PUBLIC VERSION

UNITED STATES INTERNATIONAL TRADE COMMISSION
WASHINGTON, D.C. 20436

Before the Honorable Bryan F. Moore
Administrative Law Judge

In the Matter of **CERTAIN PHOTODYNAMIC THERAPY SYSTEMS, COMPONENTS THEREOF, AND PHARMACEUTICAL PRODUCTS USED IN COMBINATION WITH THE SAME**	**Investigation No. 337-TA-1411**

RESPONDENTS BIOFRONTERA AG, BIOFRONTERA BIOSCIENCE GMBH, BIOFRONTERA PHARMA GMBH, AND BIOFRONTERA INC. RESPONSIVE POST-HEARING BRIEF

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TABLE OF ABBREVIATIONS

Abbreviation	Meaning
CX-	Complainant's Exhibit
CX-xxxxC	Confidential Complainant's Exhibit
RX-	Respondents' Exhibit
RX-xxxxC	Confidential Respondents' Exhibit
JX-	Joint Exhibit
JX-xxxxC	Confidential Joint Exhibit
'512 Patent	U.S. Patent No. 11,446,512
'028 Patent	U.S. Patent No. 11,697,028
4170D	BLU-U® 4170 or BLU-U® 4170D
4170E	BLU-U® 4170E
Asserted Patents	The '512 Patent and the '028 Patent
Complainant *or* Sun	Sun Pharmaceutical Industries, Inc.
Respondents *or* Biofrontera	Biofrontera Inc., Biofrontera Pharma GMBH, Biofrontera Bioscience GMBH, & Biofrontera AG
ITC	International Trade Commission
ID	Initial Determination
Comm'n Op	Commission Opinion
USPTAB or PTAB	United States Patent Trial and Appeal Board
USPTO *or* PTO	United States Patent and Trademark Office
IPR	*Inter Partes* Review
POSA	Person of Ordinary Skill in the Art at the time of the invention
R&D	Research and Development

DI Product	Domestic Industry Product
CMIB	Complainant's Initial Markman Brief
CMRB	Complainant's Reply Markman Brief
RMIB	Respondents' Initial Markman Brief
RMRB	Respondents' Reply Markman Brief
CDO	Cease and Desist Order
LEO	Limited Exclusion Order
DOE	Doctrine of Equivalents
Compl.	Complaint
Rog No.	Interrogatory No.
PD	Photodynamic diagnosis
PDT	Photodynamic therapy
ALA	5-aminolevulinic acid
CPHB	Complainant's Prehearing Brief
RPHB	Respondent's Prehearing Brief
Tr.	Hearing Transcript
AK	Actinic Keratosis
CIUCL	Complainant's Identification of Undisputed Claim Limitations Pursuant to Ground Rule 14.1
CIB	Complainant's Initial Post-Hearing Brief
RIB	Respondents' Initial Post-Hearing Brief
Prior Art References	
Lundahl	U.S. Patent No. 6,223,071 to Lundahl, et al.
Larsen	U.S. Patent Publication No. 2005/0075703 to Larsen

Kennedy	U.S. Patent No. 5,079,262 to Kennedy, et al.
Hente	U.S. Patent Publication No. 2010/0118522 to Hente
Perutz	U.S. Patent No. 4,823,858 to Perutz
’902 prov.	U.S. Provisional Application No. 62/241,902

I. INTRODUCTION

The evidence at trial reveals that Sun cut corners to file a complaint on patents the named inventor does not understand and had "nothing to do with making [] except for signing whatever I was asked to sign." Tr.(Boyajian), 69:1-11. Despite Sun's efforts to stretch the Asserted Patents to match its market monopolization aspirations, Sun has failed to meet its burden of establishing infringement, while clear and convincing evidence has been presented that the Asserted Patents are invalid.

Noninfringement. Sun's infringement claims continue to rest on expansive views of the claims and weak evidence. To argue for induced infringement of the asserted method claims, Sun cannot find support in Biofrontera's label or product manual, so it turns to selectively excerpted internal documents that, viewed in their totality, confirm Biofrontera's intent that a physician follow the label, which requires use of three adjacent panels. Under applicable Federal Circuit law, merely describing an infringing mode, such as use of five panels, does not demonstrate inducement when the label requires something else (*i.e.*, use of three adjacent panels).

Sun spends much of its brief arguing about hinges. In a challenge to the plain language of the claim construction— "hinges that ***fit on*** inner side surfaces of adjacent panels"/"hinged structures ***on*** inner side surfaces of adjacent panels"—Sun argues that the RhodoLED®XL's hinges, which extend through the inner side surface of adjacent panels, infringe the Asserted Claims. Sun never explains how a hinge that is not *on* and does not *fit on* the inner side surface can meet the claim limitation. Sun transforms the ALJ's construction of hinges that fit on an inner side surface to a hinge that has any portion—barrel or flange—between, or touching any part of the inner side surfaces into "on inner side surfaces of adjacent panels." Moreover, Sun's expansive

reading of what constitutes a hinge under the Asserted Patents undermines its arguments that Larsen does not teach the hinge limitations.

Obviousness. The evidence shows that by 2015, with the ubiquity of LED technology established, it would have been obvious to combine the teachings of Lundahl and Larsen to render the Asserted Claims invalid. There is little dispute that Lundahl teaches the ***how*** of improving uniformity by "varying the lateral spacing of the tubes (relative horizontal spacing…)." Lundahl, 6:23-24. But Lundahl also teaches the ***why*** of the lateral spacing, explaining 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." Lundahl, 6:28-30. With this and other teachings in hand, it would have been obvious to incorporate the five panel LED design of Larsen into the Lundahl device. Sun's hand-waiving arguments about long-edges and short-edges and hindsight bias fall short. Even a cursory review of Larsen and Lundahl's figures and specification demonstrate that Larsen and Lundahl are oriented the same way relative to a patient's forehead and chin. Moreover, both Lundahl and Larsen are directed to photodynamic illuminators, supplying a motivation to combine.

Given the broad reading Sun ascribes to its hinge claim element, its arguments are unconvincing there as well. In its infringement case, Sun asserts that any hinge element attached on, or present between, the inner side surfaces of adjacent panels would practice its Asserted Claims. The evidence shows that Larsen's hinges teach the hinge claim elements, certainly under Sun's broad interpretation of them. Additionally, a POSA, having both ordinary skill and creativity, certainly could have determined how to position hinges on the inner side surfaces of the five adjacent panels.

Written Description and Enablement. Sun's opening brief is ***wholly devoid*** of any case law supporting its positions on written description. That is revealing. The crux of Biofrontera's argument is that the Asserted Patents' specification lacks teaching and examples for photodynamic diagnosis. Indeed, there really is no legitimate factual dispute on that point: Sun's expert testimony, introduced at the witness statement stage, is that photodynamic diagnosis must occur in milliseconds or nearly instantaneously, which Sun concedes is absent from its specification. Sun's main argument is that photodynamic diagnosis is the same thing as photodynamic treatment. This argument fails for two reasons. First, as Sun's glaring lack of case law demonstrates, there is no legal authority for the proposition that a complete lack of written description or enablement can be overcome by written description and enablement for a different claimed embodiment. For written description, the test is possession as demonstrated by the four corners of the specification. For enablement, the Supreme Court has emphasized that the more one claims, the more it must enable. Second, even Sun's testimony demonstrates that photodynamic diagnosis and photodynamic treatment differ from each other: the difference between illuminating for minutes or hours, as the specification calls for, and illuminating for milliseconds is profound. The lack of teaching about the latter conclusively demonstrates the lack of written description and enablement. A twenty-year monopoly, let alone an exclusion order, should not rest on such a dearth of disclosure.

II. NONINFRINGEMENT

A. Biofrontera Does Not Infringe the Asserted Claims of the '512 Patent

1. Biofrontera Does Not Infringe the "Nested Hinges" Element of the '512 Patent

Sun's assertion that the RhodoLED®XL meets the "nested hinges" limitation on inner side surfaces of adjacent panels" rests on the contention that the "inner side surfaces...comprise multiple components" including portions of the RhodoLED®XL's internal support structure

(called "tabs" or "hinge holders" by the parties), which extend laterally through openings in each panel. CIB, 14. But, "[n]ested hinges on inner side surfaces of adjacent panels" was construed to mean "hinges that ***fit*** on inner side surfaces of adjacent panels." Order No. 18, 35. As both Dr. Jokerst and Dr. Grove agree, RhodoLED®XL's friction hinges extend ***past*** both the panel casing and the tabs to a connection point on the planar support structure within the interior of the panels. Tr.(Jokerst), 214:17-23; RX-0009C (Grove), Q/A31. And, Dr. Jokerst agrees that the planar support structure within the panel's interior is not a part of the inner side surfaces. Tr.(Jokerst), 210:19-211:12. Accordingly, even if the tabs were part of the inner side surfaces as Sun asserts, it is undisputed that the friction hinges do not ***fit*** on the tabs or on any inner side surface.

Further, Sun's identification of the tabs as part of the inner side surfaces strains the bounds of both the English language and the claim language. As noted previously, a straw that extends through a cup lid does not become part of the lid's surface and bolt that passes through a nut does not merge into the nut's surface. RIB, 19-20. So too, the internal support structure does not become part of the surface through which it extends. Further, while Sun argues that the tabs must be part of the inner side surfaces because they are "between the front and back of the panels," (CIB, 17) neither the claims nor the construction merely require hinges ***between*** the front and back of the panels – rather, both require hinges "***on*** inner side surfaces."

To support its tenuous position, Sun resorts to mischaracterizing Dr. Grove's testimony. While Sun notes that Dr. Grove testified that the inner side surface of a panel can be "made up of multiple components," (CIB, 17) it fails to mention that Dr. Grove was clearly referring to the front and back portions of the panel casing, which fit together like a clamshell to form the inner side surface – not to the internal support structure that extends through openings in that surface. Tr.(Grove), 439:14-440:3. Similarly, while Sun highlights Dr. Grove's testimony that "it's

possible" for a hinge to be on a surface with the flanges attached to something else (CIB, 1), it fails to mention that this statement was merely addressing a general hypothetical posed by Sun's counsel and divorced from the context of the claims and the Asserted Patents. Tr.(Grove), 447:20-448:18. Dr. Grove's very next statement clarifies that "[i]n the claims, either the nested hinges or the hinge structures need to be mounted on the inner side surfaces...." Tr.(Grove), 448:22-24.

A POSA would understand "on" to mean "in contact with and supported by the top surface of." JX-0029.1; RX-0009C, Q/A 32. Accordingly, despite Sun's arguments to the contrary (CIB, 20), a POSA would understand that some incidental contact between the hinge flanges and the panel casing as the hinge passes through the opening in the casing does not mean that the hinge is "on" the panel casing, because that incidental contact does not "support" the hinge. RX-0009C (Grove), Q/A 69. The same is true of the friction hinges' contact with the tabs (*i.e.*, hinge holders). *Id*. Even assuming these tabs could be considered inner side surfaces (they are not), the support for the friction hinges comes from their bolted attachment points in the interior of the panel – which all parties agree is not an inner side surface. Additionally, as Dr. Jokerst has admitted, the friction hinges contact the front surface of the tabs – not any side surface whatsoever. RX-0009C, Q/A66; Tr. (Jokerst), 215:8-14 (testifying that it is "correct" that the "hinges are attached to the ***front side*** of the support structure") (emphasis added).

2. Biofrontera Does Not Infringe the "Recess" Limitation of Claims 17-18 of the '512 Patent

Biofrontera does not meet the recess limitation because claims 17-18 still require hinges that fit ***on*** an inner side surface (as opposed to extending through it) via their dependence from claim 8, meaning that the hinge flange must fit into an indentation, small hollow, or cleft ***on*** the continuous inner side surface. RX-0009C, Q/A107. RIB, 20-22.

Sun's contention the RhodoLED®XL satisfies the recess limitation only serves to illustrate the strained nature of its infringement argument. On one hand, Sun alleges that the openings in the RhodoLED®XL's panel casing are "recesses" in the inner side surface. But, on the other hand, Sun alleges that the hinge holders are part of the inner side surface. CIB, 47. If Sun's arguments are to be believed, as illustrated in Dr. Jokerst's CDX-0004C.235 below, a portion of the inner side surface (*i.e.*, the hinge holder) extends through a recess in itself.

CDX-0004C.325; JX-0111.

3. Biofrontera Does Not Induce Infringement of the Asserted Method Claims

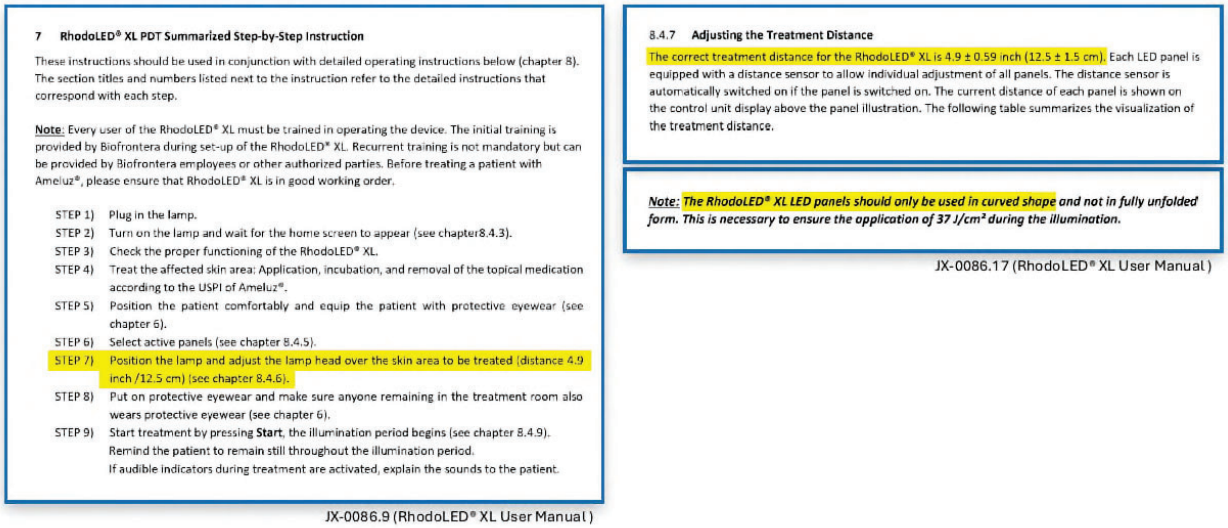
Biofrontera does not induce HCPs to use all five panels of the RhodoLED®XL, as required by the Asserted Method Claims. RIB, Section V.B.3. Rather, the Ameluz® label, RhodoLED®XL

user manual, and Biofrontera's marketing materials consistently *require* three panels, while five panels is *optional*. *Id*.

Sun misrepresents Biofrontera's documents to argue that Biofrontera encourages HCPs to use all five panels. CIB, Section V.A.2. For example, Sun points to "Biofrontera's presentations and videos" as evidence of inducement, but those materials merely demonstrate that the device *has* five panels, not that all five should be used. *Id*., 32-33 (citing JX-0078; CX-0010C, Q/A512-13), 34-35 (citing JX-0104), 45 (citing JX-0073C; CX-0009C (Shmuylovich), Q/A168); *see also* RX-0011C (Ehrenreich), Q/A118-133.

Sun also mischaracterizes the "step-by-step instruction[s]" in the RhodoLED®XL user manual, CIB, 35-38, 42-45, arguing that because the RhodoLED®XL activates all five panels by "default," Biofrontera induces infringement. *Id*. But Sun overlooks that ***before*** starting treatment, HCPs are told to "[s]elect[] active panels (see chapter 8.4.5)" (step 6). JX-0086.16-17; RX-0011C, Q/A105-107; Tr.(Ehrenreich), 543:21-545:15; Tr.(Shmuylovich), 156:22-157:20. Chapter 8.4.5 of the user manual (referenced in step 6) explains that "[t]he device has 5 LED panels," and that each of the individual panels "can be deactivated via the software" on the device's touchscreen. JX-0086.16. While "[a]ll panels are activated by default" (*i.e*., ***when the device is first turned on, before treatment is started***), each individual panel can be easily "deactivated" using the software, and a separate step (Step 9) is required to start the treatment:

Infringement – Claim 8[b]: positioning an illuminator proximate to the patient



7 RhodoLED® XL PDT Summarized Step-by-Step Instruction

These instructions should be used in conjunction with detailed operating instructions below (chapter 8). The section titles and numbers listed next to the instruction refer to the detailed instructions that correspond with each step.

Note: Every user of the RhodoLED® XL must be trained in operating the device. The initial training is provided by Biofrontera during set-up of the RhodoLED® XL. Recurrent training is not mandatory but can be provided by Biofrontera employees or other authorized parties. Before treating a patient with Ameluz®, please ensure that RhodoLED® XL is in good working order.

STEP 1) Plug in the lamp.
STEP 2) Turn on the lamp and wait for the home screen to appear (see chapter8.4.3).
STEP 3) Check the proper functioning of the RhodoLED® XL.
STEP 4) Treat the affected skin area: Application, incubation, and removal of the topical medication according to the USPI of Ameluz®.
STEP 5) Position the patient comfortably and equip the patient with protective eyewear (see chapter 6).
STEP 6) Select active panels (see chapter 8.4.5).
STEP 7) Position the lamp and adjust the lamp head over the skin area to be treated (distance 4.9 inch /12.5 cm) (see chapter 8.4.6).
STEP 8) Put on protective eyewear and make sure anyone remaining in the treatment room also wears protective eyewear (see chapter 6).
STEP 9) Start treatment by pressing **Start**, the illumination period begins (see chapter 8.4.9). Remind the patient to remain still throughout the illumination period. If audible indicators during treatment are activated, explain the sounds to the patient.

JX-0086.9 (RhodoLED® XL User Manual)

8.4.7 Adjusting the Treatment Distance

The correct treatment distance for the RhodoLED® XL is 4.9 ± 0.59 inch (12.5 ± 1.5 cm). Each LED panel is equipped with a distance sensor to allow individual adjustment of all panels. The distance sensor is automatically switched on if the panel is switched on. The current distance of each panel is shown on the control unit display above the panel illustration. The following table summarizes the visualization of the treatment distance.

Note: The RhodoLED® XL LED panels should only be used in curved shape and not in fully unfolded form. This is necessary to ensure the application of 37 J/cm² during the illumination.

JX-0086.17 (RhodoLED® XL User Manual)

Confidential Business Information Subject to Protective Order CDX-0005C.25

CDX-0005C.25 (citing JX-0086.9); Tr.(Shmuylovich), 157:2-20; Tr.(Thompson), 109:7-110:19, 136:18-137:16; Tr.(Ehrenreich), 543:25-545:15.

A pop-up message appears on the touchscreen if fewer than five panels are selected, but that message ***in no way*** stops HCPs from using fewer than five panels to treat patients. RX-0011C, Q/A57, 105-106, 133; Tr.(Thompson), 109:7-119:19, 136:18-137:16. The RhodoLED®XL user manual's step-by-step instructions clearly explain that HCPs are ***required*** to use at least ***three*** adjacent panels, and that they may choose to use all five panels, which does not amount to inducing infringement. *H. Lundbeck A/S v. Lupin Ltd.*, 87 F.4th 1361, 1370 (Fed. Cir. 2023)*; see also* RX-0011C, Q/A51, 105-110.

Sun further relies on selectively excerpted ***internal*** documents as evidence of inducement. CIB, 35-38 (citing JX-0105C; JX-0067C) (emphasis added). But nonpublic statements "are not available to downstream users and therefore cannot cause inducement." *Metacel Pharms. LLC v. Rubicon Rsch. Priv. Ltd.*, 2025 WL 1178384, at *4 (Fed. Cir. Apr. 23, 2025); *Bayer Schering Pharma AG v. Lupin, Ltd.*, 676 F.3d 1316, 1324 (Fed. Cir. 2012).

B. Biofrontera Does Not Infringe the Asserted Claims of the '028 Patent

1. Biofrontera Does Not Infringe the "Hinged Structure" Element of the '028 Patent

For the reasons discussed above (incorporated here), the friction hinges of the RhodoLED®XL do not infringe the hinged structure limitation because they extend *through* the inner side surfaces of adjacent panels, and are not "*on*" inner side surfaces. *Supra* Section I.A.1; RIB, 12-22. Further, the RhodoLED®XL's strain relief structures also do not infringe this limitation because (i) they are cable sleeves and not hinges, and (ii) they are not *on* inner side surfaces of adjacent panels. RIB, 24-27.

2. Biofrontera Does Not Infringe the "Within Approximately Four Inches" Element of the '028 Patent

Sun argues that Biofrontera directly infringes the "within approximately four inches" limitation of claims 1, 2, 4, 20, and 21 of the '028 Patent because "these system claims do not require performance of a step." CIB, 75. According to Sun, it is a legal impossibility for "system claims" to include a "requirement of ***use*** to infringe." *Id*., 55. That is simply wrong. *IPXL Holdings, L.L.C. v. Amazon.com, Inc.*, 430 F.3d 1377, 1384 (Fed. Cir. 2005); *Lyda v. CBS Corp.*, 838 F.3d 1331, 1339 (Fed. Cir. 2016); RIB, Section V.C.2.

Sun relies on *R.A.C.C.* and *Finjan* to support its position. CIB, 55. But *R.A.C.C.* was nonprecedential and *pre-dated* the *precedential* opinion in *IPXL* and its progeny of cases. And *Finjan* is not a sweeping proclamation that system claims *never* require "use," as Sun argues. CIB, 55. Rather, *Finjan* "cautioned, 'in every infringement analysis, the language of the claims, as well as the nature of the accused product, dictates whether an infringement has occurred.'" *Finjan, Inc. v. Secure Computing Corp.*, 626 F.3d 1197, 1204 (Fed. Cir. 2010) (quoting *Fantasy Sports Props. v. Sportsline.com, Inc.*, 287 F.3d 1108, 1118 (Fed. Cir. 2002)). In *Finjan*, the "non-method claims describe[d] capabilities without requiring" use. *Id*. But *Finjan* shows that system claims must be

analyzed for use requirements (or method steps), exactly as Biofrontera has done here. *Id*.; RIB, Section V.C.2.

In contrast, Sun has offered no analysis or expert testimony to explain why the phrase "the five panels ***are positioned to allow treatment*** within approximately four inches of ***the treatment surface***" does not require "use" to infringe, other than pointing to the word "system" in the preamble. CIB, Section V.B.1.e. On the contrary, to satisfy its infringement and domestic industry burdens on the "within approximately four inches" system claims, Sun relies on how HCPs position the devices relative to a patient's treatment surface. CIB, Sections V.B.1.e, VII.B.1.a.v. Indeed, Sun relies on the RhodoLED®XL and 4170E user manuals to prove the "proximate" and "within approximately four inches" elements in the method claims, CIB, Sections V.A.2.a.iii-iv; VII.A.2.iii; VII.B.2.a.iv, and relies on those same documents on to prove those elements in the system claims, CIB, Sections V.B.1.e; VII.B.1.a.v.

Sun simply has failed to carry its burden to prove that Biofrontera infringes. *Id*. At bottom, Sun relies on Dr. Jokerst's unsupported testimony to contend that "approximately four inches" means plus-or-minus ten percent, and therefore Biofrontera's 4.9+/-0.6 inch-treatment distance infringes, directly or indirectly. CIB, 53, 75; Tr.(Jokerst), 206:18-207:10. But unsupported expert testimony, like Dr. Jokerst's testimony here, should be given no weight. *Arthur A. Collins, Inc. v. N. Telecom Ltd.*, 216 F.3d 1042, 1046 (Fed. Cir. 2000) ("it is well settled that an expert's unsupported conclusion on the ultimate issue of infringement is insufficient …") (citing *Zelinski v. Brunswick Corp.*, 185 F.3d 1311, 1317 (Fed.Cir.1999)); *see also Cephalon, Inc. v. Watson Pharms., Inc.*, 707 F.3d 1330, 1338 (Fed. Cir. 2013); *Phillips v. AWH Corp.*, 415 F.3d 1303, 1318 (Fed. Cir. 2005).

Sun also argues that Biofrontera's 1.2-inch and Sun's "3+/-1in" treatment distance ranges means that "'approximately' must encompass" a "wide degree of variation" and that "4.3 inches and 4.0 inches" are equivalent under the DOE.[1] CIB, 54-56. This argument is illogical. The Asserted Patents show that uniformity was contemplated *between* 2-4 inches, not *above* four inches, meaning that 4.0 inches is already the outer-bound, like Sun's "3+/-1in" range. RX-0011C, Q/A152-154; JX-0001, 8:39-63. Thus, the claimed "approximately four inches" is not a reference to the center-point of a treatment range like Biofrontera's 4.9-inch and Sun's "3+/-1in" distances—any deviation above four inches should be *de minimus*, not up to 4.3 inches. Tr.(Ehrenreich), 525:10-526:8.

Sun also fails to prove that Biofrontera induces HCPs to infringe. Sun argues that the RhodoLED®XL is *capable* of illuminating at distances below four inches, but that has no bearing on Biofrontera's *intent*. CIB, 50-51; Tr.(Ehrenreich), 513:1-10. Sun says that, "[i]n practice, dermatologists … 'don't use a ruler to measure' the distance … they 'just eyeball' it." *Id*., 54-55 (quoting Tr.(Ehrenreich), 528:24-529:5). But that testimony was about Dr. Ehrenreich's use of Sun's 4170D device, *which does not have distance sensors*. Tr.(Ehrenreich), 528:24-529:5, 537:22-538:18. The RhodoLED®XL has distance sensors and actively tells HCPs when patients are too close to the panels and should be "further away," showing that Biofrontera encourages HCPs to treat patients at 4.9+/-0.6 inches at all times. *Id*.; *see also* JX-0086.18; RX-0011C, Q/A162-164; Tr.(Thompson), 115:8-118:9, 135:20-136:17; Tr.(Jokerst), 198:6-201:22.

[1] As explained in Biofrontera's opening brief, the DOE cannot be used to expand terms of approximation like approximately. RIB, 29.

3. Biofrontera Does Not Infringe the "Individually Configurable" Limitation of the '028 Patent

Sun asserts that Biofrontera infringes the "individually configurable" limitation of claims 16, 17, 19, and 21 of the '028 Patent. CIB, 63-70. The parties' dispute on this issue boils down to whether the panels of the claimed "illuminator" must be "individually configurable" for "photodynamically … treating a patient," as Biofrontera argues, RIB, 29-30, or whether this phrase "describes a capability of the system" that "does not impose any requirements on who must perform the adjustments or when," as Sun argues, CIB, 69-70.

Sun's argument fails because it reads the preamble and "individually configurable" phrase separately instead of together. *Id*. But "the context in which a term is used in the asserted claim" is important. *Phillips*, 415 F.3d at 1314. The "individually configurable" phrase, read in the context of the preamble and other elements of the claims shows that the RhodoLED®XL panels must be "individually configurable" for PDT to infringe. RIB, 29-30. Because turning individual panels off, or adjusting the "light intensity" of the panels [redacted], is not controlling illumination as part of a system for treating a patient, Biofrontera does not infringe. *Id*.

III. INVALIDITY

A. Obviousness - Under 35 U.S.C. § 103

1. The Prior Art

See RIB, 31-39.

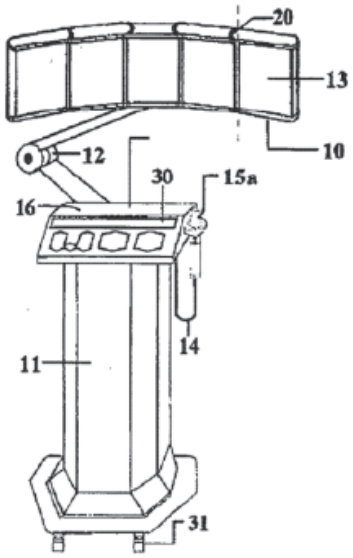
2. The Elements of the Asserted Claims Are Taught in the Prior Art

In addition to the limitations of the Asserted Claims identified as undisputed in CIUCL, the following limitations of the Asserted Claims are not disputed by virtue of omission from CIB: "light sources limitation" ('028 Patent, claims 1, 16, 20, 21; '512 Patent, claims 1, 8, 20); "first

and second edges limitation" ('028 Patent, claims 1, 16, 20, 21; '512 Patent, claims 1, 8, 20); "positioning proximate limitation" ('512 Patent, claim 8); "variable irradiance limitation" ('028 Patent, claim 20); and "16-light sources output light uniformly" ('028 Patent, claim 16).

i. "Hinges" Limitation

Contrary to Sun's assertion that there is a "lack of disclosure in the art" regarding hinges, it is undisputed that Larsen discloses a 5 panel PDT illuminator, with adjacent panels connected by hinges. RX-0099, Fig. 1, [0072]; CIB, 79-80.



Specifically, Larsen discloses "for the treatment of large-area tissues according to Fig. 1, ***several applicators 13 are flexibly connected to each other through hinges***...." RX-0099, [0072].

There are really only three options for placing hinges to connect adjacent panels – (1) between adjacent panels; (2) on the top or bottom of the panels; or (3) on the rear surface of the panels. Tr.(Grove), 591:5-7 ("Yeah, in general, there are three locations to connect adjacent panels."); RX-0006C, Q/A157. Among these three, the most common option is to put "hinges

between the two panels." Tr.(Grove), 592:2-8. People have been doing this for generations prior to 2015. *Id*.

The examiner of the Asserted Patents was able to understand this, noting in the file history that Larsen's hinges had been erroneously labeled as element number 10 in the specification while being correctly shown as element number 20 (*i.e*., between the panels) in the Figures. JX-0004.160 ('512 File History); Tr.(Jokerst), 744:6-15; RX-0006C, Q/A152. The PTAB was able to understand this, rejecting Sun's arguments that "Larsen does not teach or suggest hinged structures on inner side surfaces." Tr.(Jokerst), 744:20-745:22; RX-1374.0018-19. A POSA certainly would be able to understand this. *Facebook, Inc. v. Windy City Innovations, LLC*, 973 F.3d 1321, 1343 (Fed. Cir. 2020) ("A person of ordinary skill is also a person of ordinary creativity…the fact that it would take some creativity to carry out the combination does not defeat a finding of obviousness."). The choice of whether to place hinges between panels, on the top or bottom, or on the back is not an act of invention – especially where a POSA has a Ph.D. in engineering and at least a year of relevant experience. Order No. 18, 13

While Sun cites *In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, 676 F.3d 1063 (Fed. Cir. 2012), the inquiry in that case was whether it would have been obvious to develop a therapeutically effective drug formulation absent any disclosure in the art of a pharmacokinetic (PK)/pharmacodynamic (PD) relationship. Such development involved estimation of PK values, multiple iterations of computer modeling of PK profiles, and clinical testing. *Id*., 1067. In short, *Cyclobenzaprine* was not a selection of one out of three locations to place hinges. *Id*. As noted by the court in *In re Cyclobenzaprine*, "[w]here a skilled artisan merely pursues 'known options' from a 'finite number of identified, predictable solutions,' the resulting invention is obvious...." *Id*., 1070.

Sun's additional arguments do not change this conclusion. Although Sun argues that Larsen's element number 20 identifies regular row arrangements in Figs. 2a-d (as opposed to hinges between panels) (CIB, 81-82), Dr. Jokerst admitted that Figs. 2a-d do not list the element number 20. Tr.(Jokerst), 746:6-19; RX-0099, Figs. 2a-d; RX-0006C, Q/A154. Similarly, although Sun argues that the dotted line corresponding to element number 20 "instructs the reader as to the location of the more detailed views in Figures 2a-d," Figs. 2a-d show the front surfaces of illuminators – which would not make sense for the location between panels indicated by element number 20.

Sun's reliance on Fig. 1 of RX-0059 (Larsen '381 Patent) similarly fails to move the needle. CIB, 79-80. RX-0059 is a different patent, with a different disclosure, from a different family than Larsen and therefore of dubious relevance, at best. Further, although Sun points out that the '512 Patent was allowed over Larsen, such allowance was not based solely on the absence of hinges in the prior art. JX-0004.1731. In fact, earlier in prosecution, the examiner cited Larsen as anticipatory to claims including the term "nested hinges" - which, according to Sun and Order No. 18, mean hinges "on inner side surfaces of adjacent panels." JX-0004.555.

Although Sun argues that a POSA would have been discouraged from placing hinges on inner side surfaces because this may have caused gaps between panels, neither Dr. Jokerst nor Sun cite any reference that shows a POSA would have believed this prior to 2015. CIB, 82; CX-0014C, Q/A232-235. Further, Dr. Jokerst opines that both the RhodoLED®XL and the 4170E achieve uniformity despite including panels with gaps. Tr.(Jokerst), 739:20-23; CX-0010C (Jokerst), Q/A107.

The language of claim 20 of the '512 Patent requiring that "the nested hinges be[] configured so as to allow continuous illumination across the at least five panels" is also disclosed

by Larsen. RIB, 45; RX-0006C, Q/A158. Although Sun argues that the combination of Lundahl and Larsen would not provide continuous illumination because Lundahl's fluorescent tubes contain dark spaces near the cathodes (CIB, 102), this would not be the case in a device utilizing LEDs. Tr.(Jokerst), 768:10-13 ("Q: Dr. Jokerst, you wouldn't typically incorporate the shortcomings of a prior device when developing a new device, right?" A: That's correct.").

To the extent a POSA needs additional instruction to place hinges on inner side surfaces of adjacent panels, Hente teaches this – disclosing hinge 50, depicted between panels. RIB, 45-47.

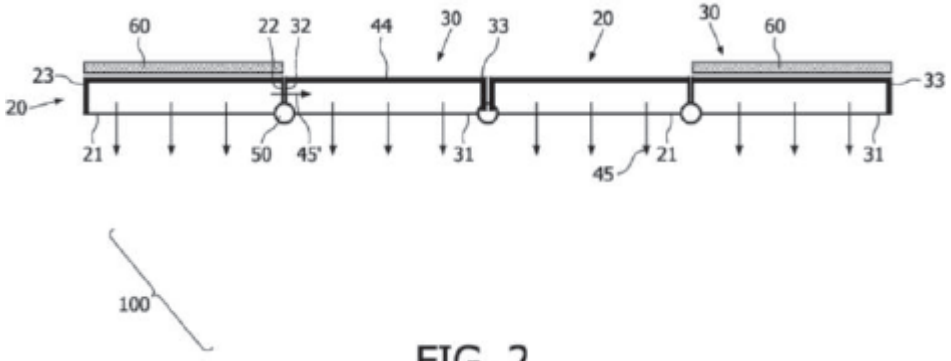
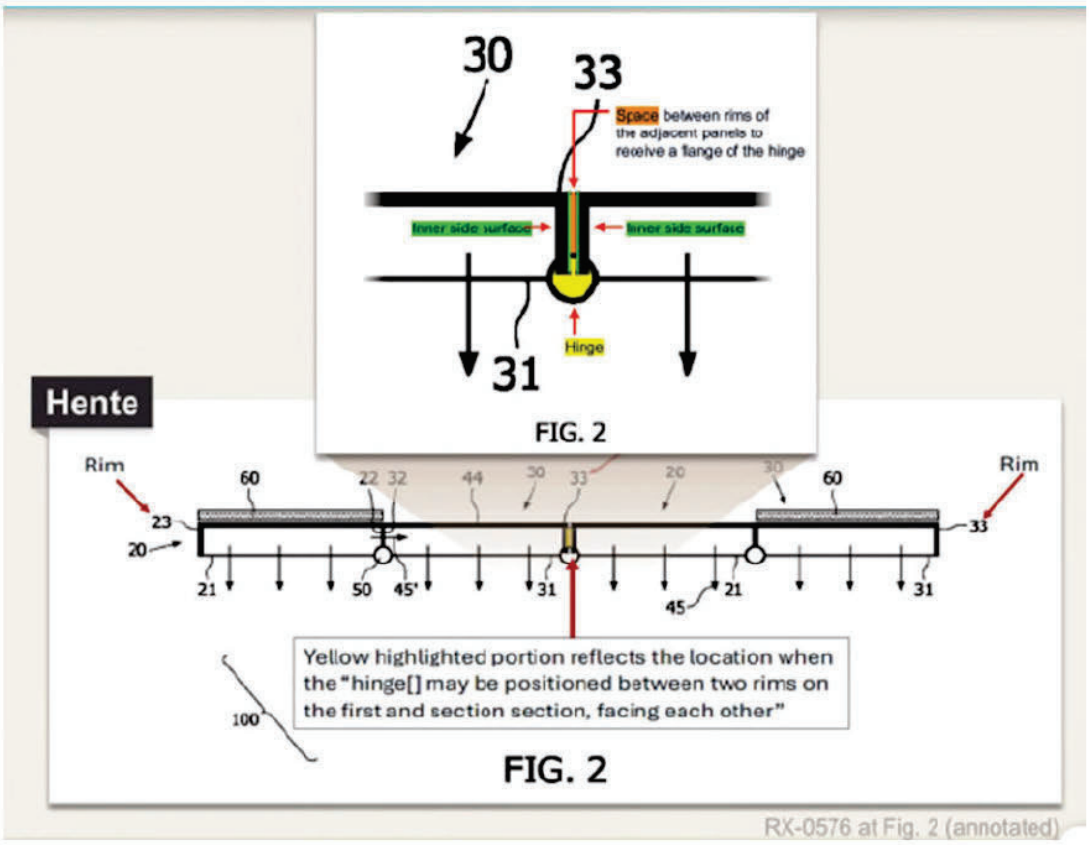


FIG. 2

RX-0576, Fig. 2.

Hente is also analogous art. *Supra* Section III.A.3.iii; RIB, 82-83.

Figure 2 of Hente clearly illustrates a space between the rims of adjacent panels, within which a hinge is placed. RX-0006C, Q/A292.



RDX-0017C.084 (excerpt); RX-0576, Fig. 2 (annotated). Thus, not only is the space between the rims of adjacent panels explicitly disclosed by Hente, a far cry from Sun's allegation that "Dr. Grove invents with no support in the reference a 'space between the rims of adjacent panels of Hente to receive a flange of the hinge,'" (CIB, 105), but Hente discloses the placement of the hinge in this space. RX-0006C, Q/A292; RX-0576, Fig. 2.

Moreover, placing a hinge in this space would not block light that flows through the rims. CIB, 105-106. As seen in Sun's own annotations, there is only an arrow indicating light emitting through the sides between side surfaces 22 and 32 in the annotated figure shown on the left below. CIB, 105-106. This can be contrasted with the lack of arrow indicating light emitting through the sides of the rim 33 in the middle of Figure 2 (shown in both the left and right annotated figures below). CIB, 105-106.

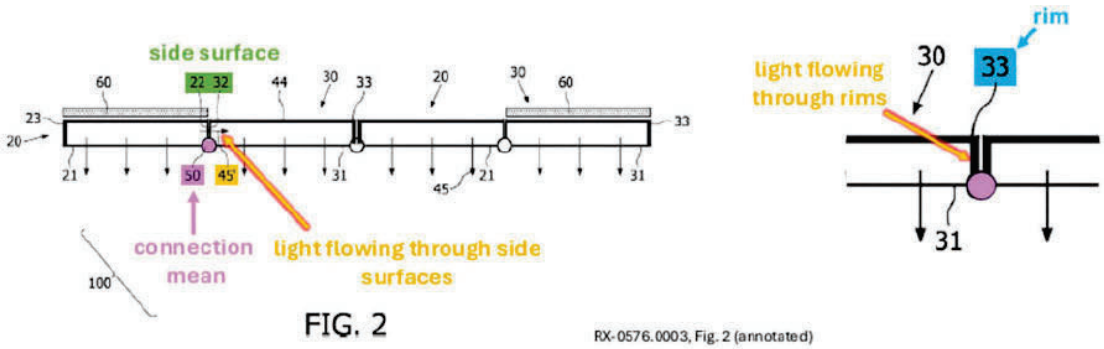


FIG. 2

RX-0576.0003, Fig. 2 (annotated)

CDX-0018C.117 (excerpt). Even if the hinges did protrude beyond the front of the panels, the distance or "gap" between the panels would nonetheless by minimized or eliminated when the panels are angled toward each other (as would be the case, *e.g.*, when the panels are angled to surround the face/scalp of a patient). RX-0006C, Q/A341.

ii. "Uniform Illumination" Limitation

Sun does not dispute that Lundahl teaches uniform illumination within the meaning of the claims. CIB, 97. Rather, Sun merely argues that Lundahl is only able to achieve this uniformity via integration of at least four components – U-shaped tubes, 9-segmented reflector, a specific electrical control system, and a specific cooling system. CIB, 97-98. However, as fully explained in Biofrontera's opening brief, three of these four components – the reflector, the specific electrical control system, and the specific cooling system – are only necessary to solve uniformity problems specific to Lundahl's fluorescent tubes. RIB, 50-52. As these problems are not present in LEDs, a POSA would not reasonably expect to need their solutions to achieve comparable uniformity in an LED device.

Instead, in combining Lundahl and Larsen, a POSA would logically only retain components that provide a uniformity benefit that goes beyond simply patching-up the numerous uniformity problems of fluorescents. For instance, a POSA would logically incorporate a configuration capable of conforming to a treatment surface, as both Larsen's hinged panels and

Lundahl's U-shape are intended to do. Similarly, the proposed combination also retains Lundahl's light source distribution, which a POSA would recognize as being useful in an LED device to combat fall off effect – which is not a problem specific to fluorescents. RX-0006C, Q/A40-44; RIB, 32-34; RX-0065, 6:16-25 ("uniformity can also be adjusted by varying the lateral spacing of the tubes...").

While Sun argues that Biofrontera has failed to adequately show reasonable expectation of success because Dr. Grove did not conduct uniformity measurements for his combination, there is no "law-required minimum for what can support a 'reasonable' expectation of success" and the Federal Circuit has stated that testing is not required. *Acorda Therapeutics, Inc. v. Roxane Labs, Inc.*, 903 F.3d 1310, 1333 (Fed. Cir. 2018). Sun's assertion that Dr. Grove did not analyze whether a combination of Lundahl and Larsen would achieve the claimed uniformity is incorrect. CIB, 99. Dr. Grove testified that "the device resulting from combining the teachings of Lundahl and Larsen...has effectively the same light arrangement and pattern as Fig. 2 of Lundahl. Because of this, a POSA would at least reasonably expect that this resulting device would provide an irradiance of at least 60% of the measured maximum over the entire treatment surface, as required by the Asserted Claims." RX-0006C, Q/A321.

Although Sun points to a statement Dr. Grove made that a POSA would be required to "perform undue experimentation to make and use an illuminator that provides uniform illumination ***over the full scope of the claims***," this statement is taken out of context. CIB, 99 (emphasis added); Tr.(Grove), 579:15-25 (Q: you said that in your opening expert report, right? A: In a different context, I did, yes."). Dr. Grove's statement was in relation to the difficulty of providing uniform illumination to the far reaches of the claim scope – *e.g.*, of providing uniform illumination to a patient's extremities and torso. Tr.(Grove), 587:4-588:21. This statement was not

made in relation to providing uniform illumination of, *e.g.*, the face, which is both within the claim scope and clearly disclosed in Lundahl. RX-0006C, Q/A92, 96, 328; RX-0065, 2:35-40, 2:60-67, 3:29-38.

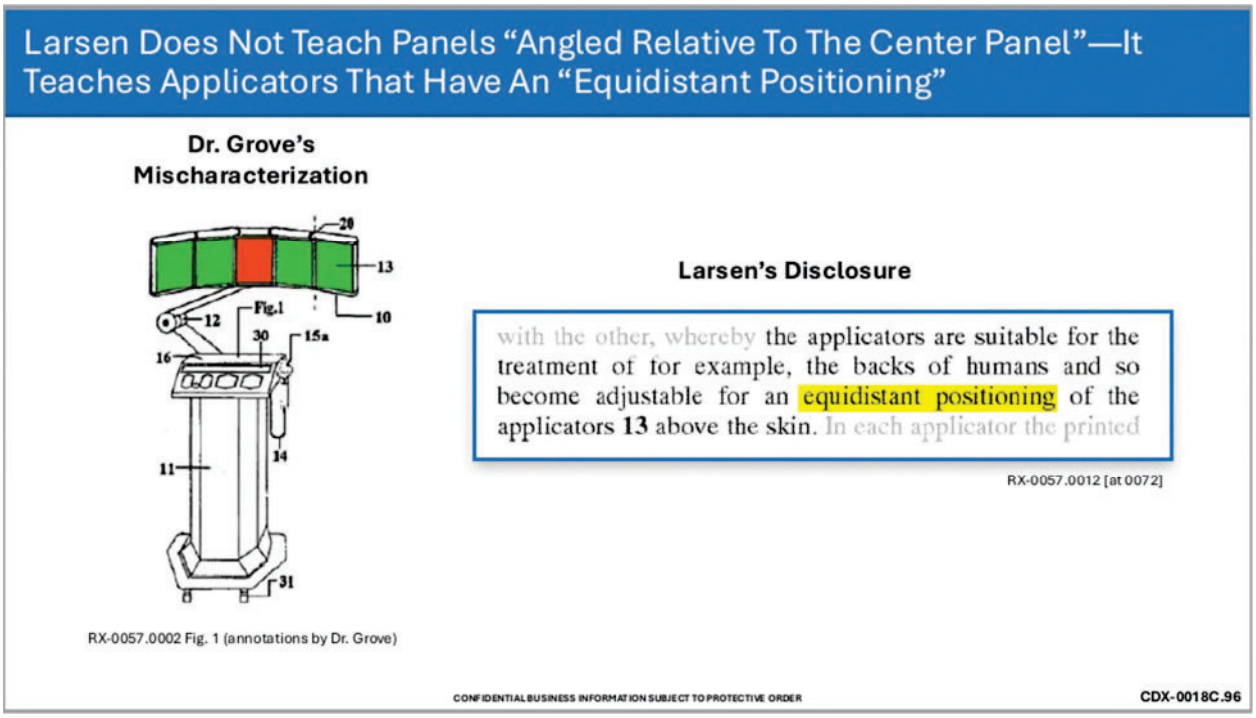
In short, Lundahl successfully achieved uniform illumination within 60% of maximum, using fluorescents (RX-0065, 15:22-27), which – according to Mr. Lundahl – "are very hard to control, very hard to regulate power, uniformity, et cetera." JX-0017C, 36:10-13. LEDs, on the other hand, provide much better control of light output characteristics than fluorescents. RX-0006C, Q/A40; CX-1231.1. A POSA would have had a reasonable expectation of success in achieving at least the same uniformity with a better light source.

iii. "Center Panel" Limitation

Sun's continued dispute that the prior art fails to teach or render obvious "one of the five panels 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" is perplexing. CIB, 103-14. Figure 1 of Larsen clearly depicts this configuration. RX-0099, Fig. 1. Dr. Jokerst agrees, stating the following in reference to demonstrative CDX-0018C.96 (containing Fig. 1 of Larsen):

> Q: These green panels in the figure of [Larsen] are drawn in at an angle to the orange panel in the center, correct?
> A: They're at a slight arc, yes.
> Q: They're at an angle, correct?
> A: Yes.
> Q: They're angled relative to the center panel, correct?
> A: In this figure, yes.

Tr.(Jokerst), 738:13-739:2.



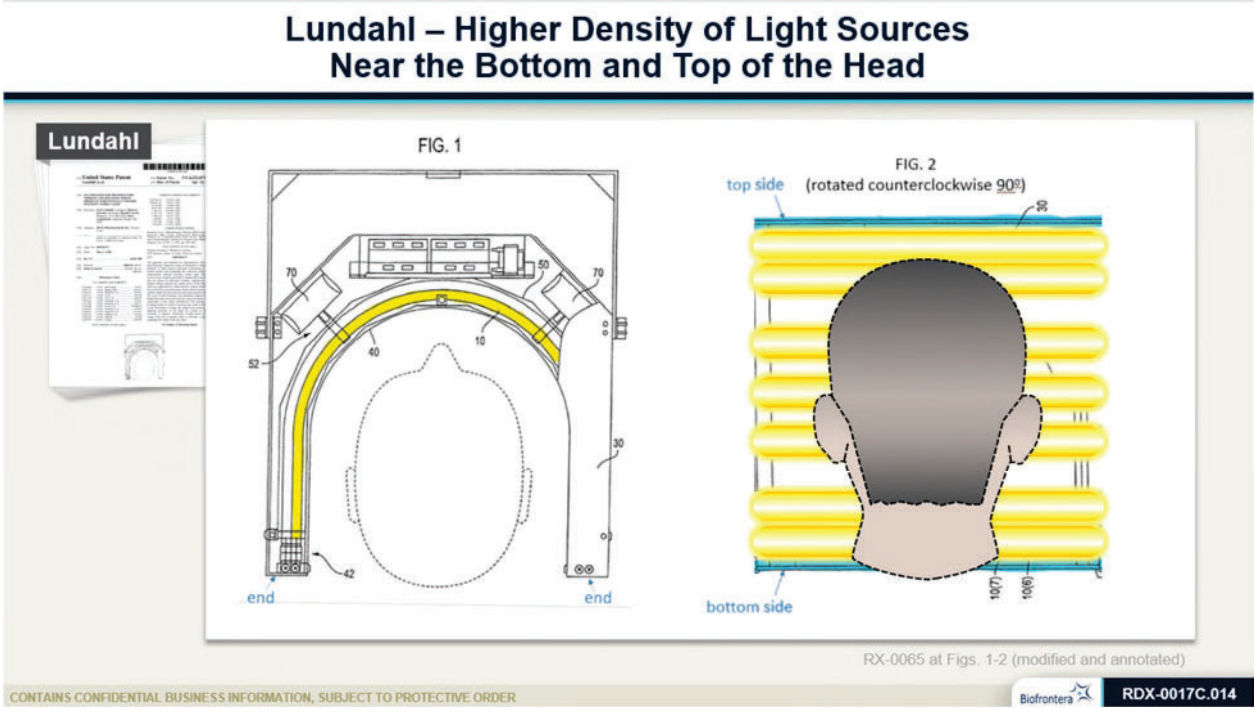
CX-0014C.83-84; CDX-0018C.96; RX-0099, [0072], Fig. 1. Further, Larsen teaches panels connected by hinges, which are adjustable. RX-0099, [0072]. This configuration would allow angling of side panels with respect to the center panel.

Accordingly, the "center panel" limitation is disclosed and/or rendered obvious.

iv. "First and Second Edges" and "Higher Intensity Proximate Second Edges" Limitations

Sun's argument that the "higher intensity close to the second shorter edges" limitation rests on two main assertions: (1) that Lundahl would lead a POSA to increase intensity near the *longer* edges; and (2) a POSA would replicate Lundahl's low output areas in a combination with Larsen. CIB, 86-95. These assertions rest on the assumption that a POSA is an automaton, lacking capacity for logical interpretation of the teachings in the art. This is not the law, however. *KSR Intern. Co. v. Teleflex Inc.*, 550 U.S. 398, 420-21 (2007) ("[I]n many cases a person of ordinary skill will be able to fit the teachings of multiple patents together like pieces of a puzzle…A person of ordinary skill is also a person of ordinary creativity, not an automaton.").

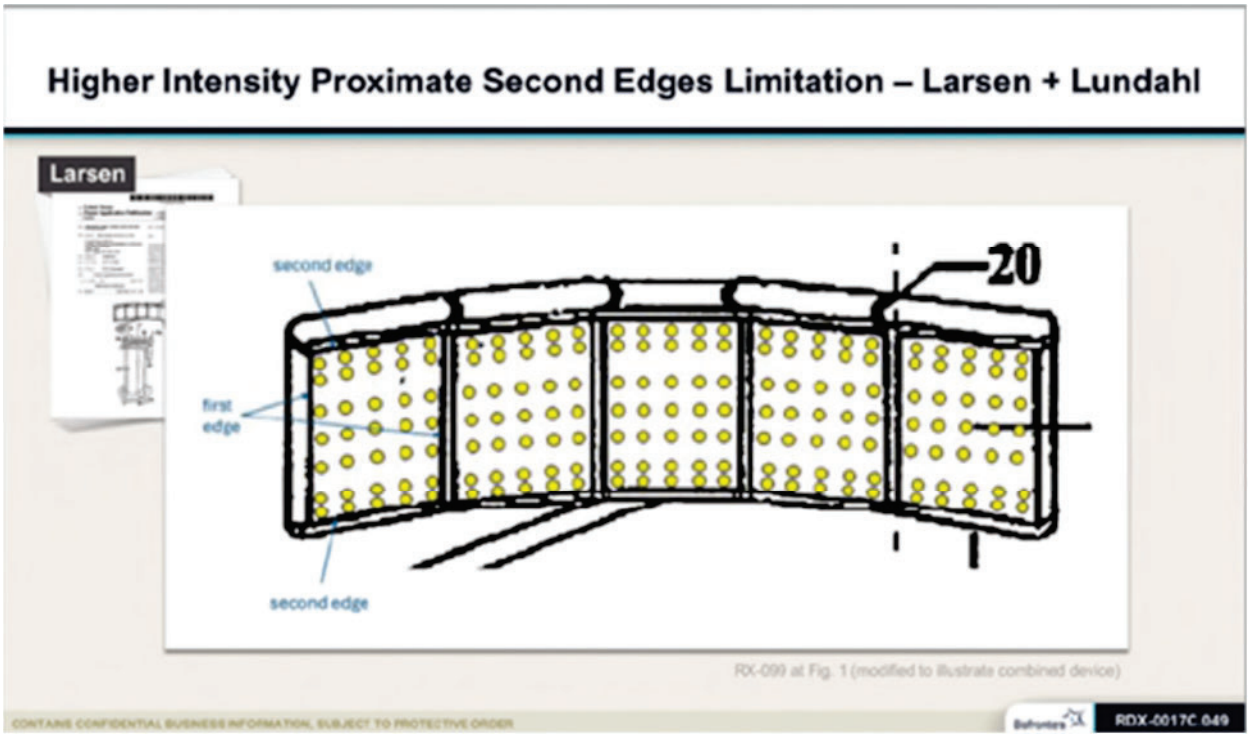
With respect to the first point, as Dr. Jokerst admits, Lundahl teaches a light source distribution that increases intensity near a patient's forehead and chin, when the device is used as shown in Figure 1 of Lundahl. Tr.(Jokerst), 740:25-741:5, 748:10-21; RX-0065, Fig. 1; RX-0006C, Q/A97.



RDX-0017C.014.

As more fully explained in Biofrontera's opening brief (RIB, 58-59), Lundahl teaches that the uniformity benefits provided by its light distribution are realized by providing increased intensity at the edges, which would correspond to a patient's forehead and chin, when the device is used as shown in Figure 1. RX-0065, 6:25-30; RX-0006C, Q/A95, 97. A POSA would be able to understand this and apply this principle in combining Larsen with Lundahl. As Dr. Jokerst admits, if Lundahl's device were divided into five panels, the panel edges near the patient's forehead and chin would be the shorter edges. Tr.(Jokerst), 748:22-749:7. Accordingly, a POSA

applying ordinary logic and creativity would arrive at a device providing increased intensity along these shorter edges. RX-0006C, Q/A215.

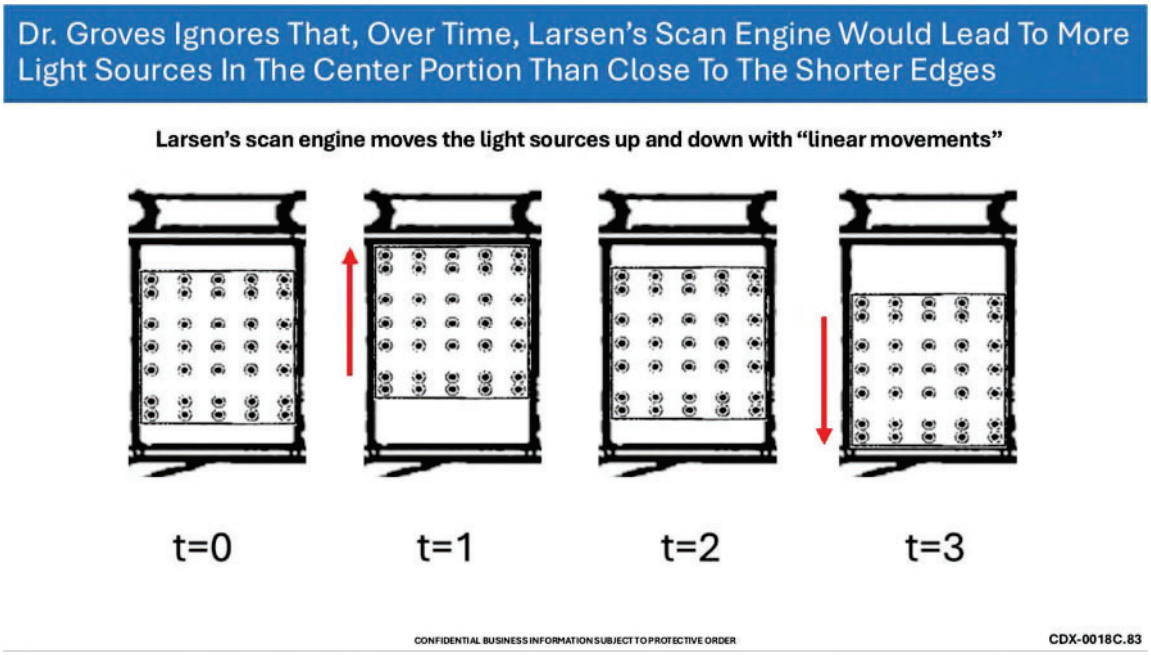


RDX-0017C.049.

With respect to the second point, Sun points out that Lundahl's light sources have "low output area[s]" or "areas of reduced emission." CIB, 92. Sun is correct on this point – Lundahl discloses that its fluorescent tubes have what are known as "Faraday dark space[s]" near their cathodes. RX-0065, 6:9-22. Sun is not correct, however, that a POSA would incorporate these dark spaces into a combination using LEDs. It was well-known that Faraday dark spaces were a problem specific to fluorescents. *Id.*; Tr.(Jokerst), 732:7-10 ("Q:...there was a known problem, right, that fluorescent tubes had dark areas, right? A: It was known that fluorescent tubes had dark areas, yes."); CX-0011C, Q/A26. LEDs did not have such dark spaces, and, as Dr. Jokerst noted, it's correct that a POSA "wouldn't typically incorporate the shortcomings of a prior device when developing a new device." Tr.(Jokerst), 768:10-13.

Accordingly, the proposed combination is not hindsight reconstruction as Sun accuses (CIB, 89-90), but rather the simple application of logic to the disclosures of the prior art. The PTAB agreed, stating that "Petitioner's proposed modification applies Lundahl's disclosure of providing greater light intensity *at the top and bottom side* to the top and bottom sides of Larsen, *which are the shorter edges in Larsen.*" Tr.(Jokerst), 749:8-16; RX-1374.0019.

Finally, Sun's argument that "Biofrontera incorporates Larsen's 'scan engine' in its combination...lead[ing] to a higher intensity of light emitted from the center of the panels...because the engine moves the lights up and down...." is baseless. CIB, 90. First, Biofrontera has never argued that Larsen's scan engine need be incorporated in a combination to achieve uniformity. RIB, 49-52. Second, while Dr. Jokerst imagines hypothetical movements of a scan engine and illustrates these in CDX-0018C.83, she admitted that none of these imaginings is actually disclosed in Larsen.



CDX-0018C.83. For example, Dr. Jokerst admitted that Larsen fails to disclose whether the scan engine causes movement up or down or side to side, any pattern of movement for the scan engine,

any range of movement for the scan engine, any rate of movement for the scan engine, or any specific time points. Tr.(Jokerst), 741:22-742:20. Dr. Jokerst further admitted that she didn't provide any units, dimensions, or measurements for her illustration in CDX-0018C.83. Tr.(Jokerst), 742:22-743:5. As a result, Sun's argument that the scan "engine would lead to a higher intensity of light emitted from the center of the panels, not the shorter edges, because the engine moves the lights up and down with linear movements" is a construct of Dr. Jokerst and Sun that is wholly unsupported by any evidence.

Accordingly, the "first and second edges" and "higher intensity proximate second edges" limitations are disclosed and/or rendered obvious.

v. "Individually Configurable" Limitation

Although Sun argues that Larsen does not disclose panels being individually configurable to control illumination from each of the five panels because "the control mechanism 16 controls the device as a whole, not the output from the panels individually" (CIB, 100), this is inaccurate. Larsen does not specify that its controller only controls the entire device. Further, Sun's assumption as much ignores the basic functionality of a controller. It was known as early as 2008 that "LED control systems allow the user to set various parameters of system operation including ***brightness***, time on or off, photo periods, ***light quality***...Controls are usually interfaced to the driver circuitry to ***allow the brightness of the individual LEDs to be set.***" CX-1231.2.

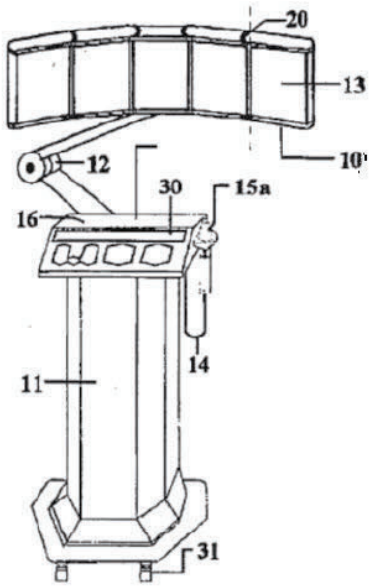
Sun recognizes that claim 5 of Larsen recites that "the light sources are individually selected—switched ON or OFF." CIB, 101; RX-0099, cl. 5; RX-0006C, Q/A243. Thus, Larsen teaches illuminating or darkening individual light sources within a panel containing multiple light sources, which necessarily alters or configures the power output and/or light intensity of the panel – *i.e.*, by allowing for brightening or dimming of the panel. RX-0006C, Q/A243.

In attempt to avoid this clear disclosure, Sun argues that this refers to "switching between semiconductor diodes and/or laser diodes." CIB, 101. However, this argument finds no basis in logic or normal principles of claim interpretation. There is no indication that claim 5 refers to switching only between LEDs and laser diodes. In fact, claim 5 depends from claim 1, which recites "the light source consists of ***at least one*** semiconductor diode ***and/or*** at least one laser diode..." meaning that claim 1 does not even require the presence of both LEDs and laser diodes. Rather, claim 1 includes embodiments that only contain LEDs and embodiments that only contain semiconductor diodes. In either embodiment, Sun's argument that claim 5 refers only to switching between LEDs and laser diodes does not make sense.

Accordingly, the "individually configurable" limitation is disclosed and/or rendered obvious.

vi. "Mobile Base Supported By At Least Four Wheels"

Sun's argument that "there is no express disclosure in Larsen of four wheels – Dr. Grove points to Figure 1, but shows two wheels" (CIB, 107), merely supports Dr. Grove's conclusion that including four wheels would be obvious.



RX-0099, Fig. 1.

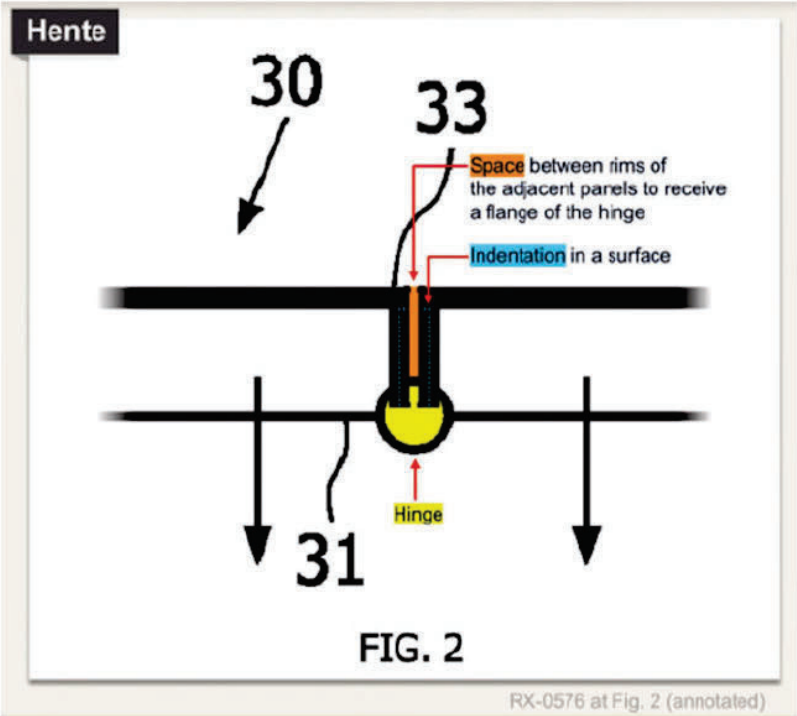
Although Larsen's Figure 1 shows two wheels due to its perspective, it would be clear to a POSA that more than two wheels, *e.g.*, four wheels would provide superior stability. RX-0006C, Q/A252-53. Further, changes in the number of a component are not typically a basis for patentability. *Application of Harza*, 274 F.2d 669, 744 (Cust. & Pat. App. 1960) ("It is well settled that the mere duplication of parts has no patentable significance unless a new and unexpected result is produced.").

vii. "Recess" and "Recess Location" Limitations

Initially, it is undisputed that Perutz discloses the "recess" and "recess location limitations." CIUCL, 4.

Further, Hente suggests these limitations even absent Perutz. The most common option for connecting panels with hinges known to a POSA prior to 2015 would have been to put hinges between the panels, specifically a butt hinge that has flanges. Tr.(Grove), 592:2-5. As Hente discloses a space between panels within which a hinge is placed, a POSA would have been

motivated to include an indentation at the inner side surfaces of Hente between adjacent panels to receive a flange of the hinge to minimize the space between the panels. RX-0006C, Q/A292. It would have been nothing more than the application of known design elements and strategies to incorporate such an indentation into the adjacent panels of Larsen, as both Larsen and Hente teach minimizing the space between panels. RX-0006C, Q/A292.



RDX-0017C.085 (excerpt); RX-0576, Fig. 2 (annotated).

viii. The Prior Art Teaches Every Limitation of the Asserted Claims

Accordingly, the prior art teaches each and every limitation of the Asserted Claims, as illustrated below. RX-0006C, Q/A 304.

Limitations	Asserted Claims of the '028 Patent							
	1	2	4	16	17	19	20	21
Preamble	Not Disputed							
Hinges Limitation	✓	✓	✓	✓	✓	✓	✓	✓
Light Sources on Five Panels	Not Disputed							
Uniform Illumination	✓	✓	✓	✓	✓	✓	✓	✓
Center Panel	✓	✓	✓	n/a	✓	n/a	✓	✓
Within Approximately Four Inches	Not Disputed							
First and Second Edges	Not Disputed							
Higher Intensity Proximate Second Edges	✓	✓	✓	✓	✓	✓	✓	✓
Administering ALA	Not Disputed							
Positioning Proximate to Patient	Not Disputed							
Variable Irradiance	Not Disputed							

RDX-0017C.092 (excerpt, annotated).

Limitations	Asserted Claims of the '028 Patent							
	1	2	4	16	17	19	20	21
Individually Configurable	n/a	n/a	n/a	✓	✓	✓	n/a	✓
Mobile Base	n/a	n/a	n/a	✓	✓	✓	n/a	n/a
Pillar	n/a	n/a	n/a	Not Disputed			n/a	n/a
Controller	n/a	n/a	n/a	Not Disputed			n/a	n/a
Arm	n/a	n/a	n/a	Not Disputed			n/a	n/a
Illuminator Connected	n/a	n/a	n/a	Not Disputed			n/a	n/a
Light Sources Output Light Uniformly	n/a	n/a	n/a	Not Disputed			n/a	n/a
Fans	n/a	n/a	n/a	Not Disputed			n/a	n/a
Red Light	n/a	n/a	n/a	n/a	n/a	Not Disputed	n/a	n/a
Dose Range	n/a	Not Disputed	n/a	n/a	n/a	n/a	n/a	n/a
Wavelength	n/a	n/a	Not Disputed	n/a	n/a	n/a	n/a	n/a

RDX-0017C.093 (excerpt, annotated).

Limitations	Asserted Claims of the '512 Patent						
	1	3	5	8	17	18	20
Preamble	Not Disputed						
Hinges Limitation	✓	✓	✓	✓	✓	✓	✓
Light Sources on Five Panels	Not Disputed						
Uniform Illumination	✓	✓	✓	✓	✓	✓	✓
Center Panel	✓	✓	✓	n/a	n/a	n/a	✓
First and Second Edges	Not Disputed						
Higher Intensity Proximate Second Edges	✓	✓	✓	✓	✓	✓	✓

RDX-0017C.094 (excerpt, annotated).

Limitations	Asserted Claims of the '512 Patent						
	1	3	5	8	17	18	20
Administering ALA	Not Disputed						
Positioning Proximate to Patient	Not Disputed						
Dose Range	n/a	✓	n/a	n/a	n/a	n/a	n/a
Wavelength	n/a	n/a	✓	n/a	n/a	n/a	n/a
Recess	n/a	n/a	n/a	n/a	✓	✓	n/a
Recess Location	n/a	n/a	n/a	n/a	n/a	✓	n/a

RDX-0017C.095 (excerpt, annotated).

3. A Motivation Existed to Combine the Teachings of the Prior Art and A Reasonable Expectation of Success Existed

i. A Motivation Existed to Incorporate the Hinged Panels and LEDs of Larsen into the Illuminator of Lundahl

As explained in Biofrontera's opening brief, there would have been motivation to modify Lundahl's fixed U-shape device that utilized fluorescent tubes with Larsen's (1) hinged panels to provide flexibility and (2) LEDs to replace the fluorescent tube technology that was obsolete by 2015. RIB, 31, 74-79. In arguing otherwise (CIB, 108), Sun urges this tribunal to adopt a rigid

application of the obviousness standard that is contrary to well-established law mandating that "[t]he motivation to combine analysis is a flexible one." *Intel Corp. V. PACT XPP Schweiz AG*, 61 F.4th 1373, 1379 (Fed. Cir. 2023); *see also* 550 U.S. at 421 ("Rigid preventative rules that deny factfinders recourse to common sense, however, are neither necessary under our case law nor consistent with it.").

Initially, Sun deliberately misses the point by arguing that "a POSITA would not have been motivated to look to Larsen to address the precise issues of uniformity Lundahl already solves...." CIB, 108. Biofrontera has never argued that a POSA would have been motivated to modify Lundahl in order to achieve uniformity – Lundahl already achieves uniformity. RX-0065, 15:22-27; RX-0006C, Q/A99. Instead, Biofrontera has consistently argued (RIB, 74-79) that a POSA would have been motivated to modify Lundahl's device to provide flexibility and to replace obsolete (and arguably illegal) fluorescent tube technology. RX-0006C, Q/A315; *see also* JX-0015C, 36:11-16; Tr.(Jokerst), 735:13-22; JX-0006C (Mazejka), 53:13-16; JX-0014C (Boyajian), 33:16-34:10. There is nothing in the law that limits a POSA to one particular motivation (*i.e.,* improving uniformity) in lieu of others (*i.e.*, improving flexibility and updating obsolete fluorescents). *In re Fulton*, 391 F.3d 1195, 1202 (Fed. Cir. 2004) ("[A]s long as some motivation or suggestion to combine the references is provided by the prior art taken as a whole, the law does not require that the references be combined for the reasons contemplated by the inventor.").

While Sun argues that a POSA would not have been motivated to modify Lundahl's U-shape with panels because "such modification would create unwanted gaps," (CIB, 108-109) this argument once again does not comport with the law, which states that "[t]he fact that the motivating benefit comes at the expense of another benefit, however, should not nullify its use as a basis to modify the disclosure of one reference with the teachings of another." *Medichem, S.A.*

v. Rolabo, S.L., 437 F.3d 1157, 1165 (Fed. Cir. 2006). "Trade-offs often concern what is feasible, not what is, on balance, desirable. Motivation to combine requires the latter." 391 F.3d at 1200. As admitted by Sun's named inventor, Mr. Carota, and its VP, Mr. Lundahl, it was desirable to increase the flexibility of the older, fixed U-shaped device that embodied the Lundahl patent. RX-0015C (Carota), 37:2-6 (Q: And were there problems with a rigid curved device? A: It was limiting."); JX-0017C, 42:19-43:2 (Mr. Lundahl admitting that the fixed U-shape posed a problem for larger patients).

Despite the admissions by its own inventors and employees that the fixed U-shape limited treatment (*i.e.*, of different sized patients and body areas), Sun argues unconvincingly that a POSA would not be motivated to modify the device. (CIB, 111-114). However, while Sun tacitly acknowledges that the Lundahl device would not be able to treat a patient's chest and back, it argues that treatment of the chest and back was "uncommon." CIB, 112-113. Similarly, while Sun implicitly recognizes that some treatments with the fixed U-shape device require "jury-rigging" (*i.e.*, with pillows, instrument stands, and similar) in order to properly position the treatment surface with respect to the fixed U-shape (RX-0007C, Q/A159), Sun argues that such "'jury-rigging' is a normal scenario, not a motivation to modify." CIB, 112-113. These complaints amount to an argument that there is not *enough* motivation to combine. However, the law does not require some specific threshold quantity of motivation that must be met for obviousness – improvements to already functional technology are sufficient. *DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co.*, 464 F.3d 1356, 1368 (Fed. Cir. 2006) ("motivation to combine exists…[when] the combination of references results in a product or process that is more desirable, for example because it is ***stronger, cheaper, cleaner, faster, lighter, smaller, more***

durable, or more efficient[;]…the desire to ***enhance*** commercial opportunities by ***improving*** a product or process is universal....") (emphasis added).

Sun also persistently ignores the teachings of the prior art references as a whole. *Palo Alto Networks, Inc. v. Centripetal Networks, LLC*, 122 F.4th 1378, 1386 (Fed. Cir. 2024) ("Where, as here, the grounds for obviousness are based on a specific combination of references, arguments that 'attack the disclosures of the two references individually' lack merit...[references] must be read together, not in isolation...."). Although Sun accuses Dr. Grove of "cherry-picking" Larsen's teaching of LEDs while leaving behind Larsen's teaching of "regular row arrangements" of light sources, it is Sun that fails to consider the teachings of the prior art in their entirety. CIB, 109. Larsen only once mentions "regular row arrangements" (RX-0099, [0071]) and fails to teach any benefit or advantage to this arrangement. In contrast, Lundahl extensively explains that its arrangement of light sources improves uniformity, stating, *e.g.*, that:

> [U]niformity can also be adjusted by varying the lateral spacing of the tubes....This is important since it is necessary to compensate for the fact that the output from a flat plane emitting light source drops near the edges. Varying the lateral spacing of the tubes creates the same effect as folding the edges of a larger illuminator in on itself, thus emulating an infinite plane emitter with a compact unit.

RX-0065, 6:22-30.

> The number of tubes used and the spacing between them were chosen to achieve desired uniformity and power output specifications....The present invention provides a highly uniform output irradiance without the use of an additional diffusing element.

RX-0065, 6:43-57. A POSA reading both references, considering them holistically, and applying common sense, would logically choose to incorporate the lighting distribution with explicitly taught uniformity benefits, as opposed to the distribution with no disclosed benefits. *Perfect Web Techs., Inc. v. InfoUSA, Inc.*, 587 F.3d 1324, 1329 (Fed. Cir. 2009) ("[O]bviousness…may include recourse to logic, judgment, and common sense available to the person of ordinary skill that do

not necessarily require explication in any reference or expert opinion.). Despite Sun's arguments otherwise (CIB, 109), Dr. Grove has explained this extensively. RX-00006C, Q/A42, 93-97, 177-178, 213-216, 307, 321, 328.

Similarly, while Sun argues that "Lundahl criticizes 'flat emitting surface[s]'" like Larsen's (CIB, 109), this is a mischaracterization that ignores the broader context of the reference. Lundahl does not criticize "flat emitting surface***s,***" in the plural, nor does it criticize a multi-panel device. Instead, Lundahl notes that a ***single*** "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." RX-0065, 4:29-33. To ameliorate this difficulty, Lundahl suggests an emitter that more closely follows the contours of the treatment surface – which is the exact solution provided by Larsen's multi-panel emitter. RX-0006C, Q/A111. Accordingly, this discussion in Lundahl would simply provide a further motivation to adopt Larsen's panels.

Tellingly, Sun does not attempt to argue that a POSA would not have been motivated to switch from fluorescent tubes to LEDs. CIB, 108-114.

ii. There Was a Reasonable Expectation of Success in Combining Lundahl and Larsen

As explained in Biofrontera's opening brief, a POSA would have had a reasonable expectation of success in maintaining the uniformity of "at least within 60% of the measured maximum" required by the claims and disclosed by Lundahl, in the combination of Lundahl and Larsen. RIB, 31, 79-82.

Initially, Sun incorrectly argues that "Biofrontera and Dr. Grove do not discuss how the combined modified device meets the 'uniformly illuminate' claim limitation" (CIB, 110). Dr. Grove explains that a POSA would have reasonably expected the combined device to achieve

uniformity by applying Lundahl's light source distribution using LEDs. RX-0006C, Q/A178, 321. To the extent Sun is seeking uniformity testing of a combined device, it is black letter law that "expectation of success need only be reasonable, not absolute," *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1364 (Fed. Cir. 2007), and "conclusive proof of efficacy" is not required. *Acorda Therapeutics, Inc. v. Roxane Labs, Inc.*, 903 F.3d 1310, 1333 (Fed. Cir. 2018). As the Federal Circuit has explained, "expert and other evidence indicates that a person of ordinary skill...*can* draw reasonable inferences about the likelihood of success even without a perfectly designed clinical trial..." or other test. *Id*., 1334.

Here, it is reasonable to infer that a combined device with an upgraded light source could achieve at least the uniformity that Lundahl did with fluorescents. As Mr. Lundahl admits, "fluorescent tubes [were] in some ways not well suited for PDT." JX-0017C, 36:7-13. For example, Mr. Lundahl explained that:

> The output from fluorescent tubes is not inherently uniform. The fluorescent tubes have low output areas (*i.e*., areas of reduced emission) near the end of the tubes. Fluorescent tubes are also temperature sensitive. For example, fluorescent lights lose output when they get too hot or cold.

CX-0011C, Q/A26. The Lundahl reference itself notes that: "output from a fluorescent tube is not inherently uniform" (RX-0065, 6:10-11), "tube output may vary over its length" (RX-0065, 4:41-42), tubes have a "non-emitting area at their ends" (RX-0065, 6:31-42), and "tube wall temperatures strongly affect output distribution" (RX-0065, 9:13-15). Dr. Jokerst also admits "[i]t was known that fluorescent tubes had dark areas." Tr.(Jokerst), 732:7-10. LEDs were known in the art to be a superior light source to fluorescents, lacking their drawbacks and providing greater control and flexibility. RX-0006C, Q/A38-40; CX-1231.1-3 A POSA would have had a reasonable expectation of success in achieving the same uniformity with more modern electronics and flexibility. *See Muniauction, Inc. v. Thompson Corp.*, 532 F.3d 1318, 1326-27 (Fed. Cir. 2008).

Although Sun argues that Lundahl only achieves its uniformity via a combination of "carefully engineered and selected" components (CIB, 110), the majority of these components were only necessary to solve the myriad problems specific to fluorescents. *Supra* Section III.A.2.ii. These problems would not be present in LEDs, and therefore their solutions would not be needed to achieve comparable device performance. *See* Tr.(Grove), 593:9-22; 594:17-595; Tr.(Jokerst), 768:10-13; *see also PGS Geophysical AS v. Iancu*, 891 F.3d 1354, 1366 (Fed. Cir. 2018) ("[Plaintiff's] argument relies on the presumption that one of ordinary skill would blindly incorporate [secondary reference's] exact methodology into [primary reference]. But the Board ***properly*** did not view [defendant's] proposed combination to be so limited.") (emphasis added); 550 U.S. at 420-21 (2007) ("[I]n many cases a person of ordinary skill will be able to fit the teachings of multiple patents together like pieces of a puzzle….").

Finally, while Sun leans on inventor testimony about the difficulties of achieving uniformity in the 4170E (CIB, 110), the Federal Circuit has explained that inventors' difficulties in developing a ***product*** "are not particularly probative with respect to obviousness" of ***claims***, especially where the product contains elements not required by the claims. *Allergan, Inc. v. Sandoz Inc.*, 726 F.3d 1286, 1292 (Fed. Cir. 2013). Such is the case here, where the inventor testimony in question describes their difficulties in developing the 4170E, which has a uniformities of, *e.g.* 78.6% - "a more stringent requirement than [the claimed] 60% of the maximum power." CX-0010C (Jokerst), Q/A116-122. Further, the 4170E has additional elements not recited *in the Asserted Claims*, *e.g.*, alternating panels having differing widths. CX-0010C, Q/A200-206.

iii. Motivation Existed to Combine the Teachings of Lundahl, Larsen, and Hente, and a Reasonable Expectation of Success Existed

As explained in Biofrontera's opening brief, Hente is analogous art both because (1) Hente is directed to the same field of endeavor as the Asserted Patents (*i.e.*, light-emitting devices having

multiple adjacent sections/panels that can be rotated relative to each other), and separately (2) Hente is reasonably pertinent to a problem confronted by the inventors of the Asserted Patents (*i.e.*, providing an illuminator that can adjust the size of the illuminated area). RIB, 82-84; *Sci. Plastic Prods. v. Biotage AB*, 766 F.3d 1355, 1359 (Fed. Cir. 2014). Further, as explained in Biofrontera's opening brief, a POSA would have been motivated to combine Hente with Lundahl and Larsen, with a reasonable expectation of success. RIB, 82-84.

Sun notes that Hente teaches hinged connecting individual OLEDs (rather than panels each containing multiple LEDs), that OLEDs are diffuse light sources while LEDs are point light sources, and OLEDs are smaller and thinner than LEDs panels (CIB, 115-116), but these differences are not relevant because Hente is relied upon for its teaching of hinge positioning – not for its teaching of particular light sources or for its teaching of a hinge structure. Further, the Federal Circuit has "consistently held that the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference…Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art."*MCM Portfolio LLC v. Hewlett-Packard Co.*, 812 F.3d 1284, 1294 (Fed. Circ. 2015).

iv. A Motivation Existed to Combine the Teachings of Lundahl, Larsen, Hente, and Perutz and a Reasonable Expectation of Success Existed

As explained in Biofrontera's opening brief (RIB, 84-86), Perutz is analogous art because it is "reasonably pertinent to the particular problem with which the inventor is involved." *Sci. Plastic Prods. v. Biotage AB*, 766 F.3d 1355, 1359 (Fed. Cir. 2014). Specifically, Perutz is directed to providing improved hinge structures for connecting panels, so as to allow them to rotate with respect to one another. RX-0607, 1:8-13. Accordingly, Perutz is analogous art because it "logically would have commended itself to an inventor's attention in considering his problem," which was

also faced by the inventors of the Asserted Patents. 766 F.3d at 1359; *see also In re Paulsen*, 30 F.3d 1475, 1481-82 (Fed. Cir. 1994) (prior art directed to providing hinges for use in, *e.g.*, a desktop telephone directory, a piano lid, a kitchen cabinet, a washing machine cabinet, and a wooden furniture cabinet, was analogous to a patent directed to portable computers because "the problems encountered by the inventors...were not unique to portable computers").

Further, as explained in Biofrontera's opening brief, a POSA would have been motivated to combine Perutz with Lundahl, Larsen, and Hente, with a reasonable expectation of success. RIB, 82-84.

4. Secondary Considerations

***i.* Commercial Success**

Sun attempts to rely on sales of the RhodoLED®XL, which fell below Biofrontera's expectation, to establish commercial success. But the moderate sales of the RhodoLED®XL do not show commercial success that would rise to the level of an objective indicia of nonobviousness. CIB, 117. Commercial success is "usually shown by *significant* sales in the relevant market." *Certain Power Inverters & Converters, Vehicles Containing the Same,& Components Thereof,* Inv. No. 337-TA-1267, ID at 116 (Aug. 12, 2022) (emphasis added) (citing *J.T. Eaton & Co. v. Atl. Paste & Glue Co*., 106 F.3d 1563, 1571 (Fed. Cir. 1997)) (finding that "relatively modest sales" do not "represent a level of commercial success...that should be significant to the obviousness inquiry.") Biofrontera had only placed [redacted] lamps as of April 2025, well below Biofrontera's stated goal of placing [redacted]. RX-0003C, Q/A34-37; RX-0008C, Q/A23; RX-0003C (Leffler), Q/A28-33; Tr. (Leffler) 412:3-8; 420:18-23. Indeed, since the beginning of 2025, sales of the RhodoLED®XL have decelerated. Tr. (Leffler) 420:24-421:4.

Sun cherry-picks positive public statements made by Biofrontera and its CEO Dr Luebbert about the lamp, but, in context, they show that any success has been limited. Dr. Luebbert testified that "*launching* the XL has been a success for the company, but it hasn't been the commercial success that we had hoped." Tr.(Luebbert) 318:23-319:6.[2] (emphasis added.) Indeed, Biofrontera's overall revenue following the launch of the RhodoLED®XL stayed largely flat. CX-0183 (showing a mild increase from $8.9 to $9 million between Q3 2024 and Q3 2025); Tr. (Leffler) 412:3-8.

Sun highlights that sales of the RhodoLED®XL are higher than the BLU-U® 4170D, but this difference in sales is not significant enough to show commercial success. As noted above, Biofrontera placed [redacted] lamps between June 2024 and April 2025 while between April 2023 and March 2024, Sun sold [redacted] BLU-U 4170D lamps. JX-0093C. And in other years, Sun sold even more 4170D lamps: [redacted] between April 2022 and March 2023, [redacted] lamps between April 2020 and March 2021, and [redacted] lamps between April 2019 and March 2020. JX-0093C. Biofrontera's sales of the RhodoLED®XL have plainly not been exceptional when compared to other PDT devices that Sun does not contend practice the Asserted Patents. *See Certain Power Inverters & Converters, Vehicles Containing the Same, & Components Thereof,* Inv. No. 337-TA-1267, ID at 116 (finding sales were not indicative of commercial success when considered in the context "*of the relevant market"*) (emphasis added).

ii. Industry Praise

Despite the BLU-U 4170E not yet being on the market and available for sale, Sun continues to tout the industry praise the "newly-launched" product has received. CIB, 120. Further, this industry praise allegedly highlights the "patented features" of the BLU-U 4170E. CIB, 120. It is

[2] Sun states that Dr. Luebbert testified that he considered the RhodoLED®XL to be a successful product. CIB at 117, *citing* Tr. (Luebbert), 334:1-12. In the cited testimony, Dr. Luebbert was referring to the RhodoLED, not the RhodoLED®XL.

hard to see how "a 5-panel shape for increased flexibility" is a "technological advancement" considering Larsen's five-panel design that has been known. It is even harder to call the "optimized LED arrangement" of the BLU-U 4170E a "technological advancement," since the device was specifically designed to meet the same optical specifications as the device encompassed by Lundahl using the tighter spacing near the forehead and chin.

iii. Copying

In support of allegations of copying by Biofrontera, Sun continues to rely on testimony by Dr. Jokerst. CIB, 121. However, Sun fails to acknowledge that Dr. Jokerst admitted to seeing no *direct* evidence of copying. Tr.(Jokerst), 746:21-748.5. Without "actual evidence of copying efforts as opposed to mere allegations," Sun has provided no credible evidence supporting its allegation of copying. *See Liqwd, Inc. v. L'Oreal USA, Inc.*, 941 F.3d 1133, 1137-138 (Fed. Cir. 2019).

B. The Asserted Claims are Invalid for Lack of Written Description

"[A]n objective inquiry into the four corners of the specification from the perspective of a" POSA does not "show that the inventor[s] actually invented" methods and systems for photodynamically diagnosing patients using the claimed illuminator. *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010); RIB, Section VI.B. Sun's brief does not cite *any legal authority or case law* to support its position that there is written description support. Instead, Sun simply pushed its dubious proposition that written description for one claimed embodiment (*i.e.*, treatment) can support a completely different embodiment (*i.e.*, diagnosis). Sun attempts to connect dots in the specification that do not exist, and repeatedly substitutes its speculation about what a POSA would know about PD generally with what the specification actually says. Sun's arguments are insufficient to objectively demonstrate possession, which must be "shown *in the disclosure*," as "part of the quid pro quo of the patent grant." *Ariad*, 598 F.3d at

1351, 1354 (emphasis added); *see also Novartis Pharms. Corp. v. Accord Healthcare, Inc.*, 38 F.4th 1013, 1016 (Fed. Cir. 2022) ("Disclosure is essential; it is the quid pro quo of the right to exclude.") (citation modified). Here, Sun's lack of disclosure is manifest.

To begin with, Sun provides virtually no analysis of the scope of the Asserted Claims. CIB, 122-123, 130-131. Instead, Sun simply states that "the Asserted Claims claim an illuminator with specific structural requirements that a POSITA would understand can be used to diagnose dermatological conditions amenable to PD, as well as the use of that improved illuminator in a PD procedure." *Id*. However, Sun's reading ignores the construction of the limiting and functional preamble. Rather than simply claiming "an illuminator," Sun chose to claim "a [system/method] for photodynamically diagnosing…a patient." Further, as Biofrontera explained, the claims are not so simple—they encompass five-panel illuminators with "light sources" that emit ranges of light wavelengths, doses, and intensities. RIB, 91-92. For certain Asserted Claims, the five panels must be "configured," "angled," "positioned…within approximately four inches of the treatment surface," and/or require administering ALA. *Id*.; *see also, e.g.*, JX-0001, claims 1, 8, 20; JX-0002, claims 1, 20-21.

Together, those claim limitations place Sun's claims in the category of a "generic invention" (*i.e*., a generic illuminator) for PD (*i.e*., the "function" recited in the limiting preambles). *Juno Therapeutics, Inc. v. Kite Pharma, Inc.*, 10 F.4th 1330, 1335 (Fed. Cir. 2021). To satisfy written description for a generic invention using functional language, "the written description 'must demonstrate that the applicant has made a generic invention that achieves the claimed result and do so by showing that the applicant has invented species sufficient to support a claim to the functionally-defined genus.'" *Juno*, 10 F.4th at 1335 (quoting *Ariad*, 598 F.3d at

1349). That is absent here—the specification contains no examples or explanation that would objectively demonstrate to a POSA that Sun invented a generic illuminator that achieves PD.

The specification falls short of providing "a sufficient disclosure that 'reasonably conveys to those skilled in the art that the inventor[s] had possession of" the broad claims as of the filing date. *Id.*, 1341–42 (quoting *Ariad*, 598 F.3d at 1351); *see also* RIB, 93-102. Sun focuses heavily on the fact that the specification demonstrates to a POSA that the inventors possessed (1) the illuminator itself and (2) systems and methods for *treating* patients, as if Section 112 was a best-of-three series. CIB, 123-125, 130-131. But that has no bearing on whether the specification objectively demonstrates to a POSA that the inventors possessed systems and methods for *diagnosing* patients, which the parties and experts agree entails different steps, goals, and requirements than treatment. CIB, 5-6, 123-124; RIB, 96-102; CX-0013C, Q/A18-20, 93, 169-170; RX-0007C, Q/A114, 232, 245, 302; Tr.(Shmuylovich), 678:17-679:22; Tr.(Ehrenreich), 654:9-655:8. Moreover, Sun's concession that treatment is (and must be) taught is a concession that both treatment and diagnosis are limitations that must be met. Section 112 requires that "the disclosure must show [the inventor] had invented ***each feature*** that is included as a claim limitation." *New Railhead Mfg., L.L.C. v. Vermeer Mfg. Co.*, 298 F.3d 1290, 1295 (Fed. Cir. 2002) (emphasis added); *see also Lockwood v. Am. Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997) ("One shows that one is in possession of *the invention* by describing *the invention,* with all its claimed limitations, not that which makes it obvious.") (citation modified). Here, PD is a distinct claim limitation in the Asserted Claims, and Sun's attempt to point to the specification's disclosures about treatment or the illuminator itself does not satisfy the written description requirement. At most, the specification conveys to a POSA that the inventors had vague goals of

using the illuminator for PD, which is not enough to satisfy the written description requirement. RIB, 93-102.

Sun also overstates the specification's disclosure when it argues that it "teaches a POSITA how to use that illuminator" for PD. CIB, 123. Sun points to the background section of the specification and argues that it discloses how to perform PD with the claimed illuminator. *Id*., 123-125, 130-131. But as its title implies, that section provides general background information about PD, PDT, and illuminators, and expresses little more than a goal of achieving PD—it does not demonstrate that the inventors possessed the claimed illuminator as a system or method for photodynamically diagnosing a patient. RX-0007C, Q/A284-285.

Further, Sun's reliance on examples from other parts of the specification directed to PDT do not disclose PD using the claimed illuminator. CIB, 123, 130 (citing JX-0001, 2:50-54, 8:64-9:52), 131 (citing JX-0001, 3:66-4:13). Those sections of the specification superficially refer to using the claimed illuminator for PD, without explaining how it should be done across the full scope of the Asserted Claims, JX-0001, 2:50-54, and/or are focused on *treatment*, not diagnosis, *id*., 3:66-4:13, 8:64-9:52. RIB, 93-95.

Even if Sun's arguments about the specification are taken at face-value as providing textual support for the individual claim elements, there is no question that the specification *never* describes those claim elements as "an integrated whole" where the claimed illuminator functionally achieves PD. *Novozymes A/S v. DuPont Nutrition Biosciences APS*, 723 F.3d 1336, 1349 (Fed. Cir. 2013) (even if a specification "provides formal textual support for each individual limitation recited in the claims," to satisfy the written description requirement, it must also "describe[] the actual functioning" invention "that those limitations together define … as an integrated whole"). Thus, even under the most generous reading of Sun's arguments, Sun is improperly attempting "to derive

written description support from an amalgam of disclosures plucked selectively from the" specification, which falls short of satisfying the written description requirement. *Id*.

Regardless, Sun's brief highlights a more fundamental problem—information that the parties and experts agree is essential to PD is nowhere to be found in the specification. For example, Sun states that "the length of illumination time" and "the act of detecting fluorescence" are "the difference between PD and PDT." CIB, 124. But as Dr. Ehrenreich *and* Dr. Shmuylovich testified, the specification does not disclose the illumination times needed for PD, nor does it disclose how to detect fluorescence using the claimed illuminator. Tr.(Shmuylovich), 681:11-684:9; RX-0007C, Q/A111, 232, 277-278, 300-302, 356. Indeed, as Dr. Ehrenreich explained, discussions of fluence—which is a function of the irradiance (brightness) and ***time*** of exposure—is absent from the specification. RPHB, 185-186, 193-194; RIB, 94, 97-99; RX-0007C, Q/A111, 132, 232, 252, 302. If "the hallmark of written description is disclosure" and "possession as shown in the disclosure … requires an objective inquiry into the four corners of the specification," the information above should be in the specification in some form to objectively demonstrate possession to a POSA. *Ariad*, 598 F.3d at 1351. But that information is not in the specification, demonstrating by clear and convincing evidence that the Asserted Claims are invalid for lack of written description. Tr.(Shmuylovich), 678:14-687:13, 694:8-695:17, 697:19-699:5.

Realizing that the specification fails to disclose these critical PD elements, Sun takes two approaches: (1) mischaracterize and contort the specification to make it appear as though it does disclose that missing information; and (2) fall back on a POSA's knowledge of PD.[3] CIB, 123-

[3] Sun's attempt to rely on a POSA's knowledge of that information, which is effectively an attempt to add substantive text to the specification, is improper and should be rejected. RIB, 102; *Flash-Control, LLC v. Intel Corp.,* 2021 WL 2944592, at *4 (Fed. Cir. July 14, 2021) (Quoting *LizardTech, Inc. v. Earth Resource Mapping, Inc.*, 424 F.3d 1336, 1345 (Fed. Cir. 2005)).

132. For example, Sun points to the specification's reference to illuminating a patient "for a prescribed period" and argues that a POSA would understand that to be a reference to PD's "nearly instantaneous" time requirement. *Id*., 123-124 (discussing JX-0001, 8:64-9:52). But the "prescribed period" language is discussed in the lone example in the specification, which is expressly directed to an "example of a treatment method," *not diagnosis*. JX-0001, 8:64-9:52. In the same paragraph, after explaining that patients should be illuminated for a "prescribed period" for *treatment*, the specification discloses that patients should be illuminated "for about one hour to about three hours" or "for about 20 minutes to about 30 or 40 minutes." *Id*. That is a far cry from the "nearly instantaneous" illumination Sun's expert says is necessary for PD. CX-0013C, Q/A18-20, 93, 168; Tr.(Shmuylovich), 678:14-687:13, 694:8-695:17, 697:19-699:5. It is only consistent with *treatment*. RX-0007C, Q/A295, 302.

Sun also argues that the background section's reference to being able to "selectively locate … the target tissue" is a reference to detecting, or visualizing, fluorescence for PD. CIB, 123-124. But the full sentence in which "selectively locate" is used is vague, and also references treatment. JX-0001, 1:39-43. Regardless, that was provided as basic background information, not in relation to the claimed illuminator, is silent on *how* to "selectively locate" with the claimed illuminator, and does not even mention fluorescence. In fact, as Biofrontera explained, there is not a single reference anywhere in the specification to detecting or visualizing fluorescence with the claimed illuminator, whether by eye, camera, or some other means. RIB, 95-96.

Further, Biofrontera explained in its opening brief that there are numerous other issues that show a lack of possession of the full scope of the Asserted Claims. *Id*., 96 (Shmuylovich's reliance on the Wood's lamp), 99-100 (application and incubation times of photosensitizers), 100-101 (wavelengths, fluences, and intensities of light). Sun barely grapples with these issues, instead

attempting to downplay or ignore their significance. CIB, 125-128, 130-131. Sun's arguments on these points—that they were known in the prior art, or are auxiliary elements to the claimed systems and methods for photodynamically diagnosing patients—are inconsistent with Federal Circuit precedent: "The test for written description is the same whether the claim is to a novel [invention] or a novel combination of known elements. The test is the same whether the claim element is essential or auxiliary to the invention." *Bos. Sci. Corp. v. Johnson & Johnson*, 647 F.3d 1353, 1365 (Fed. Cir. 2011).

Sun's argument that PD merely involves "applying a fluorophore/photosensitizer, exposing it to light, and detecting resulting fluorescence," CIB, 125-126, ignores that the long incubation times of photosensitizers disclosed *in the specification* work for treatment but could render it impossible to perform PD. RIB, 99-100; Tr.(Foguet), 375:2-14; 390:2-391:8; RX-0007C, Q/A248-250. In *Purdue Pharma L.P. v. Collegium Pharm., Inc.*, 86 F.4th 1338 (Fed. Cir. 2023), the patent claimed a class of chemical compounds "as an aversive agent" (even though the claims did not expressly require the compounds to be aversive agents) in a pharmaceutical formulation, but the specification included few references to that class of compounds, and only identified them as being useful for a different function (*i.e.*, "as a surfactant"). The Court concluded that the patent was invalid for lack of written description, explaining that "[j]ust because the specification states [the compounds] are useful for the invention does not suggest how [the compounds] are [aversive] agents." *Id*. The same is true here—not all photosensitizers fluoresce, as required for PD, and not all incubation times of photosensitizers will allow for PD. CX-0013C, Q/A16, 22-24, 40, 107; RX-0007C, Q/A228-231, 248-250; Tr.(Foguet), 375:2-14; 390:2-391:8. The Asserted Patents may state that the claimed illuminator is useful for PD, and that any photosensitizer will work for PD,

but the disclosure fails to suggest *how*, showing that the Asserted Claims are invalid for lack of written description.

Likewise, the specification references different colors and wavelengths of light for use in treatment, without disclosing what light to use for PD. RIB, 100-101. As above, because this information is not within the four corners of the specification, a POSA would not objectively conclude that the inventors possessed systems and methods of photodynamically diagnosing patients using the claimed illuminator. Regardless, at most, Sun's evidence (from prior art journal articles) identifies blue light, particularly at a wavelength of 405 nm, as being useful for PD. RX-0007C, Q/A226, 266, 304, 333; CX-0013C, Q/A153, 157. That 405 nm wavelength is not identified in the specification, but Sun now points to it as being what a POSA would use for PD. CX-0013C, Q/A30, 134-136; Tr.(Shmuylovich), 705:22-706:19. And blue light generally is at the bottom end of the range of visible light wavelengths encompassed by the Asserted Claims and disclosed in the specification. RX-0007C, Q/A290, 304, 333, 344. Sun claimed and disclosed a "forest" (*i.e*., all visible light wavelengths) without leaving "blaze marks on the trees" to tell a POSA what wavelengths to use for PD. *In re Ruschig*, 379 F.2d 990, 995 (C.C.P.A. 1967); *see also Novozymes*, 723 F.3d at 1349. That likewise fails to satisfy the written description requirement.

Finally, the lack of possession of PD is supported by other evidence in this Investigation, which shows that the two real-world illuminators that Sun argues are embodiments of the Asserted Claims, the 4170E and RhodoLED®XL, are not used for PD, just as the experts agree the 4170D was not used for PD as of the priority date (and still today). RX-0007C, Q/A113, 240, 262; Tr.(Shmuyloivch), 160:15-18; Tr.(Ehrenreich), 654:9-655:11. Nor has Sun cited or produced *any evidence* that indicates that those devices have *ever* been used for PD. Sun and its expert have

argued *ad nauseam* how hypothetically, it would be easy to photodynamically diagnose a patient using any light source, but have *no objective evidence* to support those claims in the context of the *claimed illuminator*. Sun's written description arguments amount to nothing more than "[a] 'mere wish or plan' for obtaining the claimed invention," which "is not adequate written description." *Centocor Ortho Biotech, Inc. v. Abbott Lab'ys*, 636 F.3d 1341, 1348 (Fed. Cir. 2011) (quoting *Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 1566 (Fed. Cir. 1997)).

Accordingly, all Asserted Claims are invalid for lack of written description.

C. The Asserted Claims are Invalid for Nonenablement

A POSA would need to engage in undue experimentation to use the claimed illuminator for PD across the full scope of the Asserted Claims. RIB, 102-105. Sun's analysis of the *Wands* factors discounts the breadth of the Asserted Claims, overstates the specification's disclosures about PD, and relies on prior art illuminators and PD techniques that would offer a POSA little guidance on how to use the claimed illuminator for PD. CIB, 122-130.

1. Nature of the Invention and Breadth of the Claims

The Asserted Claims broadly recite methods and systems for PD using a five-panel illuminator with light sources that emit ranges of wavelengths, doses, and intensities of light. *Supra* Section III.B; RIB, 102-103. Sun's cursory analysis of the scope of the claims fails to consider their breadth. *Supra* Section III.B; CIB, 122-123.

Sun's only substantive argument about the scope of the claims is that they should be limited to "dermatological conditions" that are "amenable to PD." CIB, 122-123. But that argument is unsupported by the claim language, and is contradicted by the specification, which broadly refers to PD as being used to "diagnose several types of ailments in or near the skin or other tissues, such as those in a body cavity." JX-0001, 1:24-27; RX-0007C, Q/A217. Sun's attempt to limit the scope of the claims is improper. *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir.

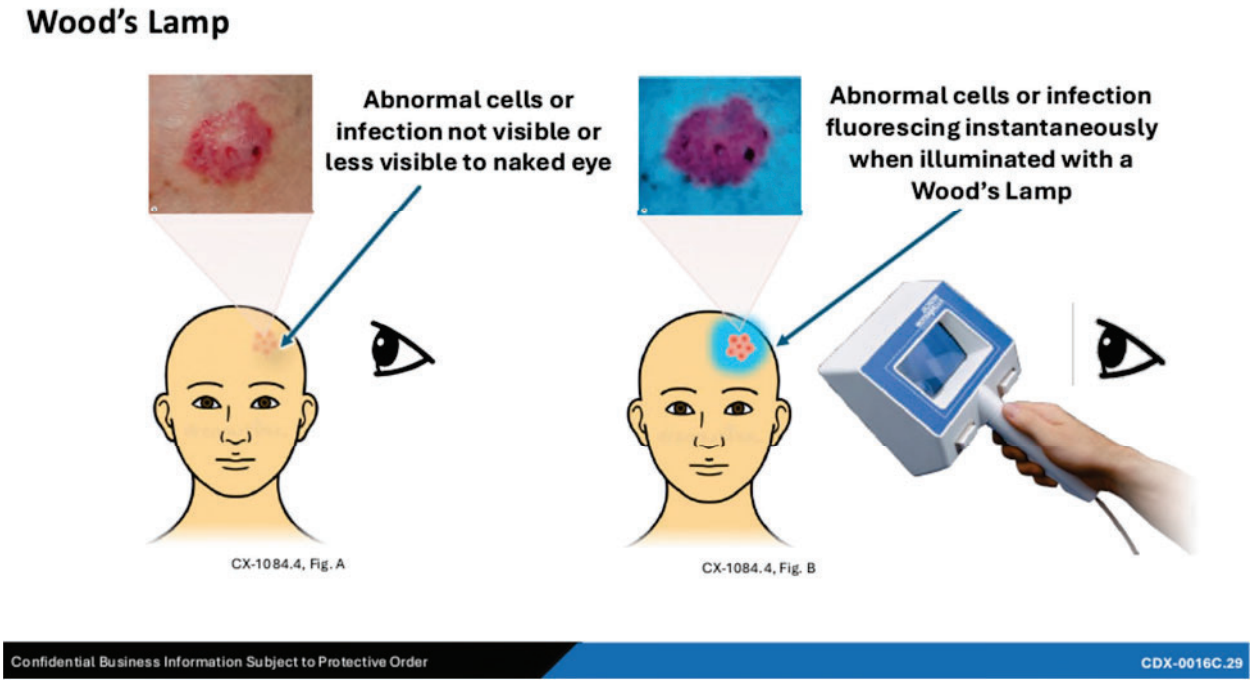
2004) ("Even when the specification describes only a single embodiment, the claims of the patent will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope …"); *Enercon GmbH v. Int'l Trade Comm'n*, 151 F.3d 1376, 1384 (Fed. Cir. 1998) .

Accordingly, because Sun chose to broadly claim methods and systems for PD using a generic illuminator, these *Wands* factors weigh in favor of a need for undue experimentation. *Amgen Inc. v. Sanofi*, 598 U.S. 594, 610 (2023) ("The more on claims, the more one must enable.").

2. The State of the Prior Art, the Level of Predictability in the Art, and the Level of Skill in the Art

Sun argues that the "level of skill in the art is high" and that because "the general concepts of PD were well-understood by 2015," PD was predictable. CIB, 125-128. But as Biofrontera has explained, almost nothing Sun relies on from the prior art for these points is applicable to the claimed five-panel illuminator, and it falls well-short of enabling the full scope of the claims. *Supra* Section III.C.2; RIB, 103-104.

Sun relies on various scientific journal articles to argue that "illuminators could be used for" PD. CIB, 125-128. But virtually *all* of those articles used a Wood's lamp—a small, hand-held, UV-based (*i.e.*, nonvisible light) device—for PD. CX-0013C, Q/A36-37, 117, 129-132; *see also* CX-1079; CX-0343; CX-1084; CX-1076. The compact size and UV light from a Wood's lamp allows for fluorescence to be detected, as Dr. Shmuylovich testified and demonstrated in his demonstratives:



CDX-0016C.29 (citing CX-1084.4); CX-0013C, Q/A124.

In contrast to a Wood's lamp, the claimed illuminator emits bright visible light requiring protective eyewear (*i.e.*, wavelengths from 400-700 nm with intensities of 10 mW/cm^2 to 30 mw/cm^2, RIB, 91-92) and physically obstructs the view of the patient (*i.e.*, panels in an "angled" configuration or "approximately four inches" from the patient), making the critical detection aspect of PD a significant challenge, as Dr. Jokerst and Sun demonstrated with the 4170E:

Claim 1 of the '512 Patent – Third Element

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

JX-0183C.2

CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER

CDX-0004C.41

CDX-0004C.41 (citing JX-0183C.2); CIB, 136; Tr.(Ehrenreich), 654:9-655:11. The same is true of U-shaped illuminators that existed as of the priority date:

CX-0009C (Shmuylovich), Q/A36 (citing CDX-0005C.9); RX-0007C, Q/A113, 240, 262; Tr.(Shmuylovich), 160:15-18.

Sun also argues that Dr. Foguet's testimony about a different *non-prior art* patent somehow applies to Sun's patents as of the priority date, CIB, 125 (citing Tr.(Foguet), 376:16-377:8), and

points to her agreement with the general proposition that photosensitizers fluoresce when exposed to light, *id*., 126 (citing Tr.(Foguet), 372:4-14). Sun similarly relies on Dr. Ehrenreich's testimony that general PD principles were known. *Id*., 125-126. But that is all irrelevant to the enablement question at hand, which is whether a POSA could use the illuminator described and claimed *in Sun's patents* for PD without undue experimentation. However, as the Federal Circuit has held, "it would be improper to rely on a POSA's knowledge…to fill the gaps in the specification." *Idenix Pharmas. LLC v. Gilead Sciences Inc.*, 941 F. 3d 1149, 1159 (Fed. Cir. 2019).

Accordingly, Sun's reliance on the Wood's lamp and general PD principles is largely inapplicable to whether a POSA could use the claimed illuminator for PD across the full scope of the claims without undue experimentation. RX-0007C, Q/A239-241; RIB, 103-104. Even if general PD principles using any type of illuminator could be applied to the claimed illuminator, as Sun argues, the prior art falls well-short of enabling a POSA to use the claimed illuminator to diagnose any dermatological condition, using different photosensitizers and incubation times, by illuminating a patient and instantaneously detecting fluorescence (*e.g*., with a camera/filter). RIB, 103-104. Thus, these *Wands* factors demonstrate that a POSA would need to engage in undue experimentation to determine how to use the claimed illuminator for PD.

Moreover, the testimony and evidence in this Investigation demonstrate that, if anything, the specification of the Asserted Patents does not support PD in material ways. The only incubation time disclosed in the specification is 14-18 hours. JX-0001, 9:6-13. Dr. Foguet testified that such a lengthy incubation time would make PD difficult or impossible. Tr.(Foguet), 375:2-14, 390:2-391:8.

Likewise, the patent teaches illumination periods from 10 minutes to several hours. JX-0001, 9:35-43. Indeed, Sun relies on this as an example to support its argument that the claims are

enabled. However, Dr. Shmuylovich testified that PD "is nearly an instantaneous process," but he admits that the specification does not disclose "instantaneous" illumination (*i.e.*, in a matter of seconds or milliseconds) for PD. CX-0013C, Q/A20; *see also, id.*, Q/A93; Tr.(Shmuylovich), 678:14-687:13, 694:8-695:17, 697:19-699:5. As Biofrontera has explained, and as Dr. Ehrenreich testified, exposure to higher intensities and durations of light can lead to photobleaching, a situation where PpIX no longer fluoresces, thus rendering it ineffective for PD. RPHB, 185-186, 193-194; RIB, 94, 97-99; RX-0007C, Q/A111, 132, 232, 252-256, 302.

Accordingly, the specification discloses incubation and illumination times that work for treatment but not diagnosis. But when the specification will not work for a claimed embodiment, the claims are invalid for lack of enablement. *National Recovery Techs. v. Magnetic Separation Systems*, 166 F. 3d 1190, 1196 (Fed. Cir. 1999) ("If, by following the steps set forth in the specification, one of ordinary skill in the art is not able to replicate the claimed invention without undue experimentation, the claim has not been enabled as required by § 112, paragraph 1."); c*f. AK Steel Corp. v. Sollac and Ugine*, 344 F. 3d 1234, 1244 (Fed. Cir. 2003) (holding specification's teaching away supported affirmance of non-enablement).

3. The Amount of Direction Provided by the Patents, Existence of Working Examples, and Quantity of Experimentation Needed

Contrary to Sun's arguments, CIB, 123-125, the specification offers virtually no guidance to a POSA, and no working examples of how to use the illuminator for PD across the full scope of the claims. *Supra* Section III.B; RIB, 104.

Based on its erroneous interpretation of the specification and prior art, Sun argues that a POSA would be able to "practice the full scope of the claims without undue experimentation." CIB, 128-130. Sun again focuses on general principles of PD that were known—certain wavelengths and intensities of light could activate certain photosensitizers under the right

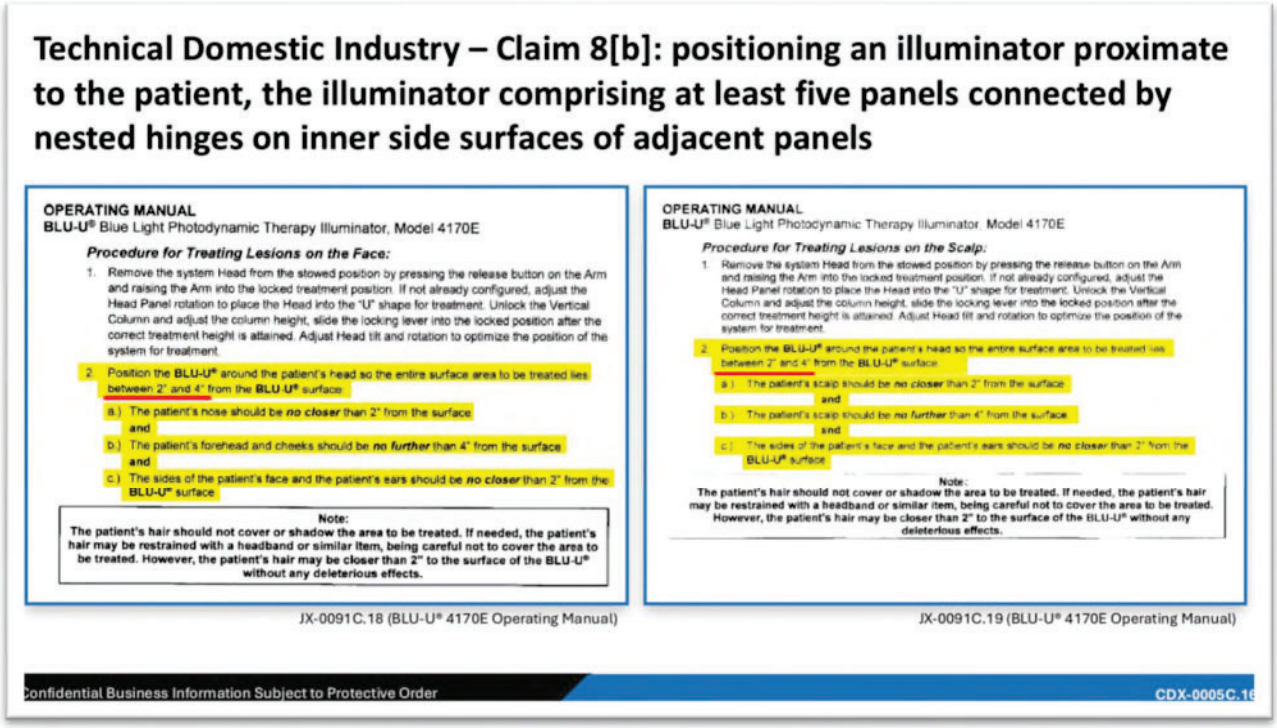
conditions, and PD only takes "seconds" to perform via "observation or imaging." *Id*. But as explained previously, the *claimed* illuminator is not used for PD in the real-world, and Sun has offered no real evidence (in the specification or prior art) indicating that a POSA would know how to diagnose patients with the type of illuminator claimed in the Asserted Patents. *Supra* Section III.B; RIB, 104-105. Those illuminator-challenges are amplified by the broad scope of the claims (*i.e*., using different types, amounts, and incubation times of photosensitizers; wavelengths, intensities, and fluences of light; instantaneous illumination and detection; for any dermatological condition). *Supra* Section III.B; RIB, 104-105. The end result is that an undue amount of trial-and-error experimentation would be needed for a POSA to be able to practice the full scope of the Asserted Claims.

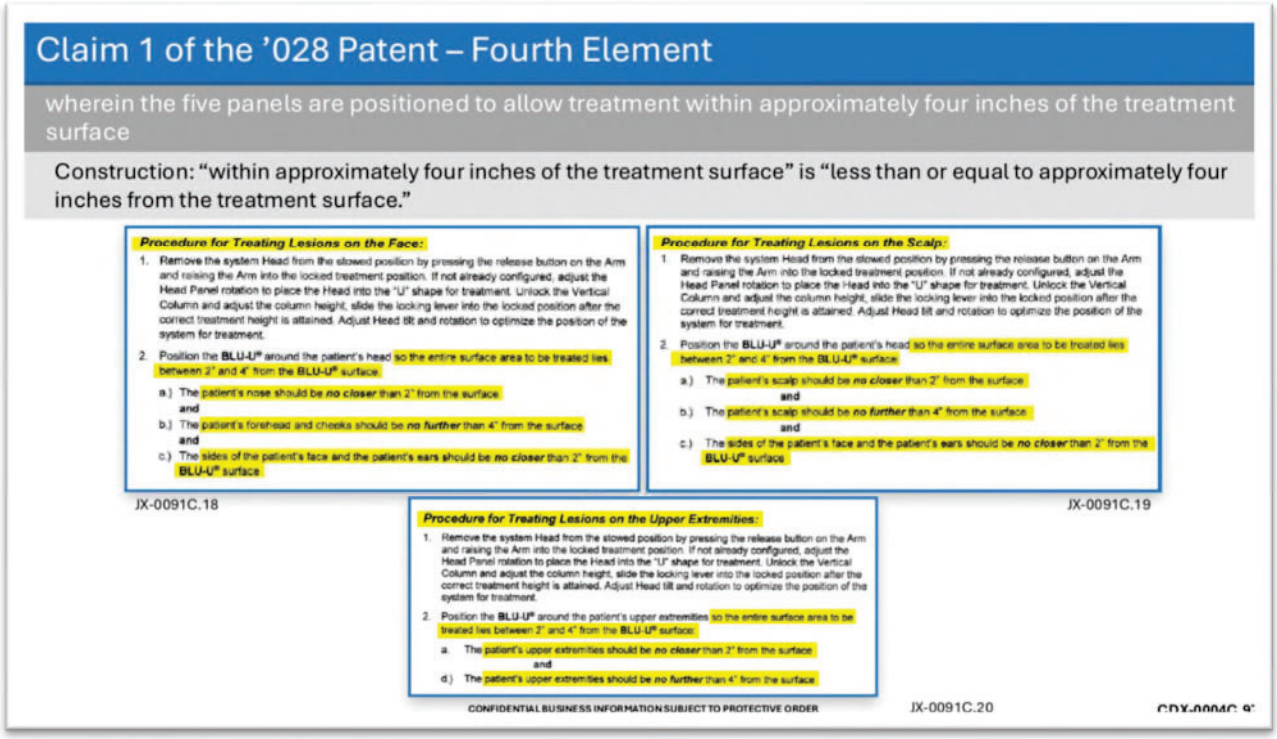
Accordingly, all Asserted Claims are invalid for non-enablement.

IV. DOMESTIC INDUSTRY – TECHNICAL PRONG

Sun has not carried its burden to show that the technical prong of the domestic industry has been met. Contrary to its assertions, there is no evidence on the record that Sun practiced the claims, especially the method claims, before it filed its complaint in June 2024. Indeed, Sun's evidence lacks any information by reference to dates that the claims were practiced before it filed the complaint. CX-0011C.36, QA 170-71. In fact, it was only on cross examination and redirect that details of the who, when, and where of Sun's alleged practicing of the claims. On cross examination, Sun pointed to purported treatment that occurred [redacted], ***after*** its complaint. The only evidence of the method claims and the method steps of the systems claims being practiced before the date of the complaint is Sun's reliance on new uncorroborated testimony elicited on redirect that [redacted] ***treated patients*** "over the last year and a half" in [redacted]. Tr. (Lundahl) 97:4-22. Sun belatedly argues that

this is proof that the method claims and method steps in the system claims were practiced before the complaint was filed. However, [redacted] prohibit the [redacted]. [redacted]. With respect to the systems claims, Sun's evidence for elements 1[d], 20[d], and 21[d] of the '028 Patent systems claims rely on the Sun user manual to show how a healthcare provider must position the lamp relative to the patient's treatment surface. *See* CPHB, 196, 201-202, 206; CIB 148, 158. This is the same evidence that Sun relies on to satisfy the method claim elements 8[b] of the '512 Patent and 5[b] of the '028 patent. *Compare* CDX-0005C.16 ('512 Patent Method Claim) *to* CDX-0004C.97 ('028 Patent System Claims).





Again, these elements can only be practiced with a physician and a patient. CIB 143-44, 159-60. The record evidence shows that these elements were not practiced, unless [redacted] treated patients in [redacted] before filing the complaint.

V. REMEDY AND BONDING

Sun has failed to show that any issued remedial order should include Ameluz® or that a bond is necessary.

A. LEO and CDO

Sun does not argue that the requested remedial orders should include Ameluz® and has therefore waived any such argument. "Any contentions that are not set forth in detail in the post-hearing initial brief shall be deemed abandoned or withdrawn." Order No. 2, G.R. 14.2. Indeed, Sun mentions only sales and inventory of the RhodoLED® XL in its brief. CIB, 161. Sun makes no argument regarding the applicability of remedial orders to Ameluz® and has waived any such argument. *Certain Tobacco Heating Articles & Components Thereof,* Inv. No. 337-TA-1199,

Comm'n Op. at 40 (Oct. 19, 2021) (finding that complainant "failed to argue in its post-hearing brief" for a position and therefore waived any such argument"). Therefore, any LEO or CDO issued should not include Ameluz®.

Furthermore, Sun has not shown that Biofrontera's inventory of RhodoLED®XLs is commercially significant and that a CDO is warranted at all. Sun claims that Biofrontera currently has [redacted] RhodoLED®XLs in inventory, which could support [redacted] months of sales. CIB, 161. But it does not explain why [redacted] months of sales is commercially significant or how this inventory would undermine any issued LEO, that would last through the lifetime of the Asserted Patents.

B. Bond

Sun's analysis regarding bond is facially flawed, as it disregards basic business concepts like trade-in discounts, selling refurbished units, and leasing programs to argue that a bond of 100% is appropriate for an Accused Product priced higher than a DI Product with no documented sales. Sun claims that Biofrontera's prices for its RhodoLED®XL are "all illusory." CIB, 161. Sun makes this extraordinary claim despite having access to the sales records of the RhodoLED®XL and can plainly see that this is not the case. RX-0837C (Sales and Inventory Report for Q3-2024). Specifically, Sun claims that "Biofrontera's net revenue for a given unit is routinely well below [redacted] (the purported floor price), net of trade-in discounts" due to these trade in discounts and sales of refurbished RhodoLED®XLs at below Biofrontera's floor price. CIB, 162 (citing JX-0229C ("Sales_10.1 thru 11.30" tab)). To be clear, of the [redacted] purchases shown in JX-0229C, there is only [redacted] instance of a RhodoLED®XL being sold with an invoice price of less than the floor price of [redacted], and it was refurbished, as indicated by its item number: "LAMPXL-***R***". JX-0229C, col. E. (emphasis added); Tr. (Vander Veen), 302:23-303:6. Neither Sun nor its expert, Dr.

Vander Veen, explain how [redacted] sale of a refurbished Accused Product at a lower price would create a need for bond in this matter, nor does this make a price comparison impossible.

Biofrontera's practice of offering trade-in discounts is also ordinary in the PDT business and does not affect the bond analysis. Sun also plans to offer a trade-in discount when it releases its BLU-U® 4170E, wherein the customer would trade-in their old 4170Ds for value applied to their purchase of the 4170E. Tr.(Lundahl) 95:6-95:14. Sun has presented no argument that Biofrontera's trade-in program is out of the ordinary, and it was in its Initial Post-Hearing Brief that Sun first claimed that Biofrontera had been "aggressive" in its trade-in program. CIB, 162. But this claim is not backed by any evidence suggesting that the offered-value for the traded-in RhodoLED®s was unusual in the industry. *Id.* Indeed, these trade-in values are standardized based on the age of the lamp. RX-0003C (Leffler WS) Q/A45. While it is true that the total invoice price of several RhodoLED®XLs was lower than the floor price, after the trade-in value was applied, a trade-in program is not a straight discount and the customer is losing their access to the old RhodoLED® through the trade-in. RX-0003C (Leffler WS) Q/A45; Tr.(Vander Veen) 302:1-16. Biofrontera, in turn, can resell the old lamp, which Sun does not dispute. Tr.(Vander Veen) 302:1-16 (admitting that the sale of traded-in lamps is possible). Sun is therefore incorrect that Biofrontera's trade-in program lowers the sales price of the RhodoLED®XL or makes a price comparison between the lamps impossible.

Sun incorrectly argues that Biofrontera's evaluation program reduces the cost of the RhodoLED® XL to $3000. CIB, 162. This argument relies on a fundamental misunderstanding of how Biofrontera's evaluation program works. Biofrontera customers who lease a lamp under its evaluation program pay $500 a month for up to 6 months to evaluate and use the RhodoLED®XL in their office. RX-0003C (Leffler WS) Q/A45. However, at the end of this time period, the

customer must either return the lamp or pay the remaining value of the lamp to purchase it. *Id.*; RX-0010C (Rowe Rebuttal WS) Q/A88. Sun claims that, due to this program, a "customer can compete with Sun Pharma for up to 6 months for $3000 or less." CIB, 162. But Sun ignores the fact that this evaluation program does not change the price of purchasing the lamp, and therefore does not change the price comparison between the RhodoLED® XL and BLU-U® 4170E.

Finally, and tellingly, Sun does not even attempt to claim the price of the BLU-U® 4170E is higher than the RhodoLED®XL. CIB, 162. Nor could it. As explained in Biofrontera's Initial Post-Hearing Brief, Sun has not established a price for its yet-to-be-released lamp, but it will certainly be priced at less than [redacted]. RIB at 111-112; CIB at 161 (stating that the "list price" for the 4170E is [redacted]). Therefore, any argument that Biofrontera would lower its price in the face of competition from Sun is based on pure speculation and contradicts the testimony of Biofrontera's own employees that it cannot sell the lamps below the floor price. RX-0003C (Leffler) Q/A50-52; CIB, 162.

CERTIFICATE OF COMPLIANCE WITH WORD LIMIT

The foregoing filing complies with the word limits set forth in Ground Rule 11.2 and contains 14,836 words. The brief has been prepared using Microsoft Word in 12-point Times New Roman font. As permitted by G.R. 1.6, the undersigned has relied upon the word count feature of this word processing system in preparing this certificate.

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Dated August 4, 2025

Respectfully submitted,

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CERTIFICATE OF SERVICE

I, Antoine R. Bland, hereby certify that on September 10, 2025, copies of the foregoing were served upon the following as indicated:

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