

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

v.

SUN PHARMACEUTICAL INDUSTRIES, INC.,
Patent Owner.

IPR2024-01312
Patent 11,697,028 B2

Before WILLIAM V. SAINDON, ERICA A. FRANKLIN, and
ROBERT A. POLLOCK, *Administrative Patent Judges*.

FRANKLIN, *Administrative Patent Judge*.

DECISION
Granting Institution of *Inter Partes* Review
35 U.S.C. § 314

I. INTRODUCTION

Biofrontera Inc., Biofrontera Bioscience GmbH, Biofrontera Pharma GmbH, and Biofrontera AG (“Petitioner”) filed a Petition requesting an *inter partes* review of claims 1, 2, 4–6, 16, 17, and 19–21 of U.S. Patent No. 11,697,028 B2 (Ex. 1001, “the ’028 patent”). Paper 3 (“Pet.”). Additionally, Petitioner filed a Notice Regarding Parallel Petitions, as it had previously filed a petition challenging the same patent in IPR2024-00874. *See* IPR2024-00874, Paper 3. In the Notice, Petitioner ranked the petition in IPR2024-01312 higher. *See* IPR2024-01312, Paper 2, 1.

Sun Pharmaceuticals Industries, Inc. (“Patent Owner”) filed a Preliminary Response to the Petition. Paper 7 (“Prelim. Resp.”). Additionally, Patent Owner filed a response to Petitioner’s Notice Regarding Parallel Petitions. Paper 8.

Based on the circumstances, we determine that the issue of whether the Board should exercise its discretion to institute more than one petition by Petitioner challenging the same patent is moot, as we denied the first petition on the merits. *See* IPR2024-00874, Paper 9.

We have authority to determine whether to institute an *inter partes* review. 35 U.S.C. § 314. Upon considering the parties’ arguments and evidence, we determine that Petitioner has established a reasonable likelihood that it would prevail in showing the unpatentability of at least one claim challenged in the Petition. Accordingly, we institute an *inter partes* review of all claims and all grounds asserted in the Petition.

A. *Real Parties-in-Interest*

Petitioner identifies itself, Biofrontera Neuroscience GmbH and Biofrontera Development GmbH as the real parties-in-interest. Pet. 5. Patent Owner identifies itself as the real party-in-interest. Paper 5, 1.

B. Related Matters

The parties relay that the following proceedings are related, both filed on June 24, 2024: *In re Certain Photodynamic Therapy Systems, Components Thereof, And Pharmaceutical Products Used In Combination With The Same*, Investigation No. 337-TA-1411 (U.S.I.T.C.); and *Sun Pharmaceutical Industries, Inc. v. Biofrontera Bioscience GmbH, Biofrontera Pharma GmbH, Biofrontera AG, and Biofrontera Inc.*, Civil Action No. 1:24-cv-11637 (D. Mass). Pet. 6; Paper 5, 1. The parties also identify IPR2024-00874. *Id.*

C. The '028 Patent

The '028 patent relates to “an adjustable illuminator that provides a uniform distribution of visible light in a number of configurations and is suitable for use in photodynamic therapy and diagnosis.” Ex. 1001, 1:19–22. A perspective view of the illuminator attached to a stand, shown below, is in Figure 4.

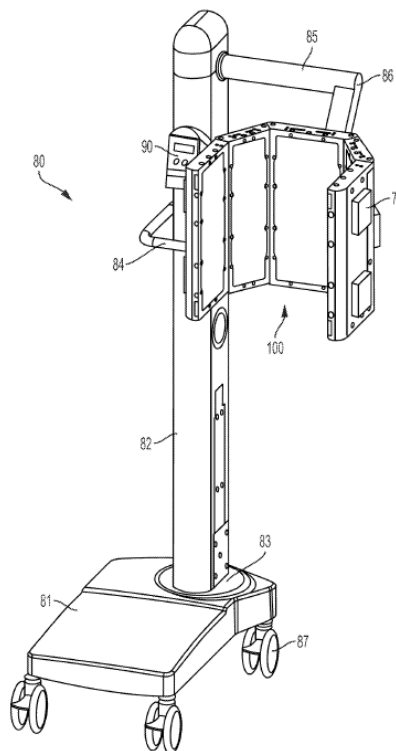


Figure 4 shows main body 100 of the illuminator mounted by a connecting arm 85 to a movable stand 80, which includes a base 81 with wheels 87. *Id.* at 5:16–33.

The Specification describes that main body 100 “preferably has five individual panels 10a-10e, each of which are connected in a rotatable manner via nested hinges 50.” *Id.* at 3:54–56. Further, “[e]ach panel contains an array of light emitting diodes (LED) 60, which may be configured in an evenly spaced pattern across the face of the panel.” *Id.* at 3:56–59. The patent explains that the “LED arrays 60 emit light at an appropriate wavelength according to the intended treatment or to activate the particular photoactivatable agent used in treatment or diagnosis.” *Id.* at 4:1–4. The main body 100 is shown below in perspective view in Figure 2b.

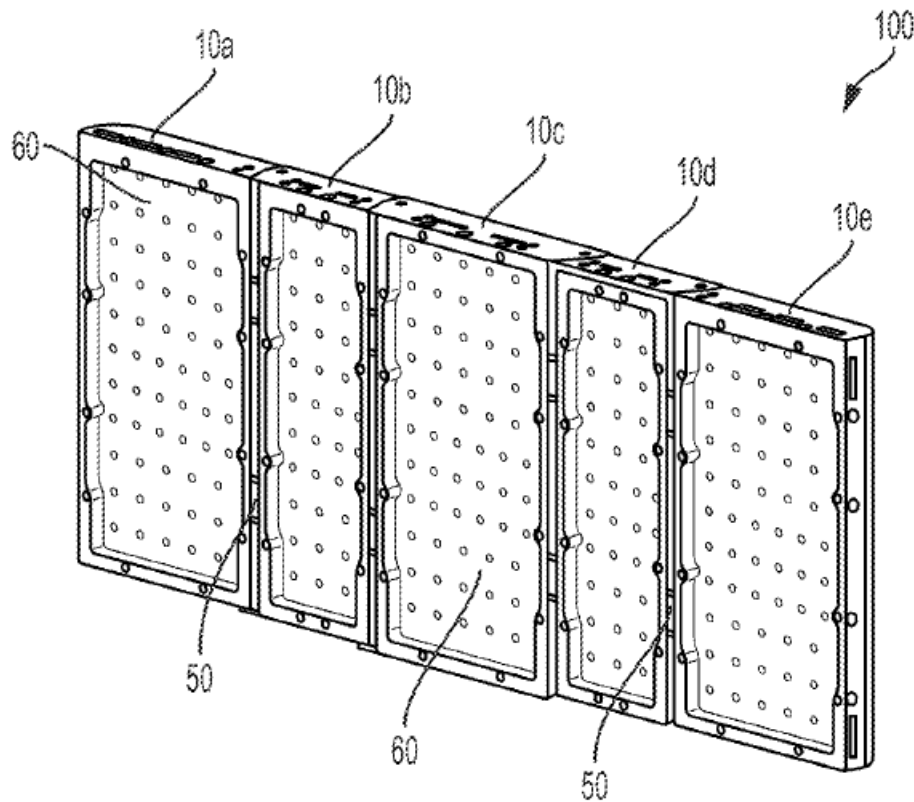


Figure 2b shows main body 100, comprising LED arrays 60, hinges 50, and panels 10a–10e. *Id.* at 3:52–59. The patent describes that “the five

panels 10a-10e are of different widths relative to one another,” and connected to each other by hinges 50. *Id.* at 4:25–26, 4:47–48. The hinges “may take the form of nested hinges, which may include hinges 50 that substantially reduce or eliminate optical dead spaces.” *Id.* at 4:48–50.

The Specification also describes that “[a]t least one control unit is also connected to the panels to regulate power to the lights to achieve the required uniformity and intensity for the target treatment,” and that “each panel may have a dedicated control unit to regulate power to the individual LED array on a given panel.” *Id.* at 5:52–62. A schematic view illustrating an exemplary configuration of LEDs mounted on the main body of the illuminator is shown below in Figure 5.

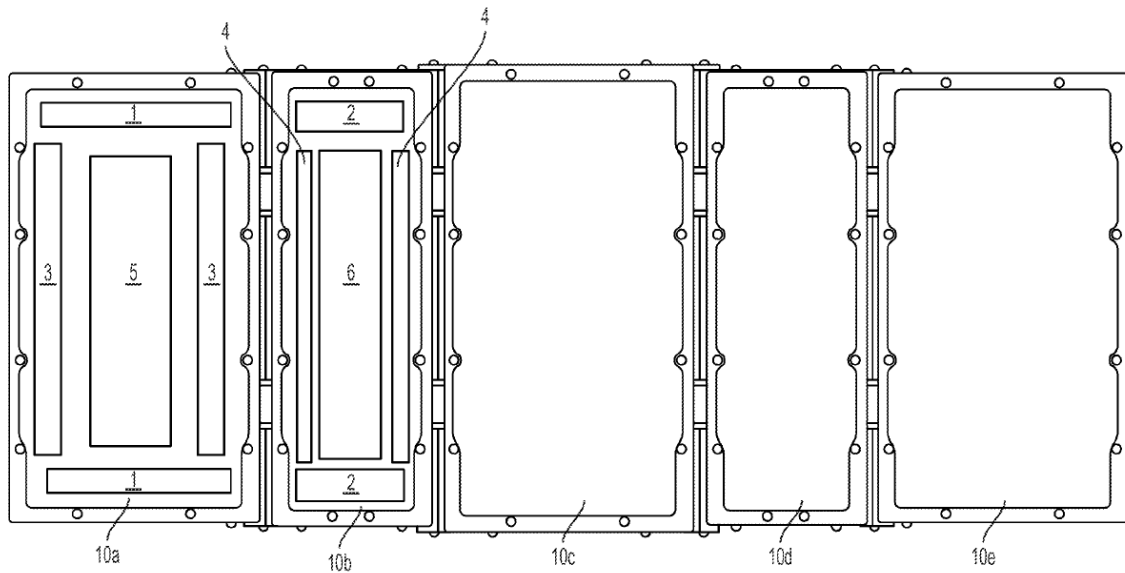


Figure 5 shows LED arrays 60 divided into three general areas, areas 1, 3, and 5 on the wider panels 10a, 10c, and 10e, and areas 2, 4, and 6 on the narrower panels 10b and 10d. *Id.* at 6:24–31. The Specification explains, “to increase the uniformity of light exposure to the treatment area while maintaining a practical size of the illuminator, the LED arrays 60 may be individually configured to increase the intensity of light emitting from

certain diodes,” which may allow for a reduction of any “fall off” of light exposure that tend to occur at the edges of a curved surface. *Id.* at 6:7–8, 6:18–22. For example, “a higher current may be supplied to areas 1 and 2 than the current supplied to areas 3 and 4 such that areas 1 and 2 emit a higher intensity of light than areas 3 and 4.” *Id.* at 6:33–36.

D. Illustrative Claims

Petitioner challenges claims 1, 2, 4–6, 16, 17, and 19–21 of the ’028 patent. Independent claims 1 and 5, set forth below, are illustrative of the claimed subject matter.

1. A system for photodynamically diagnosing or treating a patient, comprising:
 - an illuminator comprising five panels connected by hinged structures on inner side surfaces of adjacent panels; and
 - light sources disposed on surfaces of the five panels, the illuminator being configured to uniformly illuminate a treatment surface of the patient via the light sources, one of the five panels being positioned as a center panel configured to face the treatment surface, and two or more of the five panels being configured to be angled relative to the center panel,
- wherein the five panels are positioned to allow treatment within approximately four inches of the treatment surface, and
- wherein each of the five panels has two first edges and two second edges shorter than the two first edges, and the light sources are arranged such that a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges.

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

administering 5-aminolevulinic acid (ALA) to the patient;
positioning an illuminator proximate to the patient, the illuminator comprising five panels connected by hinged structures on inner side surfaces of adjacent panels; and
uniformly illuminating a treatment surface of the patient with light sources disposed on the five panels of the illuminator, the five panels being positioned to allow treatment within approximately four inches of the treatment surface,

wherein each of the five panels has two first edges and two second edges shorter than the two first edges, and the light sources are arranged such that a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges.

Ex. 1001, 10:24–44; 10:54–11:3.

Independent claims 16, 20, and 21 also recite systems for photodynamically diagnosing or treating a patient. Dependent claim 2 recites a red light dosage. Dependent claim 4 recites wavelength ranges. Dependent claim 6 recites a minimum duration for outputting red light. Dependent claim 8 recites changing intensities of the light sources based on curvature of a treatment surface. Dependent claims 10, 11, 13, and 14 recite adjusting dose based on size or shape of a treatment surface. Dependent claim 17 recites panel positioning. Dependent claims 18 and 19 recite outputting blue light and red light, respectively.

E. Asserted Grounds of Unpatentability

Petitioner asserts that claims 1, 2, 4–6, 16, 17, and 19–21 are unpatentable on the following two grounds:

Claim(s) Challenged	35 U.S.C. §¹	Reference(s)/Basis
1, 2, 4–6, 16, 17, 19–21	103	Lundahl, ² Larsen ³
1, 2, 4–6, 16, 17, 19–21	103	Lundahl, Larsen, Bansal ⁴

Petitioner also relies upon the Declarations of Robert E. Grove, Ph.D. (Ex. 1015) and Eric Bretschneider, Ph.D. (Ex. 1016). Patent Owner relies upon the Declaration of Jose Sasian, Ph.D. (Ex. 2001).

II. ANALYSIS

A. *Person of Ordinary Skill in the Art*

The level of skill in the art is a factual determination that provides a primary guarantee of objectivity in an obviousness analysis. *Al-Site Corp. v. VSI Int’l Inc.*, 174 F.3d 1308, 1323 (Fed. Cir. 1999) (citing *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966)); *Ryko Mfg. Co. v. Nu-Star, Inc.*, 950 F.2d 714, 718 (Fed. Cir. 1991)).

Petitioner asserts that a person of ordinary skill in the art (“POSITA” or “POSA”) at the time of the earliest effective filing date of the application for the ’028 patent:

¹ The Leahy-Smith America Invents Act, Pub. L. No. 112–29, 125 Stat. 284 (2011) (“AIA”), amended 35 U.S.C. § 103, effective March 16, 2013. The earliest claimed priority date for the ’028 patent is after the effective date of the applicable AIA amendment. *See* Ex. 1001, code (60). Accordingly, we apply the AIA version of §103.

² Scott Lundahl, U.S. 6,223,071 B1, issued Apr. 24, 2001 (Ex. 1014, “Lundahl”).

³ Eric Larsen, U.S. 2004/0075703 A1, published Apr. 7, 2005 (Ex. 1004, “Larsen”).

⁴ Vineet Bansal et al., U.S. 2004/0068305 A1, published Apr. 8, 2004 (Ex. 1005, “Bansal”).

would have been an individual or member of a multi-disciplinary team with education of (1) at least a Bachelor of Science degree in one or more fields of electrical engineering, physics, biomedical engineering, computer engineering, chemical engineering or material science, in fields relating to optics, optoelectronics, radiometry, photometry, photodynamic diagnosis (PD), photodynamic therapy (PDT), phototherapy (PT), and related technologies; and (2) a medical degree in fields relating to the diagnosis and treatment of skin conditions and related disease states.

Pet. 23–24. Additionally, Petitioner asserts,

Alternatively, individually or members of the multi-disciplinary team would have had at least four years of experience in one or more fields of optics, optoelectronics, radiometry, photometry, photodynamic diagnosis (PD), photodynamic therapy (PDT), or phototherapy (PT), and at least four years of experience in one or more fields of medical treatment of skin conditions and related disease states.

Id. at 24.

According to Petitioner, Dr. Ehrenreich “provides testimony about the background knowledge of a POSITA for medical treatments involving PDT and explains the teachings of medical treatments in the cited prior art.” *Id.* 24 (citing Ex. 1016 ¶¶ 28–37).

According to Patent Owner, a person of ordinary skill in the art at the time of invention “would have had a M.D. and/or a Ph.D. in an electrical engineering, physics, optical sciences, optical engineering, or a related scientific or engineering field, and at least one to two years of work or research experience in optical engineering, optics, optoelectronics, phototherapy (‘PT’), PDT, or a related field.” Prelim. Resp. 22. In the alternative, Patent Owner asserts that, “a POSITA could have a Bachelor’s degree in one of the above areas and at least three to four years of work or research experience in that area.” *Id.* (citing Ex. 2001 ¶¶ 29–30).

Patent Owner asserts that Petitioner has not provided a valid justification for requiring a POSITA to have both an engineering degree and a medical degree. We agree, insofar as Petitioner has not clearly set out any particular explanation or evidence in support of its dual-degree requirement.

In all other respects, we note that the parties' proposed definitions are largely similar. Because we determine that Patent Owner's proposed definition is reasonable and consistent with the '028 patent and the cited art, we adopt Patent Owner's definition for purposes of this Decision. In any event, our decision whether to institute does not turn on this level of skill determination.

B. Claim Construction

The Board applies the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. § 282(b); 37 C.F.R. § 100(b). Under that standard, claim terms “are generally given their ordinary and customary meaning” as understood by a person of ordinary skill in the art at the time of the invention. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–13 (Fed. Cir. 2005) (en banc) (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)). See *Wellman, Inc. v. Eastman Chem. Co.*, 642 F.3d 1355, 1361 (Fed. Cir. 2011) (“[C]laim terms need only be construed ‘to the extent necessary to resolve the controversy.’”) (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999)).

Petitioner and Patent Owner assert that the Board need not construe any claims for the purpose of deciding whether to institute an *inter partes* review. Pet. 12; Prelim. Resp. 24. We agree.

C. Obviousness over Lundahl and Larsen

Petitioner asserts that the challenged claims would have been obvious over the combined teachings of Lundahl and Larsen. Pet. 25–73. Patent Owner disagrees. Prelim. Resp. 32–71.

A patent claim is unpatentable under 35 U.S.C. § 103 if the differences between the claimed subject matter and the prior art are such that the subject matter, as a whole, would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains. *See KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). “An obviousness determination requires finding both ‘that a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success in doing so.’” *CRFD Research, Inc. v. Matal*, 876 F.3d 1330, 1340 (Fed. Cir. 2017) (quoting *Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1367–68 (Fed. Cir. 2016)).

1. Lundahl

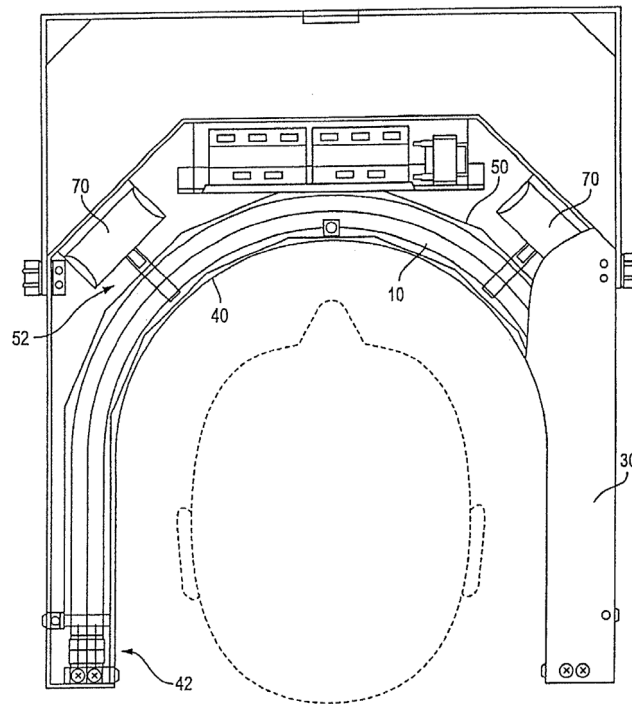
Lundahl is “directed to an apparatus and method for photodynamic treatment (PDT) or diagnosis (PD) of actinic keratosis of the scalp or facial areas of a patient,” as well as other areas of the patient, such as the arms and legs. Ex. 1014 ¶ 1. The photodynamic therapy uses an illuminator to provide a uniform distribution of visible light. *Id.* The Specification explains,

The inverse square law of optics states that the intensity of light from a point source received by an object is inversely proportional to the square of the distance from the source. Because of this behavior, distance from the source is an important variable in all optical systems. Thus, in order to achieve uniform facial or scalp irradiation, variations in output irradiance with distance must be minimized.

Id. at 4:22–28. The Specification teaches that “[a] flat emitting surface would not deliver a uniform light dose to all contours of the face simultaneously because the non-planar facial and scalp surfaces could not be placed at a constant distance from the emitting surface.” *Id.* at 4:28–32. According to the Specification, “[t]o ameliorate this problem, the present invention uses a U-shaped emitting surface that more closely follows the contours of the human face and scalp, and minimizes lamp to target distance variations which in turn minimizes irradiance variations at the target.” *Id.* at 4:32–37.

A partial cross-section, front elevation view of an illuminator according to the present invention is shown below, in Figure 1.

FIG. 1



Lundahl Figure 1 shows a preferred embodiment of the invention, along with the position of a patient's head and nose. *Id.* at 5:22, 33–34. The illuminator has seven U-shaped fluorescent tubes 10 that are supported by a

housing 30 and are covered by a polycarbonate shield 40. *Id.* at 5:22–27. An aluminum reflector 50 increases both the output irradiance and the uniformity of the output distribution. *Id.* at 5:29–31. Lundahl explains 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.” *Id.* at 6:30–32. The U-shape also “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.” *Id.* at 6:38–41.

Figure 4A of Lundahl is reproduced below.

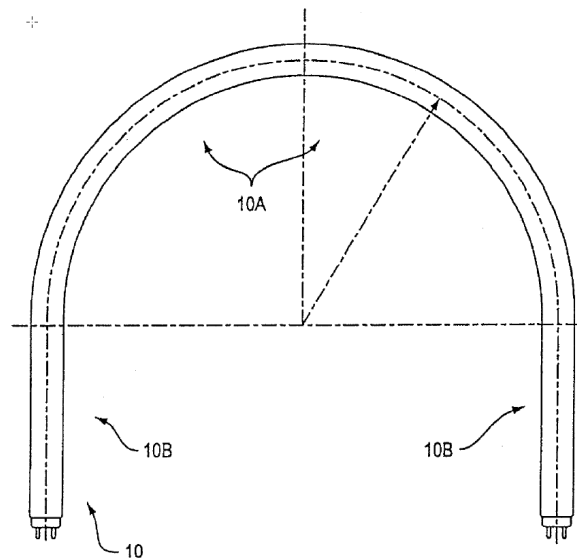
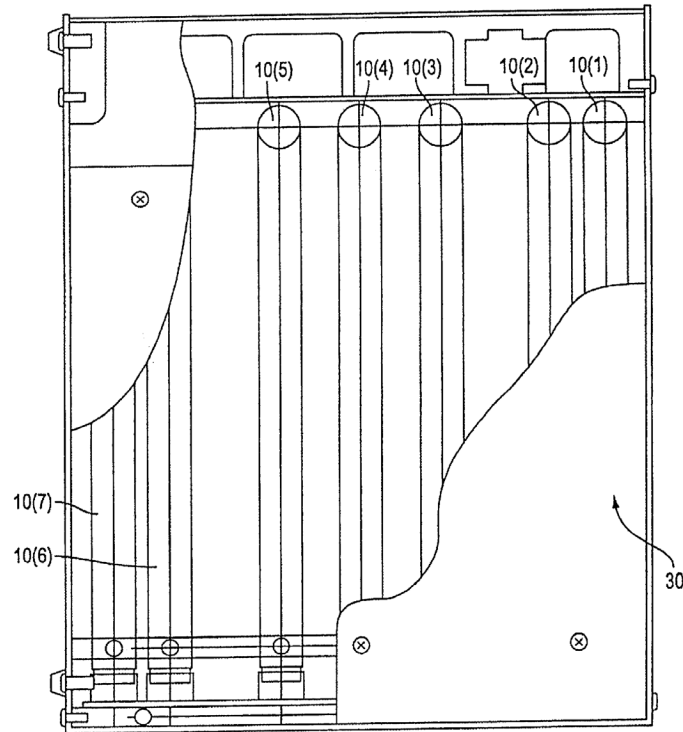


FIG. 4A

Figure 4A is a detail view of the fluorescent tube light source shown in Figure 1. *Id.* at 4:66–67.

A partial cross-section, side elevation view of the illuminator shown in Figure 1 is shown below, in Figure 2.

FIG. 2



Lundahl Figure 2 shows the lateral spacing of the seven U-shaped tubes 10(1)–10(7). *Id.* at 6:17–25. The partial tubes shown in Figure 2 are rotated 90° as compared to Figure 4A and the patient’s perspective in Figure 1. The Specification explains that “[v]arying 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.” *Id.* at 6:27–30. According to the Specification, “[t]he present invention provides a highly uniform output irradiance without the use of an additional diffusing element.” *Id.* at 6:55–57.

2. *Larsen*

Larsen describes a “treatment device which uses a light radiation of multiple wavelengths and pulse-shaped electromagnetic fields for the photodynamic stimulation of cells, especially cells of human tissue, and also for the activation and stimulation of light sensitive substances (PTD).”

Ex. 1004, code (57). Larsen's device produces energy radiation through the use of "semiconductor and/or laser diodes, which emit light in several separate wavelengths." *Id.* The device comprises a stand, a jointed arm, "machine applicators," wheels, and a control mechanism. *Id.* A diagram of Larsen's device is shown in Figure 1, below.

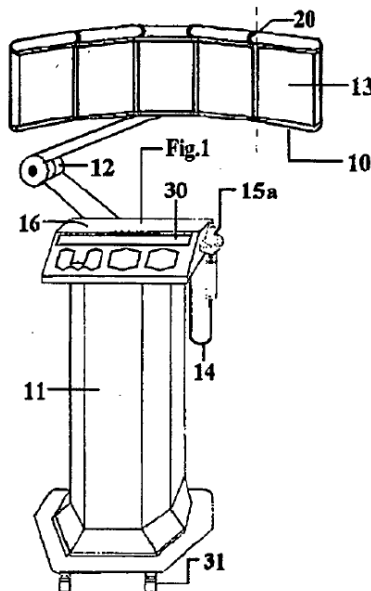


Figure 1 shows device 10, with stand 11, jointed arm 12, machine applicators 13, electric circuit 14, hand applicator 15, control mechanism 16, control panel 30, and wheels 31. *Id.* ¶ 69. Larsen describes that "applicators 13 are flexibly connected to each other through hinges 10, respectively connecting one edge with the other." *Id.* ¶ 72.

3. Discussion

Petitioner explains that its proposed combination of Lundahl and Larsen "incorporate[s] the hinged panel LED displays of Larsen into the PDT device of Lundahl." Pet. 25 (citing Ex. 1015 ¶ 118). Petitioner refers to Lundahl's teaching that, for its U-shaped PDT device, "the tube dimensions were chosen based on the average dimensions of the adult human head." *Id.* at 27 (quoting Ex. 1014, 6:31–42). According to Petitioner, a POSITA

would have “envisioned 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.” *Id.* at 29 (citing Ex. 1015 ¶124; Ex. 1016 ¶¶ 44–44). Additionally, Petitioner asserts that a “POSITA would have understood that there are other bodily anatomies that could use treatment for AK lesions, such as the arms, back and other body parts.” *Id.* (citing Ex. 1016 ¶¶ 42–43).

Thus, Petitioner contends, a “POSITA would have been motivated to change the design of the system of Lundahl to allow for adjustment of the light panels to ensure a 2-4["] distance from the face and from other varying anatomies.” *Id.* at 30 (citing Ex. 1016 ¶¶ 70–74, 87). According to Petitioner, the “POSITA would have understood that the easiest way to modify the fixed, curved U-shape of Lundahl would be to incorporate hinged panels that could be individually adjusted to account for variations in head shape/size or other anatomy selected for treatment.” *Id.* (citing Ex. 1015 ¶ 126).

To that end, Petitioner turns to Larsen’s disclosure of a PDT device “[f]or the treatment of large-area tissues,” such as the backs of human patients, wherein several applicators are “flexibly connected to each other through hinges.” *Id.* (quoting Ex. 1004 ¶ 72). Petitioner asserts that a POSITA would have been motivated “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.” *Id.* (citing Ex. 1015 ¶ 127). According to Petitioner, a “POSITA would have had a reasonable expectation of success in combining Lundahl with Larsen, because both references describe similar illuminators for using light to treat conditions on a patient’s skin.” *Id.* at 31 (citing Ex. 1015 ¶ 128).

Petitioner’s proposed modification of Lundahl also involves using LEDs as a light source instead of Lundahl’s fluorescent tubes. *Id.* According to Petitioner, a POSITA would have been motivated to make this change because: (1) LEDs have a lower cost and a longer lifetime than fluorescent tubes; (2) fluorescent tubes are known to have inconsistent light output within the tube itself; and (3) “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.” *Id.* (citing Ex. 1014, 4:41–42, 6:31–42; Ex. 1015 ¶ 129). Petitioner asserts that a POSITA would have had a reasonable expectation of success with this modification because Lundahl and Larsen “describe similar illuminators and the conversion from fluorescent tubes to LEDs was a routine practice prior to 2015.” *Id.* at 32 (citing Ex. 1015 ¶ 131).

Petitioner alleges that its proposed combination of Lundahl and Larsen teach or suggest each limitation of the challenged claims. *Id.* at 35–73. With respect to claim 1, Petitioner begins by asserting that Lundahl and Larsen each disclose a device and methods for photodynamically diagnosing or treating a patient. *Id.* at 35. Petitioner asserts also that Larsen teaches or suggests a PDT device comprising an illuminator having five panels connected by hinged structures on the inner side surfaces of adjacent panels, wherein light sources are disposed on the surfaces of the panels. *See id.* at 35–39. Petitioner contends that the combined teachings of Larsen and Lundahl disclose illuminators configured to uniformly illuminate a treatment surface of a patient. *Id.* at 39–42. Petitioner contends also that Larsen’s device has one of its five panels positioned as a center panel which is configured to face the treatment surface, while two or more of the five

panels are configured to be angled relative to the center panel. *Id.* at 42–43. Petitioner asserts that Lundahl teaches or suggests positioning it device at a distance of between two and four inches of the treatment surface. *Id.* at 44–45.

Further, Petitioner asserts that Larsen’s panels each have two first edges (vertical side edges) and two shorter second edges (horizontal top edges). *Id.* at 45. According to Petitioner, Lundahl teaches or suggests arranging light sources 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. *Id.* at 46–48.

At this stage in the proceeding, we determine that Petitioner’s foregoing assertions are supported by the combined teachings and suggestions of Lundahl and Larsen, as well as the testimony of Petitioner’s declarants. In particular, based on the current record, we determine that Petitioner has shown sufficiently for institution that the proposed combination of Larson and Lundahl satisfies each element of challenged claim 1. In reaching our determination, we have considered Patent Owner’s arguments. We address those arguments in the following discussion.

Patent Owner contends that Larsen does not teach or suggest hinged structures on inner side surfaces of adjacent panels. Prelim. Resp. 32. According to Patent Owner, Larsen instead depicts the hinges at a location on the bottom of the applicators. *Id.* at 32–36; Ex. 1004, Figure 1 (element 10); Ex. 1004 ¶ 72). However, Petitioner provides a reasonable argument that a skilled artisan considering Larsen’s Figure 1 would have appreciated that, even if the hinges in Larsen were not located on the inner surface of the adjacent panels, placing the hinges in that location would have been a

predictable means within the skill in the art for flexibly connecting the panels. *See* Pet. 37–38 (citing Ex. 1015 ¶¶ 154–156).

Next, Patent Owner contends that the combination of Lundahl and Larsen does not render obvious arranging light sources 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. Prelim. Resp. 59. For this contention, Patent Owner asserts that the “Lundahl’s disclosure relied upon by Petitioner does not meet the claim requirements because the ‘top and bottom sides’ [of Lundahl’s depiction] that Petitioner alleges emit a higher intensity of light are the longer edges, not the shorter second edges required by the claims.” *Id.* at 61. However, based on our review of the Petition, our understanding is that Petitioner’s proposed modification applies Lundahl’s disclosure of providing greater light intensity at the top and bottom sides to the top and bottom sides of Larsen, which are the shorter edges in Larsen. *See, e.g.*, Pet. 45–48.

Patent Owner also contends that Petitioner has not met its burden to show that a POSITA would have been motivated to combine Lundahl and Larsen with a reasonable expectation of success. *Id.* at 49. According to Patent Owner, Petitioner’s argument that a POSITA would have incorporated Larsen’s hinged panels in the combination to provide irradiance and irradiance uniformity to all target areas during PDT is insufficient because Lundahl already provides this feature. *Id.* at 50. In particular, Patent Owner refers to Lundahl’s disclosure that its U-shape design “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.” *Id.* (quoting Ex. 1014, 6:39–45, 15:22–27). Additionally, Patent Owner asserts that Petitioner’s rationale that a POSITA would have

modified Lundahl with Larsen's panels to allow for treatment of other body parts lacks merit as Lundahl expressly teaches that its device is "directed to ... other areas of the patient (e.g., arms, legs, etc.)." *Id.* at 50–51 (citing Ex. 1014, 1:14–17; Ex. 2001 ¶ 143).

Based on our review of the Petition, Petitioner explains that a driving motivation for a POSITA to modify Lundahl to include Larsen's five panels is "to increase the flexibility of the device to ensure the light panels could be maintained at a distance of 2-4" from surface of the treatment area, whether the face, arm, or back, etc." Pet. 29 (emphasis added). As Lundahl's device is not flexible, and such flexibility would improve its ability to treat areas other than an average sized face, we determine, at this stage in the proceeding, that this motivation for the combination is sufficient.

Patent Owner also challenges Petitioner's assertion that a POSITA would have been motivated to modify Lundahl's device by incorporating Larsen's use of LEDs on the surface of the light applicators in place of Lundahl's fluorescent tubes with a reasonable expectation of success. Prelim. Resp. 55. Patent Owner argues that Petitioner's modification is based on improper hindsight bias because "Petitioner cherry-picks Larsen's LEDs (together with the five panels) and purports to arrange them according to the [sic] 'the uneven spacing' of Lundahl's fluorescent tubes." *Id.* at 56 (citing Pet. 46–49; Ex. 1015 ¶¶ 175–80). According to Patent Owner, "Petitioner cannot on the one hand argue that a 'POSITA would have understood that Larsen's applicator is configured to uniformly illuminate a treatment surface of the patient,' while on the other ignore Larsen's teaching that the 'light sources 17 are placed in regular row arrangements.'" *Id.* Patent Owner asserts that Petitioner's proposed modification "mish-mashes aspects of Lundahl and Larsen ([while] avoiding the overall teachings of

each) because it was targeting the ‘higher intensity’ limitation of the [challenged] claims.” *Id.* at 56–57.

As discussed above, based on our consideration of the current record, Petitioner has provided sufficient motivation for employing Larsen’s flexible five panel configuration. These panels in Larsen already use LEDs as their light source. So, in our view, Petitioner’s incorporation of the five panels includes the lighting source, i.e., LEDs, for those panels taught by Larsen. Further, we note that Petitioner has persuasively asserted that a skilled artisan would have been motivated to use Larsen’s LEDs as they are more cost-efficient and last longer. *See* Pet. 31.

Patent Owner asserts also that “Petitioner fails to explain how or why a POSITA would have expected the combinations of fundamentally different systems to work.” Prelim. Resp. 57 (citing Ex. 2001 ¶¶ 141, 164, 166). Specifically, Patent Owner asserts that a skilled artisan would be concerned that Lundahl’s fluorescent system with high voltage supplied by the control system could damage or destroy LEDs. *Id.* Additionally, Patent Owner asserts that Petitioner has not explained how or why the skilled artisan would have combined Lundahl’s control system that employs light sources at stationary positions with Larsen’s scan engine that moves the light source with linear movements. *Id.* at 57–58. Further, Patent Owner asserts that Petitioner has not shown that the POSITA would have had a reasonable expectation of success in combining Lundahl’s tube-based device with Larsen’s LEDs. *Id.* at 58.

We note, however, “[t]o justify combining reference teachings in support of a rejection it is not necessary that a device shown in one reference can be physically inserted into the device shown in the other.” *In re Keller*, 642 F.2d 413, 425 (CCPA 1981) (citations omitted). Instead, we consider

“what the combined teachings of the references would have suggested to those of ordinary skill in the art.” *Id.* At this stage in the proceeding, we understand Petitioner’s proposed incorporation of Larsen’s five panels with LED lighting to include Larsen’s control system and supply of light source voltage. Further, on this record, we find Petitioner has supported its motivation for applying Lundahl’s teaching to space the light sources closer together at the top and bottom edges “to increase the intensity of light emitted” from those edges to provide a more uniform exposure of light to the treatment surface. *See* Pet. 49 (citing Ex. 1015 ¶ 181).

Accordingly, we determine that Petitioner has shown a reasonable likelihood of prevailing in its obviousness challenge of at least one claim, i.e., claim 1, over the combined teachings of Lundahl and Larsen.

D. Obviousness over Lundahl, Larsen, and Bansal

For this ground, Petitioner asserts that claims 1, 2, 4–6, 16, 17, and 19–21 would have been obvious also over the combined teachings of Lundahl, Larsen, and Bansal. Pet. 73–77. Patent Owner disagrees. Prelim. Resp. 32–71.

We do not provide an analysis of this second ground, as we have already determined that Petitioner has demonstrated a reasonable likelihood that it would prevail in showing the unpatentability of each of the challenged claims based upon the combined teachings of Lundahl and Larsen. We refer the parties, however, to our discussion of regarding the deficiencies in Petitioner’s reliance on Bansal explained in our decision denying institution in IPR2024-00874. *See* IPR2024-00874, Paper 9, 12–13, 17–18.

E. Discretion under 35 U.S.C. § 314(a)

Patent Owner contends the Board should exercise its discretion to deny institution under 35 U.S.C. § 314, citing the discretionary denial factors articulated in *General Plastic Industries Co., Ltd. v. Canon Kabushiki Kaisha*, IPR2016-01357, Paper 19 (PTAB Sept. 6, 2016) (precedential as to § II.B.4.i) (“General Plastic”). Prelim. Resp. 24–31.

The Director has discretion to deny institution of an *inter partes* review, which discretion has been delegated to the Board. *See* 35 U.S.C. § 314(a); 37 C.F.R. § 42.4(a); *SAS Inst. v. Iancu*, 584 U.S. 357, 366 (2018). However, as the Board has previously explained, *General Plastic* is inapplicable where a Petitioner filed parallel petitions, rather than serial petitions. *See, e.g.*, IPR2023-00543, Paper 8, 8 (citing *General Plastic*, Paper 19, 10 (applying General Plastic factors to the follow-on petitions). As noted above, the petition was filed in this proceeding before the preliminary response was filed in the earlier case. Thus, the instant petition is a parallel petition and not a serial one. *See* Consolidated Trial Practice Guide,⁵ 59. Accordingly, we decline to exercise our discretion under 35 U.S.C. § 314(a) to deny *inter partes* review under the factors set forth in *General Plastic*.

III. CONCLUSION

For the foregoing reasons, we conclude that Petitioner has established a reasonable likelihood of prevailing in its assertion that at least one challenged claim of the ’028 patent is unpatentable. Accordingly, we grant the Petition and institute the requested *inter partes* review.

⁵ Available at <https://www.uspto.gov/TrialPracticeGuideConsolidated>.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that pursuant to 35 U.S.C. § 314(a), an *inter partes* review of claims 1, 2, 4–6, 16, 17, and 19–21 of the '028 patent on all grounds set forth in the Petition is instituted, commencing on the entry date of this decision; and

FURTHER ORDERED that pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, notice is hereby given of the institution of review.

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