

Case IPR2024-00874
U.S. Patent No. 11,697,028

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

v.

DUSA PHARMACEUTICALS, INC.
Patent Owner

Case IPR2024-00874

U.S. Patent No. 11,697,028

PATENT OWNER'S PRELIMINARY RESPONSE

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All emphases are added unless otherwise noted.

PATENT OWNER’S EXHIBIT LIST

EX #	DESCRIPTION
2001	Declaration of Dr. Jose Sasian
2002	<i>Curriculum Vitae</i> of Dr. Jose Sasian
2003	Complainant’s Initial Statement Regarding The Public Interest filed in ITC Investigation No. 337-TA-1411, dated June 25, 2024
2004	Australian Patent Application Publication No. AU 200143869 published September 6, 2001 to Eric Larsen entitled <i>Device and methods for the stimulation of body cells through electromagnetic radiation</i> (“Larsen Publication”)
2005	United States Trademark Serial No. 78214595 Statement of Use and correspondence for BEAUTYLIGHT
2006	United States Patent No. 4,832,294 issued May 23, 1989 to John C. Eldem entitled <i>Portable I.V. Stand</i> (“the ’294 patent”)

All citations to Patent Owner’s Exhibits 2001-2006 refer to stamped exhibit page numbers.

I. Introduction

The inventions claimed in U.S. Patent No. 11,697,028 (the “’028 patent”) are revolutionary in the photodynamic therapy (PDT) field. Conventional PDT devices at the time left “optical dead spaces” near the edges of the device panels, which “reduce[d] the uniformity of the light along the treatment area, thereby reducing the effectiveness of PDT.” EX1001, 2:41-44, 2:52-56. As such, there was a longstanding need for a PDT device that provides uniform illumination and eliminates optical dead spaces. EX1001, 2:30-51. Sun Pharma¹ and its many scientists spent decades researching and developing unique technology to aid those suffering from certain skin conditions. EX2003, 1-2, 4. After years of research, Sun Pharma developed a novel five-panel PDT device that provides uniform illumination during PDT treatment without optical dead spaces. *Id.*; EX1001, 2:52-3:21. In particular, the PDT device of the ’028 patent uses hinges “mounted to the inner side surfaces of adjacent panels,” which “reduc[e] the area in which no light source is present on the illuminator.” EX1001, 3:11-21, 4:65-5:1, FIG. 3A. The light sources are arranged on the panels to provide uniform illumination such that those near the

¹ DUSA Pharmaceuticals, Inc., the named Patent Owner, merged with Sun Pharmaceutical Industries, Inc. (“Sun Pharma”) effective March 31, 2024, with Sun Pharmaceutical Industries, Inc. remaining as the surviving corporation.

shorter edges of the panels “emit a higher intensity of light” than those near the longer edges of the panels. EX1001, 6:18-40, FIG. 5. Sun Pharma’s unique illuminator configuration produces “light output uniformity” that 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.” EX1001, 8:43-67, FIG. 8. Sun Pharma became an established and recognized leader in PDT treatments—indeed, its products (Levulan® and BLU-U®) are the “#1-prescribed photodynamic therapy.” See <https://www.levulanhcp.com/>. Sun Pharma’s next-generation device (BLU-U® device Model 4170E) embodies the ’028 patent and received FDA Special Premarket Notification clearance on June 13, 2024. EX2003, 4.

The Petition should be denied for at least five reasons..

First, Petitioner argues that Bansal discloses “the light sources are arranged such that a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges.” In other words, the claims **distinguish between first edges and second edges of the panels**. But, as Petitioner and its expert admit, “Bansal’s solution provides higher intensity (or density) of lights **around all edges** of the panel.” Bansal does not disclose this limitation because it requires a higher intensity of light emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges,

which includes at least the first edges. Petitioner’s failure to meet its burden with respect to this limitation, which is present in *all* the independent claims, is *alone* sufficient for the Board to deny institution.

Second, Larsen does not disclose or render obvious “hinged structures on *inner side surfaces of adjacent panels.*” Petitioner misreads Larsen’s disclosure. Larsen clearly labels the hinges **10** at the *bottom* of the panels, *not* the inner side surfaces. And Petitioner’s expert *admits* “Larsen is silent on the type of hinges.” Unable to show express disclosure, Petitioner argues the hinges must *necessarily* be on the inner side surfaces. But Petitioner’s inherency argument also fails because Larsen itself discloses hinges on the *bottom* of the panels, and there were other known panels that were spaced close together and connected by hinges at the *bottom* of the panels. Recognizing that Petitioner’s inherency argument cannot hold water, Petitioner alternatively argues that hinges on inner side surfaces of adjacent panels must be obvious. But the Petition does not provide any objective support for its argument, merely relying on its expert, who simply regurgitated the obviousness argument found in the Petition. Such opinion unsupported by actual underlying evidence is insufficient to support Petitioner’s alleged obviousness. *Xerox Corp. et. al. v. Bytemark, Inc.*, IPR2022-00624, Paper 9 at 16-18 (Aug. 24, 2022) (precedential).

Third, Larsen does not disclose “wherein the five panels are individually configurable to control illumination from each of the five panels.” Again, Petitioner misreads Larsen’s disclosure. Larsen does not disclose that each of the five applicators is *individually* adjustable. Rather, Larsen merely discloses that the device as a whole is adjustable. Specifically, Larsen discloses only *one* control mechanism for the *entire* device as compared to the ’028 patent, which discloses that “each panel may have a dedicated control unit to regulate power to the individual LED array on a given panel.” None of Larsen’s disclosures relied on by Petitioner disclose that “the five panels are individually configurable to control illumination from each of the five panels.” Petitioner thus fails to meet its burden.

Fourth, a POSITA would not have been motivated to combine Larsen’s device (as argued to be modified by Bansal) with Jones’s treatment distance of about 5-8 cm with a reasonable expectation of success. Petitioner makes unsupported leaps for its alleged motivation to combine Larsen (as modified by Bansal) with Jones, failing to explain how or why a POSITA would have been motivated to apply Jones’s treatment distance to Larsen’s entirely different device (as modified by Bansal). And, in fact, the express teaching of Bansal undermines the combination advanced in the Petition. Petitioner fails to explain why a POSITA would have looked to Jones for a treatment distance of about 5-8 cm (about 2-3 inches) to apply to Larsen’s device (as modified by Bansal), when Bansal already teaches that a

treatment distance of 12 inches can produce acceptable light intensity for phototherapy treatment.

Fifth, Petitioner does not show that Larsen discloses or renders obvious “a mobile base supported by at least four wheels.” As Petitioner’s expert admits, Larsen discloses that “only two wheels are shown in Fig. 1.” As such, Petitioner yet again relies on inherency, which is without merit as Larsen does not *necessarily* disclose at least four wheels—known stable three-wheel designs were a possibility. Again recognizing that Petitioner’s inherency argument cannot hold water, Petitioner again resorts to an obviousness theory. However, Petition does not provide any objective support for its argument, merely relying on its expert, who simply regurgitated the obviousness argument found in the Petition. Such opinion unsupported by actual underlying evidence is insufficient to support Petitioner’s alleged obviousness. *Xerox* at 16-18.

Due to at least these deficiencies, the Petition does not establish “a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.” 35 U.S.C. § 314(a). While Patent Owner reserves the right to present additional arguments, the deficiencies of the Petition noted herein are sufficient for the Board to find that Petitioner has not met its burden and deny institution.

II. Background

A. Overview Of The '028 Patent

The '028 patent relates to an “adjustable illuminator that provides a uniform distribution of visible light” and “is suitable for use in photodynamic therapy [PDT] and diagnosis.” EX1001, 1:19-22; EX2001, ¶¶33-35.

The '028 patent addressed the problem of “optical dead space that can occur at or near the hinges of conventional adjustable illuminators,” which “reduces the uniformity of the light along the treatment area, thereby reducing the effectiveness of PDT.” EX1001, 2:41-44; EX2001, ¶36. The illuminator panels of an embodiment of the present invention are “coupled together using nested hinges, thereby reducing the area in which no light source is present on the illuminator” and “the light sources on each of the panels are individually configurable to provide specific power output to certain areas of the light sources on the panels to compensate for decreased uniformity.” EX1001, 3:11-21; EX2001, ¶37.

As shown below in FIG. 2B, the illuminator “preferably has five individual panels 10a-10e, each of which are connected in a rotatable manner via nested hinges 50.” EX1001, 3:52-56. Each of the five panels contains an array of light emitting diodes (LED) 60, which preferably “extend[] as far to the edges as possible.” EX1001, 3:56-64.

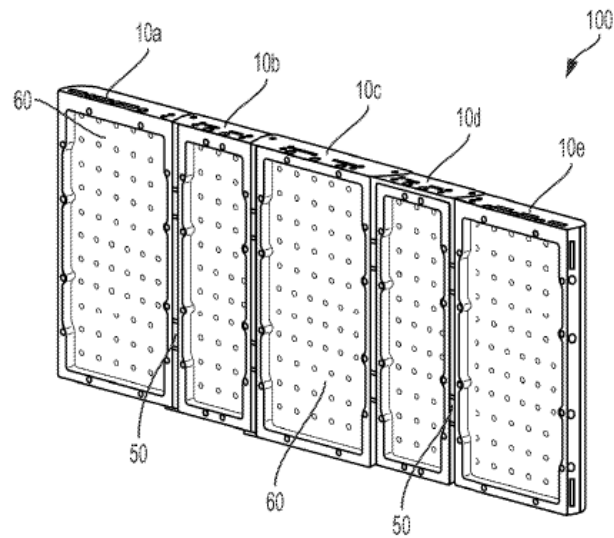


FIG. 2B

EX1001, Fig. 2B; EX2001, ¶38. The “nested hinges 50” (shown in blue) are “mounted to the inner side surfaces of adjacent panels (e.g. 10a, 10b),” as shown in FIG. 3A below. EX1001, 4:65-5:1.

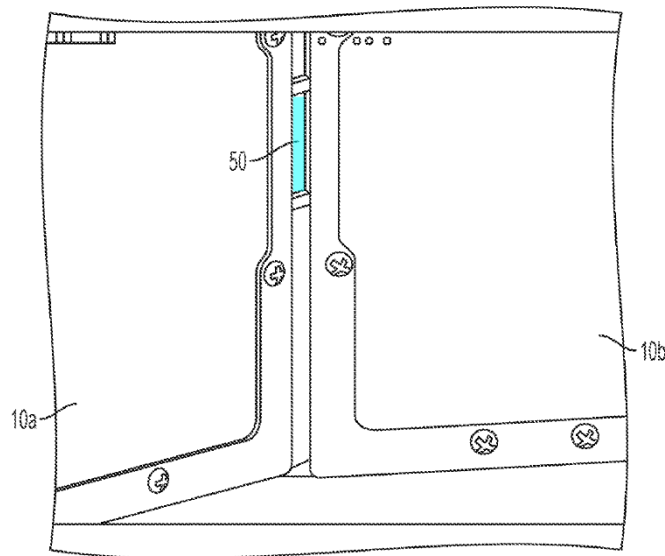


FIG. 3A

EX1001, Fig. 3A; EX2001, ¶39.

As shown in FIG. 5, the LED arrays “are divided into three general areas.” EX1001, 6:24-31. A higher current is supplied to areas 1 and 2 (shown in red) than areas 3 and 4 (shown in yellow) “such that areas 1 and 2 emit a higher intensity of light than areas 3 and 4.” EX1001, 6:32-40.

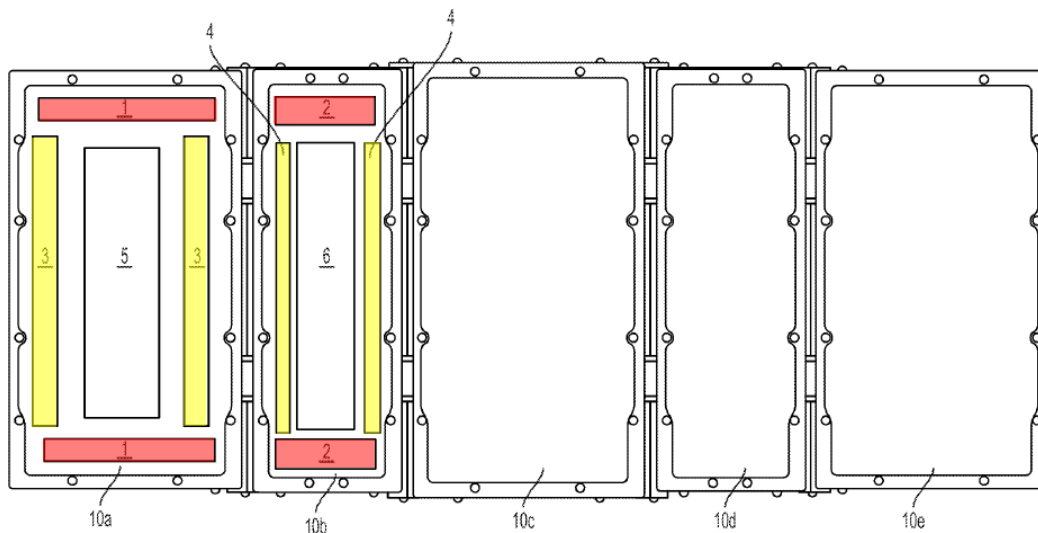


FIG. 5

EX1001, FIG. 5; EX2001, ¶¶40-41.

As shown in FIG. 4, the illuminator’s main body 100 with the five LED panels is “mounted to a movable stand 80,” which includes a base 81 and vertical pillar 82. EX1001, 5:15-20. The base has “wheels 87 at its bottom in order to allow the user to horizontally move the illuminator to an appropriate position.” EX1001, 5:21-23; EX 1002, 469 (disclosing “a mobile base supported by at least four wheels”). Each of the five LED panels “may have a dedicated control unit to regulate power to the individual LED array on a given panel.” EX1001, 5:57-62.

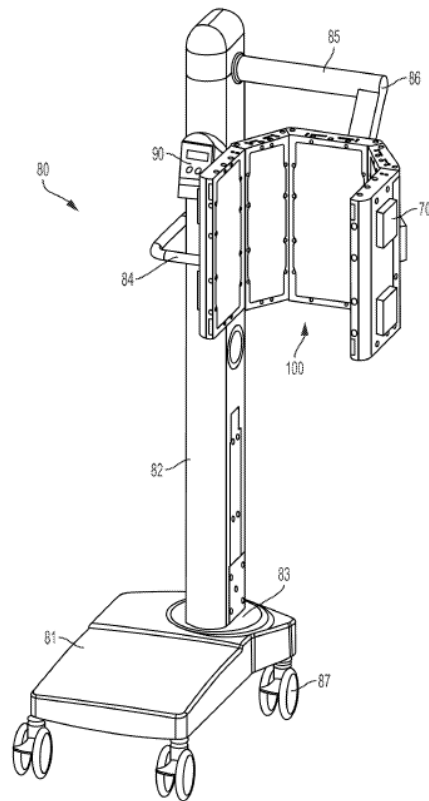


FIG. 4

EX1001, FIG. 4; EX2001, ¶¶42, 46. The '028 patent discloses that the “light output uniformity” produced by an embodiment of the illuminator of the present invention is “greatly enhanced across the patient’s face and exhibits little to no deviation from the light output measured in the center of the patient’s face to the light output measured at the edges of the patient’s face” over an operating “distance of two and four inches.” EX1001, 8:43-67, FIG. 8 (comparing light uniformity produced by a conventional illuminator in FIG. 7 to the light uniformity produced by an embodiment of the present invention in FIG. 8). EX2001, ¶¶43-46.

B. Overview Of The '028 File History

The application that issued as the '028 patent was filed on September 12, 2022 and claimed priority to a provisional application filed on October 15, 2015.

In an Office Action dated November 18, 2022, the Examiner rejected pending claims 18 and 20-22 as unpatentable over the Larsen '381 patent (EX1008) in view of Fan (U.S. 2006/0253175). EX1002, 328-330. The Examiner stated that claims 3, 6, 9, and 19 would be allowable if rewritten in independent form. EX1002, 333.

In response, on February 16, 2023, Applicant amended pending claim 18 to recite the subject matter of claim 19: “each of the five panels having two first edges and two second edges shorter than the two first edges, 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.” EX1002, 203-204, 207.

Following the amendment, the Examiner issued a Notice of Allowance on March 1, 2023. EX1002, 114. The Examiner stated in the reasons for allowance that “the art of record neither anticipates nor renders obvious ‘wherein each of the five panels has two first edges and two second edges shorter than the two first edges, and the light sources are arranged such that a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate

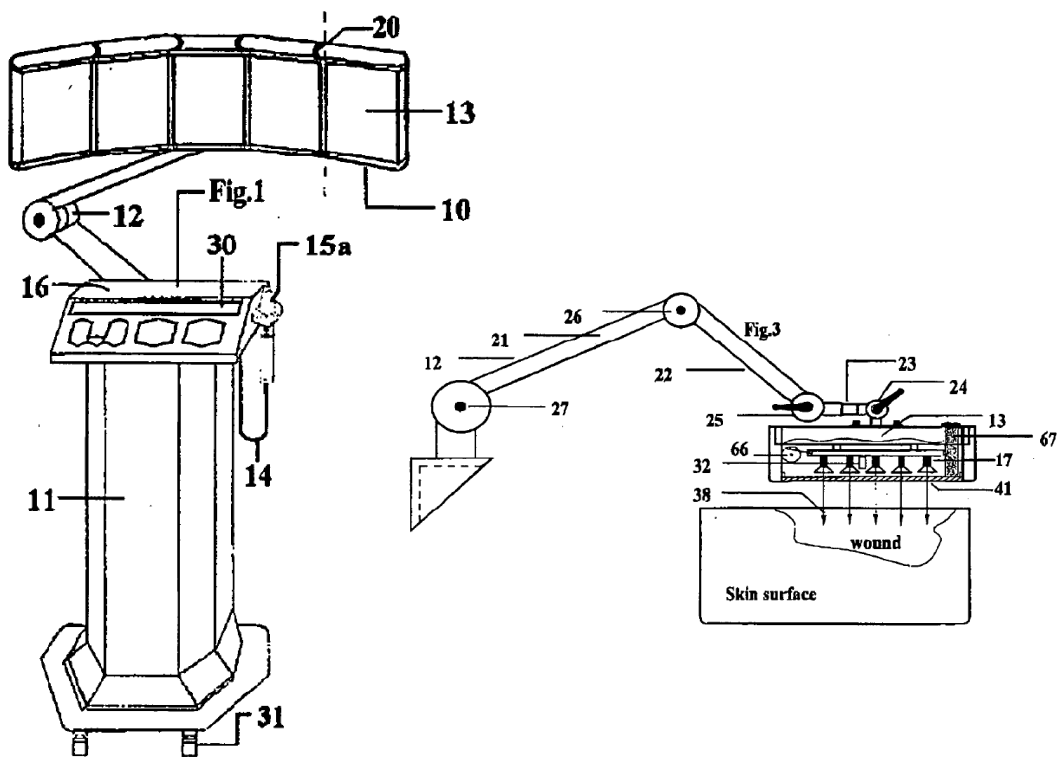
the second edges' in combination with the rest of the claimed limitations set forth in the independent claim." EX1002, 120. EX2001, ¶¶68-72.

III. Overview Of The References

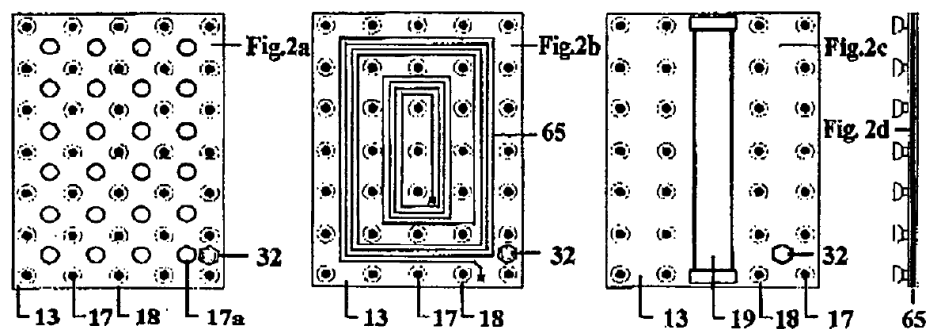
A. Larsen (EX1004)

Larsen discloses a device for photodynamic therapy (PDT) with applicators that are "equipped with an adjustable scan system, which permits an even and gap-free radiation of the surface with the multiple wavelengths of light." EX1004, [0028].

Figure 1 illustrates the device, "consist[ing] of a stand 11, with which machine applicators 13...are connected through a jointed arm 12." EX1004, [0069], [0040]. The "applicators 13 are flexibly connected to each other through hinges 10, respectively connecting one edge with the other." EX1004, [0072], [0027].



EX1004, FIGS. 1, 3. “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.” Ex. 1004, [0072]. The applicators 13 have printed circuit boards with light sources 17 “placed in regular row arrangements, i.e., 20 equidistant from each other.” EX1004, [0071].



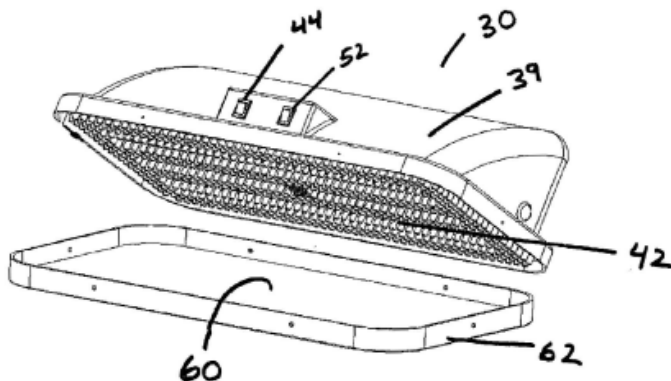
EX1004, FIGS. 2a, 2b, and 2c.

As shown in FIGS. 2a, 2b, and 2c, the applicators 13 “are equipped with sensors 32 arranged between the semiconductor and/or laser diodes 17.” EX1004, [0079]. Larsen discloses that “[w]ith the help of the control mechanism 16, the invented device is adjustable within a relatively large range with reference to duration, amplitude and frequency of surge of current, so that the semiconductor diodes 17, 17a and 18, as well as laser 17 diodes with the same realisation as semiconductor diode 17, can be used as light sources.” EX1004, [0074]. EX2001, ¶¶48-56.

B. Bansal (EX1005)

Bansal discloses a “phototherapy system including a non-uniform array of light sources.” EX1005, [0010]; EX2001, ¶58. Shown below in Figure 2, Bansal’s device has an enclosure 30 that supports the LED board 42. EX1005, [0023], [0012].

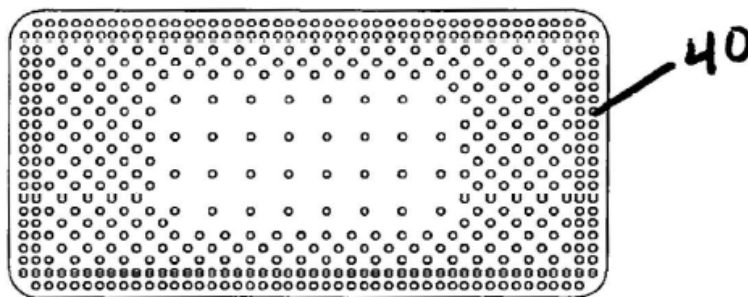
Fig. 2



EX1005, FIG. 2. Bansal also has “a light diffusing panel 60 placed between the array 40 and a subject.” EX1005, [0021].

Bansal discloses that the array of light sources “can take a number of different non-uniform forms to achieve the goal of even exposure on the subject's skin.” EX1005, [0025]. In one embodiment, “the density of light source distribution would vary throughout the array, such as with higher density in the periphery and a lower density in the center. In yet another version of the invention, low intensity light sources could be used in one portion of the array, and higher intensity light sources could be used in another section. This can be achieved by either using different intensity light sources or driving the light sources with a lower power in the center and a higher power on the outer edges....Some exemplary light source configurations are provided in FIGS. 9a-9d.” *Id.* Fig. 9b of Bansal is shown below.

Fig. 9b



EX1005, FIG. 9b.

Bansal further discloses that PDT devices with light sources arranged in “uniform arrays” that are “suspended 12 inches above a subject” can “produce sufficient intensity...to be a clinically useful phototherapy device.” EX1005, [0007]. EX2001, ¶¶58-61.

C. Jones (EX1006)

Jones describes “a dual panel photodynamic therapy lamp.” EX1006, [0002]. Figure 3 of Jones illustrates a preferred embodiment of the lamp in use, with the two panels in an “angled orientation” and “separated from each other by a gap.” EX1006, [0079], [0014].

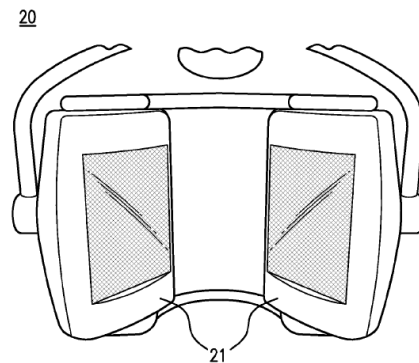


FIG. 3A

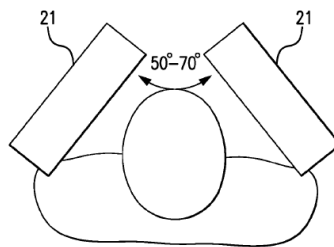


FIG. 3B

EX1006, FIGS. 3A and 3B.

Jones discloses that “when the photodynamic therapy lamp is in use, a distance between the lamp modules and a treatment surface of a patient is between about 5 cm to about 8 cm.” EX1006, [0024], [0041], [0093]-[0095]. For the embodiments with a treatment distance of about 5-8 cm, Jones discloses that the two-

dimensional array of LEDs is covered by a “matching array of lenses” that “collimate the light emitted from the LEDs.” EX1006, [0092], [0117]-[0124], [0080]. EX2001, ¶¶64-67.

IV. The Level Of Ordinary Skill In The Art

A person of ordinary skill in the art (“POSITA”) at the time of the invention of the ’028 patent would have had a M.D. and/or a Ph.D. in 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. Alternatively, 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. EX2001, ¶¶30-31.

Petitioner advances a different definition. Pet. 8; EX1003, ¶37. For purposes of this Preliminary Response, the Petition is deficient under either party’s proposed definition. EX2001, ¶32.

V. Claim Construction

Claim terms in IPRs are construed according to their “ordinary and customary meaning” to those of skill in the art. 37 C.F.R. § 42.100(b); *see also Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-13 (Fed. Cir. 2005) (*en banc*). Patent Owner submits that the Board need not construe any terms to deny institution. *Nidec Motor Corp.*

v. Zhongshan Broad Ocean Motor, Co., 868 F.3d 1013, 1017 (Fed. Cir. 2017).²

VI. Institution Should Be Denied Because The Petition Does Not Establish A Reasonable Likelihood Of Prevailing On Any Ground

Petitioner presents three grounds based on obviousness, with only Ground 1 challenging the five independent claims (bolded in the chart below). Pet. 3.

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

As set forth below, Petitioner fails to show that the combinations of prior art render obvious the limitations of challenged claims for multiple independent reasons. Because Petitioner has not demonstrated a reasonable likelihood of prevailing on any of its asserted grounds, institution should be denied.³

² Patent Owner reserves the right to raise other/additional claim construction arguments in any other/parallel proceedings.

³ On the eve of filing this Patent Owner Preliminary Response, Petitioner submitted to the PTAB in IPR2024-01312 a second Petition and Notice of Parallel Petitions on the *same* '028 patent. While no Notice of Parallel Petitions has been filed in this proceeding, Patent Owner reserves the right to seek authorization from the Board to

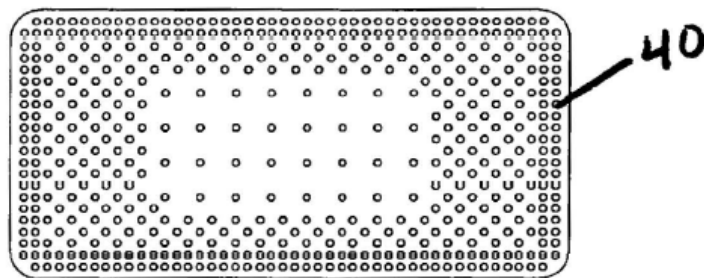
A. Larsen In View Of Bansal Does Not Render Obvious “The Light Sources Are Arranged Such That A Higher Intensity Of Light Is Emitted Proximate The Second Edges Compared To The Intensity Of Light Emitted Not Proximate The Second Edges”

Petitioner argues that Larsen in view of Bansal renders obvious “the light sources are arranged such that a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges,” as required by independent claims 1, 5, 16, 20 and 21 of the ’028 patent. Pet. 11-12, 17-21, 36-38, 44, 56, 61-62; EX1003, ¶¶120-121, 151-162, 219-221, 246-247, 295, 314, 325. However, Petitioner *admits* that Larsen “does not expressly teach” this limitation. Pet. 36. And Bansal does not disclose this limitation in combination with Larsen, as Petitioner argues. Pet. 36-37. EX2001, ¶¶75-76.

Petitioner and Dr. Bretschneider argue Bansal discloses varying “the density of light source distribution ... throughout the array, such as with *higher density in the periphery and a lower density in the center*” and that “Figure 9b of Bansal shows one embodiment where more light sources are placed near the edges of the panel compared to the light sources in the center.”

file objections and a response to the Notice of Parallel Petitions in this proceeding after a notice of filing date is accorded in IPR2024-01312.

Fig. 9b



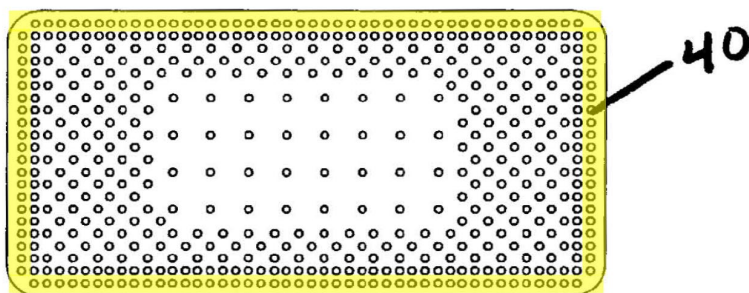
Pet. 36-37 (citing EX1005 [0025], claim 10, Figs. 9a-9d). In addition, they argue Bansal discloses “*driving the light sources with a lower power in the center and a higher power on the outer edges.*” Pet. 37 (citing EX1005, [0025]-[0026]). However, none of Bansal’s disclosures teaches that “the light 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 required by all of the independent claims. EX2001, ¶¶77-84.

Petitioner and Dr. Bretschneider fail to consider the requirements of the higher intensity limitation as a whole and instead break the limitation into disjointed pieces. Pet. 35-36. When the entire claim limitation is read (“wherein each of the five panels has *two first edges and two second edges shorter than the two first edges*, and the light sources are arranged such that a higher intensity of light is emitted *proximate the second edges* compared to the intensity of light emitted *not proximate the second edges*”), it is clear that the claims distinguish between the shorter second edges and the longer first edges of the panels. In context, the plain language of the claims requires that the intensity of light emitted *proximate the second edges* be

higher than the intensity of light emitted *not proximate the second edges, which includes at least light proximate the first edges*. EX2001, ¶¶79-83. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1314 (Fed. Cir. 2005) (*en banc*) (quoting *ACTV, Inc. v. Walt Disney Co.*, 346 F.3d 1082, 1088 (Fed. Cir. 2003) (“the context of the surrounding words of the claim also must be considered in determining the ordinary and customary meaning of those terms”).

Contrary to the claim requirements, Petitioner and Dr. Bretschneider admit “Bansal’s solution provides higher intensity (or density) of lights *around all edges* of the panel.” Pet. 18; Ex. 1003, ¶154. Bansal discloses “*higher density in the periphery* and a lower density in the center” and “lower power in the center and a *higher power on the outer edges*” Pet. 37; EX1003, ¶219 (citing EX1005, [0025]). As shown in Fig. 9b relied on by Petitioner, the intensity of light emitted proximate both the second edges and the first edges (e.g., shown in yellow below) is higher than the intensity of light emitted in the center of the array. See Pet. 37; EX1003, ¶219 (citing EX1005, Fig. 9b).

Fig. 9b



EX1005, Fig. 9b. Bansal distinguishes between higher intensity (or density) of lights ***“around all edges of the panel”*** and the center of the panel instead of between the intensity of light emitted proximate the second edges and ***not proximate the second edges***, which includes at least light proximate the first edges. Bansal thus fails to disclose ***“a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges,”*** as required by the claims. EX2001, ¶¶80-81.

Dr. Bretschneider further ignores the requirements of the '028 patent claims and argues that a “POSITA would have understood that the second edges of the '028 Patent’s panel are coincident with the periphery of the panel and hence that Bansal’s explicitly described embodiment teaches ‘the light sources are arranged such that a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges.’” EX1003, ¶219. However, as explained above, when the claims of the '028 patent are read as a whole, there is a clear distinction between the shorter second edges and the longer first edges of the panels. This distinction is supported by the specification of the '028 patent. For example, as shown in Fig. 5 below, the '028 patent distinguishes between areas 1 and 2 (shown in red) proximate the shorter second edges and areas 3 and 4 (shown in yellow) proximate the longer first edges. ***“[A]reas 1 and 2 emit a higher intensity of light than areas 3 and 4.”*** EX1001, 6:33-38; EX2001, ¶82.

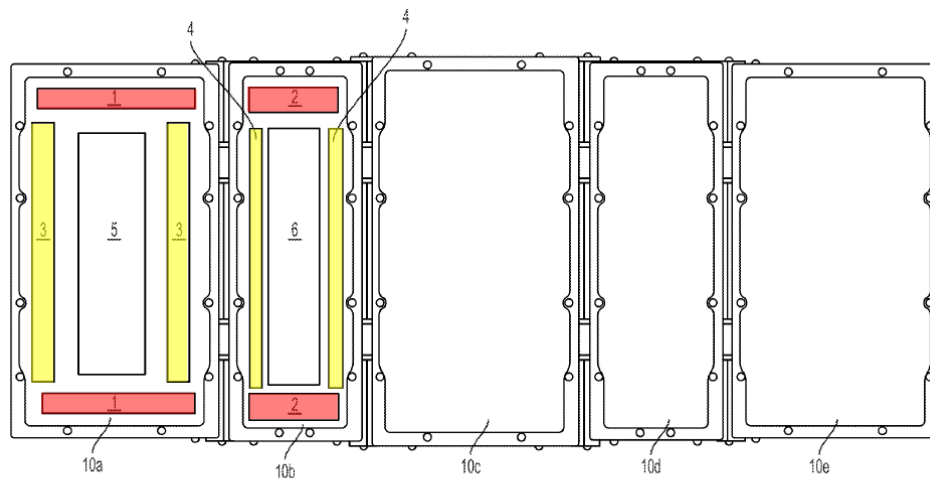


FIG. 5

EX1001, Fig. 5. This is in direct contrast to Petitioner and Dr. Bretschneider’s argument that Bansal’s solution discloses a higher intensity (or density) of lights *“around all edges of the panel.”* Pet. 18; EX1003, ¶154. Dr. Bretschneider’s reliance on Bansal’s disclosure of higher intensity *“around all edges of the panel”* is misplaced because both the specification and the claims consistently distinguish between areas proximate the shorter second edges that emit a higher intensity of light than areas proximate the longer first edges. EX2001, ¶¶80-82.

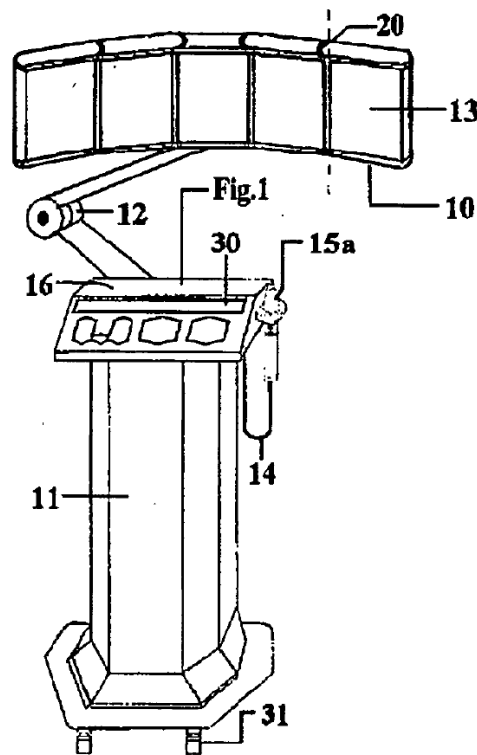
Accordingly, Larsen in view of Bansal does **not** render obvious the higher intensity limitation present in all of the independent claims of the ’028 patent “wherein each of the five panels has two first edges and two second edges shorter than the two first edges, and the light sources are arranged 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.” Petitioner has not met its burden for claims

1, 5, 16, 20 and 21. Petitioner has not met its burden for dependent claims 2-4, 6-8, 10-11, 13-14, 17-19 for the same reasons.

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

Petitioner argues that Larsen discloses or renders obvious an “illuminator comprising five panels connected by hinged structures on inner side surfaces of adjacent panels,” as required by independent claims 1, 5, 20, and 21 of the '028 patent. Pet. 10, 26-29, 43, 59, 61; EX1003, ¶¶190-197, 239-240, 308, 316. However, Larsen does not disclose or render obvious this limitation for at least the reasons set forth below. EX2001, ¶¶85-97.

First, there is no express disclosure in Larsen of “hinged structures on inner side surfaces of adjacent panels.” EX2001, ¶¶87-92. Larsen states that “several applicators 13 are flexibly connected to each other through *hinges 10*, respectively connecting one edge with the other.” EX1004, [0072]. As shown in Fig. 1 below, element “**10**” points to the *bottom* of the applicator 13, *not* to the inner side surface of the adjacent panels on which the applicators 13 are mounted. EX1004, FIG. 1; EX2001, ¶87.

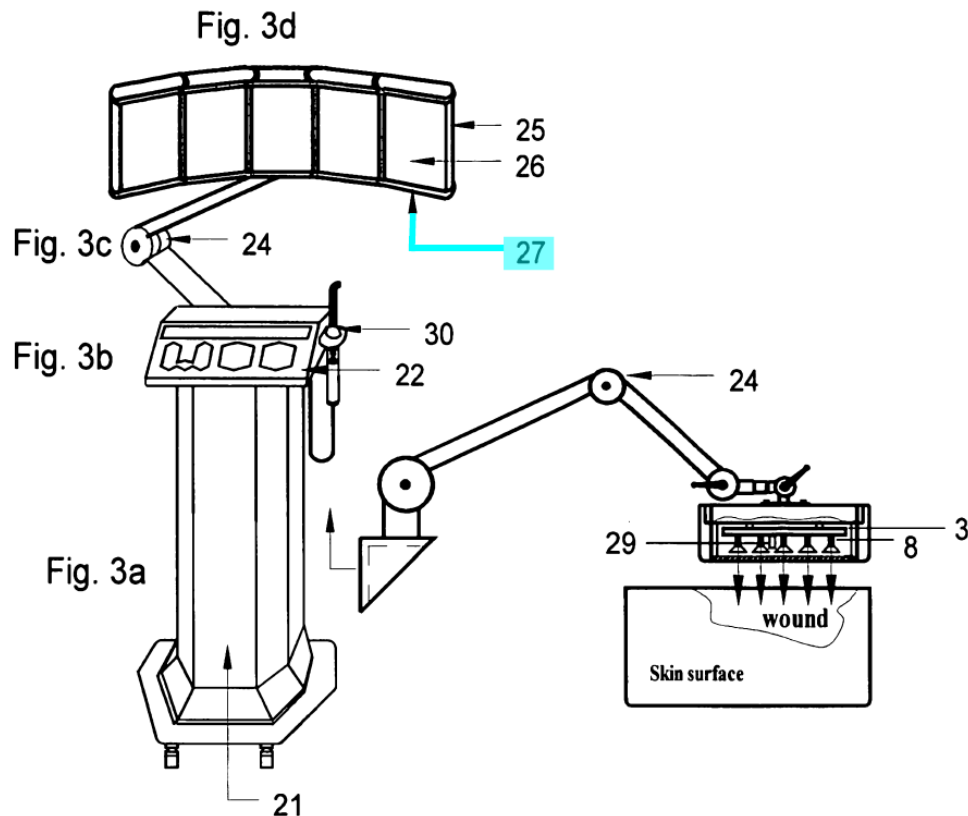


Despite Larsen’s clear labeling of “hinges” as element “**10**,” Petitioner argues that while the hinges are “indicated as element 10 in the specification,” they are “shown as element 20 in Figure 1.” Pet. 28; EX2001, ¶88.⁴ Petitioner’s argument

⁴ Petitioner makes these unsupported statements about the location of the hinges in Larsen, relying on the Examiner’s characterization of Larsen during prosecution for support of these statements. Pet. 28; EX1003, ¶191 (citing EX1009, ¶4; EX1002, 328). However, “hinged structures on inner side surfaces of adjacent panels” is simply not disclosed in Larsen, as Dr. Bretschneider admits. EX1003, ¶191 (“*Larsen is silent on the type of hinges.*”); see also EX2001, ¶¶89, 92.

is in direct conflict with Larsen's express disclosure. As described above, element "10" is clearly labeled as "*hinges*" in Larsen's specification. Element "20" is also described in Larsen's specification and is *not* referring to the hinges 10, but to the regular row arrangements of light sources on the applicators: "According to FIGS. 2b and 2c *the light sources 17 are placed in regular row arrangements, i.e., 20* equidistant from each other." EX1004, [0071]; EX2001, ¶¶89-90. As such, a POSITA reading Larsen would have understood that "hinges 10" refers to element 10 and not to element 20 in Fig. 1. EX2001, ¶88.

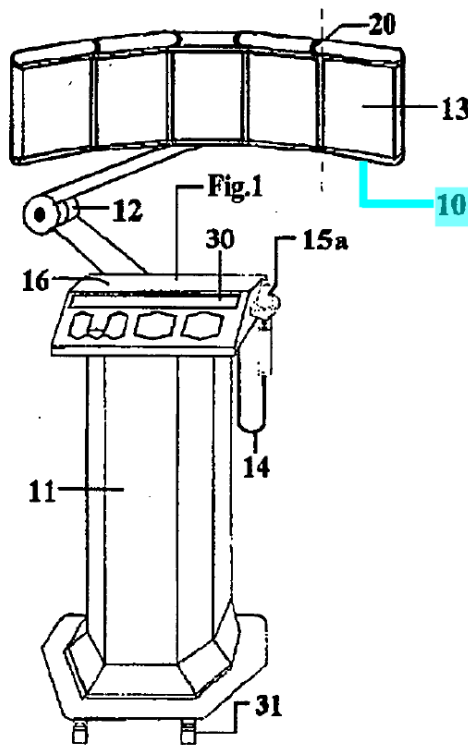
Petitioner's arguments are also in conflict with another Larsen publication (AU 2001/43869) (EX2004), which also identifies the hinges on the bottom of the applicators. EX2004, 14; EX2001, ¶91. For example, claim 19 of the Larsen publication recites "a flat applicator (25) consisting of a number of individual [*sic*] *hinged (27)* flat elements (26) which can be adjusted in angles to each other." EX2004, 14. Like Fig. 1 of Larsen, Fig. 3d of the Larsen publication points to hinges on the *bottom* of the applicators (element 27 shown in blue below), *not* to any inner side surface of adjacent panels. EX2001, ¶91.



EX2004, Fig. 3d. Like Larsen, the Larsen publication has no disclosure of hinged structures on inner side surfaces of adjacent panels. *Id.*

Second, there is no inherent disclosure in Larsen of “hinged structures on inner side surfaces of adjacent panels.” EX2001, ¶¶93-95. Petitioner asserts that “the hinges must *necessarily* be on the inner side surfaces of the panels” because they “connect[] one edge with the other,” and “the panels (13) are flush with each other.” Pet. 28; EX1003, ¶¶191-192, 195. However, a POSITA would have understood that Larsen’s hinges are *not necessarily* on inner side surfaces of adjacent panels. As explained above, Larsen expressly discloses that its applicators **13** are connected to each other by “hinges **10**.” EX1004, [0072]. Element **10** in Fig.

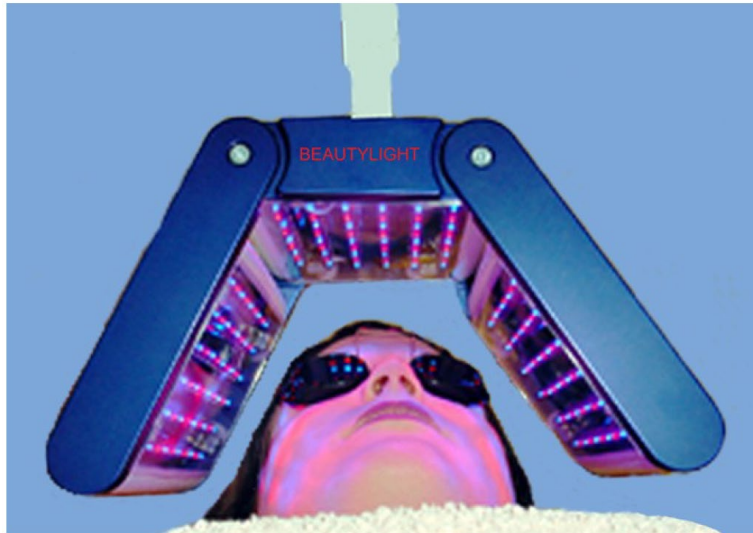
1 of Larsen (shown in blue) points to the **bottom** of the applicator **13**, not any inner side surfaces.



EX1004, Fig. 1. To reiterate, Larsen refers to element **20** as light sources “placed in regular row arrangements, i.e., **20**” and never references element **20** as hinges. EX1004, [0071]; EX2001, ¶¶93-94.

Additionally, Petitioner’s inherency argument is inaccurate. EX2001, ¶95. The hinges are **not necessarily** on inner side surfaces of adjacent panels if the panels are “flush with each other.” For example, the “BEAUTYLIGHT” illuminator (EX2005) manufactured by MDE Medizintechnik GmbH featured illumination panels flush with each other. EX2005, 10; EX2001, ¶95. As shown below, the

adjacent panels of the BEAUTYLIGHT are connected by hinges at the **bottom** of the panels. *Id.*⁵



As Dr. Bretschneider admits, a “prior art reference inherently discloses the claim element **only** if the prior art reference must **necessarily** include the undisclosed claim element. ***Inherency may not be established by probabilities or possibilities.***” EX1003, ¶43. Because Larsen’s hinges are not necessarily on the inner side surfaces of adjacent panels, Petitioner fails to meet its burden of showing inherency here.

⁵ The Statement of Use for U.S. Trademark Application Serial No. 78214595, which was submitted May 29, 2007, shows the BEAUTYLIGHT design, and the prosecution lists Eric Larsen (the named inventor of Larsen (EX1004)) as an addressee for MDE Medizintechnik GmbH. EX2005, 5-10, 14.

Third, Larsen does not render obvious “hinged structures on inner side surfaces of adjacent panels.” Petitioner and Dr. Bretschneider provide only unsupported, conclusory argument that a POSITA “would have found it obvious to try placing the hinges on the inner side surfaces of the panels.” Pet. 28-29; EX1003, ¶¶193-197. They provide no evidence suggesting such a design was known to a POSITA at the time of the invention of the ’028 patent or explain why a POSITA would have been motivated to change Larsen’s hinges from the bottom of the applicators to inner side surfaces of the panels absent hindsight. For example, as disclosed by Larsen and as shown in BEAUTYLIGHT above, a POSITA would have attached hinges to the *bottom* of the panels. EX2001, ¶96. A POSITA would have further understood that there were numerous other designs that could have attached the hinges, for example, on the bottom and top of panels. *Id.*

Petitioner argues “there were finite number of known, predictable solutions for Larsen’s panels to be ‘flexibly connected to each other through hinges.’” Pet. 29. Petitioner provides no support for its argument. Indeed, Petitioner cites only to a paragraph of its expert’s declaration that merely regurgitates its unsupported assertions. Pet. 29 (citing EX1003, ¶197). Such conclusory opinion, unsupported by actual underlying evidence, has been found to be insufficient to support alleged obviousness. *See Xerox Corp. et. al. v. Bytemark, Inc.*, IPR2022-00624, Paper 9 at 16-18 (Aug. 24, 2022) (precedential); *Johns Manville Corp. v. Knauf Insulation*,

Inc., IPR2018-00827, Paper 9 at 13 (Oct. 16, 2018) (informative). Conclusory statements are no more meaningful merely because they come from an expert. *Id.*; 37 C.F.R. §42.65(a).

Accordingly, Larsen does not disclose or render obvious an “illuminator comprising five panels connected by hinged structures on inner side surfaces of adjacent panels.” Petitioner has not met its burden for claims 1, 5, 20 and 21. Petitioner has not met its burden for dependent claims 2-4, 6-8, 10-11 and 13-14 for the same reasons.

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

Petitioner argues that Larsen discloses “the five panels are individually configurable to control illumination from each of the five panels,” as required by independent claims 16 and 21 of the ’028 patent. Pet. 20-22, 53-55, 62; EX1003, ¶¶285-288, 320-323. However, Larsen does not disclose this limitation. EX2001, ¶¶98-110

None of Larsen’s disclosures relied on by Petitioner discloses that Larsen’s “five panels are individually configurable to control illumination from each of the five panels.” *First*, Petitioner asserts that Larsen discloses this limitation because Larsen teaches that “each of the applicators (13) ‘can be used in the working model according to Fig. 2a to 2c *individually*, side by side (in large numbers) or in

combination with an applicator.” Pet. 54; EX1003, ¶286 (citing EX1004, [0070]) (emphasis by Petitioner). However, Petitioner misreads Larsen’s disclosure. When properly read in context, Petitioner’s alleged support identifies the *printed circuit boards* as the subject, *not* “each of the applicators (13).” EX1004, [0070] (“The FIGS. 2a, 2b and 2c show plain surfaced *printed circuit boards* with light sources mounted in the applicators 13. *These* can be used in the working model according to FIG. 2a to 2c individually, side by side (in large numbers) or in combination with an applicator. *Furthermore the printed circuit boards....*”). EX2001, ¶101. When properly read in context, Larsen discloses only that the printed circuit boards can be used in the working model individually, side by side or in combination with an applicator, *not* that “five panels are individually configurable to control illumination from each of the five panels.” EX2001, ¶101; *Phillips*, 415 F.3d at 1314 (“the context of the surrounding words of the claim also must be considered in determining the ordinary and customary meaning of those terms”).⁶ In fact,

⁶ Again, Petitioner points to a conclusory statement by the Examiner that “col. 5, lines 19-22” of the Larsen ’381 patent “describes that the panels can be controlled individually.” Pet. 54 (citing EX1002, 328). However, the Examiner (like Petitioner) misreads Larsen’s ’381 disclosure. As discussed, that the printed circuit

Petitioner acknowledges that [0070] of Larsen teaches that “[t]hese circuit boards can be used ‘individually, side by side (in large numbers) or in combination with an applicator.’” Pet. 20 (citing EX1004, [0070]). Under any of these three options—printed circuit boards used (i) individually, (ii) side by side, or (iii) in combination with an applicator—Larsen does not teach five panels individually configurable to control illumination from each of the panels, as claimed. That is, these 3 different use cases for the printed circuit boards do not teach each of Larsen’s applicators being individually configurable to control illumination from each applicator of a five-applicator device.

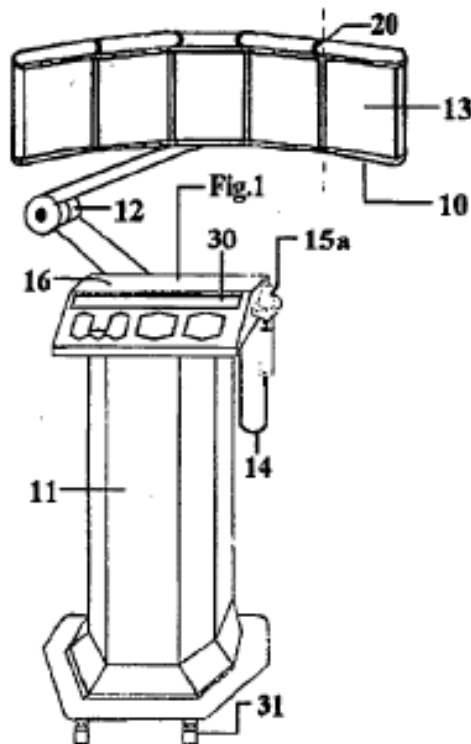
Second, Petitioner relies on Larsen’s disclosure that “[u]sing the control mechanism, ‘*the invented device* is adjustable within a relatively large range with reference to duration, amplitude and frequency of surge of current, so that the semiconductor diodes 17, 17a and 18, as well as laser 17 diodes with the same realisation as semiconductor diode 17, can be used as light sources.’” Pet. 54; EX1003, ¶286 (citing EX1004, [0074]). However, this passage discloses only that

boards “can be used in the working model according to FIG. 2a to 2c *individually*” provides no disclosure that “five panels are individually configurable to control illumination from each of the five panels.” EX2001, ¶102.

“*the invented device* is adjustable,” *not* that each of the five applicators is individually configurable. EX2001, ¶103.

Third, Petitioner relies on Larsen’s disclosure that “[t]he control mechanism includes ‘a switch select system for operating different types of semiconductor diodes 17 and/or with laser diodes. Both semiconductor diodes and/or laser diodes with tuneable wavelengths can be operated, which is a great advantage, and therefore the printed circuit boards can be equipped with a more intensive radiation effect.’” Pet. 54; EX1003, ¶286 (citing EX1004, [0074]). However, once again Larsen discloses that the control mechanism 16 is controlling and tuning the wavelengths of *the invented device*, *not* that the panels are individually configurable to control illumination from each of the five panels. EX2001, ¶103; EX1004, [0074] (“With the help of the control mechanism 16, *the invented device is* adjustable...*For that purpose the control mechanism is equipped with a switch select system* for operating different types of semiconductor diodes 17 and/or with laser diodes.”). EX2001, ¶104.

Fourth, Petitioner argues that “[e]ach of the applicators is connected to a control mechanism 16.” Pet. 54 (citing EX1004, [0070], FIGS. 1 and 4); EX1003, ¶286. However, Larsen shows only *one* control mechanism 16 for the *entire device*, not one control mechanism 16 connected to each of the applicators 13. EX2001, ¶105.



EX1004, FIG. 1. In fact, Larsen consistently depicts and refers to only “*the* control mechanism 16” and not to multiple control mechanisms. See EX1004, FIG. 4, Abstract (“The stand is freely moveable on wheels and includes *a control mechanism...*”), [0027] (“The stand, freely moveable on wheels, consists of *a control mechanism...*”), [0030] (“At least one of the applicator elements is equipped with feedback sensors for controlling the patient's response to the therapy, and via an automatic regulation system in *the control mechanism* it is possible to optimise the therapy results.... *The control mechanism* is also connected with a hand applicator...”), see also [0043], [0069], [0073], [0074], [0079], FIG. 4. EX2001, ¶¶105, 107-108. This is in contrast to the '028 patent, which discloses that “each

panel may have a dedicated control unit to regulate power to the individual LED array on a given panel.” Ex. 1001, 5:57-62; EX2001, ¶106.

Fifth, Petitioner argues that “each applicator is individually configurable, since each one can be adjusted by the controller based on feedback from its own sensors.” Pet. 54-55; EX1003, ¶287. To allegedly support its argument, Petitioner relies on Larsen’s disclosure that “each applicator includes sensors that ‘measure the amount of energy radiated away from the skin surface, which is indicative of the total energy penetrating into the tissue.’... A ‘sensor 32a is also contained in at least one of the machine applicators, measuring the temperature change of the radiated tissue, whereby the control unit can react with a feedback regulation of the radiation parameters depending on the therapy indication, location and (PDT) light sensitive substance used.’” Pet. 54-55; EX1003, ¶287 (citing EX1004, [0079]-[0080], Figs. 2a-2c). However, Larsen does not teach that each applicator 13 is adjusted individually based on the feedback received at the sensors 32. Rather, Larsen discloses that “[a]n increase of the registered amount of energy *can be achieved by the invented device* by increasing the operating potential (and thereby the pulse amplitude) or the pulse frequency and/or prolonging the duration of the treatment time *through an adjustment of the control mechanism 16*.” EX1004, [0079]. Larsen discloses changing the amount of energy emitted *by the device, not* by each applicator 13. EX2001, ¶109.

Accordingly, Larsen does not disclose that “the five panels are individually configurable to control illumination from each of the five panels.” Petitioner has not met its burden for claims 16 and 21. Petitioner has not met its burden for dependent claims 17-19 for the same reasons.

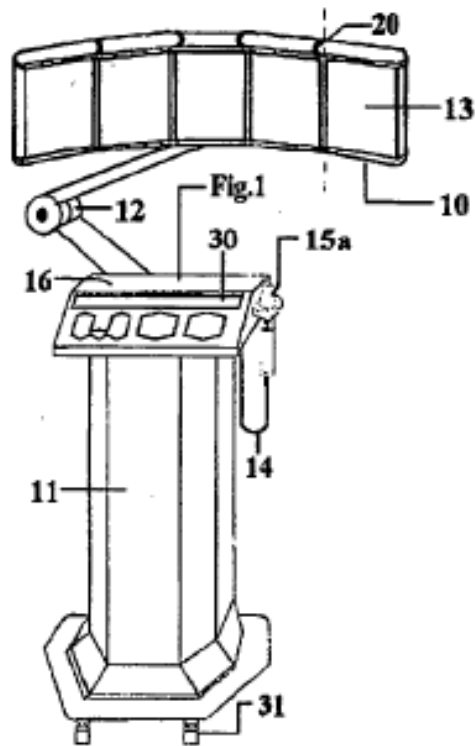
D. Petitioner Fails To Show That A POSITA Would Have Been Motivated To Combine Larsen (As Modified By Bansal) With The Treatment Distance Described In Jones With A Reasonable Expectation Of Success

Petitioner admits that Larsen “does not expressly teach” “wherein the five panels are positioned to allow treatment within approximately four inches of the treatment surface” (as required by independent claims 1, 5, 20, and 21), arguing instead that this limitation is disclosed by Jones. Pet. 34. Specifically, Petitioner argues Jones teaches “a distance between the lamp modules and a treatment surface of a patient is between about 5 cm to about 8 cm” and a “POSITA would have found it obvious and would have been motivated with a reasonable expectation of success to incorporate the treatment distance described in Jones into Larsen.” Pet. 24-26, 34-35, 44, 60, 62; EX1003, ¶¶169-172, 212-216, 241-243, 312, 319. However, Petitioner fails to show that a POSITA would have been motivated to combine Larsen (as modified by Bansal) with Jones’s treatment distance with a reasonable expectation of success, as explained below. EX2001, ¶¶111-126.

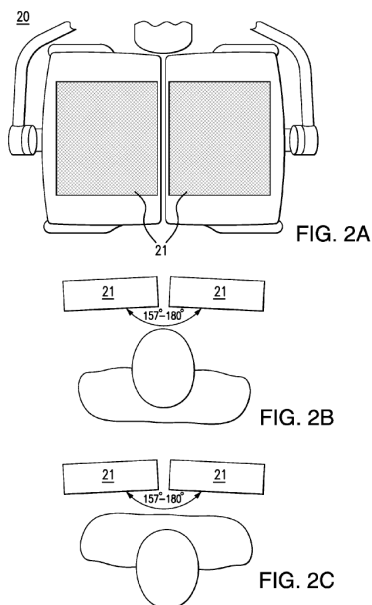
First, a POSITA would not have been motivated to combine Larsen’s device (as modified by Bansal) with Jones’s teaching of a treatment distance of about 5-8 cm (about 2-3 inches) when Bansal discloses that a treatment distance of **12 inches** was acceptable for phototherapy treatment. EX1005, [0007] (“For instance, it has been found that a 10 inches by 20 inches array of approximately 750 blue LEDs suspended **12 inches above a subject can produce sufficient intensity...to be a clinically useful phototherapy device**” and “**can produce an acceptable average light intensity for phototherapy treatment**”); EX2001, ¶114. Petitioner does not explain why a POSITA would have looked to Jones’s treatment distance of 5-8 cm when Bansal discloses that a much greater distance of 12 inches was acceptable. *Id.*

Second, Petitioner does not address the various **significant differences** between Larsen’s and Jones’s devices, and therefore fails to show that a POSITA would have been motivated to combine Larsen’s device (as modified by Bansal) with the treatment distance of about 5 cm to 8 cm taught by Jones. EX2001, ¶¶115-120.

For example, Larsen’s and Jones’s devices differ in the number and configuration of panels on the illumination device. For example, as shown below, Larsen discloses a device with **five panels** and a scan system that “permits an even and **gap-free** radiation of the surface” and does not “leav[e] any unradiated gaps.” EX1004, [0028], [0072], FIG. 1; EX2001, ¶116.



EX1004, FIG. 1. In contrast, Jones discloses a device with *two panels* and a “gap between the lamp modules” as shown below. EX1006, [0015]-[0016], [0078]-[0079], FIGS. 2A-C and 3A-B.



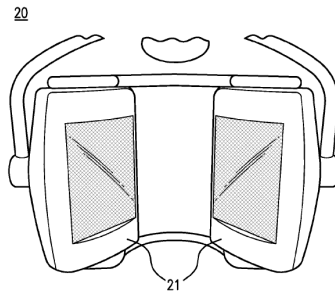


FIG. 3A

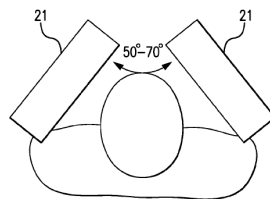


FIG. 3B

In fact, Jones distinguishes its “dual panel photodynamic therapy lamp” from devices with more than two panels, stating that “4 panels makes the lamp fairly complex” and the devices with more than two panels “will also have a considerable weight.” EX1006, [0002], [0011]; EX2001, ¶117. Thus, a POSITA would not have been motivated to combine Larsen’s five-panel device with gap-free radiation with the treatment distance taught by Jones for a two-panel device with an angled gap between panels. EX2001, ¶117.

As another example, Larsen and Jones differ in the way that they deliver light. EX2001, ¶¶118-119. Larsen discloses that “[t]he light sources 17 and 17a are mounted with *reflectors* 18,” whereas Jones discloses that the LED array has a “matching array of *lenses*.” EX1004, [0070], [0028], FIGS. 2A-C; EX1006, [0092]

(lamp module comprising “two-dimensional array” and “a matching array of lenses” “positioned at a distance of 5-8 cm from the face”), [0117]-[0124] (embodiments disclosing “matching array of lenses” and “distance of 5-8 cm”). A POSITA would have understood that the optical effects of the reflectors disclosed by Larsen can be significantly different than the optical effects of the lenses in the embodiments disclosed by Jones, and such differences can impact the treatment distance. EX2001, ¶119. Larsen’s reflectors “collect the radiation and bundle them in front of the applicator.” EX1004, [0028]. Lenses, like those described by Jones, “collimate the light emitted from the LEDs.” EX1006, [0080], [0017]. Larsen’s LEDs with reflectors result in divergent forward-emitted light with bundled radiation collected by the reflectors, whereas Jones’s LEDs with lenses result in parallel light collimated by the lenses. EX2001, ¶119. A POSITA would not have been motivated to combine Larsen’s device (as modified by Bansal) with Jones’s treatment distance of about 5 cm to about 8 cm given the differences in directing the emitted rays of light. EX2001, ¶119.

As a further example, Larsen and Jones differ in the positioning of the device. Larsen discloses that the scan engine in the device “can *move the light sources* with linear movements.” EX1004, [0072], [0028]. Jones, on the other hand, discloses “locking elements configured to *lock the lamp modules* in the first and second positions” and emphasizes “maintain[ing] the precise positioning of the lamp

modules.” EX1006, [0020], [0070], [0039], [0074], [0086], [0087], FIG. 5. A POSITA would not have been motivated to combine Larsen’s device (as modified by Bansal) that moves during treatment with the distance taught by Jones for a device that locks into a precise position. EX2001, ¶120.

Given the significant differences between Larsen’s device and Jones’s device, and Bansal’s disclosure that 12 inches is an “acceptable” treatment distance, the only plausible explanation for Petitioner’s cherry-picking of Jones’s 5-8 cm is hindsight analysis based on Sun Pharma’s own invention. EX2001, ¶121. As the Supreme Court has held, “[a] factfinder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant upon ex post reasoning.” *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007). It is improper to use the patented invention as a blueprint or template to perform a hindsight reconstruction of the invention from prior art elements. *Ecolochem, Inc. v. So. Cal. Edison Co.*, 227 F. 3d 1361, 1371–72 (Fed. Cir. 2000). Using the invention as a roadmap to re-create the invention from the prior art would improperly discount the value of combining various existing features or principles in a new way to achieve a new result, which is often the very essence or definition of invention. *KSR*, 550 U.S. at 418-19. Similarly, the motivation to combine references cannot come from the invention itself. *In re Oetiker*, 977 F.2d 1443, 1447 (Fed. Cir. 1992); *In Touch Techs., Inc. v. VGo Commc’ns, Inc.*, 751 F.3d 1327, 1351-52 (Fed. Cir. 2014).

Petitioner additionally argues that a “POSITA would have known that the distance between the illuminator and the treatment surface is a result-effective variable” and that “[d]etermining an optimum distance would have required nothing more than routine experimentation.” Pet. 25; EX1003, ¶169. However, Petitioner makes only conclusory statements without any explanation of how or why a POSITA using Larsen’s device (as modified by Bansal) would have arrived at Jones’s treatment distance of about 5 cm to about 8 cm. EX2001, ¶¶122-123. Such a conclusory opinion, unsupported by actual underlying evidence, has been found insufficient to support an alleged motivation to combine. *See Xerox*, IPR2022-00624, Paper 9 at 16-18 (Aug. 24, 2022) (precedential); *Johns Manville*, IPR2018-00827, Paper 9 at 13 (Oct. 16, 2018) (informative); 37 C.F.R. § 42.65(a) (“Expert testimony that does not disclose the underlying facts or data on which the opinion is based is entitled to little or no weight.”).

Petitioner fails to show that treatment distance was a “result-effective variable” that “required nothing more than routine experimentation” because there were a variety of other factors that can affect treatment distance, such as the number of light sources, the arrangement of light sources, the distance between light sources, treatment time, wavelength of light, size of the panels, treatment dose, light intensity, and location of the area to be treated on the patient. EX2001, ¶¶124-125; EX1005, [0005]; *Twinstrand Biosciences, Inc. v. Guardant Health, Inc.*, IPR2022-01400,

Paper 41 at 41-42 (Jan. 26, 2024) (rejecting Twinstrand’s argument that tagging efficiency was a result-effective variable that only requires routine skill to optimize where the tagging efficiency “depend[ed] on a variety of other factors”); *ModernaTx, Inc. v. Arbutus Biopharma Corp.*, 18 F.4th 1364, 1375-77 (Fed. Cir. 2021) (finding Moderna failed to make the showing that reaching the claimed phospholipid range would have been achievable through routine optimization where there were “other lipid components in the prior art nucleic acid-lipid particles”).

Even if Petitioner’s unsupported argument is considered, applying Jones’s treatment distance of 5-8 cm to Larsen’s device (as modified by Bansal) would have required undue experimentation. EX2001, ¶124. Undue experimentation would have been required at least because of the differences between the devices discussed above, including: (1) Larsen’s five-paneled device with gap-free radiation compared to Jones’s dual paneled device with a gap between panels, (2) Larsen’s LEDs with reflectors compared to Jones’s LEDs with lenses, and (3) Larsen’s moving light sources compared to Jones’s locked panels. ¶¶124, 115-120. In addition, there were a variety of other factors that can affect the treatment distance and radiation received at the treatment surface, including, for example, the number of light sources, the arrangement of light sources, the distance between light sources, treatment time, wavelength of light, size of the panels, treatment dose, light intensity, and location of the area to be treated on the patient. EX2001, ¶124; EX1005, [0005]. The

differences between Larsen and Jones, in addition to the factors affecting the treatment distance listed above, weigh against Petitioner's unsupported argument that a POSITA would have "arrive[d] at the optimal distances described in Jones" through "routine experimentation." *Id.*

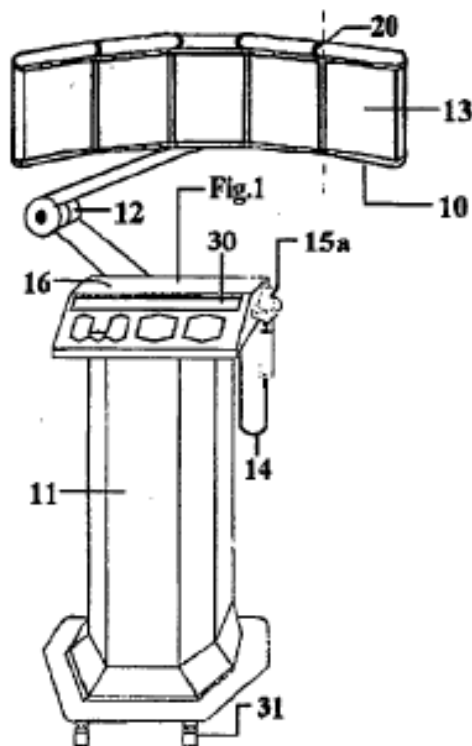
Moreover, for at least the same reasons discussed above, Petitioner's argument that "it may be necessary and would be desirable to place the panels of Jones at a further distance of about four inches (about 10 cm), and a POSITA would have been motivated to do so" fails. EX1003, ¶¶213-214; Pet. 35. EX2001, ¶125.

In sum, Petitioner cherry-picks Jones's operating distance in hindsight and makes unsupported leaps for its alleged motivation to combine Larsen (as modified by Bansal) with Jones. As explained above, Petitioner fails to explain how or why a POSITA would have been motivated to apply Jones's treatment distance of 5-8 cm to Larsen's entirely different device (as modified by Bansal). Accordingly, a POSITA would not have been motivated to combine Larsen's device (as modified by Bansal) with Jones's treatment distance with a reasonable expectation of success. Petitioner has not met its burden for claims 1, 5, 20 and 21. Petitioner has not met its burden for dependent claims 2-4, 6-8, 10-11 and 13-14 for the same reasons.

E. Petitioner Does Not Show That Larsen Discloses Or Renders Obvious “A Mobile Base Supported By At Least Four Wheels”

Petitioner argues that Larsen discloses or renders obvious “a mobile base supported by at least four wheels,” as required by independent claim 16 of the ’028 patent. Pet. 48-50; EX1003, ¶¶98, 109-110, 138, 171, 262-267. However, Petitioner fails to meet its burden to show that Larsen discloses or renders obvious this limitation as set forth below. EX2001, ¶¶127-136.

First, Larsen does not expressly disclose “a mobile base supported by at least four wheels.” EX2001, ¶¶127-129. Petitioner argues that Larsen “discloses a mobile base supported by at least four wheels” in Fig. 1. Pet. 48-49. However, as shown below in Fig. 1 and stated by Dr. Bretschneider, “only two wheels are shown in Fig. 1 of Larsen.” EX1003, ¶109.



EX1004, Fig. 1. Therefore, Larsen does not expressly disclose “a mobile base supported by at least four wheels.” EX2001, ¶129.

Second, Larsen does not inherently disclose “a mobile base supported by at least four wheels.” EX2001, ¶¶130-133. Petitioner and Dr. Bretschneider argue that (1) Larsen’s device *necessarily* has four wheels “in order to provide stability,” (2) that if Larsen’s device only had two wheels, “the system would rest on the back of the base which would require a user to tilt the entire system forward to move the system. This would create an unbalanced system which would significantly impair the ability of a user to move the system and the system would thus not be ‘freely moveable,’” and (3) the “generally hexagonal shape of the base of the

device...would be most stable and freely moveable with at least four wheels.” Pet. 49; EX1003, ¶¶265, 110.

However, Petitioner and Dr. Bretschneider’s arguments do not show that Larsen *necessarily* discloses “a mobile base supported by at least four wheels,” but merely establish the *possibility* that Larsen’s device has four wheels. EX2001, ¶¶130-133. With three wheels, Larsen’s device would still have been “freely moveable” and would not “require a user to tilt the entire system forward” or “create an unbalanced system.” EX2001, ¶¶131-133. For example, U.S. Patent 4,832,294, issued May 23, 1989, describes a stand for a medical device with three wheels that “rolls smoothly, easily and stably over irregular surfaces.” EX2006, 2:4-8, 2:20-29, FIG. 1; EX2001, ¶131.

As Dr. Bretschneider acknowledges, “[i]nherency may not be established by probabilities or possibilities.” EX1003, ¶43. The mere *possibility* that Larsen’s device has four wheels does *not* establish that Larsen’s device inherently discloses “a mobile base supported by at least four wheels.” EX2001, ¶133.⁷

⁷ Petitioner points to the Examiner’s statement during prosecution of the ’028 patent that, in the Larsen ’381 patent, “it is inherent that there are [at] least two more wheels, for a total of 4, in order for the device to be stable.” Pet. 49 (citing EX1002,

Third, Petitioner and Dr. Bretschneider have not met their burden to show that Larsen renders obvious “a mobile base supported by at least four wheels.” EX2001, ¶135. Petitioner and Dr. Bretschneider argue that using four wheels to support the base of Larsen would have been obvious to a POSITA because “it was well known that a four-wheeled stand is much more stable than a stand with only three wheels” and such a stand “was one of a finite number of known solutions.” Pet. 49-50; EX1003, ¶¶266-267. However, Petitioner’s arguments fail because they are conclusory and merely repeat declaration testimony that is unsupported by any evidence. *TQ Delta, LLC v. Cisco Sys., Inc.*, 942 F.3d 1352, 1362 (Fed. Cir. 2019) (rejecting conclusory expert opinions “[u]ntethered to any supporting evidence, much less any contemporaneous evidence); *see also Xerox*, IPR2022-00624, Paper 9 at 16-18 (Aug. 24, 2022) (precedential); *see also* 37 C.F.R. §42.65(a).

Moreover, contrary to Petitioner and Dr. Bretschneider’s arguments, it was known that three-wheeled stands provided good stability, because each of the wheels is in contact with the floor. EX2001, ¶¶131, 135. For example, as discussed above,

328). But the Examiner failed to show inherency, because there were other known possibilities, including a three-wheeled device that moved “easily and stably.” *See*, e.g., EX2006, 2:4-8, 2:20-29, FIG. 1; EX2001, ¶¶131-134. And, like Petitioner, the Examiner’s conclusory statement is devoid of any evidence.

U.S. Patent No. 4,832,294 (EX2006) describes a medical device with a three-wheeled stand that “rolls smoothly, easily and stably over irregular surfaces.” EX2006, 2:4-8, 2:20-29. In contrast, a four-wheeled stand may not have each of the wheels in contact with the floor simultaneously, creating instability. EX2001, ¶135.

Accordingly, Petitioner has not shown that Larsen discloses or renders obvious “a mobile base supported by at least four wheels.” Petitioner has not met its burden for claim 16. Petitioner has not met its burden for dependent claims 17-19 for the same reasons.

VII. Conclusion

For the foregoing reasons, Patent Owner respectfully requests that the Board deny institution of the Petition.

Dated: August 22, 2024

Respectfully submitted,

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U.S. Patent No. 11,697,028

CERTIFICATION UNDER 37 C.F.R. § 42.24(d)

I hereby certify that this paper, excluding the portions exempted under 37 C.F.R. § 42.24(a), has 8,890 words as counted by Microsoft Word 365, the word-processing system used to prepare this paper.

Dated: August 22, 2024

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CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6(e), the undersigned certifies that on August 22, 2024, a complete copy of the foregoing was served on counsel of record for Petitioner by filing this document through P-TACTS and by sending this document via electronic mail to the following addresses:

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