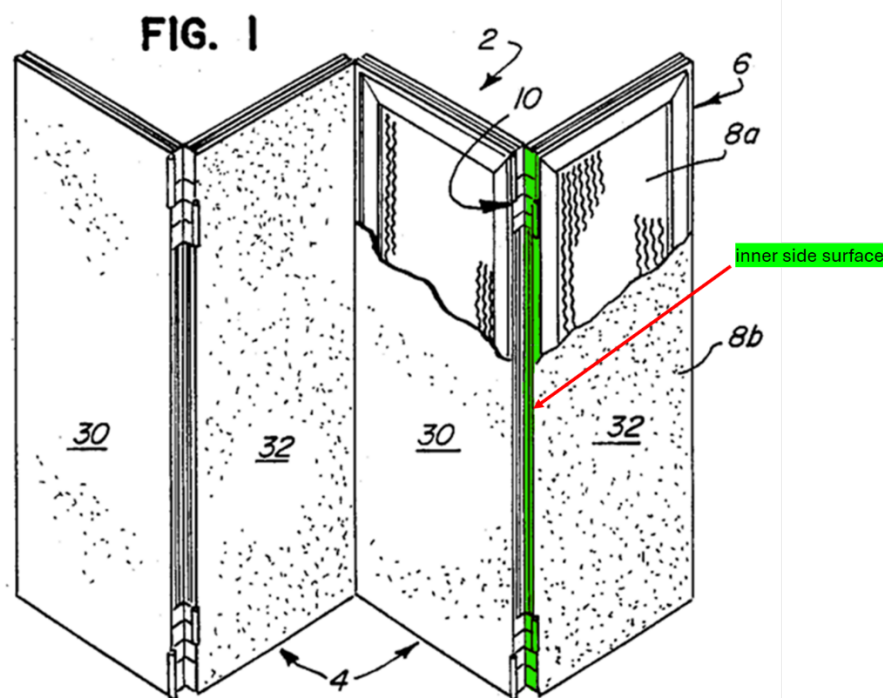
b) Lundahl in view of Larsen, further in view of Hente, and further in view of Perutz, renders obvious at least claims 17 and 18 of the '512 Patent

549. 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 above is incorporated herein in its entirety.

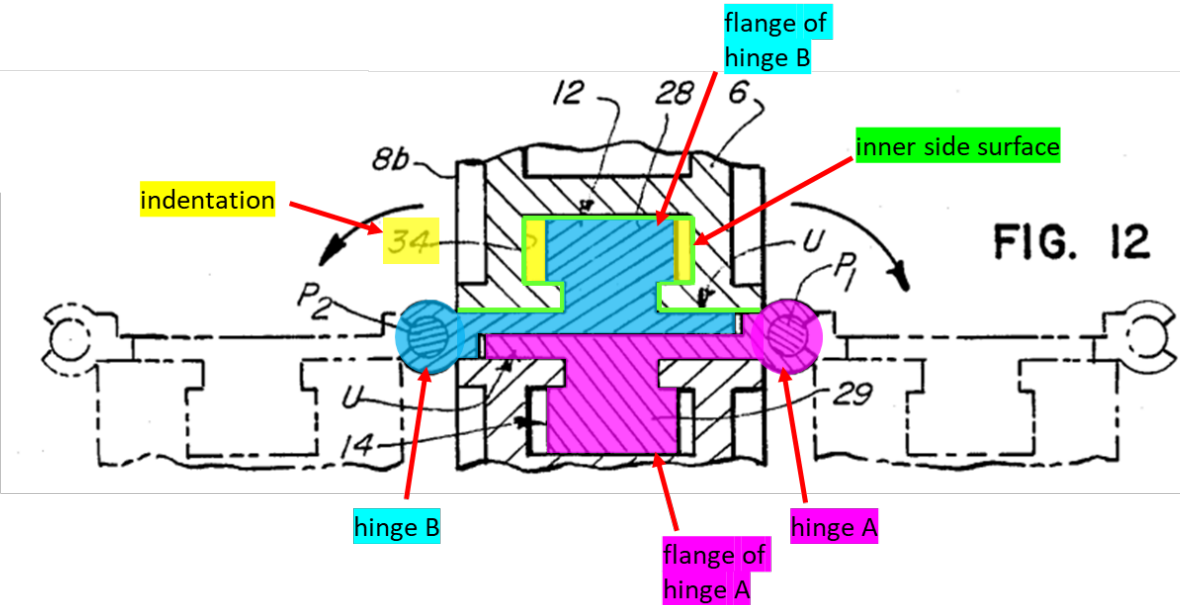
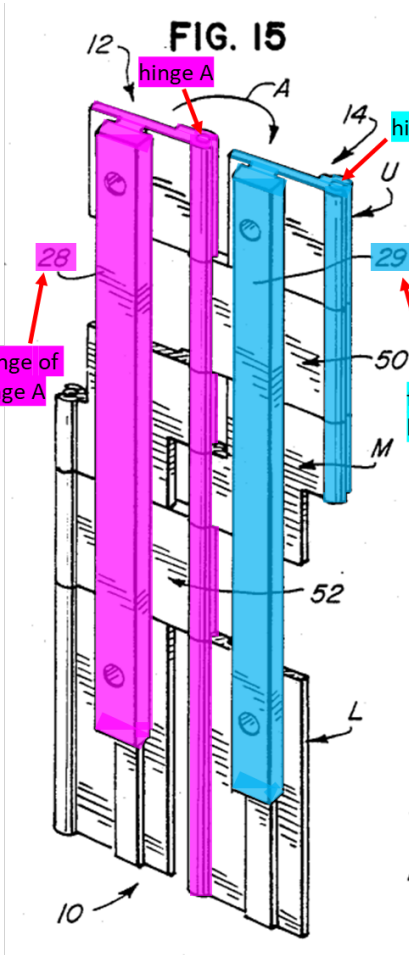
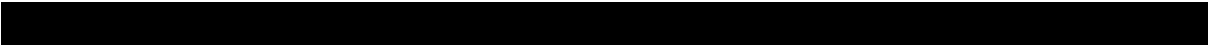
Claim 17: “The method of claim 8, wherein at least one panel includes a recess configured to receive a flange of one of the nested hinges.”

550. 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.



551. 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.



552. A POSA 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.

553. 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).

554. 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.”

555. 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.”

556. 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.

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X. CONCLUSION

615. For the reasons set forth above, the claims of the Asserted Patents are invalid.

Respectfully submitted,

Signed by:
ROBERT E. GROVE, PH.D.
75791E926920490

DR. ROBERT E. GROVE, PH.D.