PUBLIC VERSION

UNITED STATES INTERNATIONAL TRADE COMMISSION
WASHINGTON, D.C.

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**	**Inv. No. 337-TA-1411**

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

TABLE OF CONTENTS

I. INTRODUCTION 1
A. Procedural History 3
B. The Parties 3
Complainant Sun Pharmaceutical Industries, Inc. 3
Respondent Biofrontera Inc. 4
Respondent Biofrontera AG 4
Respondent Biofrontera Pharma GmbH 4
Respondent Biofrontera Bioscience GmbH 5
C. Overview of the Technology 5
D. The Asserted Patents 6
E. The Products at Issue 6
DI Product 6
Respondents' Product 7
II. JURISDICTION/IMPORTATION 7
A. Subject Matter, Personal, and Statutory Jurisdiction 7
B. Importation 8
III. THE ASSERTED CLAIMS 8
IV. CLAIM CONSTRUCTION 8
A. Person of Ordinary Skill in the Art ("POSA") 10
V. BIOFRONTERA DOES NOT INFRINGE THE ASSERTED PATENTS 11
A. Legal Standards 11
B. Biofrontera Does Not Infringe the Asserted Claims of the '512 Patent 12
C. Biofrontera Does Not Infringe the Asserted Claims of the '028 Patent 24
VI. THE ASSERTED PATENTS ARE NOT VALID 30
A. Obviousness - Under 35 U.S.C. § 103 30
B. Asserted Claims Invalid for Lack of Written Description for Failing to Provide Support for *Photodynamically Diagnosing* a Patient 90
C. The Asserted Claims Are Invalid for Lack of Enablement 102
VII. DOMESTIC INDUSTRY – TECHNICAL PRONG 105
A. Sun's Burden on Domestic Industry Claims 105
VIII. REMEDY AND BONDING 106

A. LEO 107
B. CDO 109
C. Bond 110

TABLE OF AUTHORITIES

Cases

141 S. Ct. 112 (2020) 11
476 Fed. Appx. 746 (Fed. Cir. 2012) 12
ABT Sys., LLC v. Emerson Elec. Co.,
797 F.3d 1350 (Fed. Cir. 2015) 86
Adapt Pharma Operations Ltd. v. Teva Pharms. USA, Inc.,
25 F.4th 1354 (Fed. Cir. 2022) 71
ALZA Corp. v. Andrx Pharms., LLC,
603 F.3d 935 (Fed. Cir. 2010) 104
Amgen Inc. v. Sanofi,
598 U.S. 594 (2023) 102, 103, 104
Application of Fisher,
427 F.2d 833 (C.C.P.A. 1970) 80
Ariad Pharms., Inc. v. Eli Lilly & Co.,
598 F.3d 1336 (Fed. Cir. 2010) 91, 92
Centocor Ortho Biotech, Inc. v. Abbott Lab'ys,
636 F.3d 1341 (Fed. Cir. 2011) 91
E.I. du Pont de Nemours & Co. v. Synvina C.V.,
904 F.3d 996 (Fed. Cir. 2018) 90
Flash-Control, LLC v. Intel Corp.,
2021 WL 2944592 (Fed. Cir. July 14, 2021) 102
In re Ethicon, Inc.,
844 F.3d 1344 (Fed. Cir. 2017) 74
In re Keller,
642 F.2d 413 (C.C.P.A. 1981) 84
In re Paulsen,
30 F.3d 1475 (Fed. Cir. 1994) 85
In re Wands,
858 F.2d 731 (Fed. Cir. 1988) 102, 103
Juno Therapeutics, Inc. v. Kite Pharma, Inc.,
10 F.4th 1330 (Fed. Cir. 2021) 92
LizardTech, Inc. v. Earth Resource Mapping, Inc.,
424 F.3d 1336 (Fed. Cir. 2005) 102
Medichem, S.A. v. Rolabo, S.L.,
437 F.3d 1157 (Fed. Cir. 2006) 76
Metacel Pharms. LLC v. Rubicon Rsch. Priv. Ltd.,
2025 WL 1178384 (Fed. Cir. Apr. 23, 2025) 23
Nuvo Pharmaceuticals (Ireland) Designated Activity Co. v. Dr. Reddy's Labs. Inc.,
923 F.3d 1368 (Fed. Cir. 2019) 95
Power Integrations, Inc. v. Fairchild Semiconductor Int'l, Inc., 843 F.3d 1315 (Fed. Cir. 2016) 11
Purdue Pharma L.P. v. Faulding Inc.,
230 F.3d 1320 (Fed. Cir. 2000) 101
Regents of the Univ. of Cal. V. Eli Lilly & Co.,
119 F.3d 1559 (Fed. Cir. 1997) 93, 95

S. Alabama Med. Sci. Found. v. Gnosis S.P.A.,
808 F.3d 823 (Fed. Cir. 2015) 87
Sci. Plastic Prods. v. Biotage AB,
766 F.3d 1355 (Fed. Cir. 2014) 82, 84, 85
Univ. Of Rochester v. G.D. Searle & Co.,
358 F.3d 916 (Fed. Cir. 2004) 93

Statutes
19 U.S.C. § 1337 106
19 U.S.C. § 1337(a)(3) 106
19 U.S.C. § 1337(d) 106
19 U.S.C. § 1337(j)(3) 110
19 U.S.C. §§ 1337(a)(1)(B)(i) 8
19 U.S.C. §§ 1337(a)(1)(C) 8
19 U.S.C. §§ 1337(a)(2) 8, 106
35 U.S.C. § 271 106
35 U.S.C. § 271(b) 11

Other Authorities
89 Fed. Reg. 62790 (Aug. 1, 2024) 3

Administrative Decisions
Certain Routers, Access Points, Controllers, Network Management Devices, Other Networking Prods. & Hardware & Software Components Thereof, Inv. No. 337-TA-1227, ID (Dec. 7, 2021) 110
Certain Rubber Antidegradants,
Inv. No. 337- TA-533, Comm'n Op. (July 21, 2006) 110
Certain Table Saws Incorporating Active Injury Mitigation Technology & Components Thereof,
Inv. No. 337-TA-965, Comm'n Op. (Jan. 27, 2017) 111
Certain Televisions, Remote Controls, & Components Thereof,
Inv. No. 337-TA-1263, Comm'n Op. (Nov. 30, 2022) 105

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

Abbreviation	Meaning
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
Prior Art References	
Lundahl	U.S. Patent No. 6,223,071 to Lundahl, et al.

Abbreviation	Meaning
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

Founded by scientists, Respondents Biofrontera Inc., Biofrontera AG, Biofrontera Bioscience GmbH, and Biofrontera Pharma GmbH ("Biofrontera") have developed an innovative, differentiated photodynamic therapy ("PDT") combination product for the treatment of pre-cancerous skin lesions. Today, Biofrontera continues its innovation as the only company conducting Phase III clinical studies in the U.S. for PDT. Biofrontera entered the US market differentiating itself from the incumbent, DUSA Pharmaceuticals, later acquired by Complainant Sun Pharmaceuticals, Inc. ("Sun") with a proprietary nanoemulsion formulation of aminolaevulinic acid ("ALA") called Ameluz® and the deep penetrating red BF-RhodoLED® and RhodoLED®XL illuminators. Biofrontera developed the RhodoLED®XL on its own and gained FDA approval before the Asserted Patents issued. Not interested in competition, Sun, the global incumbent, has chosen litigation on weak patents as a business strategy to extend the monopoly on its late-1990s pharmaceutical product and obvious lamp technology into the 2030s.

The evidence demonstrates that Sun made an obvious modification based on its legacy BLU-U® 4170D fluorescent tube lamp, covered by the Lundahl patent first filed in 1998, and claimed another 20-year patent monopoly. Specifically, Sun developed a new lamp to precisely match the performance characteristics of the BLU-U® 4170D that it claimed in Lundahl in 1998, even matching the structure by increasing LED light-source density in the area proximate to the forehead and chin. The only named inventor present at trial, Thomas Boyajian, testified he "had nothing to do with making the patent except for signing whatever I was asked to sign" and that he "wouldn't claim to understand everything in this patent." Tr.(Boyajian), 69:1-11. The U.S. patent system was not developed to enable this kind of evergreening.

The obviousness of the Asserted Patents follows a parallel story: it would be obvious for a POSA to combine the teachings from Lundahl with the teachings of a five-panel LED lamp set forth in Larsen to arrive at the Asserted Claims. The prior art provided a POSA with ample motivation to do so to address the known deficiencies with the fixed U-shape of Lundahl, which could not be conveniently used by doctors to treat varying anatomies, along with updating Lundahl's fluorescent bulb technology, which was becoming obsolete and being replaced by LEDs. And, a POSA would have had a reasonable expectation of successfully doing so. Recognizing this, the PTAB has instituted an IPR against the '028 Patent on the combination of Lundahl and Larsen.

Additionally, Sun's claims fail for lack of written description and enablement because the specification does not provide teaching or examples related to the claimed system or method for photodynamically diagnosing a patient. The specification does not provide working examples of photodynamic diagnosis, only photodynamic therapy. The testimony in this case, including from Sun's expert, demonstrates that the two things differ in meaningful ways such that examples of PDT do not show possession and do not enable photodynamic diagnosis.

Sun's infringement claims fare little better. For most of the asserted claims, Sun's infringement claim depends on stretching the meaning of "[nested hinges / hinged structures] on inner side surfaces of adjacent panels" to cover hinges placed inside the panels themselves. For claims of induced infringement of method claims, Sun relies on a single internal document to rebut the unambiguous instructions from the label that only three adjacent panels are required to be used. More than three panels are at a physician's option and, under well-settled Federal Circuit law, this does not constitute infringement. Indeed, Sun's unusual system claims all require patients, treatment surfaces, and positioning of lamps relative thereto, thus requiring method steps to practice the system claims.

Sun rushed to file this Complaint before their new lamp was ready for market. The only "evidence" that the technical prong of domestic industry was met was an uncorroborated statement by Mr. Lundahl that a doctor in Arizona treated a patient, well after the Complaint was filed and before the FDA approved the lamp for use with Sun's pharmaceutical product. Section 337 is a powerful tool meant to prevent unfair imports, not to award incumbents a permanent monopoly for weak, obvious patents.

A. Procedural History

Sun filed the Complaint in this case on June 25, 2024, naming Biofrontera entities as Respondents. The Commission instituted the Investigation on July 26, 2024. 89 Fed. Reg. 62790 (Aug. 1, 2024). On August 19, 2024, the ALJ issued an Initial Determination setting a target date of February 2, 2026, and a Final Initial Determination date of October 1, 2025. *See* Order No. 5 (Sep. 16, 2024). The ALJ issued a *Markman* Order. Order No. 18 (Mar. 4, 2025).

On May 6, 2025, Sun filed a Corrected Motion for Summary Determination on the economic prong of the domestic industry requirement, which Biofrontera opposed. Mot. No. 1411-13. The ALJ granted Sun's Motion. Order No. 23 (Jun. 25, 2025). The evidentiary hearing was held June 30- July 3, 2025. In light of Order No. 23, no evidence on economic prong was presented at the hearing.

B. The Parties

Complainant Sun Pharmaceutical Industries, Inc.

Sun is a pharmaceutical company incorporated in Delaware with its principal place of business in Princeton, NJ. In November 2012, Sun purchased DUSA Pharmaceutical, Inc., the assignee of the Asserted Patents. CX-0011C (Lundahl WS), Q/A12; CX-0020C (Albert WS), Q/A10. Among its hundreds of products, Sun sells its two BLU-U® lamps and Levulan® prescription medicine. CX-0011C (Lundahl WS), Q/A5-6; CX-0020C (Albert WS), Q/A8.

Respondent Biofrontera Inc.

Biofrontera Inc. is a biopharmaceutical company incorporated in Delaware and located in Woburn, Massachusetts. RX-0003C (Leffler WS), Q/A9. Biofrontera Inc. is a research-based dermatology company focused on PDT. RX-1383 ("Products," Biofrontera website). Biofrontera Inc. markets its FDA-approved combination therapy consisting of its photodynamic illuminators, RhodoLED® or RhodoLED®XL, and Ameluz.® RX-1175 (Biofrontera Announces U.S. FDA Approval). Biofrontera Inc. is independent from Biofrontera AG. RX-0004C (Luebbert WS), Q/A11; JX-0008C (Luebbert Dep. Tr.), 31:4-7. RX-0004C (Luebbert WS), Q/A11; Tr.(Luebbert), 307:3-14. On June 30, 2025, Biofrontera Inc. announced that it had restructured its agreement with Biofrontera AG and Biofrontera Inc. and is now responsible for the manufacturing, quality control, and regulatory work related to Ameluz® and Biofrontera PDT lamps. Tr (Luebbert), 305:15-306:5.

Respondent Biofrontera AG

Biofrontera AG is a German pharmaceutical company organized under the laws of Germany and has a principal place of business in Leverkusen, Germany. JX-0008C, 31:4-7; RX-0004C, Q/A11; RX-0002C (Foguet WS), Q/A26; Tr.(Luebbert), 307:3-308:5. Before the June 30, 2025 transaction, Biofrontera AG sold the RhodoLED®XL lamps to Biofrontera Inc. RX-0003C (Leffler WS), Q/A9; Tr.(Luebbert), 307:15-308:5; Tr.(Leffler), 421:18-422:4; Tr.(Luebbert), 307:15-308:5.

Respondent Biofrontera Pharma GmbH

Biofrontera Pharma GmbH is a wholly-owned subsidiary of Biofrontera AG, responsible for the manufacture of the RhodoLED®XL for sale to Biofrontera Inc. prior to the June 30, 2025, transaction. JX-0011C, 28:16-18; RX-0002C, Q/A26; Tr.(Luebbert), 330:11-13; JX-0008C, 35:2-6; Tr.(Luebbert), 307:15-308:5.

Respondent Biofrontera Bioscience GmbH

Biofrontera Bioscience GmbH is also a wholly owned German subsidiary of Biofrontera AG. It carries out research, development tasks and regulatory functions for the Biofrontera Group and holds the patents and FDA regulatory approvals for Ameluz® and the BF-RhodoLED®. JX-0011C, 28:16-18; RX-0002C (Foguet WS) Q/A26, 28. It manufactures Ameluz.® JX-0008C, 36:2-6; RX-0002C (Foguet WS), Q/A28.

C. Overview of the Technology

Photodynamic Therapy ("PDT") uses light to activate a photosensitive compound, or photosensitizer, on or within the body to achieve a therapeutic effect. Photosensitizers applied to a patient accumulate in tissues, and preferentially in pre-cancerous and cancerous tissues. The photosensitizer absorbs light, which induces photocytotoxic reactions that destroy cells.

PDT has been known in the art and used for decades and, for instance, was described in RX-1354.0005-6 (Silapunt). PDT uses a light source with sufficient irradiance within a narrow wavelength band to activate the photosensitizer using a prescribed dose of light energy, called fluence. For instance, Sun's BLU-U® 4170D and BLU-U® 4170E emit light in the blue range at a 417 nm wavelength and a fluence of 10 J/cm^2. JX-0091C.6 (BLU-U® 4170E Operating Manual). Biofrontera's RhodoLED® and RhodoLED®XL emit red light at a 635 nm wavelength and a fluence of 37 J/cm^2. JX-0072C.7 (RhodoLED®XL User Manual).

Topical 5-aminolevulinic acid ("ALA") photosensitizers, including Sun's Levulan® and Biofrontera's Ameluz®, are used for treatment of scaly dermatological lesions called actinic keratosis ("AKs"). Left untreated, AKs may develop into skin cancer (specifically squamous cell carcinoma). ALA is applied to the treatment surface on a patient's skin and left to incubate. Sun's Levulan® label recites an incubation period of 14-18 hours for the face or scalp and 3 hours for

upper extremities, whereas Biofrontera's Ameluz® label recites an incubation period of 3 hours for all applications. *See* JX.0197C.3 (Levulan® label), JX-0074.4 (Ameluz® label).

The treatment surface is then illuminated by a photodynamic illuminator that deposits a predetermined fluence on the treatment surface. ALA, which is converted to protoporphyrin IX ("PPIX") in cells, releases reactive oxygen species ("ROS") that destroy the treated cells. According to Silapunt, PpIX absorbs light in the "400-700 nm wavelength, with maximal absorption at 410, 630, and 690 nm wavelengths, but corresponding decrease in light penetration into the skin from 6 mm at 630 nm to 1.5 mm at 410 nm." RX-1354.0005-6.

D. The Asserted Patents

The Asserted Patents share a specification and claim priority to U.S. Provisional Application No. 62/241,902 filed October 15, 2015. JX-0001 ('512 Patent), 1:8-13; JX-0002 ('028 Patent), 1:8-15. The prior art references relied upon were all published well before October 15, 2015. RX-0006C, Q/A87-88, 105-106, 117-118, 125-126, 134-135. The Asserted Patents are directed to an adjustable illuminator for photodynamically diagnosing or treating a surface. JX-0001, Abstract; JX-0002, Abstract. In all material respects, the text, figures, and specification of the Asserted Patents are identical. Order No. 18, 12, n. 4. Herein, we cite to the specification of the '512 Patent, JX-0001.

E. The Products at Issue

DI Product

Sun alleges that its BLU-U® 4170E device individually, or in combination with Levulan® Kerastick, practices each of the Asserted Patents. CX-0010C (Jokerst WS), Q/A26, 79; CX-0016C (Vander Veen WS), Q/A27. As of the filing of the Complaint, Sun received FDA approval to market the BLU-U® 4170E on its own, but not in combination with Levulan®. JX-0198, ¶ 45. [redacted]

[redacted]

Respondents' Product

Biofrontera's RhodoLED®XL ("Accused Product") is accused of infringing the Asserted Claims, either on its own or in combination with Ameluz®. Ameluz®, a nanonemulsion gel with the active ingredient ALA, is used with the RhodoLED®XL or its predecessor device, the BF-RhodoLED®, for PDT. JX-0194C.1 (Ameluz® Prescribing Information). Specifically, Ameluz® is a porphyrin

precursor that when used in combination with the BF-RhodoLED® or RhodoLED®XL is indicated for lesion-directed and field-directed treatment of actinic keratoses of mild-to-moderate severity on the face and scalp. JX-0194C.2, 6. Ameluz® gained FDA approval in May 2016, initially for use with the BF-RhodoLED®, Biofrontera's single-panel photodynamic illuminator. RX-0002C, Q/A14, 19.

In September 2017, Biofrontera began developing the RhodoLED®XL, an improvement on the BF-RhodoLED®, which gained FDA approval in 2021. RX-0004C, Q/A51, 67. Both lamps use red light, which penetrates the skin more deeply than blue light and reaches abnormal cells deeper in the skin. *Id.,* Q/A36-37. The RhodoLED®XL user manual requires the use of three adjacent panels, although HCPs may choose to use up to five panels. *Id*., Q/A66.

II. JURISDICTION/IMPORTATION

A. Subject Matter, Personal, and Statutory Jurisdiction

Section 337 confers subject matter jurisdiction on the Commission to investigate, and if appropriate, to provide a remedy for, unfair acts and methods of competition in importation, the sale for importation, or the sale after importation of articles into the United States. *See* 19 U.S.C.

§§ 1337(a)(1)(B)(i), (C), (a)(2). Biofrontera does not contest the subject matter jurisdiction of the Commission to adjudicate this Investigation and Biofrontera has submitted to the personal jurisdiction through its participation in this Investigation. Furthermore, Biofrontera notes that, to the extent that "the terms 'subject matter jurisdiction,' 'personal jurisdiction,' and 'in rem jurisdiction' are not necessarily applicable to the Commission's investigative authority under section 337" Biofrontera does not contest that the Commission has statutory authority to investigate Biofrontera's alleged violation of section 337.

B. Importation

Biofrontera has entered a joint stipulation with Sun that it has imported into the United States the Accused Product identified in that stipulation. *See* Updated Joint Stipulation of Importation and Inventory at 2 (Jan. 2, 2024). Therefore, Biofrontera does not contest that the importation requirement has been satisfied in this Investigation as to the Accused Product.

III. THE ASSERTED CLAIMS

Sun is asserting claims 1, 3, 5, 8, 17-18, and 20 of the '512 Patent and claims 1-2, 4, 16-17, 19-21 of the '028 Patent (collectively "Asserted Claims"). As of April 17, 2025, Sun withdrew claims 5 and 6 of the '028 Patent, which were initially asserted in the Complaint. JX-0198, ¶ 3.

IV. CLAIM CONSTRUCTION

During claim construction in this Investigation, the parties agreed to the constructions below, which were adopted by the ALJ, and submitted briefing and supporting expert declarations as to the remaining disputed terms.

Claim Term	Relevant Claims	Parties' Agreed Construction
"uniformly illuminate a	'028 patent: claims 1, 16, 20,	"irradiating light over the

Claim Term	Relevant Claims	Parties' Agreed Construction
treatment surface"	21 '512 patent: claims 1, 2, 20	active emitting area such that the measured irradiance at a treatment surface of the patient is at least within 60% of the measured maximum"
"uniformly illuminating a treatment surface"	'512 patent: claim 8	"irradiating light over the active emitting area such that the measured irradiance at a treatment surface of the patent is at least within 60% of the measured maximum"

On November 31, 2024, a *Markman* hearing was held. On March 4, 2025, a *Markman* Order issued. Order No. 18. Below are the constructions from the *Markman* Order:

Claim Term[1]	ALJ Moore's Construction
"a higher intensity of light is emitted proximate the second edges compared to	"a higher intensity of light is emitted close to the second shorter edges compared to the intensity

[1] Biofrontera raised several arguments in its claims construction briefing regarding the indefiniteness of the terms "a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges" and "nested hinges." RMIB (Oct. 31, 2024). Biofrontera expressly reserves the right to assert its indefiniteness arguments on appeal and in any related proceedings, and that the adopted construction is also indefinite.

Claim Term[1]	ALJ Moore's Construction
the intensity of light emitted not proximate the second edges"	of light emitted not close to the second shorter edges"
"photodynamically diagnosing or treating a patient"	Preamble is limiting.
"nested hinges"	"hinges that fit on inner side surfaces of adjacent panels"
"recess"	"indentation, small hollow, or cleft"
"the five panels are individually configurable to control illumination from each of the five panels"	Plain and ordinary meaning. "the power output and/or light intensity of each panel can be Individually controlled."
"within approximately four inches of the treatment surface"	"less than or equal to approximately four inches from the treatment surface"

Id.

A. Person of Ordinary Skill in the Art ("POSA")

In the *Markman* Order, ALJ Moore adopted the following POSA definition:

A person of ordinary skill in the art would have a M.D. and/or a Ph.D. in an electrical engineering, optoelectronics, physics, optical sciences, optical engineering, or related scientific or engineering field, and at least one to two years of work or research experience in optical engineering, optics, optoelectronics, phototherapy, photodynamic therapy, or a related field.

Id., 13.

Biofrontera relies on the expert opinions and testimony of Dr. Robert Grove, Ph.D, and Dr. Michael Ehrenreich, M.D. *See, e.g.*, RX-0006C (Grove Initial Witness Statement); RX-0007C (Ehrenreich Initial Witness Statement); RX-0009C (Grove Rebuttal Witness Statement); RX-0011C (Ehrenreich Rebuttal Witness Statement). Dr. Grove was admitted as an expert in the fields of photodynamic therapy devices, medical lighting devices, electrical engineering, optoelectronics, and the development, operation, and analysis of light-emitting diodes and devices. Tr.(Grove), 432:7-14. Despite Sun's untimely objection, Dr. Ehrenreich was admitted as an expert, in the fields of dermatology, photodynamic therapy, and photodynamic diagnosis. Tr.(Grove) 492:12-23, 505:12-508:22.

V. BIOFRONTERA DOES NOT INFRINGE THE ASSERTED PATENTS

A. Legal Standards

To carry its burden, Sun "must supply sufficient evidence to prove that the accused product or process contains, either literally or under the doctrine of equivalents, every limitation of the properly construed claim." *Eli Lilly & Co. v. Hospira, Inc.*, 933 F.3d 1320, 1328 (Fed. Cir. 2019), *cert. denied* 141 S. Ct. 112 (2020) (citation omitted).

When a patent claims a method of treating ("MOT") a patient, pharmaceutical manufacturers generally do not directly infringe. *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1363 (Fed. Cir. 2003). To infringe MOT claims, complainant must prove that respondent indirectly infringes by inducing HCPs to treat patients according to the claims of the patent. *Id*. Induced infringement requires proof that: (1) there is underlying direct infringement; (2) respondent intended to cause the direct infringement; and (3) respondent knew the acts of the directly infringing party would constitute direct infringement. 35 U.S.C. § 271(b); *see also Power Integrations, Inc. v. Fairchild Semiconductor Int'l, Inc.*, 843 F.3d 1315, 1332 (Fed. Cir. 2016).

Typically, the inducement analysis in cases involving pharmaceutical products and MOT claims involves considering whether the accused infringer's drug product label and other relevant materials "encourage, recommend, or promote" infringement of the claims to induce HCPs to directly infringe. *HZNP Medicines LLC v. Actavis Lab'ys UT, Inc.*, 940 F.3d 680, 685–86, 702 (Fed. Cir. 2019). A respondent does not induce infringement when a label permits, but does not encourage, recommend, or promote an infringing use. *Acorda Therapeutics Inc. v. Apotex Inc.*, 2011 WL 4074116, *18 (D.N.J. 2011), *aff'd*, 476 Fed. Appx. 746 (Fed. Cir. 2012); *H. Lundbeck A/S v. Lupin Ltd.*, 87 F.4th 1361, 1370 (Fed. Cir. 2023) (quoting *Takeda Parms. U.S.A v. West-Ward Parm. Corp.*, 785 F.3d at 625, 631 (Fed. Cir. 2015)).

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

1. Biofrontera Does Not Infringe the "Panels Connected by Nested Hinges On Inner Side Surfaces of Adjacent Panels" Element of the '512 Patent

All Asserted Claims of the '512 Patent require "panels connected by nested hinges on inner side surfaces of adjacent panels." JX-0001, cls. 1, 3, 5, 8, 17-18, 20. As construed, this requires "panels connected by hinges that fit on inner side surfaces of adjacent panels." Order No. 18, 35.

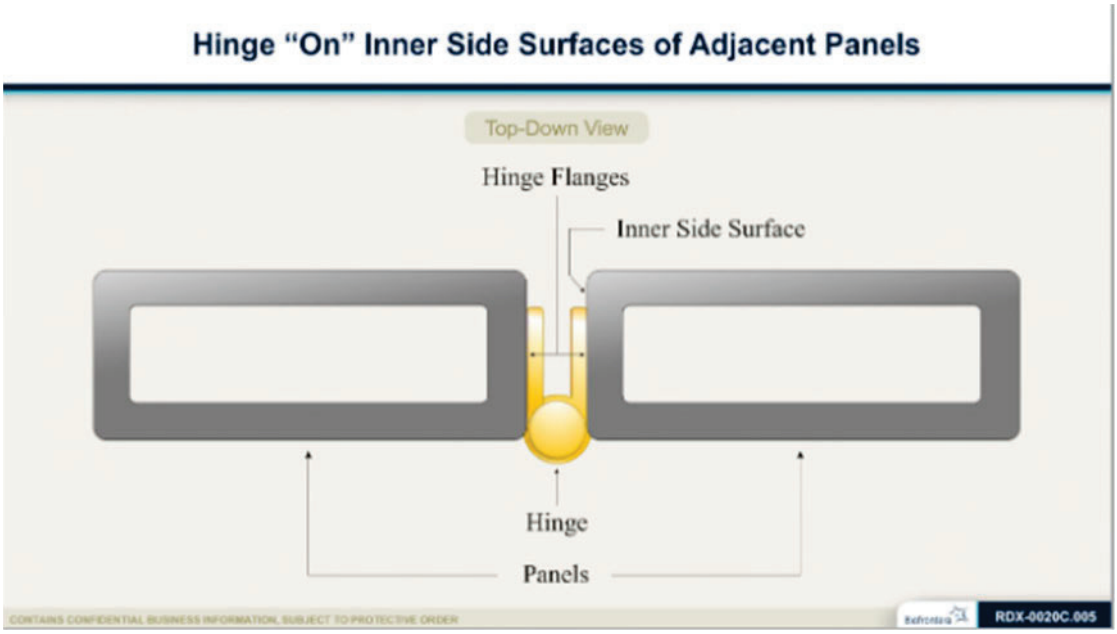
The RhodoLED®XL does not meet this limitation. As admitted by Dr. Jokerst, the RhodoLED®XL does not contain "panels connected by hinges that fit ***on*** inner side surfaces of adjacent panels," because the hinges of the RhodoLED®XL extend ***through*** inner side surfaces of adjacent panels to connect to a planar support structure within the interior of the panels. Tr.(Jokerst), 214:17-23; RX-0009C (Grove), Q/A31.

The inner side surfaces refer to the side surfaces of the exterior of a panel between the front and the back – i.e., the surfaces of the panel casing that face the adjacent panel. RX-0009C, Q/A36.



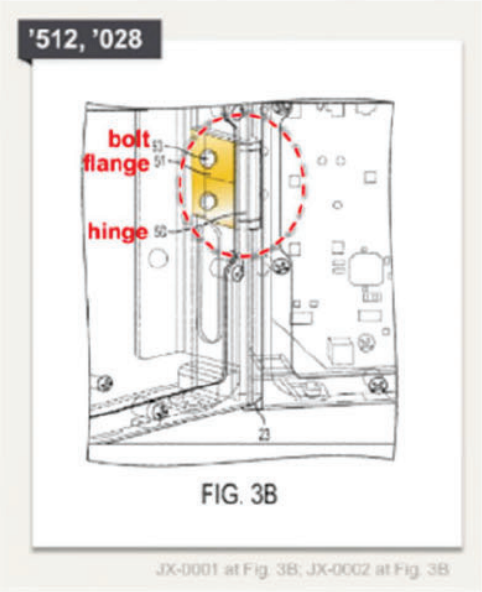
RDX-0020C.012; JX-0131.1; JX-0134.1.

The construed claim language requires that the hinges be "on" these inner side surfaces. JX-0001, cls. 1, 8, 20; Order No. 18, 35; *see also Bicon, Inc. v. Straumann Co.*, 441 F.3d 945, 950 (Fed. Cir. 2006). "On" means "in contact with and supported by the top surface of." JX-0029.1; RX-0009C, Q/A32. Accordingly, "hinges that fit on inner side surfaces of adjacent panels" must be in contact with and supported by the top or exterior of the inner side surfaces. RX-0009C, Q/A33. As illustrated below, such hinges would necessarily be laid flat against, and parallel to, the inner side surfaces of adjacent panels.



RDX-0020C.005.

Dr. Jokerst argued that "the claim language is silent as to whether the hinge must be 'mounted on or affixed to' an inner side surface of adjacent panel." CX-0014C (Jokerst), Q/A473. But as Dr. Jokerst admits, the specification only contains one depiction of a hinge on inner side surfaces (i.e., FIG. 3B), which shows hinge flanges laid flat against and mounted to inner side surfaces with bolts. JX-0001, Fig. 3B, 4:63-66; *see also* Tr.(Jokerst), 231:5-22, 232:7-10.



RDX-0020C.006 (excerpt). Accordingly, for panels to be "connected by hinges that fit on inner side surfaces," the hinges must be affixed to those surfaces in some way. RX-0009C, Q/A70.

This logic is consistent with how Sun applies this claim term to its own product, the BLU-U® 4170E, which has hinges laid flat against the inner side surfaces of adjacent panels and mounted to these surfaces via a bolt. CX-0014C, Q/A99; RX-0009C, Q/A41-44.

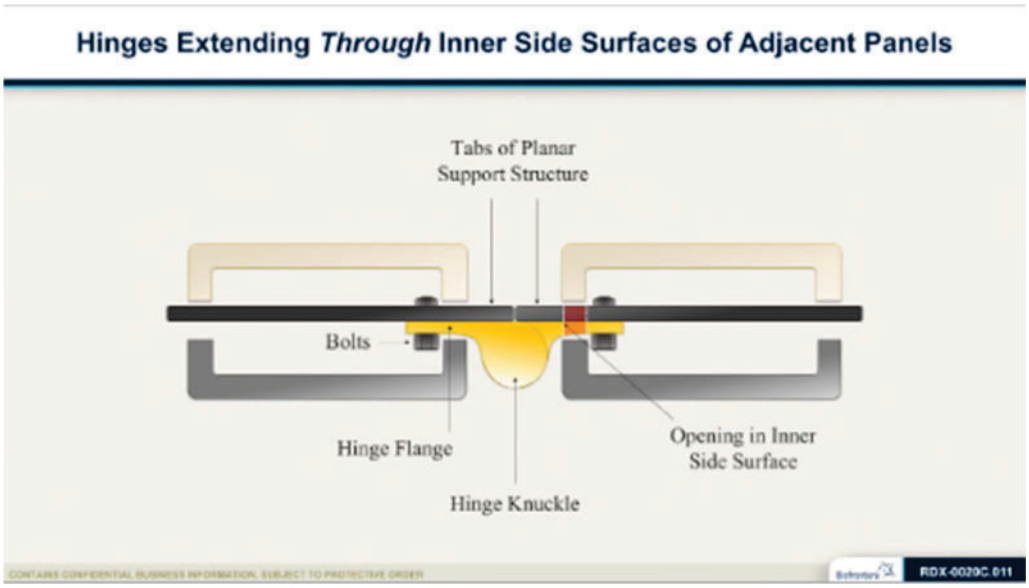


RDX-0020C.0007.

[redacted]

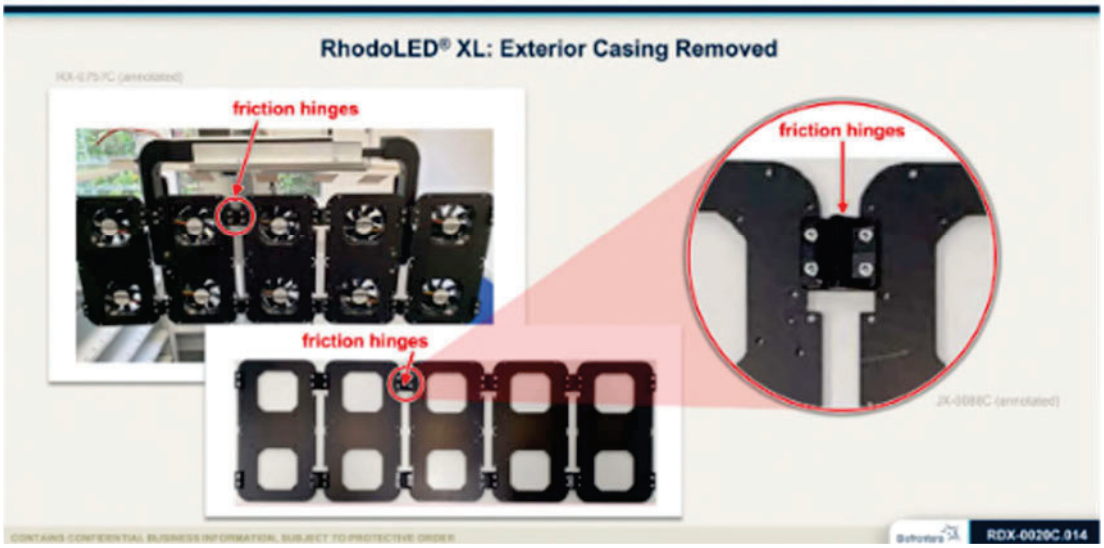
RDX-0020C.0008; RX-1202C.

The RhodoLED®XL, on the other hand, has a very different hinge structure. Specifically, the panels of the RhodoLED®XL include two "friction hinges" that extend ***through*** openings in the inner side surfaces of adjacent panels to connect to a planar support structure housed within an interior compartment of the panels, as illustrated below. RX-0009C, Q/A31,49; Tr.(Jokerst), 214:17-23.

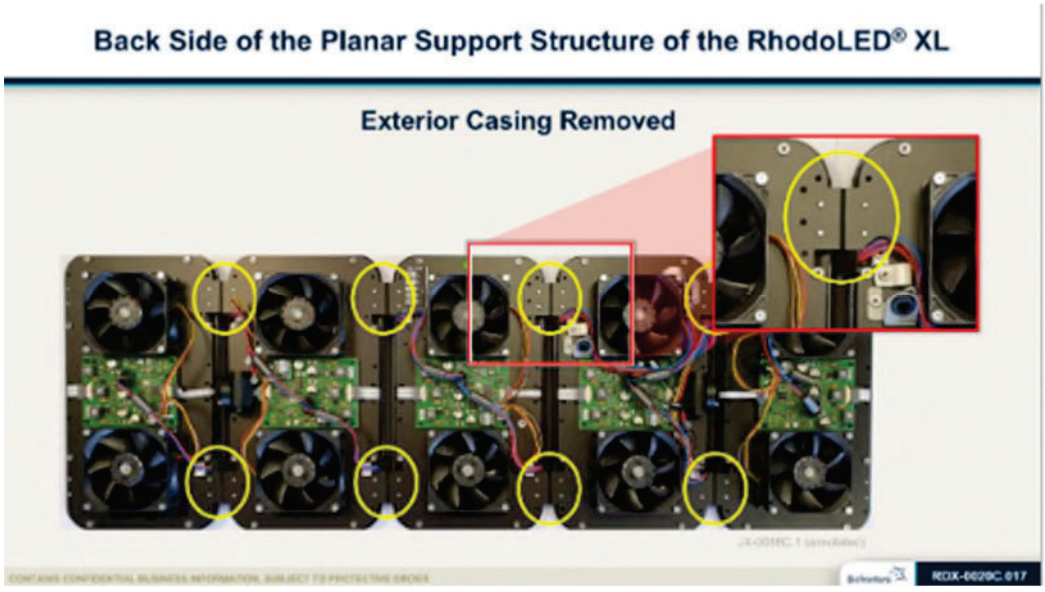


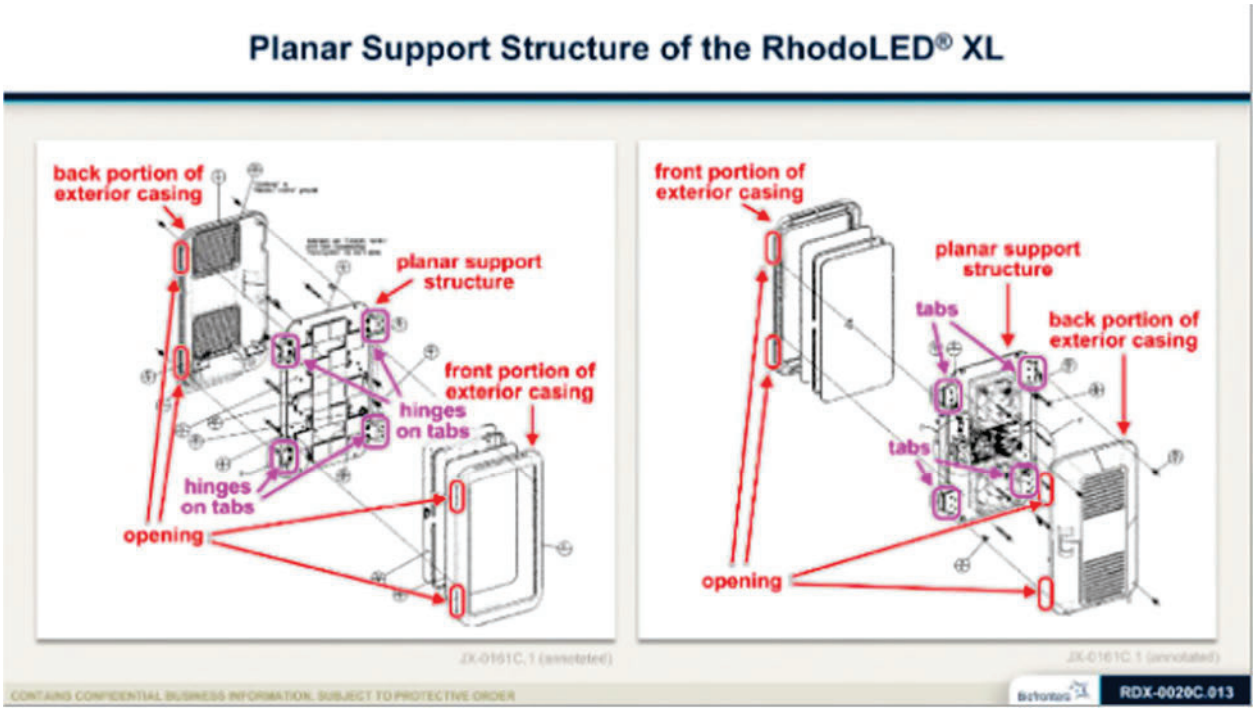
The planar support structures support the LED circuit board, heatsinks, cooling fans, and the exterior casing of the panels. RX-0009C, Q/A52. As Dr. Grove testified and illustrated in the demonstratives below, the hinges of the RhodoLED®XL are secured to the front side of tabs (or "hinge holders") of the planar support structure using bolts that extend through the back side of the planar support structure:

Front Side of the Planar Support Structure of the RhodoLED® XL

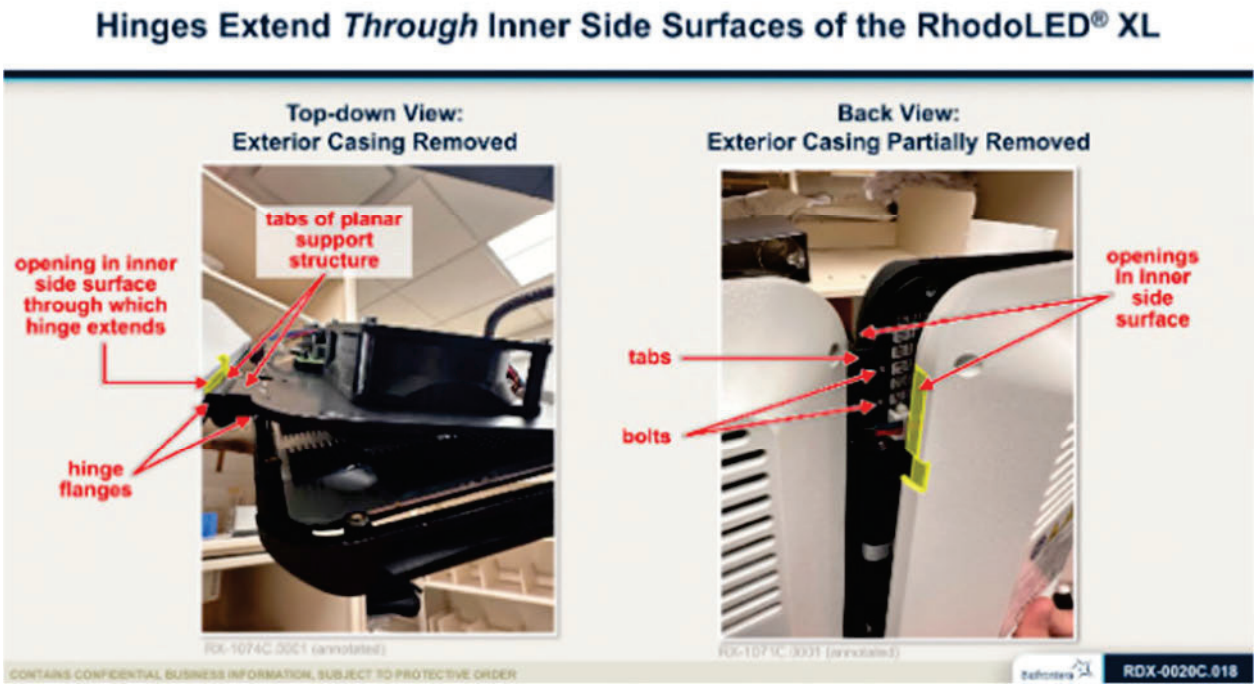


Back Side of the Planar Support Structure of the RhodoLED® XL





RX-0009C, Q/A49-59,63; *see also* Tr.(Jokerst), 209:16-210:11; RDX-0020C.013, RDX-0020C.014, RDX-0020C.017; JX-088C; JX-0161C.1. The hinges of the RhodoLED®XL are laid flat on the front side of the tabs and the hinge flanges extend through openings on the inner side surfaces to bolted attachment points located within the interior compartment of the panel, as depicted below. RX-0009C, Q/A65; Tr.(Jokerst), 213:9-214:23.



RDX-0020C.018; RX-1074C.0001; RX1071C.0001.

Accordingly, the friction hinges of the RhodoLED®XL are not "***on*** inner side surfaces of adjacent panels" because, as Dr. Jokerst admits, they extend ***through*** inner side surfaces of adjacent panels to ***connection points inside of the panels***. Tr.(Jokerst), 214:17-23; RX-0009C, Q/A66. Further, because the friction hinges extend through the inner side surface to the interior of the panel, the RhodoLED®XL panels are not connected by "hinges that ***fit*** on inner side surfaces of adjacent panels," as required by the claims. RX-0009C, Q/A67. Thus, Biofrontera's RhodoLED®XL does not infringe the Asserted Claims of the '512 Patent.

Sun's assertion that the tabs of the planar support structure are part of the inner side surfaces of the panels (CPHB, 43-45), is inaccurate. RX-0009C, Q/A60. The tabs are not part of the inner side surfaces of the panels—they are part of an interior structure of the panel, which extends through openings in the inner side surface. RX-0009C, Q/A53, 60-61. Objects that extend through a surface are not part of that surface: a straw that extends through the lid on a cup would not be

considered part of the lid's surface; a bolt that extends through a nut would not be considered part of the nut's surface. Even if the planar support structure is considered part of the panel surfaces (which it is not), the friction hinges are still disposed on the *front* surface of the planar support structure—not any side surface whatsoever. RX-0009C, Q/A66; *see also* Tr.(Jokerst), 215:8-14 (Dr. Jokerst testifying that it is "correct" that the "hinges are attached to the *front side* of the support structure.") (emphasis added).

While Dr. Jokerst alleges that there may be incidental contact between the friction hinge flanges and the opening in the inner side surface (CX-0014C, Q/A470), the claim language requires the hinges to be "on" (i.e., in contact with ***and supported by*** the top surface of) inner side surfaces. RX-0009C, Q/A69. The support for the RhodoLED®XL hinge flanges comes from being bolted to the front surface of the hinge holders. RX-0009C, Q/A69. Therefore, Biofrontera does not literally infringe the Asserted Claims of the '512 Patent.[2]

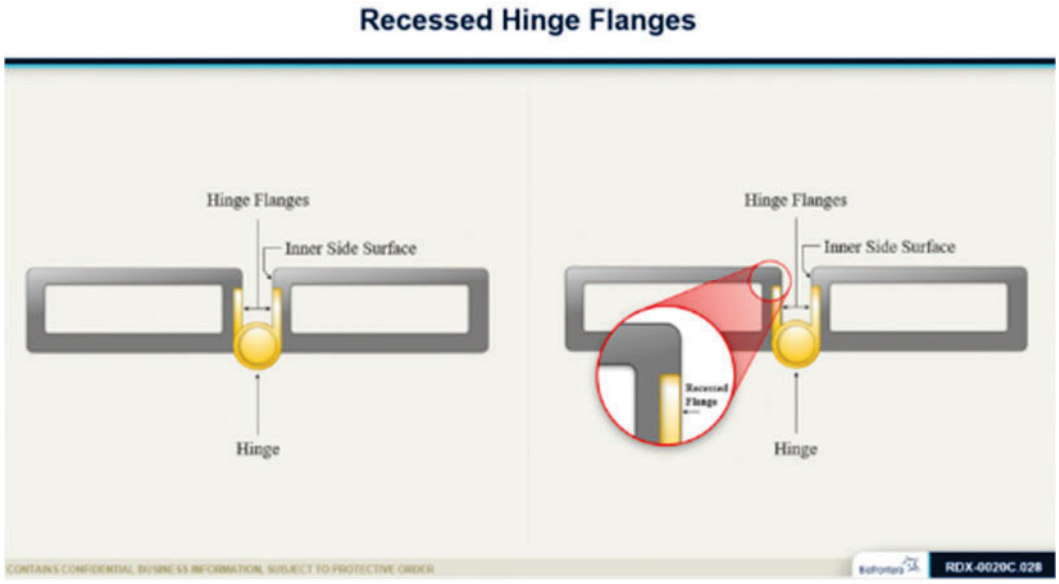
2. Biofrontera Does Not Infringe the "Recess" Limitation of Claims 17 and 18 of the '512 Patent

Dependent claims 17 and 18 of the '512 Patent depend from independent claim 8 and recite a "recess configured to receive a flange of one of the nested hinges" (claim 17) where "the recess is positioned at an inner side surface of the at least one panel" (claim 18). JX-0002, cls. 17-18. The term "recess" was construed to mean "indentation, small hollow, or cleft," and the construction of "nested hinges" was discussed above. Order No. 18, 35, 47; *see also supra* Section IV. Accordingly, claim 17 requires an "indentation, small hollow, or cleft configured to receive a flange of one of the hinges that fit on inner side surfaces of adjacent panels." And claim 18 requires "the indentation, small hollow, or cleft is positioned at an inner side surface of the at least one

[2] Sun has not alleged that the RhodoLED®XL infringes this limitation under the DOE.

panel." Biofrontera does not infringe claims 17-18 of the '512 Patent because the RhodoLED®XL does not contain an indentation, small hollow, or cleft configured to receive a hinge flange ***on*** an inner side surface. RX-0009C, Q/A102-103.

For the reasons explained above, claims 17-18 require hinges that fit ***on*** an inner side surface (as opposed to extending through it), *supra* Section IV, and the "indentation, small hollow, or cleft" configured to receive the flange of this hinge must be ***on*** the same inner side surface. RX-0009C, Q/A103-104. For a hinge flange to be received in a recess and still be ***on*** an inner side surface of adjacent panels, the hinge flange must fit into an indentation, small hollow, or cleft in the continuous inner side surface, as Dr. Grove illustrated below. RX-0009C, Q/A107.



RDX-0020C.028.

As illustrated above, the RhodoLED®XL's panels do not include indentations, small hollows, or clefts on a continuous inner side surface—they include an opening ***through*** which hinge flanges extend for attachment within the interior compartment of the RhodoLED®XL panels. *Supra* Section V.B.1; *see also* RX-0009C, Q/A107-108; Tr.(Jokerst), 214:17-23.

Accordingly, Biofrontera does not literally infringe claims 17-18 of the '512 Patent.[3] RX-0009C, Q/A108-109.

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

Sun and its experts alleged that Biofrontera induces HCPs to infringe claims 8, 17, and 18 of the '512 Patent (the "Asserted Method Claims").[4] CX-0009C (Shmuylovich WS), Q/A132-134; CX-0010C, Q/A591-593.

One step required by the Asserted Method Claims is "uniformly illuminating a treatment surface of the patient with light sources disposed ***on the at least five panels of the illuminator***." JX-0001, claim 8; RX-0011C (Ehrenreich WS), Q/A61. Consistent with the plain and ordinary meaning of this phrase, light sources disposed on all of "***the at least five panels***" must be used to "uniformly illuminate a treatment surface." *Baldwin Graphic Sys., Inc. v. Siebert, Inc.*, 512 F.3d 1338, 1342-43 (Fed. Cir. 2008). The use of fewer than five panels to uniformly illuminate a patient does not infringe. RX-0011C, Q/A80-81.

Biofrontera does not instruct HCPs to use *all five* panels of the RhodoLED®XL. RX-0011C, Q/A94; RX-0004C (Luebbert WS), Q/A102; JX-0009C, 47:16-48:11; JX-0074.3-5; JX-0086.9-10, 16-17. Rather, Biofrontera's *intent* is for HCPs to use at least three panels; the use of all five panels is *optional*. RX-0011C, Q/A94-110; RX-0004C, Q/A102; JX-0009C, 47:16-48:11; JX-0074.3-5; JX-0086.9-10, 16-17. The Ameluz® label's only "instruction" to HCPs is to "[i]lluminate the treatment area," JX-0074.4; RX-0011C, Q/A97, and it "recommend[s]" the use of "3 adjacent

[3] Sun has not alleged that the RhodoLED®XL infringes this limitation under the DOE.
[4] Because Biofrontera does not diagnose or treat patients according to the claimed method, Biofrontera does not directly infringe the Asserted Method Claims. *Warner-Lambert*, 316 F.3d at 1363; *see also* RX-0011C.0017-18, Q/A61-64.

panels," but gives HCPs an option to use all five panels. JX-0074.4; RX-0011C, Q/A95-98; Tr.(Shmuylovich), 156:1-16; Tr.(Ehrenreich), 539:11-543:20. Providing HCPs an *option* to use five panels does not amount to inducing HCPs to infringe. *H. Lundbeck*, 87 F.4th at 1370 ("[T]o support inducement liability, instructions may not merely describe an infringing mode; they must 'evidence 'intent to encourage infringement.'") (quoting *Takeda*, 785 F.3d at 631).

Likewise, the RhodoLED®XL user manual does not instruct HCPs to use all five panels—it reinforces that HCPs may *choose* to use five panels and that only three adjacent panels *must* be used. JX-0086.9-10, 16-17; RX-0011C, Q/A51, 57, 104-110, 133; Tr.(Ehrenreich), 543:21-545:15; Tr.(Shmuylovich), 156:22-157:20; Tr.(Thompson), 109:7-110:19, 136:18-137:16.

Sun mischaracterizes other documents, including nonpublic FDA correspondence, ***internal*** discussions at Biofrontera, and other marketing or promotional materials. CX-0009C, Q/A114-115, 130, 188, 198 (Shmuylovich citing JX-0108C, JX-0085C, JX-0073C, JX-0089C, JX-0105C); CX-0010C, Q/A432-433, 512, 516, 596 (Jokerst citing JX-0067C, JX-0078C, JX-0073C, JX-0222, JX-0221, JX-0167C). Nonpublic documents like JX-0105C (mistakenly characterized by Shmuylovich as a "marketing" presentation but actually "intended for internal educational use only" and not for "HCPs") and JX-0067C (FDA correspondence cited by Jokerst), bear no weight on the inducement issue. CX-0010C, Q/A516; Tr.(Ehrenreich), 535:11-536:23; Tr.(Shmuylovich), 149:8-153:23; *Metacel Pharms. LLC v. Rubicon Rsch. Priv. Ltd.*, 2025 WL 1178384, at *4 (Fed. Cir. Apr. 23, 2025) ("nonpublic statements," including "FDA submissions," "are not available to downstream users and therefore cannot cause inducement"). Regardless, JX-0105C states that "**AT LEAST 3 CONSECUTIVE PANELS REQUIRED TO BE ILLUMINATED AT ONE TIME PER LABEL.**" JX-0105C.5 (emphasis in original).

Biofrontera's documents consistently recommend HCPs use at least three adjacent panels, and that HCPs are allowed to use all five at their discretion. RX-0011C, Q/A114-133; Tr.(Shmuylovich), 149:8-153:23; JX-0177.3. Even the video of Dr. Ted Lain *never* instructs HCPs to use all five panels. RX-0011C, Q/A118-120; JX-0073C.

Because Biofrontera does not encourage, recommend, or promote the use of all five panels of the RhodoLED®XL to treat patients, Biofrontera does not induce infringement of the Asserted Method Claims.

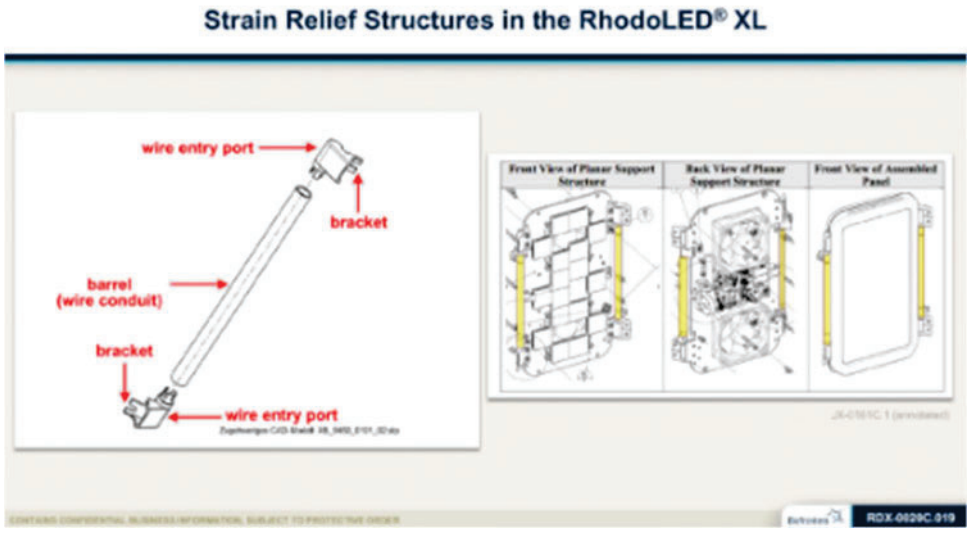
C. Biofrontera Does Not Infringe the Asserted Claims of the '028 Patent

1. Biofrontera Does Not Infringe the "Panels Connected by Hinged Structures On Inner Side Surfaces of Adjacent Panels" of the '028 Patent

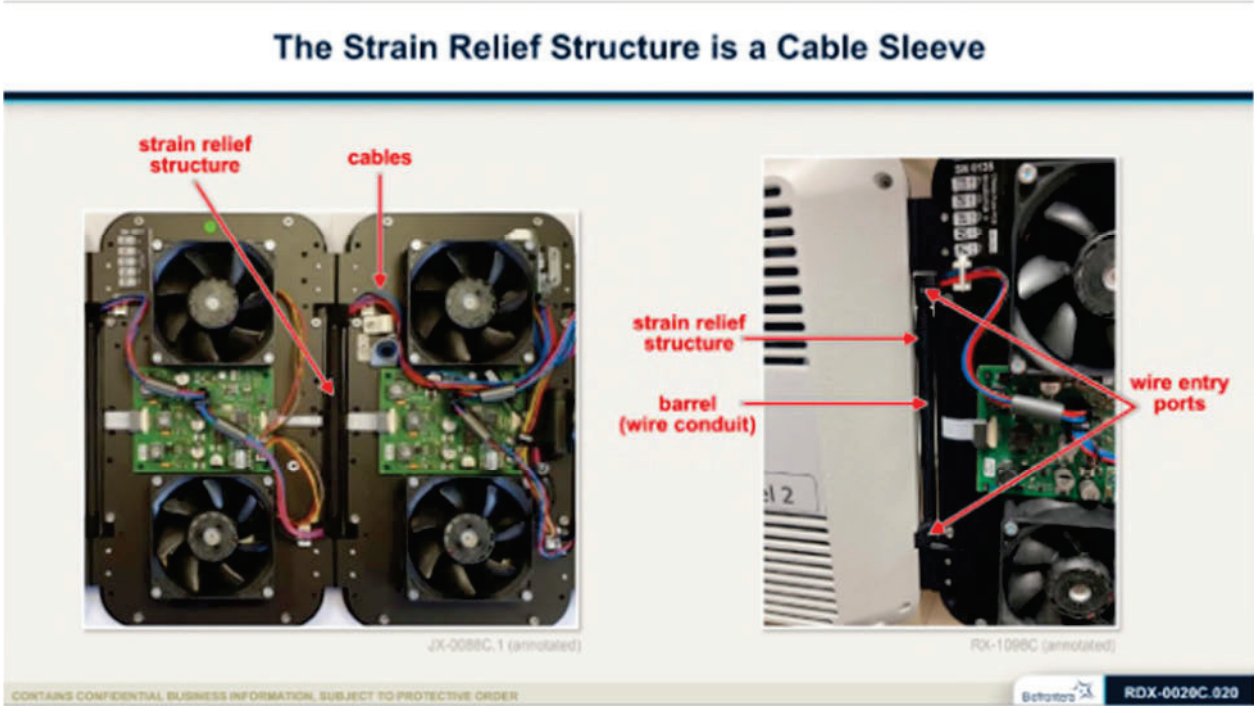
All Asserted Claims of the '028 Patent recite "panels connected by hinged structures on inner side surfaces of adjacent panels." JX-0002, cls. 1-2, 4, 20-21. For the reasons discussed above (incorporated here), the friction hinges of the RhodoLED®XL do not infringe this limitation because they extend *through* the inner side surfaces of adjacent panels. *Supra*, V.B.1.

With respect to the '028 Patent only, Sun has asserted that "strain relief structures" of the RhodoLED®XL infringe the limitation of "panels connected by hinged structures ***on*** inner side surfaces of adjacent panels." CPHB, 90-91. However, this is inaccurate for two reasons: the "strain relief structures" are not (i) hinges or (ii) "on inner side surfaces of adjacent panels." RX-0009C, Q/A82, 84, 87.

As shown below, the strain relief structures of the RhodoLED®XL are not hinges—they are cable sleeves designed to house and protect cables that run from panel to panel. RX-0009C, Q/A75-77.



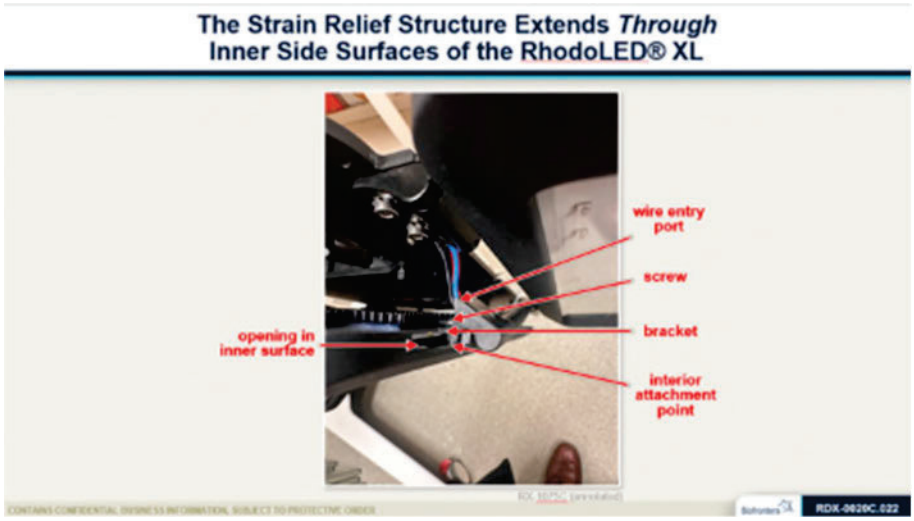
RDX-0020C.019.



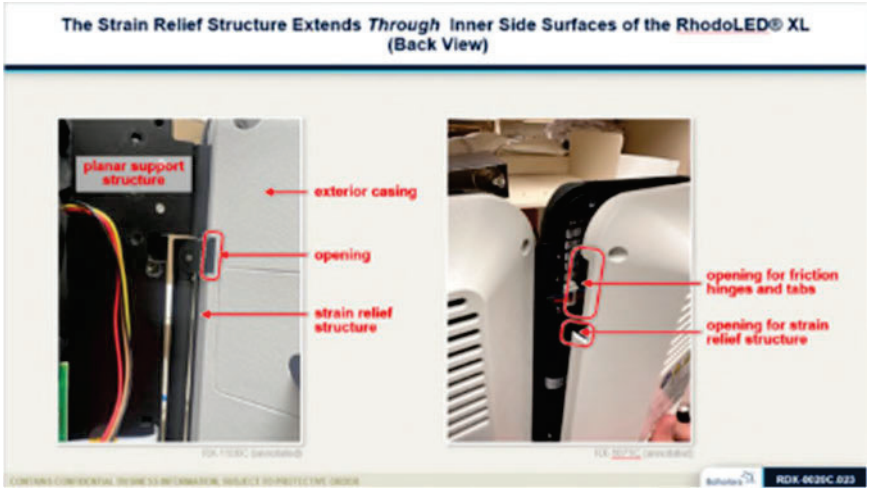
RDX-0020C.020.

The strain relief structures lack the structural strength to serve as hinges (or hinged structures) for the RhodoLED®XL panels. RX-0009C, Q/A79; *see also* RX-0009C, Q/A20-21, 29, 76, 79-83.

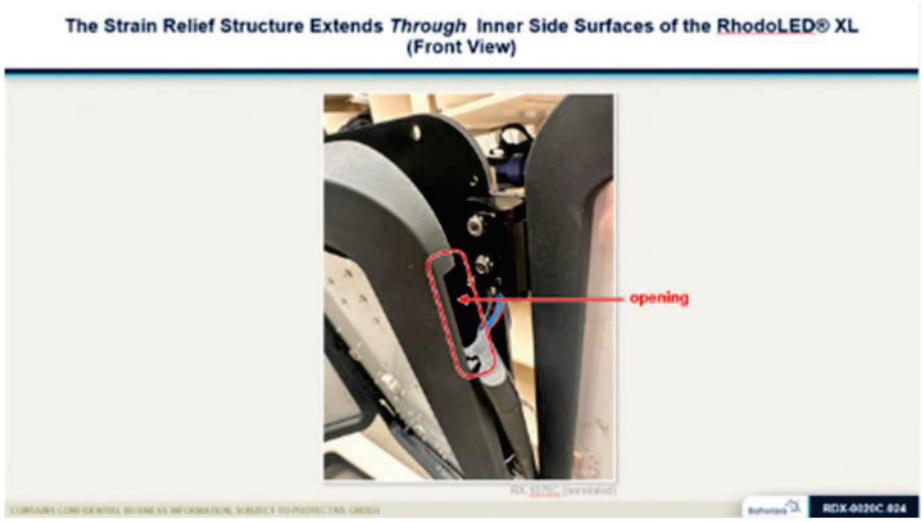
Additionally, the strain relief structures are not ***on*** inner side surfaces of adjacent panels—the bracket and wire entry port of the strain relief structures extend ***through*** an opening in the side surface, as Dr. Grove illustrated below. *Supra* Section V.B.1; *see also* RX-0009C, Q/A81-84.



RDX-0020.022; RX-1075C.



RDX-0020C.023; RX-1100C; RX-1071C.



RDX-0020C.024; RX-1076C.

Accordingly, Biofrontera does not literally infringe claims 1, 2, 4, 20, and 21 of the '028 Patent. RX-0009C, Q/A89.[5]

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

Asserted claims 1, 2, 4, 20, and 21 of the '028 Patent recite "[a] system for photodynamically diagnosing or treating ***a patient***," and include a requirement that "the five panels ***are positioned to allow treatment*** within approximately four inches of ***the treatment surface***." '028 Patent, claims 1, 2, 4, 20, and 21.

Consistent with Federal Circuit precedent holding that "system" claims at times recite "method" steps, this limitation can only be infringed by HCPs that ***position*** the RhodoLED®XL's panels relative to a ***patient's treatment surface***. *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), The plain language of the phrase "the five panels ***are positioned to allow treatment*** within approximately four inches of ***the treatment surface***" necessarily requires all five panels to be positioned ***to allow***

[5] Sun has not alleged that the RhodoLED®XL infringes this limitation under the DOE.

treatment of a patient. RX-0011C, Q/A139; Order No. 18, 29. Because Biofrontera does not position "the five panels" of the RhodoLED®XL "within approximately four inches of the treatment surface" of a patient, Biofrontera does not directly infringe these claims. *Warner-Lambert*, 316 F.3d at 1363.

Further, Biofrontera does not induce HCPs to position "the five panels" of the RhodoLED®XL "within approximately four inches of the treatment surface" of a patient, construed as "less than or equal to approximately four inches from the treatment surface." RX-0011C, Q/A137-138; Order No. 18, 45. However, the experts agree that the specification of the Asserted Patents offers no guidance on what "approximately" means, or what numerical upper bound above 4.0 inches is encompassed by the claims. CX-0010C, Q/A728-729; RX-0011C, Q/A142; Tr.(Jokerst), 206:9-207:10.

Dr. Ehrenreich testified that he interprets "approximately" as a *de minimus* increase in distance above 4.0 inches based on (1) limited guidance the specification offers about what this phrase means and (2) his experience as dermatologist. RX-0011C, Q/A152. Biofrontera does not practice or induce this limitation because the Ameluz® label and RhodoLED®XL user manual explain that the RhodoLED®XL panels should be positioned "4.9 +/- 0.6 inches" from the treatment surface. JX-0074.4; JX-0086.9-10, 18, 27; RX-0011C, Q/A155-158; Tr.(Ehrenreich), 544:22-545:9.

The RhodoLED®XL uses distance sensors in all five panels and a touchscreen display to inform HCPs whether any of the active panels are too close to the patient. If too close, HCPs are instructed to reposition that specific panel. JX-0086.15-18; RX-0011C, Q/A162-164; Tr.(Thompson), 115:8-118:9, 135:20-136:17; Tr.(Jokerst), 198:6-201:22. Drs. Luebbert and Foguet testified that Biofrontera's *intent* is for HCPs to position the RhodoLED®XL panels 4.9

inches from the treatment surface. RX-0004C, Q/A103-109; RX-0002C, Q/A93-95. Because "4.9 +/- 0.6 inches" is more than a *de minimus* increase above 4.0 inches, Biofrontera does not infringe this limitation.

Dr. Jokerst testified that "approximately" encompasses at least plus-or-minus 10% (up to 4.4 inches), based on her experience as an engineer. CX-0010C, Q/A728-729. And Dr. Jokerst testified that the 4.3-inch lower bound of Biofrontera's treatment distance recommendation, is "less than or equal to approximately four inches," and therefore infringes literally or under the DOE. CX-0010C, Q/A688, 746-750. But Sun has not produced evidence to support this arbitrary and conclusory testimony—nothing in the specification supports a "10%" margin, and no scientific articles or evidence was offered to support this position. Tr.(Jokerst), 206:9-207:10. Likewise, Sun's DOE argument fails because the doctrine cannot be used to further expand the scope of terms of approximation. *Cohesive Techs., Inc. v. Waters Corp.*, 543 F.3d 1351, 1371–72 (Fed. Cir. 2008); *Ortho-McNeil Pharm., Inc. v. Caraco Pharm. Lab'ys*, Ltd., 476 F.3d 1321, 1328–29 (Fed. Cir. 2007). Accordingly, Biofrontera does not infringe, directly or indirectly, literally or under the doctrine of equivalents, claims 1, 2, 4, 20, and 21 of the '028 Patent.

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

Claims 16, 17, 19, and 21 of the '028 Patent require that "the five panels are individually configurable to control illumination from each of the five panels," which was "construed with its plain and ordinary meaning, which is 'the power output and/or light intensity of each panel can be individually controlled.'" Order No. 18, 40. Reading the "individually configurable" limitation together with the limiting preamble illustrates that the panels of the illuminator must be "individually configurable" in connection with "photodynamically diagnosing or treating a patient." RX-0011C, Q/A177-178. This condition is not met by the RhodoLED®XL.

First, the claim limitation cannot be met by turning individual panels off as Sun argues, CX-0010C, Q/A800, because the claims require the use of all five panels. JX-0002, claims 16, 17, 19, 21 ("***light sources disposed on surfaces of the five panels***, the illuminator being configured to uniformly illuminate a treatment surface of the patient via ***the light sources***…"). The italicized language shows that "light sources disposed" provides antecedent basis for "the light sources." Using light sources disposed on ***fewer than five panels*** does not infringe. RX-0011C, Q/A185.

Second, HCPs cannot adjust the "light intensity" of the panels of the RhodoLED®XL as part of treatment. [redacted]—the only way to adjust the LED intensity on the panels—is password protected and can only be accessed by Biofrontera employees [redacted] (but not by HCPs to treat patients). JX-0118C.7; JX-0086.25; RX-0011C, Q/A186-191; RX-0002C, Q/A69-81 (citing JX-0199.73-77); CX-0017C, Q/A30-35, 40; Tr.(Thompson), 121:17-122:22, 135:2-19.

Configuring the LED intensity [redacted] is not controlling the illumination as part of a system for photodynamically treating a patient. *Telemac Cellular Corp. v. Topp Telecom, Inc.*, 247 F.3d 1316 (2001). Accordingly, Biofrontera does not infringe, directly or indirectly, claims 16, 17, 19, and 21 of the '028 Patent.

VI. THE ASSERTED PATENTS ARE NOT VALID

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

In 2001, Sun obtained the Lundahl patent on its older 4170D device. RX-0065.0001 (Lundahl); JX-0017C (Lundahl), 37:6-9, 41:7-10, 41:13-16. Lundahl, and the 4170D device that embodied it, provided a PDT device capable of uniform illumination using fluorescent tubes more densely packed near the top and bottom edges (near a patient's forehead and chin) in order to emit higher intensities in those areas. RX-0006C, Q/A307. However, the Lundahl device had two key drawbacks: (1) lack of flexibility due to its fixed U-shape, and (2) use of "fluorescent tubes [that

were] in some ways not well suited for PDT." JX-0017C, 36:7-13; RX-0006C, Q/A310. In 2005, Larsen provided straightforward solutions to both problems in its disclosure of a PDT device using (1) hinged panels to provide flexibility and (2) LEDs, which were rapidly replacing the fluorescent tube technology that had become obsolete by the 2015 priority date of the Asserted Patents. RX-0006C, Q/A315. Improvement of Lundahl's PDT illuminator by incorporation of Larsen's hinged panels and LEDs was nothing more than a "predictable use of prior art elements according to their established functions." *In re Ethicon, Inc.*, 844 F.3d 1344, 1349 (Fed. Cir. 2017) ("103 likely bars patentability unless 'the improvement is more than the predictable use of prior art elements according to their established functions.'").

Further, a POSA would have had a reasonable expectation of success in making this improvement and maintaining the uniformity of "at least within 60% of the measured maximum" required by the claims and disclosed by Lundahl. RX-0006C, Q/A321; Order No. 18, 13. Initially, the level of uniformity required by the claims is not high – allowing up to a 40% variation from the maximum value. Further, Lundahl had already achieved this level of uniformity, in 1998, with inferior fluorescent technology. RX-0065, 15:22-27; RX-0006C, Q/A179. A POSA would have had a reasonable expectation of success in adapting an existing device to achieve the same goal (i.e., uniformity within 60%) with more modern electronics and flexibility. *See Muniauction, Inc. v. Thompson Corp.*, 532 F.3d 1318, 1326-27 (Fed. Cir. 2008).

1. The Prior Art

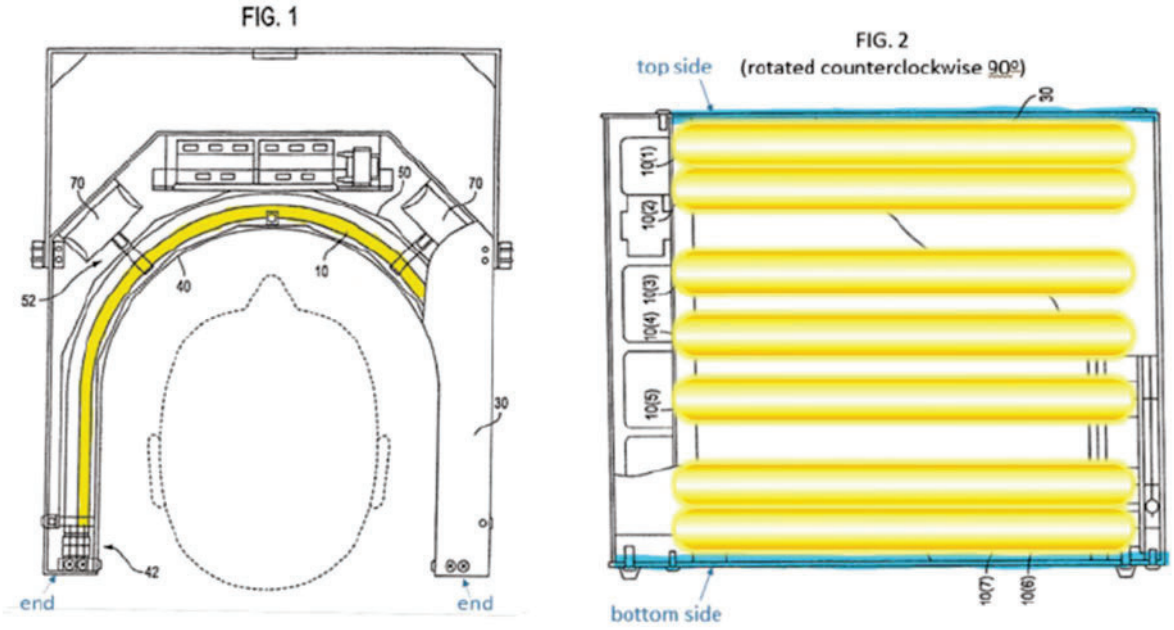
a. Lundahl incorporating Kennedy

Lundahl was filed on May 1, 1998, and issued on April 24, 2001. Lundahl qualifies as prior art under §102(a)(1) because it was published before the earliest effective filing date of the Asserted Patents. RX-0006C (Grove), Q/A87-88.

Lundahl teaches an apparatus and method for PDT of, e.g., a patient's face and head, using an illuminator comprising a plurality of light sources. RX-0065, Abstract. Lundahl preferably uses fluorescent tubes as the light sources (RX-0065, 5:22-24), which were at the time "the best available technology" for this application. JX-0017C (Lundahl), 36:7-9.

Lundahl discloses that its device provides "a uniform distribution of visible light." RX-0065, 1:9-11; RX-0006C, Q/A89. More specifically, Lundahl teaches that its device is designed to achieve uniform illumination of a treatment surface, when the device is positioned at 2 inches and 4 inches from that surface, stating that "according to a preferred embodiment of the present invention, the measured output over the active emitting area is within 70% of the measured maximum when measured with a cosine response detector at distances of 4″ and 2″." RX-0065, 15:22-27; RX-0006C, Q/A99.

Lundahl explains that one challenge in achieving a uniform illumination of a treatment surface, such as a patient's face and head, is "the fact that the output from a flat plane emitting light source drops near the edges." RX-0065, 6:25-27. To compensate for this "fall off effect," Lundahl discloses "[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." RX-0065, 6:25-30; RX-0006C, Q/A95. Lundahl explains that "uniformity can also be adjusted by varying the lateral spacing of the tubes (relative [vertical] spacing as shown in FIG. 2 [as depicted below, annotated and rotated 90 degrees counterclockwise])." RX-0065, 6:16-25; RX-0006C, Q/A94.



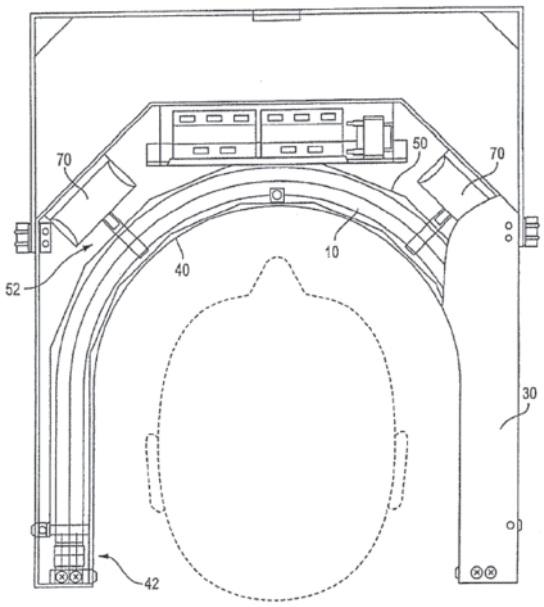
RDX-0017C.012; RX-0065, Figs. 1-2 (annotated). Specifically, Lundahl teaches arranging light sources in a higher density near the top and bottom of the device (i.e., near the forehead and chin of a patient's head) in order to improve uniformity of irradiance on the treatment surface. RX-0006C, Q/A97. Lundahl illustrates this distribution in Figure 2 and discloses exemplary values for light source spacing. RX-0065, 6:45-57; RX-0006C, Q/A213-214. A POSA would have understood that Lundahl's light sources are spaced to emit a higher intensity of light proximate the top and bottom edges compared to the intensity of light emitted not proximate these edges, and that this "provides a highly uniform output irradiance." RX-0006C, Q/A94-95, 97, 321.

Lundahl states that "[t]he number of tubes used and the spacing between them were chosen to achieve desired uniformity and power output specifications....The present invention provides a highly uniform output irradiance without the use of an additional diffusing element." Lundahl, 6:43-57; RX-0006C, Q/A95-97. Importantly, Lundahl states that other design elements were not needed to achieve the desired uniform illumination. RX-0006C, Q/A214. The spacing of lights provided the "desired uniformity" because the higher density of light bulbs at the top and bottom

compensates for the fall off effect at the edges of the illuminator, as well as for the lowered absorbance at the treatment surface resulting from the head's curvature away from the illuminator. RX-0006C, Q/A97.

Lundahl also discloses that "the present invention uses a U-shaped emitting surface that more closely follows the contours of the human face and scalp, and minimizes lamp to target distance variations which in turn minimizes irradiance variations at the target." RX-0065, 4:33-38, 6:31-35; RX-0006C, Q/A92. Lundahl illustrates the positioning of the patient's head and nose within the device in Figure 1. RX-0006C, Q/A96.

FIG. 1



RX-0065, Fig. 1. Lundahl explains that "the tube dimensions were chosen based on the average dimensions of the adult human head." RX-0065, 6:31-35; RX-0006C, Q/A98.

Lundahl additionally discloses a control system for its illuminator device including a visible light sensor to monitor fluorescent tube output and a corresponding microcontroller to adjust light output. RX-0065, 11:19-29. Lundahl also teaches a cooling system incorporating fans,

which is "provided to ensure proper [fluorescent] bulb operation." RX-0065, 9:13-18; RX-0006C, Q/A265.

Lundahl is from the same field of endeavor as the Asserted Patents – illuminators for PDT. JX-0002, 1:26-2:6; JX-0001, 1:24-2:4. Lundahl is also directed to the same problem as the Asserted Patents, namely, providing a PDT device for treatment of AKs. RX-0006C, Q/A90. Therefore, Lundahl is analogous art. RX-0006C, Q/A91.

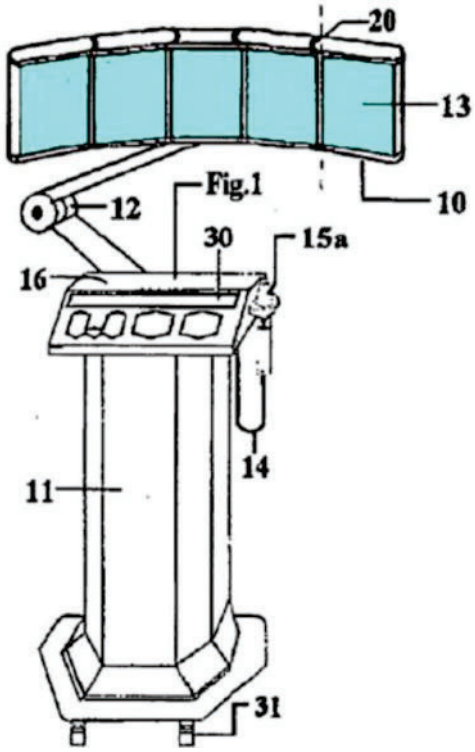
b. Larsen

Larsen was published on April 7, 2005, claiming priority back to January 22, 2001. Larsen qualifies as prior art under §102(a)(1) because it was published before the earliest effective filing date of the Asserted Patents. RX-0006C, Q/A105-106.

Larsen teaches devices and methods for PDT. RX-0006C, Q/A107; RX-0099 (Larsen), [0001]. More specifically, Larsen teaches PDT to address skin conditions including "solar keratoses, basal cell carcinoma, melanomas, etc." using topically applied substances including "5-aminolevulan acid." RX-0099, [0011]; RX-0006C, Q/A107.

Larsen teaches use of semiconductor (LED) light sources mounted on multiple panels connected with hinges. RX-0006C, Q/A110. Larsen calls its panels "applicators." RX-0006C, Q/A110. "The plain surface applicators can consist of several applicators placed side by side and flexibly connected with each other through hinges, whereby the applicators are suitable for the treatment of large-area tissues such as the human back. The applicators contain printed circuit boards mounted with semiconductor diodes and/or laser diodes (in large numbers)...." RX-0099, [0027]-[0028]. Semiconductor diodes are another term for light emitting diodes (LEDs). RX-0006C, Q/A110. Larsen describes that panels connected with hinges allow placement of panels equidistant from the skin surface and prevention of gaps in irradiance of the skin. RX-0099, [0072]; RX-0006C, Q/A111-

113. Larsen's multipaneled, hinged device is illustrated in Figure 1. RX-0099, Fig. 1; RX-0006C, Q/A110.



Larsen is from the same field of endeavor as the Asserted Patents – illuminators for PDT. JX-0002, 1:26-2:6; JX-0001, 1:24-2:4. Larsen is also directed to the same problem as the Asserted Patents, namely, providing an illuminator that can provide an "even and gap-free radiation of the surface." Larsen, [0028]. Therefore, Larsen is analogous art. RX-0006C, Q/A108-109.

c. Hente

Hente claims priority to May 2, 2007, and was published on May 13, 2010. Hente qualifies as prior art under §102(a)(1) because it was published before the earliest effective filing date of the Asserted Patents. RX-0006C, Q/A125-126.

Hente is directed to illumination devices comprising organic light emitting diodes (i.e., organic LEDs or OLEDs) that are adjustable or foldable. RX-0576 (Hente), Abstract. Hente

explains that conventional illumination devices did not have the desired flexibility to adjust for different sizes of areas to be illuminated. RX-0576, [0002], [0004]; RX-0006C, Q/A128.

As a solution, Hente teaches illuminators that have the flexibility to "illuminate large and point-like limited areas." RX-0576, [0005]. Hente discloses illuminators with at least a first and second section. RX-0576, Abstract. Hente explains that these illuminators can be expanded to provide a flat emitting surface "to illuminate large areas" (RX-0576 [0036]; RX-0006C, Q/A128) or be folded into a smaller, "compact" position. RX-0576, [0037]; RX-0006C, Q/A128-129.

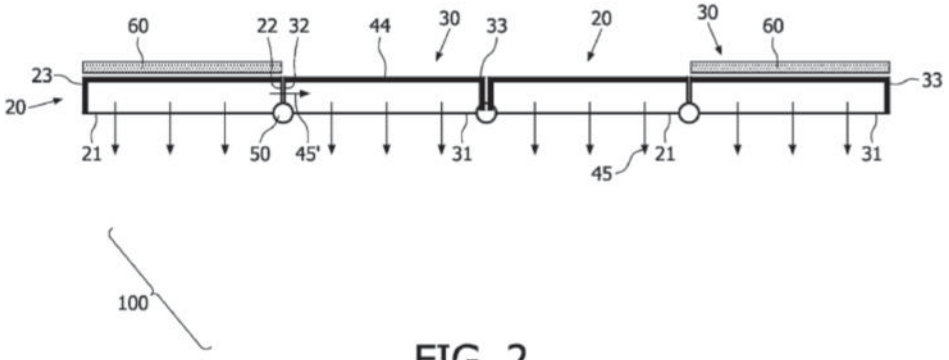
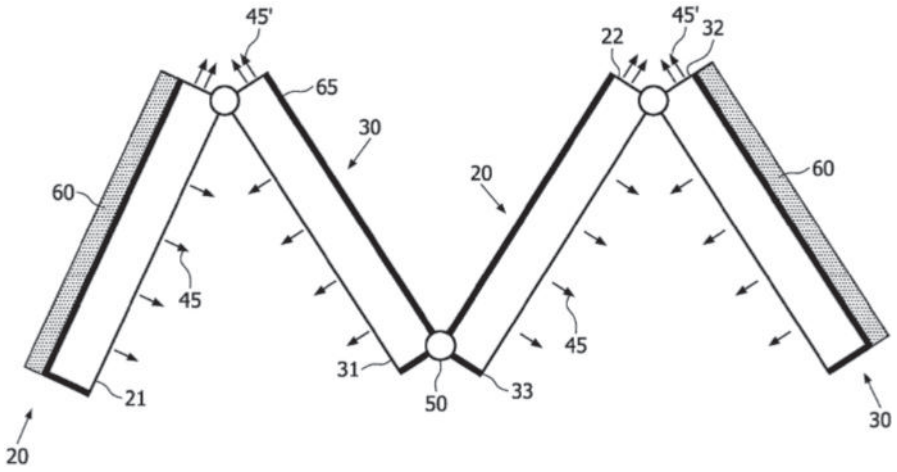


FIG. 2

RX-0576, Fig. 2.

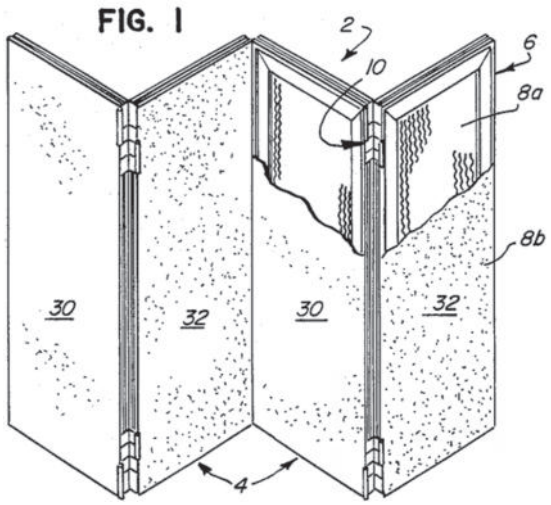


RX-0576, Fig. 3.

d. Perutz

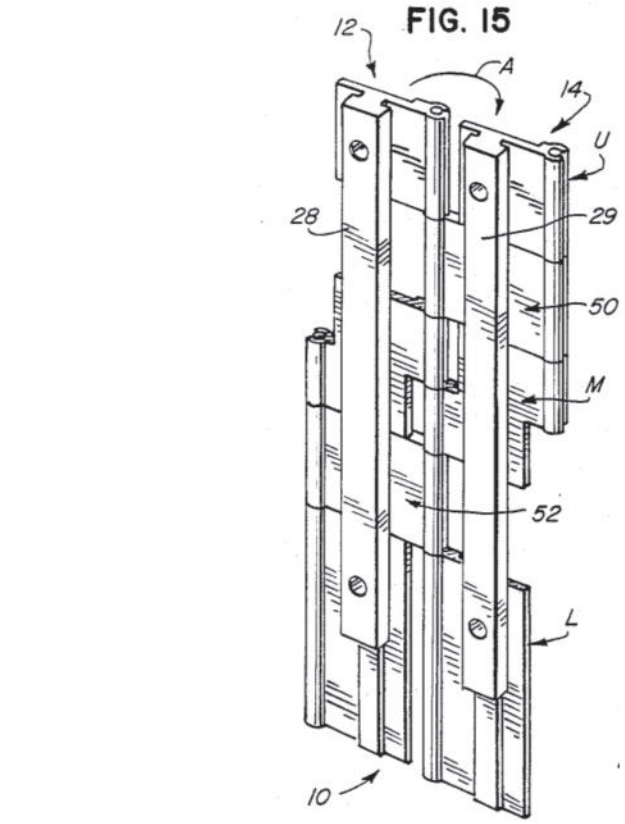
Perutz was filed on June 02, 1987, and issued April 25, 1989. Perutz qualifies as prior art under §102(a)(1) because it was published before the earliest effective filing date of the '512 Patent. RX-0006C, Q/A134-135.

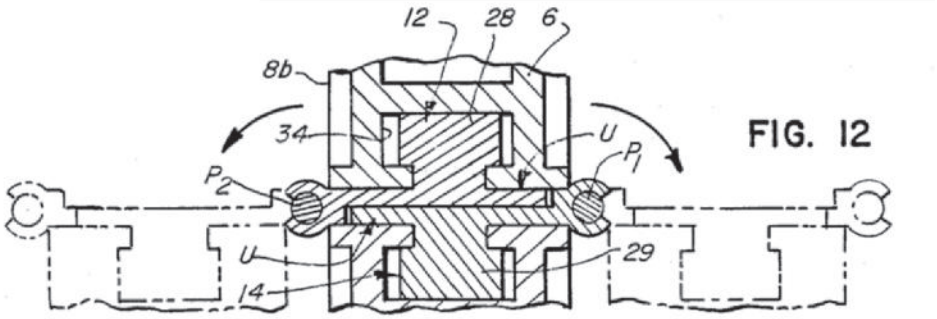
Perutz discloses "a plurality of display panels arranged in side-by-side relation and hingedly interconnected whereby one of the panels is capable of being selectively rotated relative to the other panel through a maximum arc of substantially 360°." RX-0607 (Perutz), Abstract; RX-0006C, Q/A136.



RX-0607, Fig. 1.

Perutz is directed to the challenge of connecting panels via hinges. RX-0006C, Q/A137. As a solution, Perutz teaches providing hinges 10 on the inner side surfaces of adjacent panels, which are received in a recess to reduce space between panels. RX-0607, Abstract, Figs. 12 and 15, 3:54-66, 4:16-20, 4:33-38; RX-0006C, Q/A137. In Figures 15 and 12, ribs 28 and 29 of hinges 10 are received within slots 34 of the panels. RX-0607, 4:16-20, 4:33-38; RX-0006C, Q/A137.





RX-0607, Figs. 15, 12.

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

Each element of the Asserted Claims is disclosed or rendered obvious by the prior art, as summarized below.

a. "Preamble Limitation"

Claims 1, 16, 20, and 21 of the '028 Patent and claims 1, 8, and 20 of the '512 Patent each recite "the preamble limitation." JX-0002, cls. 1, 16, 20, 21; JX-0001, cls. 1, 8, 20. RX-0006C, Q/A141.

Claim Language- Preamble	**Claims**
"a system for photodynamically diagnosing or treating a patient"	Claims 1, 16, 20, 21 ('028 Patent)
"a system for photodynamically diagnosing or treating a patient"	Claims 1, 20 ('512 Patent)
"a method of photodynamically diagnosing or treating a patient"	Claim 8 ('512 Patent)

The preamble limitation is not disputed. CIUCL, 2-3, 5.

b. Five Panels Connected by Hinges on Inner Side Surfaces ("Hinges Limitation")

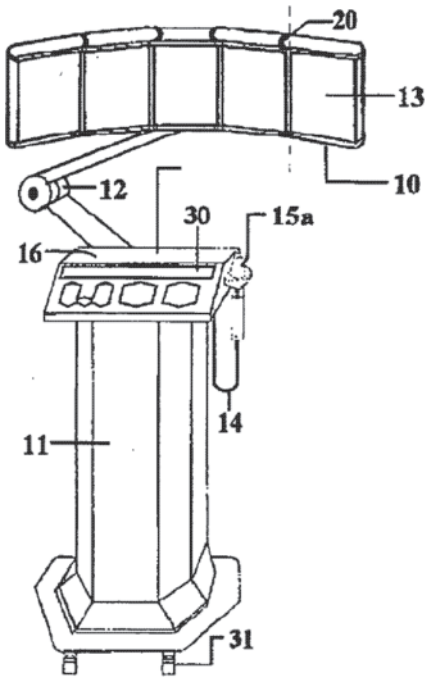
Claims 1, 16, 20, and 21 of the '028 Patent and claims 1, 8, and 20 of the '512 Patent each recite the "hinges limitation." JX-0002, cls. 1, 16, 20, 21; JX-0001, cls. 1, 8, 20. RX-0006C, Q/A145.

Claim Language — Hinges Limitation	**Claims**
"an illuminator comprising five panels connected by hinged structures on inner side surfaces of adjacent panels"	Claims 1, 20, and 21 ('028 Patent)

Claim Language — Hinges Limitation	Claims
"five panels connected by hinged structures"	Claim 16 ('028 Patent)
"an illuminator comprising at least five panels connected by *nested hinges* on inner side surfaces of adjacent panels"	Claim 1 ('512 Patent)
"an illuminator comprising at least five panels connected by *nested hinges* on inner side surfaces of adjacent panels, the nested hinges being configured so as to allow continuous illumination across the at least five panels"	Claim 20 ('512 Patent)
"the illuminator comprising at least five panels connected by *nested hinges* on inner side surfaces of adjacent panels"	Claim 8 ('512 Patent)

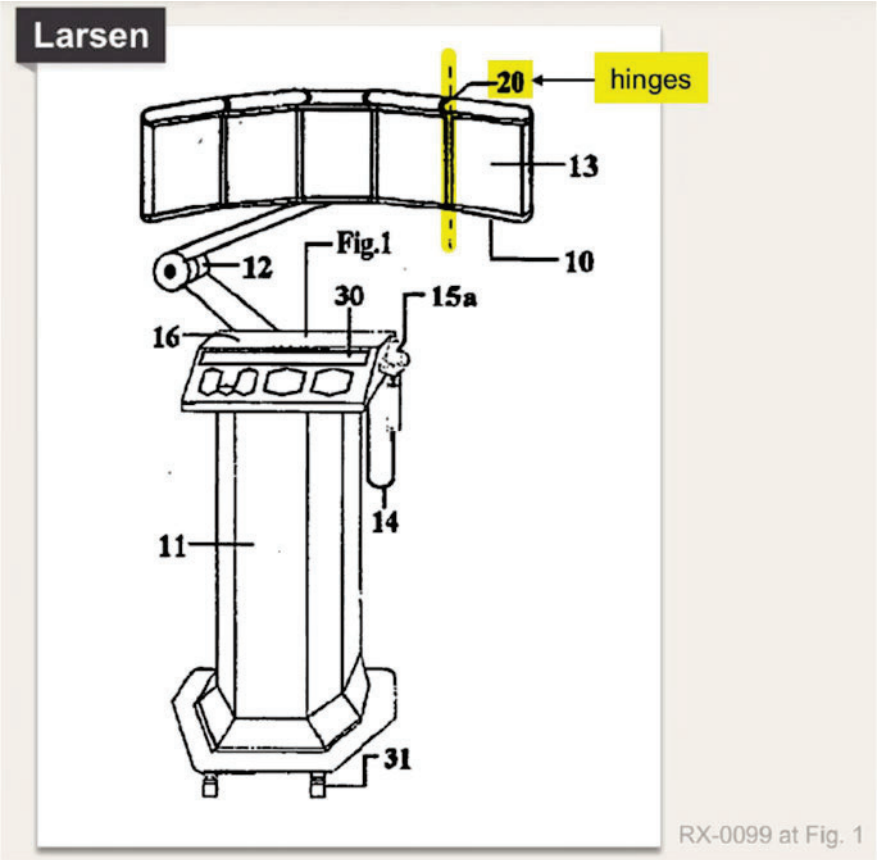
"Nested hinges" was construed to mean "hinges that fit on inner side surfaces of adjacent panels." Order No. 18, 35. Larsen individually, or Larsen further in view of Hente, teaches and renders obvious the hinges limitation. RX-0006C, Q/A149-164.

Larsen's illuminator has five panels. RX-0099, Fig. 1.



Larsen teaches that "for the treatment of large-area tissues according to Fig. 1, several applicators 13 are flexibly connected to each other through ***hinges 10***. . .." RX-0099, [0072] (emphasis added). However, as admitted by Dr. Jokerst, in paragraph [0069], Larsen identifies element number 10 as corresponding to "the ***invented device 10***." RX-0099, [0069] (emphasis added); Tr.(Jokerst), 743:14-21. Accordingly, it is clear that one of these passages must contain a typographical error. RX-0006C, Q/A151.

As Dr. Grove testified, a POSA would understand that the most logical location for hinges connecting panels would be between the panels in the location identified by number element 20. Tr.(Grove), 592:2-5; RX-0006C, Q/A151-153. Accordingly, the most likely scenario is that the "10" illustrated in Figure 1 refers to the invented device, while the reference to "hinges 10" was the typographical error. RX-0006C, Q/A149-153; RX-0099, Fig. 1.



RDX-0017C.024; RX-0099, Fig. 1.

The examiner of the Asserted Patents concurred with this conclusion. During prosecution of the '512 Patent, the examiner explicitly noted that Larsen's hinges had been erroneously labeled as element number 10 in the specification while being correctly shown as element number 20 in the Figures. JX-0004.160 ('512 File History) ("***hinges 20*** (indicated as 10 in the specification, but shown as element 20 in the Figures)....") (emphasis added); Tr.(Jokerst), 744:6-15; RX-0006C, Q/A152.

Further, Larsen notes that its panels "are flexibly connected to each other through hinges... ***connecting one edge with the other***." RX-0099, [0027] (emphasis added). The description of hinges as connecting edges of adjacent panels indicates that the hinge is located between the inner

side surfaces – which is exactly where element number 20 is illustrated in Figure 1. RX-0006C, Q/A153.

In fact, element number 20 is only referenced one time in Larsen's disclosure, where Larsen states that, "[a]ccording to FIGS. 2b and 2c the light sources 17 are placed in regular row arrangements, i.e., ***20...***" RX-0099, [0071] (emphasis added). However, as admitted by Dr. Jokerst, there is no element "20" illustrated in any of Figures 2b-c. RX-0099, Figs. 2b-c; RX-0006C, Q/A154; Tr.(Jokerst), 746:6-19. Further, element number 20 indicates a location between panels, which does not make sense as a location for "regular row arrangements" of light sources. RX-0006C, Q/A154.

As "hinges 10" is a typographical error and the hinges are actually indicated by element number 20, Figure 1 of Larsen discloses an illuminator comprising at least five panels connected by hinges on inner side surfaces of adjacent panels. RX-0006C, Q/A156.

However, even if Figure 1 does not explicitly teach hinges 20, it would have been obvious for a POSA to arrive at hinges located on inner side surfaces. RX-0006C, Q/A157. First, Figure 1 of Larsen shows that the inner edges of each of the panels (13) are nearly flush with each other. *Id*. This would have motivated a POSA to place the hinges on the inner side surfaces of panels in order to facilitate this nearly flush arrangement. *Id*. Such a modification would have involved nothing more than the use of a known prior art element according to known methods to yield predictable results. *Id*.

Second, there were "a finite number of identified, predictable solutions," *KSR Intern. Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007), for Larsen's panels to be "flexibly connected to each other through hinges," as testified by Dr. Grove and as recognized by the PTAB in its decision to institute IPR2024-01312 (challenging the validity of the '028 Patent). RX-0006C, Q/A157;

Tr.(Jokerst), 744:20-745:22. Specifically, there are only three options for locations where the hinges can be located to connect adjacent panels: (1) between adjacent panels; (2) on the top and bottom of the panels; and (3) on the rear surface of the panels. Tr.(Grove), 591:5-7; RX-0006C, Q/A157. A POSA would have viewed any of these limited options as obvious, including placing hinges on the inner side surfaces of the panels. RX-0006C, Q/A157; *Teva Pharms. U.S.A., Inc. V. Sandoz, Inc.,* 906 F.3d 1013, 1025 (Fed. Cir. 2018) (finding claims to a dosing regimen obvious to try where "a POSITA had only a limited number of permutations of dose and frequency to explore."). What is more, a POSA would have known that the most common option for locating a hinge to connect panels would be on inner side surfaces of panels. Tr.(Grove), 592:2-8.

The additional 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. RX-0006C, Q/A158. As discussed, Larsen discloses or renders obvious "nested hinges," which allow for minimization of the gap between panels as illustrated in Figure 1, which is a configuration that would "allow continuous illumination across the at least five panels." RX-0006C, Q/A158.

Additionally, Hente discloses positioning hinges between, and on inner side surfaces of, adjacent panels. RX-0006C, Q/A159. Hente teaches an illuminator "which possesses two different positions, each resulting in a different type of illumination. In the expanded position the light emitting device forms a longish stretched large area illumination device...The sections of the light emitting device may also be arranged in a V- or a W-form, depending on the type of use." RX-0576, [0011]. Hente's device bends along the connection point between panels. RX-0006C, Q/A160.

Hente includes connection means 50 between adjacent panels, which "[i]n a preferred embodiment...may be a hinges [sic]...***the hinges may be positioned between two rims of the first and the second section, facing each other***." RX-0576, [0015] (emphasis added). The "first and second section" referenced in this passage corresponds to first section 20 and second section 30 illustrated in Figure 2. Additionally, Hente explains that the "rims" are represented by 23 and 33. RX-0576, [0048], [0052].

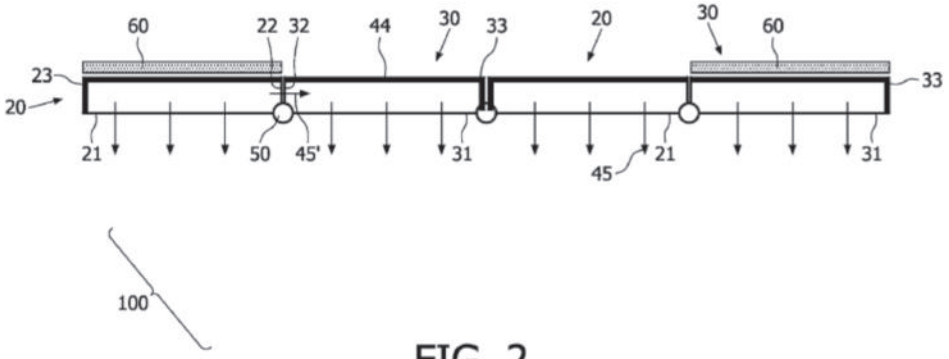
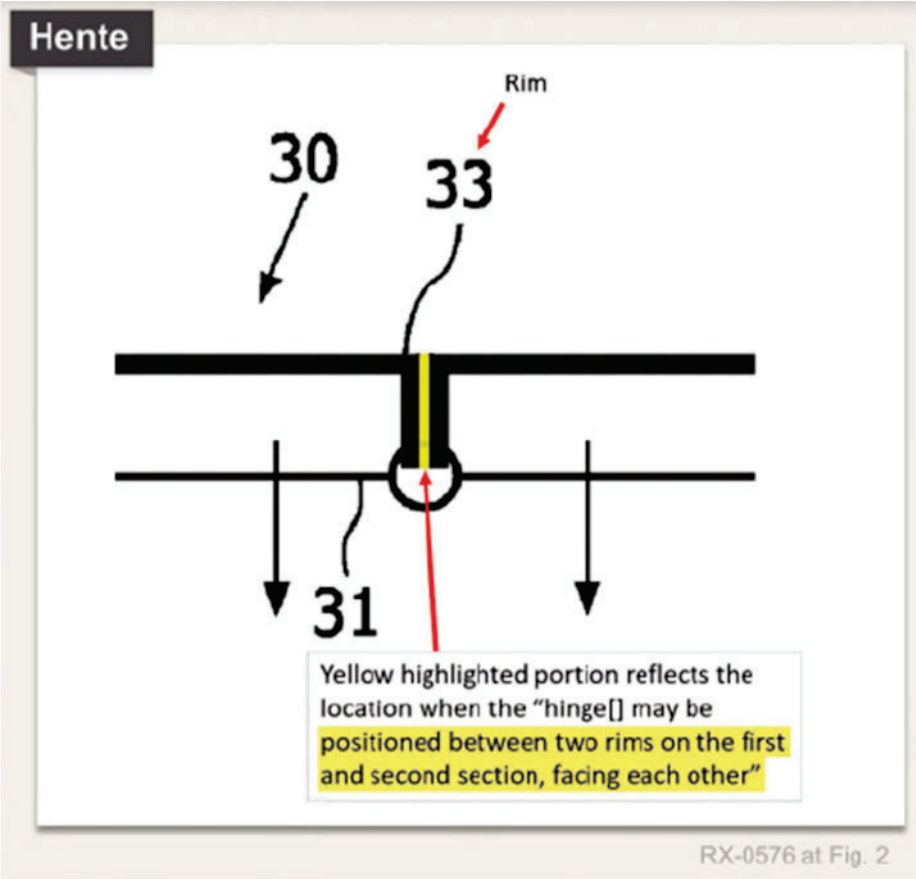


FIG. 2

RX-0576, Fig. 2.

As testified by Dr. Grove (and illustrated below), Hente discloses placement of a hinge between two rims of the first and second section, facing each other, meeting the requirement of a "hinge[] that fits on inner side surfaces of adjacent panels." RX-0006C, Q/A161.



RDX-0017C.028 (excerpt); RX-0576, Fig. 2.

Accordingly, Larsen, or Larsen further in view of Hente, disclose and render obvious the "hinges" limitation. RX-0006C, Q/A164.

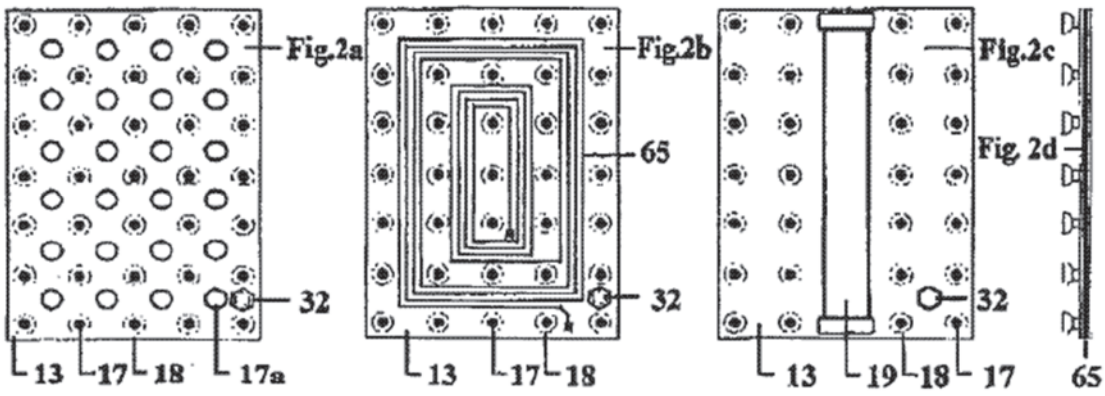
c. "Light Sources Limitation"

Claims 1, 16, 20, and 21 of the '028 Patent and claims 1, 8, and 20 of the '512 Patent each recite the "light sources limitation." JX-0002, cls. 1, 16, 20, 21; JX-0001, cls. 1, 8, 20. RX-0006C, Q/A165.

Claim Language — Light Sources Limitation	Claims
"light sources disposed on surfaces of the five panels"	Claims 1, 16, 20, 21 ('028 Patent)

Claim Language — Light Sources Limitation	Claims
"light sources disposed on surfaces of the at least five panels"	Claims 1, 20 ('512 Patent)
"light sources disposed on the at least five panels of the illuminator"	Claim 8 ('512 Patent)

Larsen discloses that light sources are disposed on the surfaces of five panels. RX-0099, [0070], Figs. 2a-d; RX-0006C, Q/A167-171.



RX-0099, FIGS. 2a-d. Larsen discloses that these light sources are LEDs. RX-0006C, Q/A170. Accordingly, Larsen discloses the "light sources" limitation. RX-0006C, Q/A171.

d. "Uniform Illumination Limitation"

Claims 1, 16, 20, and 21 of the '028 Patent and claims 1, 8, and 20 of the '512 Patent each recite the "uniform illumination limitation." JX-0002, cls. 1, 16, 20, 21; JX-0001, cls. 1, 8, 20. RX-0006C, Q/A172.

Claim Language — Uniform Illumination Limitation	Claims

"the illuminator being configured to uniformly illuminate a treatment surface of the patient via the light sources"	Claims 1, 16, 20, 21 ('028 Patent)
"the illuminator being configured to uniformly illuminate a treatment surface of the patient via the light sources"	Claims 1, 20 ('512 Patent)
"uniformly illuminating a treatment surface of the patient"	Claim 8 ('512 Patent)

"Uniformly illuminate"/"uniformly illuminating" was agreed to mean "irradiating light over the active emitting area such that the measured irradiance at a treatment surface of the patient is at least within 60% of the measured maximum." (Order No. 18, 13).

Lundahl discloses this limitation verbatim, stating "according to a preferred embodiment of the present invention, the measured output over the active emitting area is within 70% of the measured maximum when measured with a cosine response detector at distances of 4" and 2", and within 60% of the measured maximum over all operation distances." RX-0065, 15:22-26; *see also* RX-0065, 1:9-11; RX-0006C, Q/A176-185.

Lundahl teaches manipulating its light source spacing to achieve this uniformity. RX-0006C, Q/A177-178. Lundahl explains that "uniformity 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. Lundahl states that

"[t]he number of tubes used and the spacing between them were chosen to achieve desired uniformity and power output specifications," disclosing that the uniform illumination is achieved by spacing light sources to have greater density of lighting near the top and bottom of edges. RX-0065, 6:43-57. Accordingly, a POSA would be motivated to incorporate Lundahl's light source distribution in combination with Larsen's LED panels in order to achieve uniform illumination. RX-0006C, Q/A215.

While Sun has asserted that, to achieve uniformity, four features of Lundahl must be incorporated in combination with Larsen's LED panels (CPHB, 147-149), this argument is logically flawed. Sun identifies the following features as contributing to Lundahl's uniformity – U-shaped tubes, a reflector, a specific electrical control system, and a specific cooling system. CPHB, 147. Sun conveniently omits the light source distribution that Lundahl identifies as contributing to uniformity, as explained above. Among the properly enumerated ***five*** features contributing to uniformity, three of these – the reflector, specific electrical control system, and specific cooling system – are only needed to solve uniformity issues specific to fluorescent tubes, meaning that they would be rendered unnecessary once fluorescent tubes are replaced by superior LED technology.

Taking these in order, Lundahl provides a reflector positioned behind "the rear surface of the tubes" (RX-0065, 8:65-67) because "fluorescent tubes put out light 360 degrees around the circumference of the tube...if you're trying to illuminate a surface, you don't want to waste the light going away from your subject." Tr.(Grove), 593:9-22. However, as a POSA would have appreciated prior to 2015, "LEDs put out light in basically one direction." *Id*.

Similarly, Lundahl discloses an electrical control system tailored to address flaws in fluorescent tubes. RX-0065, 7:10-8:60. Specific electrical systems are necessary because

"[f]luorescent tubes, being gas discharge devices, are particularly sensitive to the electrical voltages and currents used to drive them." RX-0065, 7:14-31. Lundahl notes that "higher currents result in higher cathode temperatures, potentially increasing the erosion of the cathode emitting material and contamination of the tube atmosphere..." RX-0065, 7:18-23. On the other hand, "[t]ube currents that are too low can result in low tube wall temperatures that may cause condensation of the mercury vapor, adversely affecting the uniformity of the lamp output." RX-0065, 7:23-26. In contrast, LEDs do not utilize the same cathodes and do not rely upon tubes or mercury vapor to produce light. Accordingly, the same electrical systems are not needed to manage these problems.

Finally, Lundahl explains that "[s]ince cathode and tube wall temperatures strongly affect the output distribution, a cooling system is provided to ensure proper bulb operation." RX-0065, 9:13-16. Specifically, Lundahl notes that fluorescent tubes produce an uneven light output along their length due to variations in "phosphor coating thickness caused by the bending process" of the tubes. RX-0065, 9:39-43. Accordingly, Lundahl teaches a system to selectively cool different portions of the tube to produce a "hotter central region of the tube [which] produces higher output irradiances...and compensates for the lower emission efficiency of the central region" resulting from a thicker phosphor coating. RX-0065, 9:43-54. LEDs do not utilize tubes, do not have phosphor coatings, and therefore do not have the problem of output variation along a tube based on coating thickness and temperature. Accordingly, as a POSA would have appreciated prior to 2015, the same cooling systems are not necessary for LEDs. Tr.(Grove), 594:17-595:6.

As recognized by Dr. Jokerst, a POSA would not typically incorporate the shortcomings of a prior device when developing a new device (Tr.(Jokerst), 768:10-13) and therefore would similarly find it unnecessary to incorporate their solutions – including reflectors, specific electrical

systems, and specific cooling systems. Instead, a POSA would logically only retain components that still provide utility in an LED device – in this case, Lundahl's U-shape and its light source distribution. While the proposed combination of Lundahl and Larsen does not incorporate a fixed U-shape, it does contain a configuration capable of conforming to a treatment surface, as Lundahl's U-shape is 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. A POSA would be capable of analyzing and parsing relevance of disclosed features in order to make the proposed combination. *PGS Geophysical AS v. Iancu*, 891 F.3d 1354, 1366 (Fed. Cir. 2018) (rejecting the idea that a POSA would blindly incorporate all aspects of a prior art methodology).

Accordingly, Lundahl and Larsen disclose and render obvious the "uniform illumination" limitation. RX-0006C, Q/A185.

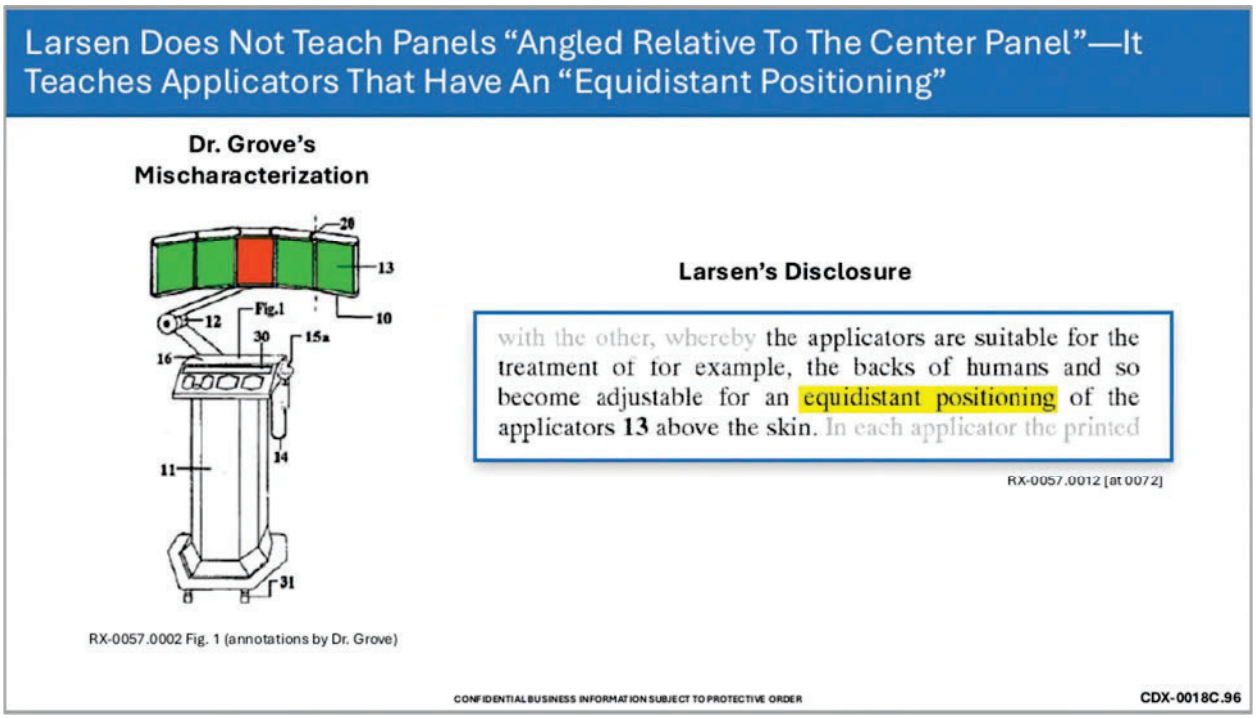
e. Center Panel with Two or More Panels Angled Relative to Center Panel ("Center Panel Limitation")

Claims 1, 17, 20, and 21 of the '028 Patent and claims 1 and 20 of the '512 Patent each recite the "center panel limitation." JX-0002, cls. 1, 17, 20, 21; JX-0001, cls. 1, 20. RX-0006C, Q/A186.

Claim Language — Center Panel Limitation	**Claims**
"one of the five panels being positioned as a center panel configured to face the treatment surface, and being configured to be angled relative to the center panel"	Claims 1, 20, 21 ('028 Patent)

"one of the five panels is positioned as a center panel configured to face the treatment surface, and two or more of the five panels are configured to be angled relative to the center panel"	Claim 17 ('028 Patent)
"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"	Claims 1, 20 ('512 Patent)

Larsen discloses the center panel limitation. RX-0006C, Q/A188-192. Larsen clearly depicts two or more panels angled around a center panel in its Figure 1 (RX-0099, Fig. 1, [0072]) and Dr. Jokerst admits as much. Referencing CDX-0018C.96, Dr. Jokerst admitted that Figure 1 shows a central panel (illustrated in orange) with panels angled around it (illustrated in green). Tr.(Jokerst), 738:13-739:2.



CX-0014C.83-84; CDX-0018C.96; RX-0057, [0072], Fig. 1. Accordingly, Larsen discloses the "center panel" limitation. RX-0006C, Q/A192.

f. "Within Approximately Four Inches Limitation"

Claims 1, 20, and 21 of the '028 Patent each recite the "within approximately four inches limitation." JX-0002, cls. 1, 20, 21. RX-0006C, Q/A193.

Claim Language — Within Approximately Four Inches Limitation	**Claims**
"wherein the five panels are positioned to allow treatment within approximately four inches of the treatment surface"	Claims 1, 20, 21 ('028 Patent)

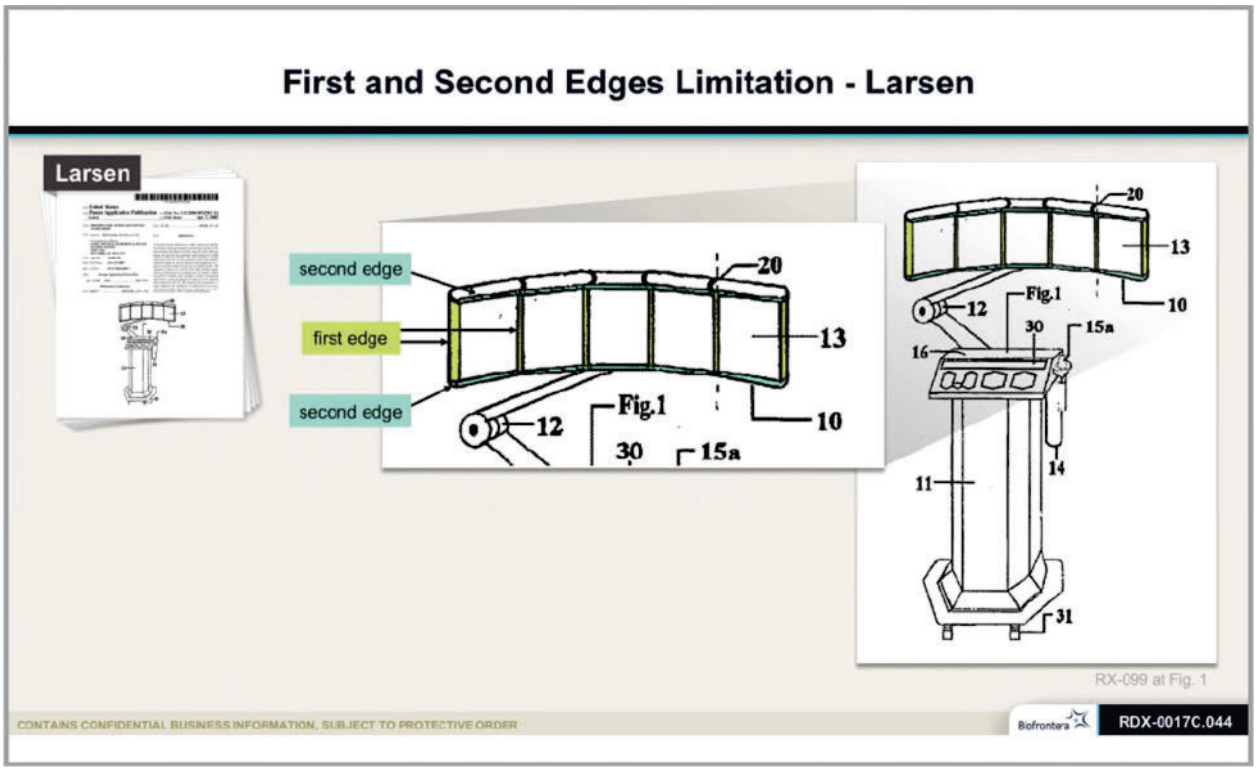
The within approximately four inches limitation is not disputed. CIUCL, 5.

g. "First and Second Edges Limitation"

Claims 1, 16, 20, and 21 of the '028 Patent and claims 1, 8, and 20 of the '512 Patent each recite the "first and second edges limitation." JX-0002, cls. 1, 16, 20, 21; JX-0001, cls. 1, 8, 20. RX-0006C, Q/A202.

Claim Language — First and Second Edges Limitation	**Claims**
"each of the five panels has two first edges and two second edges shorter than the two first edges"	Claims 1, 20, 21 ('028 Patent)
"each of the five panels having two first edges and two second edges shorter than the two first edges"	Claim 16 ('028 Patent)
"each of the at least five panels has two first edges and two second edges shorter than the two first edges"	Claims 1, 8, 20 ('512 Patent)

Larsen discloses the first and second edges limitation. RX-0006C, Q/A204-207. Figure 1 of Larsen shows five panels (13) having two first edges (vertical) and two second edges (horizontal), which are shorter than the first edges. RX-0099, Fig. 1; RX-0006C, Q/A206.



RDX-0017C.044; RX-0099, Fig. 1. Accordingly, Larsen discloses the "first and second edges" limitation. RX-0006C, Q/A207.

h. Higher Intensity of Light Proximate Second Edges Compared to Not Proximate Second Edges ("Higher Intensity Proximate Second Edges Limitation")

All of the Asserted Claims recite the "higher intensity proximate second edges limitation." JX-0002, cls. 1, 16, 20, 21; JX-0001, cls. 1, 8, 20. RX-0006C, Q/A208.

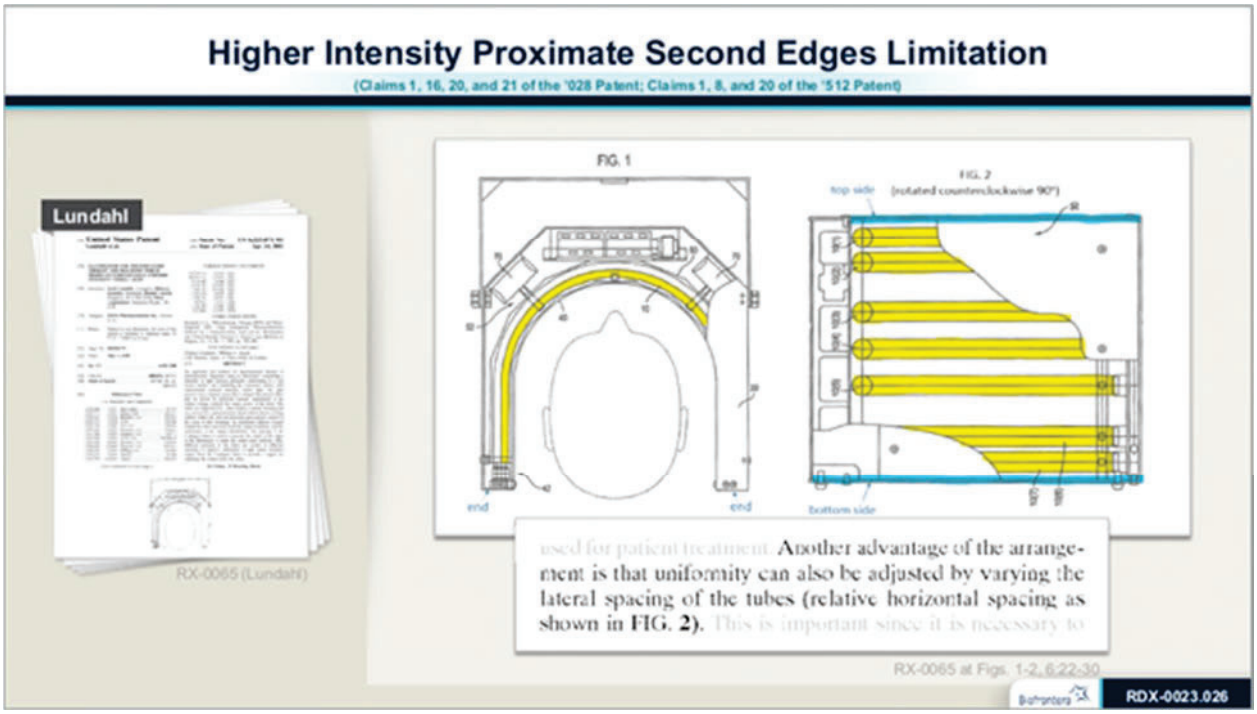
Claim Language — Higher Intensity Proximate Second Edges Limitation	**Claims**
"the light sources are arranged such that a higher intensity of light is emitted proximate the second	Claims 1, 16, 20, 21 ('028 Patent); Claims 1, 8, 20 ('512 Patent)

Claim Language — Higher Intensity Proximate Second Edges Limitation	Claims
edges compared to the intensity of light emitted not proximate the second edges"	

This limitation was construed to mean "a higher intensity of light is emitted close to the second shorter edges compared to the intensity of light emitted not close to the second shorter edges." Order No. 18, 23.

Lundahl discloses the "higher intensity proximate second edges" limitation[6] and it would be obvious to incorporate this teaching in combination with Larsen. RX-0006C, Q/A209-220. As discussed above, *supra* Section VI.A.1.a., Lundahl teaches arranging light sources in a higher density near the top and bottom edges of its device (i.e., near the forehead and chin of a patient's head) to improve uniformity of irradiance on the treatment surface. RX-0006C, Q/A95, 213-214; RX-0065, Figs. 1-2, 6:22-30, 6:48-57. A POSA would have understood that this distribution provides higher intensity emission close to the top and bottom edges compared to the intensity emitted not close to the top and bottom edges. RX-0006C, Q/A94-95, 97, 321; Tr.(Grove), 565:4-8. Dr. Jokerst agrees – "Q: And when the Lundahl device is used as shown in Figure 1, the device has a higher intensity of light emitted at the regions near the patient's forehead and chin, correct? A: Yes, in the curved region, which would be near the forehead and chin, yes." Tr.(Jokerst), 740:25-741:5.

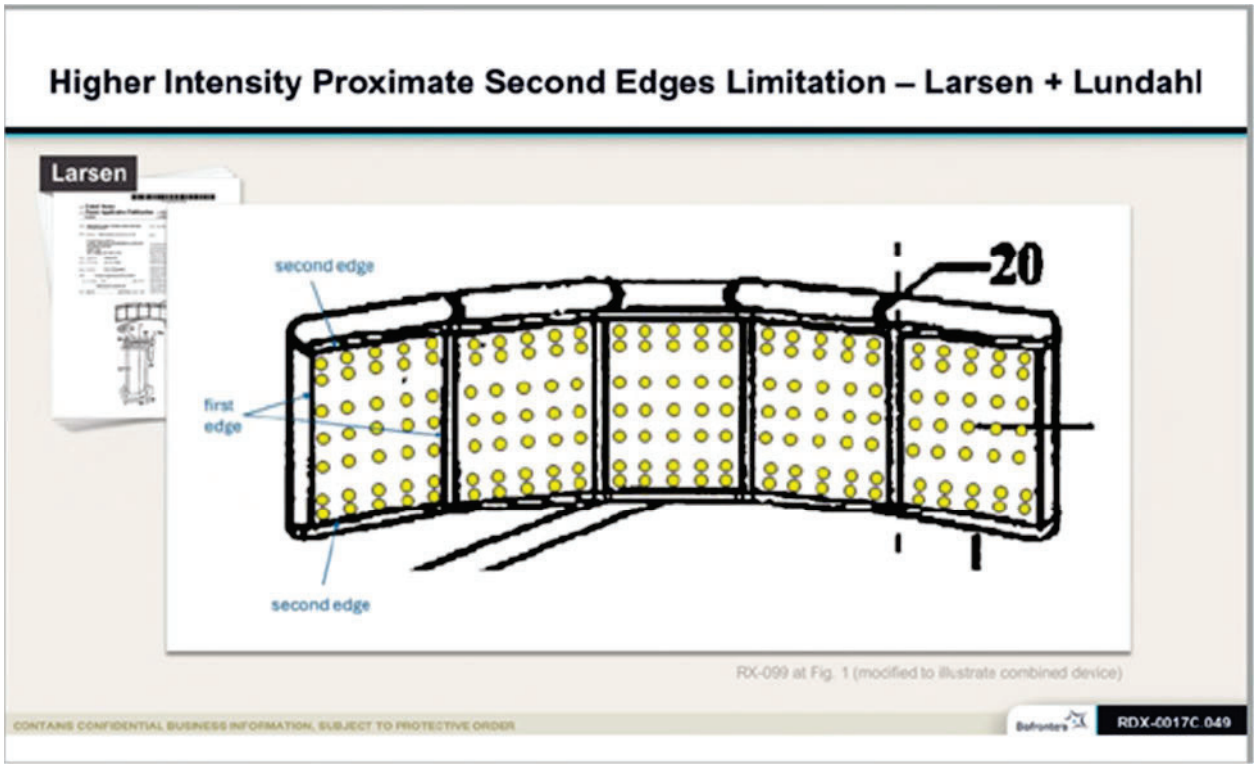
[6] Sunhas asserted that Biofrontera's RhodoLED® XL allegedly meets this claim limitation. RX-0006C, Q/A213. Using Sun's assertions of what light distribution patterns meet this claim language, Lundahl discloses this limitation. *Id*.; JX-0057C.8; JX-0057.18.



RDX-0023.026.

Lundahl teaches that this light source distribution increases uniformity by compensating for "the fact that the output from a flat plane emitting light source drops near the edges" - i.e., the "fall off effect." RX-0065, 6:25-27; RX-0006C, Q/A97. Increasing light source density (and thereby, intensity) near the edges "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, 6:25-30; RX-0006C, Q/A95. This is especially useful near the patient's forehead and chin, where there is decreased light absorbance due to the curvature of the patient's head. RX-0006C, Q/A97. Accordingly, a POSA would be motivated to incorporate this design principle in combination with

Larsen's LED panels, resulting in a device having a design similar to what is illustrated in RDX-0017C.049, with the yellow circles representing LEDs.[7] RX-0006C, Q/A215.

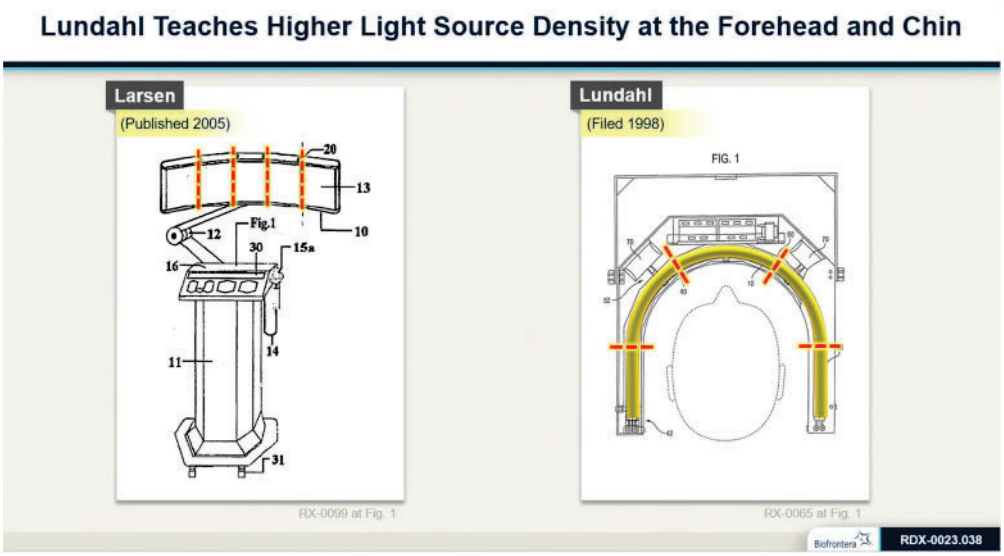


RDX-0017C.049.

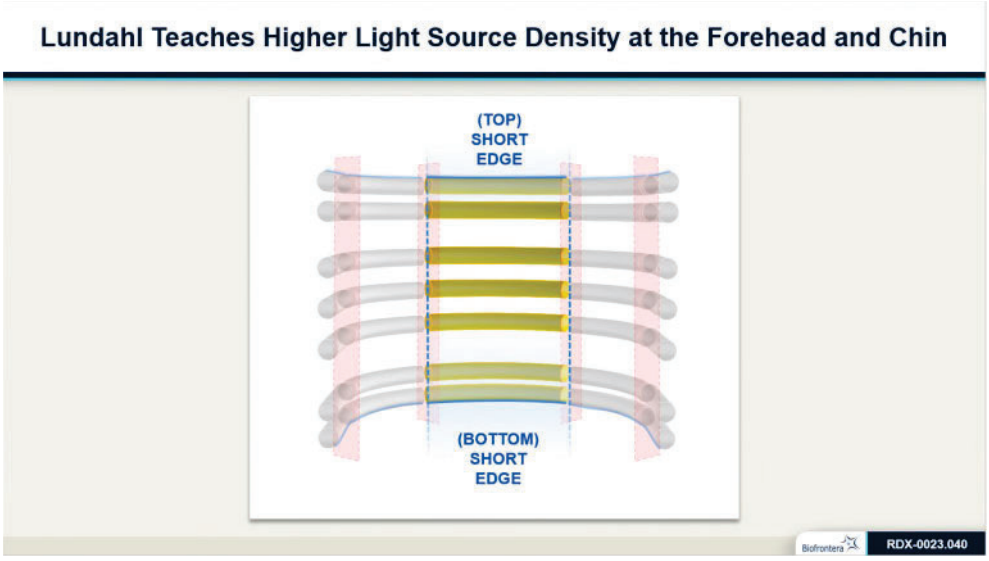
While Sun has argued that Lundahl teaches a higher intensity near the longer edges of its device (and therefore alleges that a POSA would increase intensity near the longer edges of individual panels) (CPHB, 139-140), this ignores a POSA's capacity for basic creativity and common sense. *Tyco Healthcare Group LP v. Ethicon Endo-Surgery*, Inc., 774 F.3d 968, 978 (Fed. Cir. 2014) ("[O]ne of ordinary skill is also one of ordinary creativity that knows how to combine familiar prior art elements to achieve the same function."). The advantages of Lundahl's light source distribution pattern are realized by providing increased intensity at the edges near a patient's forehead and chin, when the device is used as shown in Lundahl's Figure 1. RX-0065, 6:25-30;

[7] This demonstrative illustrates a combinationof Larsen's hinged panels and LEDs with a light distribution pattern similar to that disclosed in Lundahl. RX-0006C, Q/A215.

RX-0006C, Q/A95, 97. A POSA would recognize this and apply this principle in combining Larsen with Lundahl. And, 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.



RDX-0023.038.



RDX-0023.040.

Further, the PTAB rejected Sun's argument in its decision instituting IPR2024-01312, stating that "our understanding is that Petitioner's proposed modification applies Lundahl's disclosure of providing greater light intensity at the top and bottom sides to the top and bottom sides of Larsen, which are the shorter edges in Larsen." RX-1374.0019; Tr.(Jokerst), 749:8-16.

Accordingly, Lundahl and Larsen disclose and render obvious the "higher intensity proximate second edges" limitation. RX-0006C, Q/A220.

i. "Administering ALA Limitation"

Claim 8 of the '512 Patent recites the "administering ALA limitation." JX-0001, cl. 8. RX-0006C, Q/A221.

Claim Language — Administering ALA Limitation	**Claims**
"administering 5-aminolevulinic acid (ALA) to the patient"	Claim 8 ('512 Patent)

The administering ALA limitation is not disputed. CIUCL, 3.

j. "Positioning Proximate Limitation"

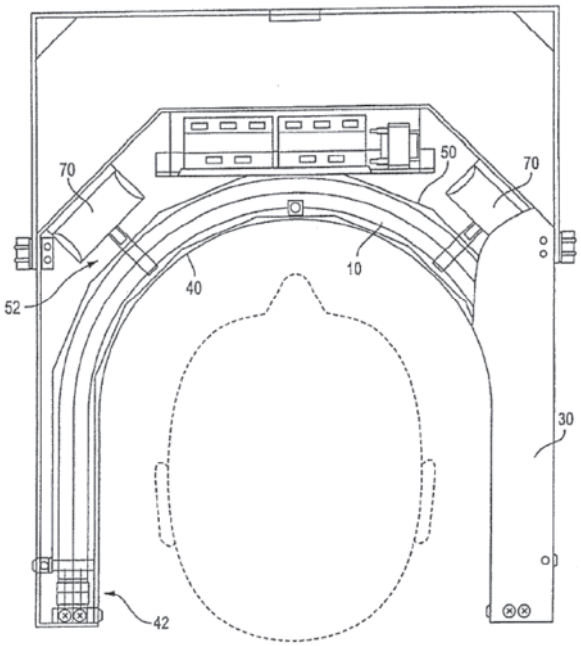
Claim 8 of the '512 Patent recites the "positioning proximate limitation." JX-0001, 8. RX-0006C, Q/A228.

Claim Language – Positioning Proximate	**Claims**
"positioning an illuminator proximate to the patient"	Claim 8 ('512 Patent)

Lundahl teaches positioning an illuminator between two and four inches from the treatment surface. RX-0007C (Ehrenreich), Q/A154; RX-0006C, Q/A230-234; RX-0065, 4:33-38.

Additionally, Lundahl illustrates positioning the PDT device proximate to the patient's head in Fig. 1. RX-0006C, Q/A233. Further, as Dr. Ehrenreich explains, "[t]his is [an] aspect of the claims that was well-understood by dermatologists in the context of PDT by 2015." RX-0007C, Q/A153.

FIG. 1



RX-0065.0003.

Accordingly, Lundahl discloses and renders obvious the positioning proximate limitation. RX-0006C, Q/A230-234; RX-0007C, Q/A152-154.

k. Individually Configurable Limitation

Claims 16 and 21 of the '028 Patent each recite the "individually configurable limitation." JX-0002, cls. 16, 21. RX-0006C, Q/A235-236.

Claim Language – Individually Configurable	**Claims**
"five panels connected by hinged structures to allow continuous illumination across the five panels, wherein the five panels are individually configurable to control illumination from each of the five panels"	Claims 16 ('028 Patent)
"the five panels are individually configurable to control illumination from each of the five panels"	Claim 21 ('028 Patent)

This limitation was construed to mean "the power output and/or light intensity of each panel can be individually controlled." Order No. 18, 40. Larsen discloses the individually configurable limitation. RX-0006C, Q/A246.

Larsen discloses applicators (*i.e.*, panels) "flexibly connected to each other through hinges..." with each panel containing multiple light sources. RX-0099, [0070]-[0072]; RX-0006C, Q/A240-243. Claim 5 of Larsen recites "wherein the light sources are ***individually selected***—switched ***ON*** or ***OFF***." RX-0099, cl. 5 (emphasis added); RX-0006C, Q/A243. Thus, Larsen teaches illuminating or darkening individual light sources within a panel, 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. Larsen further confirms that "the invented device is adjustable within a relatively large range with reference to duration, amplitude and frequency of surge of current..." RX-0099, [0074]; RX-0006C, Q/A241.

Accordingly, Larsen discloses and renders obvious the "individually configurable limitation." RX-0006C, Q/A246.

l. Illuminator Limitations of Claim 16

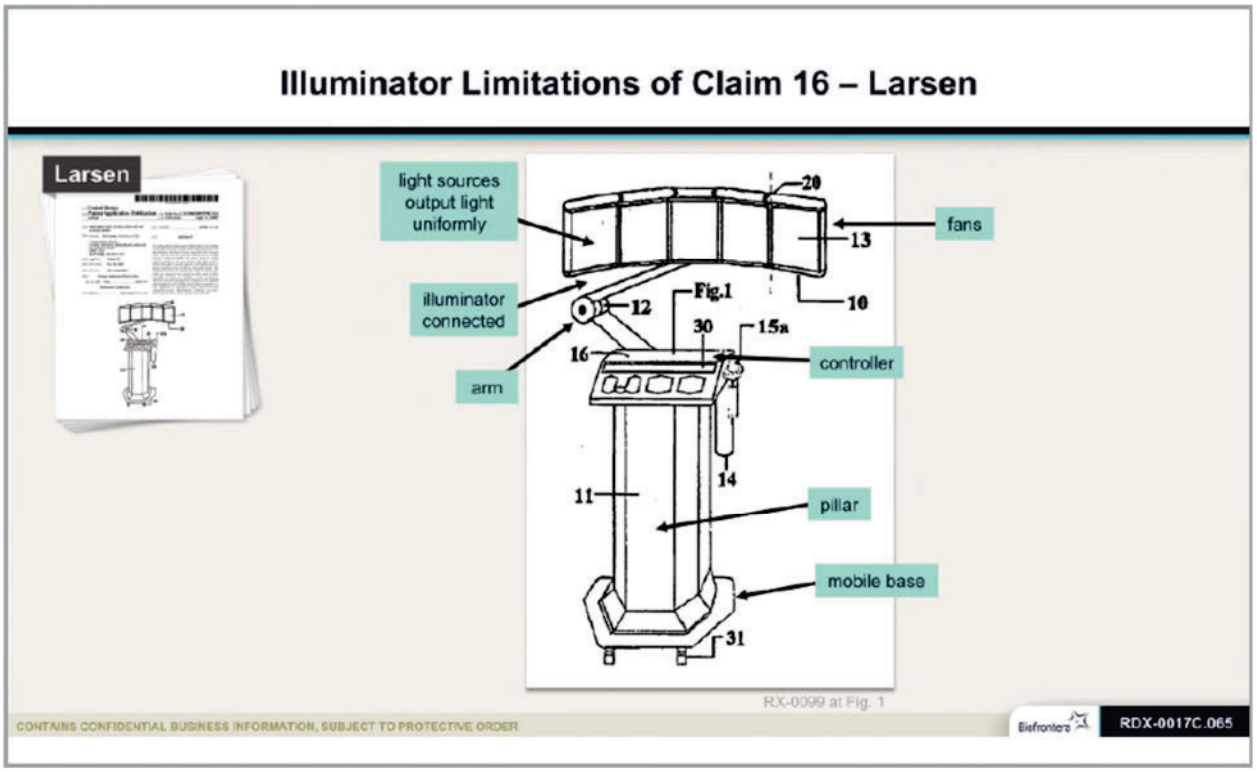
Claim 16 of the '028 Patent recites several limitations related to mechanical components of an illuminator, which do not appear in other Asserted Claims. JX-0002, cl. 16. These are shown below, along with associated abbreviations. RX-0006C, Q/A247.

Claim Language – Illuminator Limitations (Claim 16)	**Abbreviations**
"a mobile base supported by at least four wheels;	("16- mobile base")
"a pillar perpendicular to the base"	("16- pillar")
"a controller disposed to be supported by the pillar"	("16- controller")
"an arm mounted to a top portion of the pillar"	("16- arm")
"an illuminator connected at an end of the arm, the arm being hinged to allow adjustment of a position of the illuminator relative to the base	("16- illuminator connected")
"the light sources being configured to output light uniformly during at least part of a time when the treatment surface is illuminated"	("16- light sources output light uniformly")

"one or more fans mounted to at least one of the five panels."	("16- fans")

The 16-pillar, 16-controller, 16-arm, 16-illuminator connected, and 16-fans limitations are not disputed. CIUCL, 5.

Larsen teaches the 16-mobile base limitation. RX-0006C, Q/A254. Larsen teaches that the device is "freely moveable on wheels" and Figure 1 suggests that the device may incorporate four wheels, in order to provide stability. RX-0099, Fig. 1, [0027], [0069]; RX-0006C, Q/A248. Further, during prosecution of the '028 Patent, the examiner found that, based on Fig. 1 of U.S. Pat. No. 7,033,381 – which is the exact same image as Fig. 1 of Larsen - "it is inherent that there are at least two more wheels, for a total of 4, in order for the device to be stable." JX-0003.130-31; RX-0006C, Q/A249-252.



RDX-0017C.065; RX-0099, Fig. 1.

Further, using at least four wheels to support the stand was one of a finite number of known solutions to support a mobile stand. RX-0006C, Q/A253. A POSA would have been motivated with a reasonable expectation of success to use four wheels, since the resultant stability was a well-known outcome. RX-0006C, Q/A248-253. Accordingly, Larsen teaches and/or renders obvious the 16-mobile base limitation. RX-0006C, Q/A254.

Additionally, Larsen discloses the 16-light sources output light uniformly limitation. RX-0006C, Q/A264. Specifically, Larsen discloses light sources that are configured to output light uniformly during at least part of a time when the treatment surface is illuminated. RX-0006C, Q/A263. For example, Larsen teaches that "[t]he semiconductor diodes and/or laser diodes useable in this invention emit a light radiation...within the wavelength area of 300-2000 nanometers..." RX-0099, [0076], *see also* [0071] (showing light sources on all applicators can radiate light at discrete wavelengths); RX-0006C, Q/A263. As such, Larsen discloses the 16-light sources output light uniformly limitation. RX-0006C, Q/A264.

Accordingly, each of the disputed mechanical limitations specific to claim 16 is disclosed and/or rendered obvious by Larsen. RX-0006C, Q/A267.

m. Illuminator Configured to Output Light at Variable Irradiance Density ("Variable Irradiance Limitation")

Claim 20 of the '028 Patent recites the "variable irradiance limitation." JX-0002, cl. 20. RX-0006C, Q/A268-269.

Claim Language – Variable Irradiance	**Claims**
"the illuminator is configured to output light at a variable irradiance density during treatment"	Claim 20 ('028 Patent)

Larsen teaches that the panels can produce "an intensive light radiation with selective multiple wavelengths." RX-0099, [0025]-[0026]; RX-0006C, Q/A272. Larsen further teaches that the energy output from its applicators is adjustable "within a relatively large range with reference to duration, amplitude and frequency of surge of current..." RX-0099, [0074]; RX-0006C, Q/A272. Larsen's applicators are connected to sensors measuring the temperature and amount of energy radiated away from the skin surface. RX-0099, [0079]-[0080], Figs. 2a-2c; RX-0006C, Q/A272. In response to readings from the sensors, "[a]n increase of the registered amount of energy can be achieved by the invented device by increasing the operating potential (and thereby the pulse amplitude) or the pulse frequency and/or prolonging the duration of the treatment time..." RX-0099, [0079]-[0080]; RX-0006C, Q/A272.

Accordingly, Larsen discloses the variable irradiance limitation. RX-0006C, Q/A273.

n. "Red Light and Dose Range Limitations"

Claims 2 and 19 of the '028 Patent and claim 3 of the '512 Patent recite the "red light" and "dose range" limitations. JX-0002, cls. 2, 19; JX-0001, cl. 3. RX-0006C, Q/A274-275.

Claim Language – Dose Limitation	**Claims**
"the illuminator is configured to output red light at a dose of 30 J/cm^2 to 150 J/cm^2"	Claim 2 ('028 Patent)
"the illuminator is configured to output red light at a dose of about 30 J/cm^2 to about 150 J/cm^2"	Claim 3 ('512 Patent)

Claim Language – Dose Limitation	**Claims**
"the light sources are configured to output red light during at least part of the time when the treatment surface is illuminated"	Claim 19 ('028 Patent)

The red light and dose range limitations are not disputed. CIUCL, 2, 3, 5.

o. Light Having Wavelength of 400-700 nm ("Wavelength Limitation")

Claim 4 of the '028 Patent and claim 5 of the '512 Patent recite the "wavelength limitation." JX-0002, cl. 4; JX-0001, cl. 5. RX-0006C, Q/A281-282.

Claim Language – Wavelength Limitation	**Claims**
"a plurality of the light sources are configured to emit light having a wavelength in a range of 400 nm to 700 nm"	Claim 4 ('028 Patent)
"a plurality of the light sources are configured to emit light having a wavelength in a range of 400 nm to 700 nm"	Claim 5 ('512 Patent)

The wavelength limitation is not disputed. CIUCL, 2, 3, 5.

p. Recess to Receive Hinge Flange ("Recess Limitation") & Recess Located at Inner Side Surface ("Recess Location Limitation")

Claim 17 of the '512 Patent recites the "recess limitation." JX-0001, cl. 17. RX-0006C, Q/A287-288. Claim 18 of the '512 Patent recites the "recess location limitation." JX-0001, cl. 18. RX-0006C, Q/A296-297.

Claim Language – Recess Limitation & Recess Location Limitation	**Claims**
"at least one panel includes a recess configured to receive a flange of one of the nested hinges"	Claim 17 ('512 Patent)
"the recess is positioned at an inner side surface of the at least one panel"	Claim 18 ('512 Patent)

"Recess" was construed to mean "indentation, small hollow, or cleft" and "nested 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, 47. Accordingly, claim 17 requires an "indentation, small hollow, or cleft configured to receive a flange of one of the hinges that fit on inner side surfaces of adjacent panels." Claim 18 requires "the indentation, small hollow, or cleft is positioned at an inner side surface of the at least one panel." Order No. 18, 47.

It is not disputed that Perutz discloses the recess limitation and recess location limitations. CIUCL, 3-4. Hente also discloses the recess limitation and recess location limitations, as set forth below.

As explained, *supra* VI.A.2.b., Hente discloses the placement of hinge 50 in a location that fits on the inner side surfaces between adjacent panels. RX-0006C, Q/A292. As illustrated in Figure 2, the inner edges of adjacent sections 20 and 30 are nearly flush with each other. RX-0006C, Q/A292.

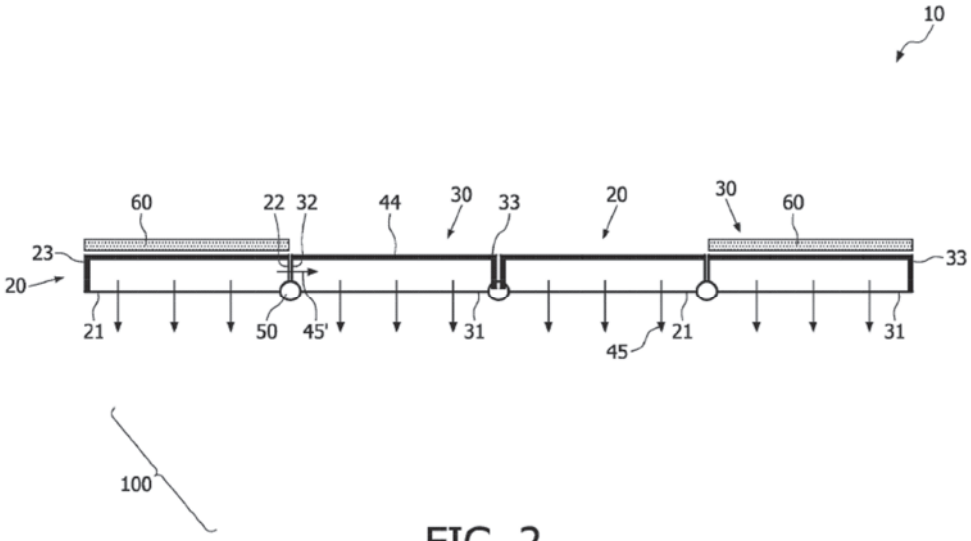
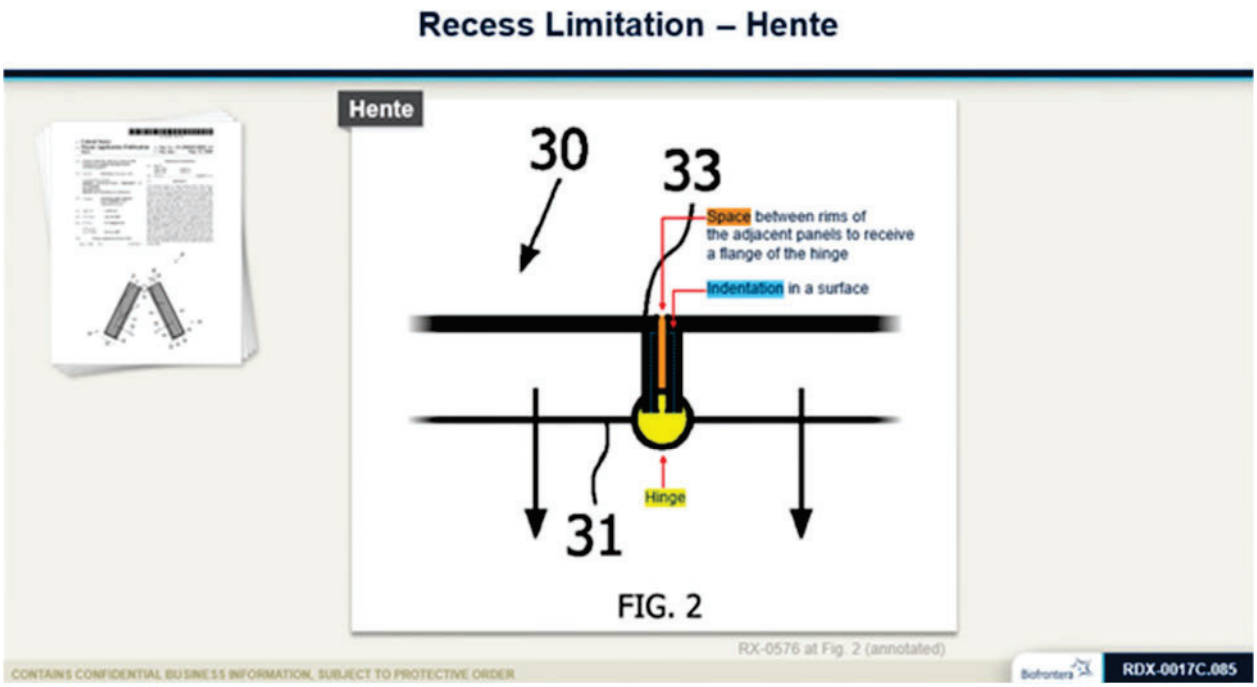


FIG. 2

Tr.(Grove), 585:13-18; RX-0576, Fig. 2.

As Dr. Grove illustrated below, this disclosure would have motivated a POSA to place the flange of the hinges in an indentation at the inner side surfaces of panels in order to minimize the space between adjacent panels, which was a well-established design motivation from the teachings of Hente and Larsen. RX-0006C, Q/A292.



RDX-0017C.085.

A POSA would recognize this as nothing more than applying known design elements and strategies to a known device (*i.e.*, the panels of Larsen) to predictably decrease the space between the adjacent panels. RX-0006C, Q/A292. *Adapt Pharma Operations Ltd. v. Teva Pharms. USA, Inc.*, 25 F.4th 1354, 1365 (Fed. Cir. 2022) (a known need within the industry would motivate a person of skill in the art to combine the prior art to obtain the claimed invention); *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 417 (2007) (patent that simply arranges known elements with each performing the same function it was known to perform and yields no more than one would expect from such an arrangement is obvious).

Accordingly, Hente discloses and/or renders obvious the recess limitation and recess location limitations. RX-0006C, Q/A295,303.

q. 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/A304.

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	✓	✓	✓	✓	✓	✓	✓	✓
Uniform Illumination	✓	✓	✓	✓	✓	✓	✓	✓
Center Panel	✓	✓	✓	n/a	✓	n/a	✓	✓
Within Approximately Four Inches	Not Disputed							
First and Second Edges	✓	✓	✓	✓	✓	✓	✓	✓
Higher Intensity Proximate Second Edges	✓	✓	✓	✓	✓	✓	✓	✓
Administering ALA	Not Disputed							
Positioning Proximate to Patient	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
Variable Irradiance	n/a	n/a	n/a	n/a	n/a	n/a	✓	n/a

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	✓	✓	✓	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	✓	✓	✓	✓	✓	✓	✓
Uniform Illumination	✓	✓	✓	✓	✓	✓	✓
Center Panel	✓	✓	✓	n/a	n/a	n/a	✓
First and Second Edges	✓	✓	✓	✓	✓	✓	✓
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	n/a	n/a	n/a	✓	✓	✓	n/a
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 Expecatation of Success Existed

a. A Motivation Existed to Incorporate the Hinged Panel System of Larsen into the Illuminator of Lundahl to Increase the Flexibility of the Lundahl Device

As admitted by Sun's expert, Dr. Jokerst, and its Associate VP of Regulatory Affairs and IP, Scott Lundahl – who is also the first named inventor on the Lundahl reference – Sun's older 4170D embodies the Lundahl reference. Tr.(Jokerst), 731:24-732:3; JX-0017C, 37:6-9, 41:7-10, 41:13-16. Accordingly, the 4170D illustrates the real-world advantages and drawbacks of the device disclosed in Lundahl. One example of those was that, while Lundahl advantageously disclosed a PDT device capable of uniform illumination of the face, the device had a fixed U-shape, whose dimensions were "chosen based on the average dimensions of the adult human head."

RX-0065, 6:31-35; RX-0006C, Q/A311. As phrased by Mr. Lundahl, "[f]or certain people, especially shall we say larger people, that posed a problem." JX-0017C, 42:19-43:2.

Mr. Lundahl's observation is corroborated by the testimony of Biofrontera's expert Dr. Ehrenreich, who has 17 years of real-world experience using the 4170D to treat patients diagnosed with AKs, extending back to before 2015. RX-0007C (Ehrenreich), Q/A106. Dr. Ehrenreich testified that a POSA would have been motivated to modify Lundahl to increase flexibility because, while its static U-shape was designed based on the average head, it is not the ideal shape or size for patients with larger or smaller heads. RX-0007C, Q/A159-161.

Distance between the light sources and the treatment surface — i.e., the skin — is important. RX-0006C, Q/A313. Irradiance of light received on a treatment surface (and uniformity thereof) is distance dependent. RX-0065, 4:23-27. Accordingly, Lundahl specifies that its device should be placed within 2-4" from all points on the treatment surface. RX-0065, 15:22-27. This is consistent with the FDA approved indication for the treatment of AK using Levulan® and the 4170D, which requires that the light surface be 2-4" from all points on the treatment surface. JX-0212.16. As noted by Dr. Grove, a POSA would have envisioned many scenarios where the shape and dimensions of the patient would not allow for the proper 2-4" treatment distance. RX-0006C, Q/A313; RX-0007C, Q/A159.

This issue is further exacerbated when considering the desire to treat areas of the body beyond the head – e.g., the chest, back, arms, legs, or hands. RX-0006C, 314, 316; RX-0007C, Q/A159. In fact, Lundahl itself echoes this desire for the disclosed device to treat "other areas of the patient (e.g., arms, legs, etc.)." RX-0065, 1:9-17. However, this statement is more aspirational than practical, with Lundahl failing to disclose any examples or any instructions addressing treatment of other areas of the body. In the real world, treatment of other body parts may be

impossible or impractical given that the surface of various body parts may be either too big or too small to fit within the fixed U-shape at the required treatment distance of 2-4". RX-0006C, Q/A314. For example, Dr. Ehrenreich testified that "[w]ith the BLU-U that I used to treat patients, I typically resort to using pillows, instrument stands, and other jury-rigged approaches to fit arms or hands into the treatment area. But this can be awkward and uncomfortable for patients, and it can make setting and controlling the distance between the light and the treatment area difficult, especially on a convex surface such as a forearm." RX-0007C, Q/A159.

To deal with these issues, a POSA would have been motivated to improve the Lundahl device to allow adjustment of the emitting surfaces to ensure a 2-4" distance from the varying anatomies of patients' heads as well as other body parts. RX-0006C, Q/A313-314; RX-0015C (Carota), 37:2-6 ("Q: And were there problems with a rigid curved device? A: It was limiting."). Larsen provides a ready solution, disclosing "[f]or the treatment of large-area tissues according to Figure 1, ***several applicators 13 are flexibly connected to each other through hinges 10...*** whereby the applicators are ***suitable for the treatment of for example, the backs of humans and so become adjustable for an equidistant positioning of the applicators 13 above the skin***." RX-0099, [0072] (emphasis added); RX-0006C, Q/A315. Consequently, a POSA would have understood that the easiest way to modify Lundahl's fixed U-shape would be to incorporate hinged panels that could be adjusted to account for variations in head shape/size or other anatomies. RX-0006C, Q/A315.

Although Sun has argued that modifying Lundahl would introduce gaps in light sources between panels, this would not affect the motivation to incorporate panels in order to increase flexibility. *Medichem, S.A. v. Rolabo, S.L.*, 437 F.3d 1157, 1165 (Fed. Cir. 2006) ("The 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.") Sun's position overlooks Larsen's fundamental design, which "comprises several single applicators hinged together so as to be adjustable *at angles with respect to one another."* RX-0099, cl. 11. (emphasis added); RX-0006C, Q/A317. By positioning the panels at angles (e.g., in a bent/curved orientation), any gaps between panels will be minimized or eliminated. RX-0006C, Q/A317. Additionally, despite gaps, multiple solutions are available to achieve uniform illumination in a multi-panel device, as evidenced by fact that both the RhodoLED®XL and the 4170E achieve uniformity despite using different hinge configurations and LED arrangements. Tr.(Jokerst), 739:20-23; CX-0010C (Jokerst), Q/A107.

b. A Motivation Existed to Replace Lundahl's Fluorescent Tubes with Larsen's LEDs to Improve Light Output Consistency and Address the Shortcomings of Fluorescent Tubes

In 1998, Lundahl's disclosed device used fluorescent tubes as light sources. "At the time, the best available technology for...PDT treatment was fluorescent tubes." CX-0011C (Lundahl), Q/A26. However, well prior to 2015, fluorescent tubes were known to have a number of problems related to both performance and safety. RX-0006C, Q/A324-325. Regarding performance, Mr. Lundahl noted "[t]he 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 . These difficulties are acknowledged in the Lundahl reference, which 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 similarly admitted that "[i]t was known that fluorescent tubes had dark areas." Tr.(Jokerst), 732:7-10.

Regarding safety, it was known by 2008 that "[f]luorescent lamps contain mercury, which can cause problems if they are accidentally broken." CX-1231.1 (published 2008). These safety issues caused fluorescent tubes to become disfavored by government at all levels, prior to 2015. Tr.(Jokerst), 735: 7-12; *see also* JX-0017C, 46:19-47:9. For example, "[m]ost municipalities also require[d] special disposal of these lamps to properly handle the mercury, usually for an extra fee." CX-1231.1. As explained by Mr. Carota, a named inventor of the Asserted Patents, "the Efficiency Act that was put in place by the federal government around ballasts that drive fluorescent tubes rendered the ballasts that we used in the BLUE-U [sic] to be essentially illegal." JX-0015C, 36:11-16; *see also* Tr.(Jokerst), 735:13-22 ("A: I think it were the ballasts that were banned first. Q: Okay. The ballasts that you use with fluorescent tubes? A: Yes, that's right."); JX-0006C (Mazejka), 53:13-16; JX-0014C (Boyajian), 33:16-34:10.

At the same time, it was well known that LEDs solved these safety issues. For example, it was recognized well before 2015 that LEDs "are much more robust than any glass-envelope lamp and contain no hazardous materials like fluorescent lamps." CX-1231.1. Accordingly, as admitted by Dr. Jokerst, LEDs became favored alternatives to fluorescents prior to 2015. Tr.(Jokerst), 735:23-736:4. LEDs also provided performance advantages over fluorescents, including higher efficiencies, longer lifetimes, and "unprecedented flexibility in lighting fixture design." CX-1231.1-2 ("A properly designed LED light system is capable of providing performance and a lifetime well beyond any traditional lighting source.); Tr.(Jokerst), 736:5-7. Additionally, the relatively narrow output spectrum of LEDs allows more precise tailoring of output wavelength to the absorption band of a photosensitizer for PDT. RX-0006C, Q/A325. For these reasons, LEDs

became widely used as their costs came down and had become the industry preferred light source for PDT by the early 2010s. Tr.(Jokerst), 7368-10; RX-0006C (Grove), Q/A38-40,310.

Accordingly, a POSA would have been motivated to look to Larsen's teaching of "semiconductor diodes (LED[s])" as light sources disposed on the surfaces of five panels connected by hinges (RX-0099, [0070]), as a replacement for the fluorescents that had become "extinct or obsolete" by the priority date of the Asserted Patents. JX-0006C, 53:13-16; RX-0006C, Q/A327.

c. There Was A Reasonable Expectation of Success in Combining Lundahl and Larsen

It is well-established that "[a]n expectation of success need only be *reasonable*, not absolute." *Pfizer Inc. v. Sanofi Pasteur Inc.*, 94 F.4th 1341, 1352 (Fed. Cir. 2024); *PAR Pharm., Inc. v. TWI Pharms., Inc.*, 773 F.3d 1186, 1198 (Fed. Cir. 2014). Here, a POSA would have had a reasonable expectation of success in combining Lundahl with Larsen because both references disclose similar PDT devices designed to conform to the contours of a treatment surface. RX-0006C, Q/A320; RX-0065, 2:61-67; RX-0099, [0037], [0072], cl. 11.

The Federal Circuit has previously found reasonable expectation of success where the differences between the claims and the prior art are slight. *Teva Pharms. USA, Inc. v. Sandoz Inc.*, 906 F.3d 1013, 1025-26 (Fed. Cir. 2018) ("Because a thrice-weekly 40mg injection would result in a total weekly dose ***very close*** to that in the already-approved daily 20mg injection. . . a POSITA would have had a reasonable expectation of success. . .This is not a situation where the prior art gave no direction in how to reach a successful result[.]"). In this instance, the modifications to Lundahl's device are simple and straightforward: (1) incorporation of hinged panels, and (2) conversion from fluorescents to LEDs.

Initially, incorporation of hinged panels was routine for a POSA by 2015. As noted by Dr. Luebbert, "there was nothing new at the time with a five-panel lamp." JX-0008C (Luebbert), 124:10-12. As Dr. Grove similarly observed, "[g]enerations of people have used [butt] hinges" to connect panels (Tr.(Grove), 592:2-8) and it was well within the capability of a POSA to design appropriate electrical connections between panels. RX-0006C, Q/A322.

Moreover, adapting the electrical systems of a device to convert from fluorescents to LEDs was within the normal engineering skill of a POSA by 2015. RX-0006C, Q/A320,329. While Sun has argued that "LEDs 'cannot simply be purchased, wired up, and turned on if a high performance level is expected'" (CPHB, 171), this is inapposite. A reasonable expectation of success does not require a plug-and-play solution. A POSA "is also a person of ordinary creativity, not an automaton." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 420-21 (2007). This is especially true in the present case in which a POSA must have a Ph.D. or an M.D., and at least one year of relevant experience. Order No. 18, 13. A POSA with the defined level of education and experience would have been capable of more than simply purchasing and turning on an LED system. In this context, both incorporation of hinged panels and conversion to LEDs would have been considered a straightforward design change by 2015, meaning a POSA would reasonably expect that these design changes could be successfully incorporated into the Lundahl device. RX-0006C, Q/A317-318,320,322. *Application of Fisher*, 427 F.2d 833, 839 (C.C.P.A. 1970) ("In cases involving predictable factors, such as mechanical or electrical elements...other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific laws.")

More specifically, there would have been a reasonable expectation of success in achieving uniform illumination via a combination of Lundahl's PDT device and light source distribution with

Larsen's hinged LED panels. RX-0006C, Q/A320-321. Lundahl had already 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 better control of light output characteristics in comparison to earlier technologies like fluorescents. RX-0006C, Q/A40; CX-1231.1 (LEDs provide "unprecedented flexibility in lighting fixture design."). "One of ordinary skill knows how to combine familiar prior art elements to achieve the same functions." *Tyco Healthcare Group LP v. Ethicon Endo-Surgery*, Inc., 774 F.3d 968, 978 (Fed. Cir. 2014). Here, a POSA would have reasonably expected to achieve the same uniformity already achieved by Lundahl, with LEDs –a superior light source.

While Sun argued that Lundahl requires integration of four specific features (CPHB, 146-147) – U-shaped tubes, light source distribution, reflector, electrical control system, and cooling system – in order to achieve uniform illumination, three of these features (i.e., reflector, electrical control system, and cooling system) are only necessary to solve problems specific to fluorescents. *Supra* Section VI.A.2.d. These problems would be eradicated using 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. In fact, Dr. Jokerst admits that the Accused Product does not have these features, but still achieves uniform illumination through the arrangement or spacing of its light sources. Tr.(Jokerst), 739:20-740:18. The remaining two factors alleged to be required for uniformity that are not specific to fluorescent tubes (U-shape and light source distribution) are both disclosed and incorporated into the combined device of Lundahl and Larsen, further supporting the reasonable expectation that the combined device would provide the required uniformity. RX-0006C, Q/A90,98,198 (Lundahl teaches a U-shaped PDT device to curve around

a patient's head and optimize uniformity); 217 ("incorporating the five panel design of Larsen into the Lundahl device (effectively taking the single, long U-shaped panel of Lundahl and dividing it into five sections, as illustrated in Larsen)").

Accordingly, the evidence shows that a POSA would have had a reasonable expectation of success in combining Lundahl and Larsen, at the time of the priority date, in order to arrive at the Asserted Claims.

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

As an initial matter, Hente is analogous art. Prior art is considered analogous if one of two conditions are fulfilled: (1) the prior art is from the same field of endeavor, or (2) the prior art is reasonably pertinent to a problem with which the inventor is involved, regardless of the field of endeavor. *Sci. Plastic Prods. v. Biotage AB*, 766 F.3d 1355, 1359 (Fed. Cir. 2014). Although it need only meet one of these criteria, Hente meets both. First, Hente is from the same field of endeavor as the Asserted Patents, which are also directed to light-emitting devices having multiple adjacent sections/panels that can be rotated relative to each other. JX-0001, 1:24-2:4; RX-0576, [0005]-[0007].

Second, Hente is reasonably pertinent to a problem confronted by the inventors of the Asserted Patents. Specifically, Hente is directed to providing an illuminator that can adjust the size of the illuminated area. RX-0576, [0002]-[0007]. Accordingly, provides an emitter having panels that are rotatable with respect to one another. RX-0576, [0011]. The Asserted Patents also provide a device wherein "panels are coupled together so as to be rotatable relative to each other. By

incorporating multiple rotatable panels, the overall size and shape of the area that is illuminated can be changed....” JX-0001, 1:67-2:4. Accordingly, Hente is analogous prior art.

As explained fully above, there was motivation to modify Lundahl to incorporate the hinged LED panels of Larsen with a reasonable expectation of success. RX-0006C, Q/A334. While a POSA would have had a reasonable expectation of success in achieving uniform illumination in light of Larsen’s disclosures of LEDs (which provided superior output control (RX-0099, [0074]-[0077]) and Lundahl’s disclosure of light source distribution (designed to ameliorate the fall-off effect (RX-0065, 6:22-30), a POSA would still have been motivated to incorporate additional features that made uniformity even easier. RX-0006C, Q/A334. For example, minimizing gaps between panels would have been known to further facilitate uniformity. RX-0006C, Q/A334.

Hente teaches hinges that allow for adjustment of adjacent panels/sections, while minimizing the gap between them. RX-0576, Title, Abstract; RX-0006C, Q/A336. Hente also teaches that its hinges are suitable for use in a light emitting device that is bendable between sections to adjust the area of illumination so as to “illuminate large and point-like limited areas.” RX-0576, [0005]; RX-0006C, Q/A336. Accordingly, a POSA would be motivated to combine the hinge structure of Hente with Lundahl and Larsen.

Additionally, a POSA would have had a reasonable expectation of success in combining Hente with Lundahl and Larsen because Hente and Larsen both describe methods of “hingedly” connecting panels. RX-0006C, Q/A339. Further, it would have been well within the ambit of a POSA to select, adjust, substitute, and implement configurations of hinges. RX-0006C, Q/A339. Accordingly, a POSA would have a reasonable expectation that the hinges of Hente could be successfully utilized in the device rendered obvious by Lundahl and Larsen. RX-0006C, Q/A339.

Although Sun notes that Hente teaches hingedly connecting individual OLEDs, rather than panels each containing multiple LEDs (CPHB, 173-174), Hente is not relied upon for panels containing LED arrays. Larsen teaches this element, while Hente teaches further detail regarding a hinge structure for connecting lighted panels. Additionally, while Sun observes that OLEDs are diffuse light sources while LEDs are point light sources and OLEDs are smaller and thinner than LEDs panels,(CPHB, 174-175), this is similarly not relevant because Hente is relied upon for its teaching of hinge positioning. *In re Keller*, 642 F.2d 413, 425 (C.C.P.A. 1981) ("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.").

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

Initially, Perutz is analogous art. While Sun argued that Perutz is not analogous because it is directed to "display panel systems utilized for exhibiting at trade shows, promotional events, and the like," (CPHB, 176) this argument ignores half of the two-criteria test for qualification as analogous art. Specifically, even if it is not directed to the same field of endeavor as the Asserted Patents, Perutz may still be analogous if 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).

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. The hinge structures provided by Perutz are recessed into the side surfaces of panels, such that "[w]hen the adjacent panels are

disposed in a substantially coplanar relation the hinges are substantially concealed." RX-0607, 2:42-68. Accordingly, Perutz provides hinged structures that minimize spaces between panels. Similarly, the Asserted Patents are directed to providing illuminators including hinged panels that minimize gaps between panels. JX-0001, 1:64-2:54. Accordingly, Perutz is analogous art because it "logically would have commended itself to an inventor's attention in considering his problem." 766 F.3d at 1359. In light of this shared problem, the fact that Perutz is directed to "display panel systems" is irrelevant. *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"). Accordingly, Perutz is available as analogous prior art.

A motivation existed to combine the teachings of Lundahl, Larsen, and Hente. RX-0006C, Q/A314. For all the reasons discussed previously, Lundahl, Larsen, and Hente disclose and render obvious the inclusion of hinged panels (as taught by Larsen) in the illumination device taught by Lundahl via attachment by hinges on the inner side surface of adjacent panels. However, to the extent that Lundahl, Larsen, and Hente do not disclose or render obvious at least one panel including a recess configured to receive a flange of one of the hinges at an inner side surface of a panel, this design option is disclosed by Perutz. RX-0006C, Q/A293,300,344. Based on the teachings of Lundahl, Larsen, and Hente, increasing degree and ease of uniformity was a design motivation that would lead a POSA to minimize gaps between adjacent panels. RX-0006C, Q/A344. Perutz teaches accommodating hinges in recesses on inner side surfaces of panels, which minimizes the gap between the adjacent panels/sections. RX-0607, 4:16-20 and 33-38; RX-0006C,

Q/A344,347. Therefore, a POSA would have been motivated to apply Perutz's hinge teachings to the aforementioned combination. RX-0006C, Q/A344.

A POSA would have had a reasonable expectation of success in combining Perutz with Lundahl, Larsen, and Hente, because Perutz, Hente, and Larsen all describe methods of connecting adjacent panels via hinges. Further, it would have been well within the ambit of a POSA to select, adjust, substitute, and implement types and configurations of hinges. RX-0006C, Q/A349.

4. Secondary Considerations

The alleged secondary considerations do not render the Asserted Claims non-obvious. RX-0006C (Grove), Q/A350. The evidence does not support Sun's assertion that the secondary considerationssupport non-obviousness of the Asserted Claims. RX-0006C, Q/A351-353.

a. Long-Felt Need

There was no long-felt need addressed by the Asserted Claims because their subject matter was widely known before the priority date of the Asserted Patents and clearly disclosed in the prior art. RX-0006C, Q/A354. *ABT Sys., LLC v. Emerson Elec. Co.*, 797 F.3d 1350 (Fed. Cir. 2015), 11362 ("The disclosures of the prior art references eliminate any serious contention that there was a long-felt need for the invention...") In fact, Sun represents a long-felt need was addressed many years earlier, by the filing of their own patents. RX-0006C, Q/A355. Specifically, Lundahl (which was assigned to DUSA Pharmaceuticals, Inc., which later became part of Sun) disclosed in 2001 an illuminator that provided "uniform illumination," as claimed in the Asserted Patents. RX-0065, 15:22-26 ("...the measured output over the active emitting area is within 70% of the measured maximum when measured with a cosine response detector at distances of 4" and 2", and within 60% of the measured maximum over all operation distances."); RX-0006C, Q/A355. Consequently, there was no "long-felt need" for "uniform illumination," because an illuminator designed to

provide "uniform illumination" of a patient's head and face (for the purposes of PDT treatment) was publicly disclosed at least 14 *years* prior to the filing of the Asserted Patents. RX-0006C, Q/A355.

Additionally, there was no long-felt need addressed by the Asserted Claims for an illuminator that can treat lesions further apart on the patient's face (for example on opposite sides of the face) in a single session. RX-0006C, Q/A356. This very "need" was already met with the filing of Lundahl which clearly shows an illuminator that could simultaneously illuminate lesions further apart (i.e., on either side) on a patient's face in Figure 1. RX-0006C, Q/A356. Thus, there was no "long-felt need" for a larger illumination area capable of illuminating lesions further apart in a single session, as an illuminator with this design was publicly disclosed at least 14 years prior to the filing of the Asserted Patents. RX-0006C, Q/A356.

b. Industry Praise

The evidence does not support Sun's allegation that the alleged invention, as recited in the Asserted Claims, was the subject of industry praise due to the features recited in the Asserted Claims. RX-0006C, Q/A357. For assessing non-obviousness, industry praise must be related to allegedly novel features of the Asserted Claims, not merely to features present in the prior art. RX-0006C, Q/A357; *S. Alabama Med. Sci. Found. v. Gnosis S.P.A.*, 808 F.3d 823, 827 (Fed. Cir. 2015) (affirming a finding of no nexus where the patent owner "failed to connect the evidence of industry praise to the novel elements of the claims.").

The 4170E is not yet on the market and available for sale. RX-0006C (Grove), Q/A358. In view of this, Sun has only provided Biofrontera's press releases and statements related to RhodoLED®XL, demonstrating praise for the "features and versatility" of RhodoLED®XL. RX-0006C, Q/A358. Sun argues that the praise for RhodoLED®XL is based on Sun's discoveries as

reflected in the claims, namely the development of a larger illumination field. RX-0006C, Q/A358. However, as noted in the above discussion of the "long-felt need," the development of an illuminator with a larger illumination field has long been known in the art, as evidenced by the filing of Lundahl in 1998.

c. Commercial Success

Sun has not established the commercial success of any product allegedly practicing the Asserted Patents. [redacted] Therefore, Sun relies on the alleged commercial success of the RhodoLED®XL. The evidence has shown that the RhodoLED®XL does not practice the Asserted Patents. Even if the ALJ finds that the RhodoLED®XL practices the Asserted Claims, and that the product has enjoyed commercial success, this success is not attributable to the claimed invention. A patentee bears the burden of demonstrating that the relevant commercial success has a nexus to the claimed invention "as opposed to other economic and commercial factors unrelated to the technical quality of the patented subject matter." *Cable Elec. Prods, Inc. v. Genmark, Inc*., 770 F. 2d 1015, 1027 (Fed. Cir. 1987).

Sun has not established that the RhodoLED®XL's alleged success is due to the inventions of the Asserted Patents. Sun alleges that commercial success of the RhodoLED®XL is due to concepts discussed in the Asserted Patents, however, those concepts are also present in the prior art, as described above in Section VI.A.2., and thus this does not show any commercial success that is relevant to the question of obviousness. *Tokai Corp. v. Easton Enterprises, Inc*., 632 F.3d

1358, 1369-70 (Fed. Cir. 2011) ("If commercial success is due to an element in the prior art, no nexus exists."); *In re Huai-Hung Kao*, 639 F.3d 1057, 1068 (Fed. Cir. 2011) ("Where the offered secondary consideration actually results from something other than what is both claimed and novel in the claim, there is no nexus to the merits of the claimed invention."); *Ormco Corp. v. Align Tech., Inc*., 463 F.3d 1299, 1312 (Fed. Cir. 2006).

Sun cannot point to sales of its own product to establish commercial success because [redacted] Thus, Sun instead relies on roughly a years' worth of mediocre RhodoLED®XL sales to attempt to establish commercial success. Biofrontera's sales have not reached a level sufficient to conclude that the RhodoLED®XL has been commercially successful. [redacted] Biofrontera had only sold 92 RhodoLED®XLs as of November 30, 2024, and 117 as of April 2025. JX-0229C (BF_1411_ITC_00185022); RX-0008C, Q/A20-21; RX-0003C (Leffler), Q/A28-33; Tr.(Luebbert) 318:23-319:6; Tr.(Leffler) 412:3-8; 420:18-23. Even this more recent figure falls short of Biofrontera's goal of placing [redacted] RhodoLED®XLs by the end of 2024. RX-0003C, Q/A34-37; RX-0008C, Q/A23; Tr.(Leffler) 420:24-421:4 (noting that installations had "decelerated" since the beginning of 2025). These sales [redacted] which does not practice the Asserted Patents, and are not enough to impact the AK market, which is still driven by cryo procedures, not PDT treatments. RX-0008C, Q/A31,38-39,53.

Finally, the evidence has also shown that there are other factors that have contributed to the sales of the RhodoLED® XL unrelated to the Asserted Patents, including: 1) the majority of the devices were purchased by existing users of Ameluz®; 2) features of the XL that were

improvements on Biofrontera's older RhodoLED® lamp; and 3) trade-in discounts for owners of the RhodoLED®. *See* RX-0008C, Q/A42-51; RX-0004C, Q/A70, 74; RX-0011C, Q/A55; Tr.(Leffler) 418:17-20; CX-1307 (Biofrontera 3/21/25 Press Release); CX-0183 (Biofrontera Q3 2024 Earnings Call Tr.).

d. Copying

The evidence does not support the Asserted Claims being copied and incorporated into Biofrontera's RhodoLED®XL. RX-0006C, Q/A359. Dr. Jokerst admitted that she has seen no direct evidence to support copying or indeed any relianceby Biofrontera on knowledge gleaned from Sun or its patents, in developing its own products. Tr.(Jokerst), 746:21-748:5. Consequently, the "copying" factor does not render the Asserted Claims non-obvious and does not change the conclusion that the Asserted Claims are obvious over the prior art. RX-0006C, Q/A359.

To the extent that Sun alleges copying from the Asserted Claims, these design features were previously disclosed and/or rendered obvious by the prior art, for all the reasons discussed in the preceding obviousness analysis. *E.I. du Pont de Nemours & Co. v. Synvina C.V.*, 904 F.3d 996, 1012 (Fed. Cir. 2018) ("Where the prior art is so close, it has not been shown that DuPont copied [the asserted patent] rather than the other references within the prior art."). Consequently, to the extent Biofrontera utilized a 5-panel design with hinges mounted/attached to inner side surfaces of adjacent panels, these design features were known in the art at least 10 years prior to the effective date of Sun's Asserted Patents. RX-0006C, Q/A360.

B. Asserted Claims Invalid for Lack of Written Description for Failing to Provide Support for *Photodynamically Diagnosing* a Patient

The Asserted Patents do not objectively demonstrate to a POSA that the inventors actually invented, or "possessed," the concept of photodynamic diagnosis when the patent application was

filed. *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (*en banc*); *Centocor Ortho Biotech, Inc. v. Abbott Lab'ys*, 636 F.3d 1341, 1348 (Fed. Cir. 2011). Indeed, the only named inventor at trial, Thomas Boyajian, testified he "had nothing to do with making the patent except for signing whatever I was asked to sign" and that he "wouldn't claim to understand everything in this patent." Tr.(Boyajian) 69:1-11. The evidence bears that out. The specification lacks guidance or examples that support written description for a system or method of photodynamically diagnosing a patient, particularly across the broad scope of the claims. The claims include broad ranges, particularly as to light wavelengths and light doses. The claims are not limited as to particular diseases, concentrations of photosensitizers, or incubation times. Faced with this lack of disclosure, Sun tries to argue that photodynamic diagnosis and photodynamic therapy are essentially the same thing. They are not.

1. The Asserted Patents Broadly Claim Photodynamically Diagnosing

By their preambles, all Asserted Claims claim systems and methods for photodynamically *diagnosing* or treating a patient. Order No. 18, 26-29; *see also* RX-0007C, Q/A210-211. The Asserted Claims place few limitations on variables relevant to PD. RX-0007C, Q/A215. There is no limit in the claims to the types of conditions to be diagnosed. *Id*., Q/A216-218. For example, while the asserted method claims include limitations requiring administering a specific photosensitizer, most claims are silent about what photosensitizer to use and what dose or concentration is applied. *Id*., Q/A228-230. In addition, the Asserted Claims are silent about what wavelengths, intensities, and fluences of light to use for diagnosis, *id*., Q/A221-227, but dependent claims recite:

- "light having a wavelength in a range of 400 nm to 700 nm." JX-0002, claim 5; JX-0002, claim 4.

- "output red light at a dose of about 30 J/cm^2 to 150 J/cm^2." JX-0001, claim 3; JX-0002, claims 2.
- "output light at an irradiance density of 10 mW/cm^2 to 30 mW/cm^2." JX-0001, claim 4; JX-0002, claim 3.

The Asserted Claims must encompass at least these ranges. RX-0007C, Q/A222-224. Moreover, the specification teaches, and Dr. Shmuylovich agrees, that the Asserted Patents are directed to treating and diagnosing with visible light, commonly understood to be in the 400 to 700 nm wavelength. CX-0013C, Q/A151-152.

Finally, the Asserted Claims do not recite any specific means for visualizing fluorescing PpIX molecules (e.g., a filter or a camera). RX-0007C, Q/A317, 356. Nor do the Asserted Claims include any limitations related to how a POSA could visualize the patient's "treatment surface" with their eyes while the "five panels" of the illuminator are configured to be wrapped around the patient's treatment surface, emitting bright visible light, and for some claims, while the five panels are "positioned to allow treatment within approximately four inches of the treatment surface." Tr.(Ehrenreich), 654:9-655:7; Tr.(Shmuylovich), 690:21-691:2.

Accordingly, the Asserted Claims encompass (1) photodynamically diagnosing a patient with virtually any dermatological condition by (2) using the claimed illuminator according to the full scope of the broad claims. RX-0007C, Q/A234. In other words, the Asserted Claims encompass a "generic invention" (i.e., a five-panel illuminator capable of emitting ranges of light wavelengths, intensities, and fluences) that must be capable to of achieving the function of "photodynamically diagnosing … a patient" with dermatological skin conditions. *Juno Therapeutics, Inc. v. Kite Pharma, Inc.*, 10 F.4th 1330, 1335 (Fed. Cir. 2021) (quoting *Ariad*, 598 F.3d at 1351).

2. The Specification Does Not Convey to a POSA that the Inventors Possessed the Claimed Invention

While the Asserted Claims are broadly directed to systems and methods for photodynamically diagnosing patients using a five-panel illuminator, s*upra* Section VI.B.1, the Asserted Patents do not demonstrate possession of these broad claims. Instead, the specification provides a single example on how to conduct PDT, interspersed with vague goals of conducting PD. The Asserted Patents' background section broadly refers to photodynamically diagnosing "several types of ailments in or near the skin or other tissues, such as those in a body cavity" and lists some examples (e.g., actinic keratosis, acne, warts, psoriasis, photo-damaged skin, and cancer). JX-0001, 1:24-27; RX-0007C, Q/A217, 284.

It also explains that a photoactivating agent, like ALA, should be administered to a patient as part of photodynamic treatment or diagnosis. JX-0001, 1:34-47. And it explains that "[t]he area in which the photoactivatable agent is administered is then exposed to visible light, which causes chemical and/or biological changes in the agent. These changes allow the agent to then selectively locate, destroy, or alter the target tissue." *Id*., 1:37-43; CX-0013C.50, Q/A189. But, the specification *never* explains how to accomplish the essential PD step with the claimed five-panel illuminator. *Infra* Section VI.B.3. The Federal Circuit has consistently held that simply naming a desired result or material that is known to exist does not suffice for written description. *Univ. Of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 923 (Fed. Cir. 2004) ("generalized language may not suffice if it does not convey the detailed identity of an invention"); *Regents of the Univ. of Cal. V. Eli Lilly & Co.*, 119 F.3d 1559, 1568 (Fed. Cir. 1997) ("The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention.").

Indeed, the parties' experts testified that the specification is missing information that would be necessary to use the claimed illuminator for PD. First, the examples Sun relies on to establish written description contradict Sun's testimony about how long light should be applied for PD, which Dr. Shmuylovich testified was the primary difference between PDT and PD.[8] *Compare* CX-0013C, Q/A18 to JX-0001, 8:64-9:43. Second, the wavelengths, intensities, and fluences of light to use for PD are not discussed. RX-0007C, Q/A290-291, 297. Third, the specification does not disclose how to detect or visualize fluorescing PpIX molecules using the claimed five-panel illuminator, which physically impairs a healthcare provider's view of the patient and outputs bright visible light, making it difficult to see with the human eye. Tr.(Ehrenreich), 654:9-655:7; Tr.(Shmuylovich), 690:21-691:2. Finally, in attempting to prop up its validity position, Sun elicited testimony from Biofrontera's scientist, Dr. Foguet, a biochemist who developed Ameluz®. Dr. Foguet explained key mechanisms for PD and explained that the examples Sun relies on to support written description disclose a 14-18 hour incubation period for a photoactivating agent that will not work for PD because after this extended time, healthy cells would also take up ALA and metabolize it into PpIX.[9] Tr.(Foguet), 375:2-14, 390:8-391:8; *see also* RX-0007C, Q/A230-231, 248-251.

Likewise, the figures of the specification include no working examples of photodynamic diagnosis. Figures 1-6, JX-0001, 3:21-40, are silent as to photodynamic diagnosis. Further, the specification provides for a wide range of potential wavelengths of light (*i.e.*, colors of light) that may be used, but the language is specifically for treatment. The specification states "when ALA is

[8] As Dr. Shmuylovich testified to, his February 2022 expert report did not include any references to "milliseconds" or "near instantaneous exposure" in the context of photodynamic diagnosis. Tr. (Shmuylovich) 694:13-695:6. Biofrontera therefore first had an opportunity to question Dr. Shmuylovich about his opinions at trial. As was its right, Biofrontera elected not to move to strike those previously undisclosed opinions because they demonstrated the invalidity of the claims.

[9] Dr. Foguet's testimony on these issues was in response to questions from counsel during cross-examination and is therefore relevant to these issues even if they were not expressly raised in her witness statement.

used as a precursor of a photoactivatable agent ***for the treatment of actinic keratosis***," the LEDs may emit blue light having wavelengths of about 430 nm, 420 nm, or 417 nm, as well as green or red light having wavelengths of about 510 nm, 540 nm, 575 nm, or 630 to 640 nm. *Id*., 4:2-13 (emphasis added). Thus, no wavelengths of light are specifically described for diagnosis. JX-0001 3:66-4:22; RX-0007C, Q/A352 ("The specification does not explain how to use these different colors and wavelengths of light for PDD, and only references using red and/or blue light at certain wavelengths for treating AK with ALA"); *Nuvo Pharmaceuticals (Ireland) Designated Activity Co. v. Dr. Reddy's Labs. Inc.*, 923 F.3d 1368, 1375, 1380-81 (Fed. Cir. 2019) (holding patent invalid for lack of written description where there was no examples to show claimed embodiment would be effective); *Regents of the Univ. of Cal.*, 119 F.3d at 1568.

Further, the specification does not include *any* examples of using the claimed illuminator to photodynamically diagnose a patient, RX-0007C, Q/A293-297, and just one detailed example describing *treating* a patient with precancerous lesions in conjunction with the application of ALA as the photoactivating agent. JX-0001, 8:64-9:43; RX-0007C, Q/A294-295.

a. The Specification Does Not Disclose How to Detect Fluorescence Using the Claimed Illuminator

At its core, PD can only be used for diagnosis if it allows a HCP to differentiate between diseased and healthy tissue. The experts in this Investigation agree that the method for diagnosing is detecting fluorescing PpIX molecules on the patient's skin. RX-0007C, Q/A239; CX-0013C, Q/A17; Tr.(Shmuylovich), 707:20-25 ("You can see it. Sometimes by eye, ***depending on the fluorophore***; sometimes with a camera."). However, the specification of the Asserted Patents is devoid of any discussion of fluorescence or means for detecting it, be it by eye or a camera. The specification only contains *one* reference to being able to "selectively locate … the target tissue"

when discussing PD generally. JX-0001, 1:37-43. But there is *no* discussion in the specification about how that locating is done. *Supra* Section VI.B.2. The absence of that essential teaching is another material deficiency showing that the inventors did not possess methods and systems for photodynamically diagnosing patients using the claimed illuminator.

Both Dr. Ehrenreich and Dr. Shmuylovich testified that they did not have experience using curved photodynamic illuminators, like Sun's 4170D, for photodynamic diagnosis. RX-0007C, Q/A113, 240, 262; Tr.(Shmuylovich), 160:15-18; Tr.(Ehrenreich), 654:9-655:15. Put simply, if a patient's face is positioned inside of the five panels, it is not possible to see the patient's face from the other side of the panels (or from above or below). Tr.(Ehrenreich), 654:9-655:15.

Dr. Shmuylovich's focus on the Wood's Lamp to prop up the validity of the Asserted Patents with respect to enablement undermines the lack of written description disclosure for detection. For example, Dr. Shmuylovich points to CX-1079 (Wan), CX-0343 (Kalka), CX-1084 (Bolognia), and CX-1076 (Redondo) for their use of a camera to visualize fluorescence. CX-0013C, Q/A36-37, 117, 129-132. Those articles show that use of the handheld Wood's Lamp enables visualization of the skin—something that is difficult or impossible with the claimed five-panel illuminators, and is not described in the specification. RX-0007C, Q/A262, 271, 333; Tr.(Ehrenreich), 654:9-655:15; Tr.(Shmuylovich), 687:14-691:10, 709:7-24.

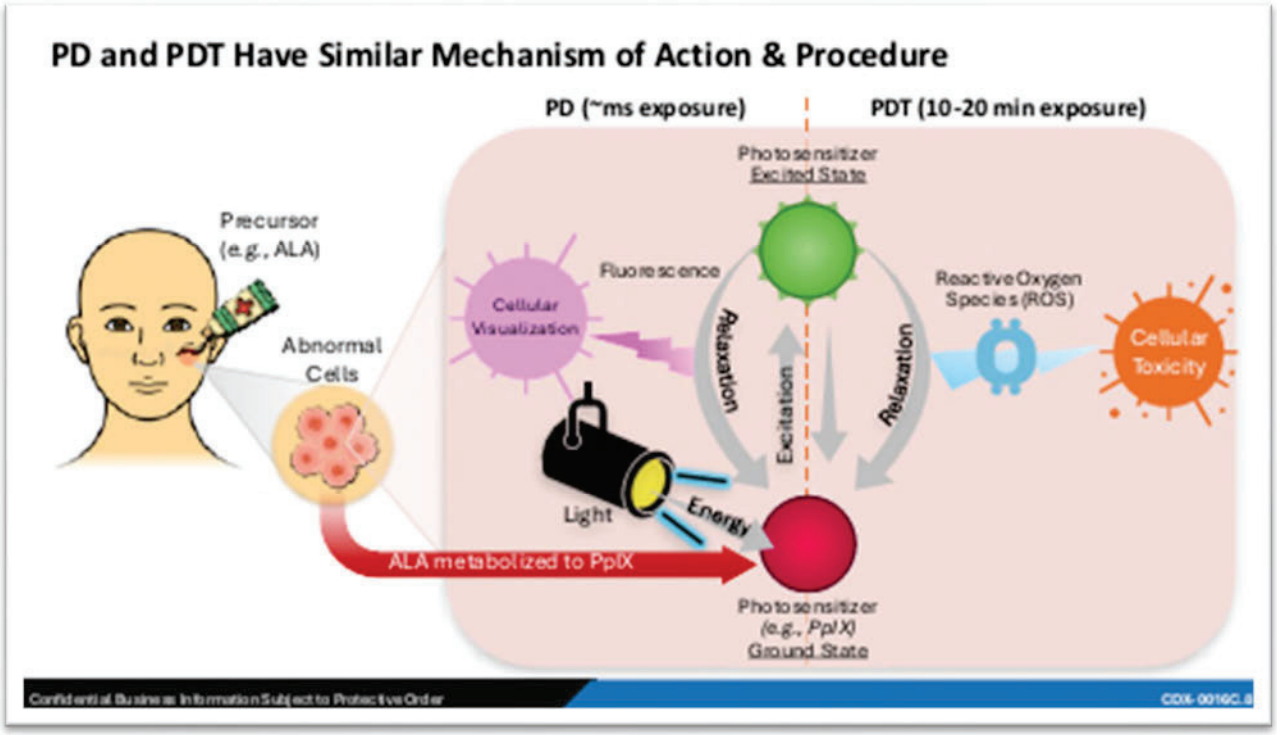
3. Photodynamic Diagnosis Is Different from Photodynamic Therapy

Faced with broad claims directed to PD and a narrow disclosure, Sun and its expert attempt to erase the differences between PD and PDT. Sun's argument relies on superficial similarities between PD and PDT: application of a photosensitizing agent, such as ALA, and exposure to illumination with light at a certain spectrum (i.e., light color). CX-0013C, Q/A17-25. That is where the similarities end. The record shows PD and PDT are different.

PD and PDT differ significantly in the length of time the treatment area is exposed to light, the fluence, and the incubation time after ALA is applied to the treatment surface. Finally, PD involves detecting or locating the fluorescing PpIX molecules, RX-0007C, Q/A114; CX-0013C, Q/A24, which may require fluorescence imaging or light filters. RX-0007C, Q/A276-277, 317, 356; CX-0013C, Q/A30, 134, 158. Indeed, in the context of enablement, Sun relies on papers that cite the importance of fluorescence photographing and/or light emission filters to visualize the fluorescence. *Supra* Section VI.B.2.a.

a. The Specification Does Not Disclose a "Nearly Instantaneous Process" for Illumination and Detection of Fluorescence

Dr. Shmuylovich testified that "[t]he main difference between PDT and PD is the length of time that the treatment area is illuminated," and that "[f]or PD, it is nearly an instantaneous process from illumination to detecting fluorescence." CX-0013C, Q/A18-20. Dr. Shmuylovich's testimony included this graphic purporting to show the similarities between PD and PDT:



CDX-016C.8. But the Asserted Claims do not include limitations directed to the length of time that the treatment area is illuminated and the specification is silent on this "main difference."

Dr. Shmuylovich's testimony, and Sun's opening statement, state that PD must be performed "instantaneously," or in a matter of "seconds" or "milliseconds." CX-0013C, Q/A20, 93, 169-170; Tr.(Shmuylovich), 678:17-679:22. In contrast, PDT is a process that requires illuminating a patient for a longer period of time—on the scale of minutes, or even hours, per the specification of the Asserted Patents. JX-0001, 9:35-43; *see also* CX-0013C, Q/A18-20. Despite testifying that this dramatic difference in illumination time is the "main difference between PDT and PDD," Dr. Shmuylovich confirmed that the Asserted Patents *never* refers to illuminating a patient for a matter of "seconds," "milliseconds," or that PD must be performed "instantaneously." CX-0013C, Q/A18; Tr.(Shmuylovich), 681:11-684:9. The specification's only references to illumination times are on the scale of minutes or hours for the purpose of *treating* patients. JX-0001, 9:35-10:11. As Dr. Ehrenreich and Dr. Foguet testified, the illumination times described in

the specification are useful for photodynamic treatment, not photodynamic diagnosis. Tr.(Foguet), 398:15-22; RX-0007C, Q/A111. And there is no disclosure in the specification that indicates that the claimed illuminator can be turned on for a matter of milliseconds, or that a patient's skin can be visualized "instantaneously" for PD.

Rather than confront this reality, Dr. Shmuylovich points to a vague statement in the specification of the Asserted Patents about illuminating a patient "for a prescribed period." CX-0013C, Q/A93 (citing JX-0001, 9:44-48). And he again falls back on the assertion—wholly unsupported by any citation to the specification or even the scientific literature—that a POSA would know that "a prescribed period" would mean "nearly instantaneous" in the context of PD. *Id*. But the word "instantaneous" is *never* used in the specification in reference to PD. *Supra* Section IV.B.3.a. His testimony is all the more unconvincing because the phrase "prescribed period" appears in a paragraph that recites times ranging from 20 minutes to 30 to 40 minutes to one to three hours, JX-0001, 9:35-40, a range that would encompass between 1.2 million and 10.8 million milliseconds.

b. The Specification Does Not Disclose How Photoactivating Agents or Fluorophores Should be Used for PD

While the experts agree that multiple photosensitizers can be used for PD, CX-0013C, Q/A107; RX-0007C, Q/A100-101, 304, only the method claims of the '512 Patent require the use of a specific agent—ALA—for PD using the claimed illuminator. JX-0001, claims 8, 17, 18. Those claims are silent on what dose or concentration of ALA to use and how long it should be allowed to incubate before illuminating the patient's skin. *Id*.; *see also* RX-0007C, Q/A229. The dose and incubation times are important variables in PD. RX-0007C, Q/A228-231.

The lone working example instructs to incubate ALA for "14-18 hours." JX-0001, 9:6-13. However, a 14-plus hour incubation period could render PD difficult, if not impossible. Dr. Shmuylovich testified that both healthy and diseased cells will accumulate PpIX if allowed to incubate long enough, and depending on the dose of ALA that is applied. CX-0013C, Q/A16, 40. Dr. Foguet agreed, testifying that, "any living cell can concentrate ALA if you wait long enough" and "if you incubate for times that are long enough, then also normal cells will start fluorescing." Tr.(Foguet), 375:2-14; *see also id*., 390:2-391:8. In other words, if ALA is allowed to incubate for 14 or more hours on a patient's skin, *both* healthy and diseased cells will accumulate PpIX molecule and *both* healthy and diseased cells will fluoresce, making it difficult, if not impossible, to photodynamically diagnose a patient (i.e., to detect or delineate the healthy cells from the diseased cells). *Id*.

Dr. Ehrenreich likewise testified that some of the scientific articles that Dr. Shmuylovich relied on highlight this very issue. For example, CX-0108 described a 4-6 hour incubation period—an incubation time one-third of that described in the specification. RX-0007C, Q/A248 (citing CX-0108.2). But even in that paper, a significant number of skin cancers could not be detected via PD. *Id*., Q/A248-250 (citing CX-0108.2-7).

c. The Specification Does Not Disclose What Wavelengths, Intensities, and Fluences of Light to Use for PD

As explained above, the Asserted Claims encompass ranges of wavelengths, intensities, and fluences of light but do not explain how these variables are used for PD. *Supra* Section VI.B.1.

First, the wavelength and color of light is important for at least two reasons: (1) only certain wavelengths of light in the visible light spectrum are effective for activating PpIX molecules to cause fluorescence and (2) PpIX molecules fluoresce with a red or pink color, meaning that the

color and wavelength of light used to excite the PpIX molecules can make it difficult to visualize the fluorescing cells. For example, both Dr. Ehrenreich and Dr. Shmuylovich testified that visible light at a wavelength of about 405 nm (which is blue light near the lower bound of the visible light spectrum), also known as the "soret" band, is considered the most effective wavelength for making PpIX fluoresce. RX-0007C, Q/A226, 266, 304, 333; CX-0013C, Q/A153, 157. However, the specification *never* calls out a 405 nm wavelength as being useful for PD among the broad range of wavelengths encompassed by the Asserted Claims (i.e., from 400-700 nm). *Supra* Section VI.B.1. If the inventors possessed methods and systems for photodynamically diagnosing patients, a POSA would expect the specification to reference that wavelength, rather than the other wavelengths it does call out (which are useful for treatment, but not necessarily ideal for diagnosis). And as explained above, the specification expressly calls out specific wavelengths of light as being useful for treatment, not diagnosis. *Supra* Section VI.B.2. *Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320, 1326 (Fed. Cir. 2000) ("[O]ne cannot disclose a forest … and then later pick a tree out of the forest and say here is my invention. In order to satisfy the written description requirement, the blaze marks directing the skilled artisan to that tree must be in the [specification]").

Further, the Asserted Patents describe the use of other colors of light, including red light at wavelengths around 625 nm to 640 nm. JX-0001, 4:7-13. But as Dr. Ehrenreich testified, PpIX emits fluorescing red light at about the same wavelength, meaning it would be difficult to detect red fluorescing PpIX molecules when a bright red light is also being applied. RX-0007C, Q/A273. Dr. Shmuylovich again relies on scientific articles to offer a solution to this issue—the use of cameras and filters designed to specifically identify the wavelength of light that PpIX emits. CX-0013C, Q/A30, 36-37. As explained above, the specification does not disclose the use of cameras

or filters for PD, or in any way explain how a camera or filter could be used in conjunction with the claimed five-panel illuminator. *Supra* Section VI.B.2.a.

In conclusion, the specification contains cursory references to PD without explaining how to make or use the claimed illuminator for PD. The aspect that Dr. Shmuylovich and Sun contend is the "main difference" between PD and PDT—exposure to light for milliseconds for PD compared to minutes or hours for PDT—is not within the four corners of the specification. *Flash-Control, LLC v. Intel Corp.*, 2021 WL 2944592, at *4 (Fed. Cir. July 14, 2021) (While "the written description is viewed from the perspective of an artisan who brings 'the knowledge of what has come before,'" Federal Circuit precedent requires that "'enough must be included [in the specification] to convince a person of skill in the art that the inventor possessed the invention'") (Quoting *LizardTech, Inc. v. Earth Resource Mapping, Inc.*, 424 F.3d 1336, 1345 (Fed. Cir. 2005) (alterations in original). Accordingly, the Asserted Claims are invalid.

C. The Asserted Claims Are Invalid for Lack of Enablement

The Asserted Patents do not enable a POSA to practice the full scope of the Asserted Claims without undue experimentation because the specification does not enable a POSA to use or make the claimed illuminator to photodynamically diagnose a patient across the full scope of the claims. "[T]he specification must enable the full scope of the invention as defined by its claims. The more one claims, the more one must enable." *Amgen Inc. v. Sanofi*, 598 U.S. 594, 610 (2023) . To determine whether experimentation would have been "undue," courts typically consider the *Wands* factors: "(1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims." *In re Wands*, 858

F.2d 731, 737 (Fed. Cir. 1988). While the analysis is based on the *Wands* factors and the underlying factual evidence, it is not necessary to discuss or show a lack of enablement on each *Wands* factor. *Amgen,* 927 F.2d 1213.

1. The Breadth of the Claims

As explained above, the Asserted claims are broad, encompassing PD for a broad range of conditions. [*Supra* Section VI.B.1]; *see also, e.g.*, RX-0007C, Q/A234. In view of the breadth of the Asserted Claims, the specification must contain a commensurate disclosure to enable the full scope of the Asserted Claims. *Amgen*, 598 U.S. at 610.

a. The State of the Prior Art and the Level of Predictability in the Art

The prior art shows PD had been used with a narrow number of dermatological conditions and relied on specific diagnostic parameters. [*Supra* Section VI.B.2.]; *see also* RX-0007C, Q/A244-245.

Sun relies on a series of papers to fill in gaps left open by the specification. *See generally* CX-0013C (Shmuylovich citing CX-0342, CX-0343, CX-1076, CX-1079, CX-1081, CX-1084). These papers focus on PD using a handheld Wood's Lamp using nonvisible light at 365 nm, allowing weak read fluorescence to become visible (CX-0342.1-2; CX-1076.1; CX-1084.1), and fluorescent photography techniques, (CX-1079.3; CX-1081.7). The Asserted Patents' Specification only discusses conducting PD with a bright illuminator operating in the visible (*i.e.*, 400-700 nm) light spectrum. RX-0007C, Q/A272-278, 317. A POSA would need to engage in experimentation to understand how to photodynamically diagnose a patient with the claimed illuminator across the full scope of the claims, particularly as to visible light wavelengths and the claimed fluences. RX-0007C, Q/A313-314, 317-318. Likewise, a POSA would need guidance about photosensitizer incubation time, how to "instantaneously" detect fluorescence, and even how

to build an illuminator that could uniformly illuminate for a matter of milliseconds and then turn off. *Supra* Section VI.B.3.A. *See ALZA Corp. v. Andrx Pharms.*, LLC, 603 F.3d 935, 941 (Fed. Cir. 2010) (finding a textbook incorporated by reference and the state of the art insufficient to enable non-osmotic dosage forms).

b. The Amount of Direction Provided by the Patents and the Existence of Working Examples

The specification lacks guidance on how to use the claimed illuminator for PD. [Supra Section VI.B.2]. *Amgen,* 598 U.S. at 610. Sun relies on an example containing lengthy time ranges—for illumination and incubation times—that the expert testimony demonstrates will not work for PD. RX-0007C, Q/A48-49, 249-250, 292-297, 302; CX-0013C, Q/A18-20, 43; JX-0001, 8:64-9:43; *see also In re Cook,* 439 F.2d 730, 736 (C.C.P.A. 1971) ("Section 112 requires not that the specifications merely say how to use the claimed invention, but that such teaching be true, i.e., in fact enabling"); *see also ALZA,* 603 F.3d at 941 (Finding "ten lines of the specification, which mention non-osmotics" insufficient to enable non-osmotic dosage forms").

c. The Quantity of Experimentation Needed to Make or Use the Invention Based on the Content of the Disclosure

A POSA would need to engage in undue experimentation to make or use the claimed invention for PD, including conducting trial-and-error experimentation to know whether the claimed illuminator could be used to diagnose using the full scope of conditions encompassed by the Asserted Claims. RX-0007C, Q/A249, 313-314, 317. The scientific articles cited by Sun demonstrate that application of different types and amounts of photosensitizers for different periods of time, different light fluences, and different wavelengths affect whether dermatological conditions can be photodynamically diagnosed. [*Supra* Section VI.B.2.]. The articles employ

Wood's Lamps using non-visible light but the invention is directed to photodynamic diagnosis using light sources in the visible spectrum. *Id*. Because the specification offers virtually no direction, or guidance that would lead a POSA away from a successful result, a POSA would be left to engage in a significant amount of experimentation. RX-0007C, Q/A313-314, 317-318. The specification offers no solutions to the problems discussed above with respect to the visualization aspect of PD—a POSA would be left to figure out how to see the patient with their eyes (if that is even possible) or how to incorporate a camera (and filters) into the illuminator to capture images of the patient. *Supra* Section VI.B.2.a. RX-0007C, Q/A319-320.

Accordingly, the Asserted Claims are invalid for lack of enablement.

VII. DOMESTIC INDUSTRY – TECHNICAL PRONG

A. Sun's Burden on Domestic Industry Claims

Sun has not carried its burden to show that the 4170E, individually or in combination with Levulan®, practices claims 1, 2, 4, 5, 8, 19, and 20 of the '512 Patent and claims 1, 3, 4, 5, 7, 9, 16–18 and 21 of the '028 Patent (collectively, "DI Claims"). Sun PHB 196, 219. "The relevant date at which to determine whether the domestic industry exists or is in the process of being established is the filing date of the complaint." *Certain Televisions, Remote Controls, & Components Thereof,* Inv. No. 337-TA-1263, Comm'n Op. at 20 (Nov. 30, 2022) (citing *Motiva, LLC v. Int'l Trade Comm'n*, 716 F.3d 596, 601 n.6 (Fed. Cir. 2013).The evidence leaves no doubt that the method claims—claims 8 and 19 of the '512 Patent and claims 5, 7, and 9 of the '028 Patent—were not practiced as of June 2024, the date of the complaint, if they have been practiced at all. The method claims require specific treatment steps, including applying ALA to a patient's skin. Under cross examination, Mr. Lundahl testified that Sun's hand-picked physician, [redacted] well after the

complaint was filed. Tr.(Lundahl) 88:15-90:17. [redacted] was not identified by name until trial, did not testify or submit herself to cross examination, or even submit a declaration to corroborate that the method was practiced according to the claims. *Id.* at 89:8-18. In fact, none of the testimony cited by Sun's witnesses establishes that the methods were actually practiced. Moreover, Mr. Lundahl testified that he never spoke with Dr. Shmuylovich, Sun's expert on ttechnical prong. *Id.* at 90:15-20.

VIII. REMEDY AND BONDING

Sun cannot show that it is entitled to any remedy in this Investigation. Neither a limited exclusion order ("LEO") nor cease and desist order ("CDO") is appropriate as there is no violation of Section 337. Respondents have not and do not infringe any valid claim of the Asserted Patents or otherwise violate 35 U.S.C. § 271 or 19 U.S.C. § 1337. Additionally, Sun has not established the existence of a domestic industry for the Asserted Patents as required by Section 337(a)(2) and defined by Section 337(a)(3).

If the Commission finds a violation, any remedy issued, including any LEO or CDO, should identify and be restricted to (1) the specific parties who import into the U.S., sell for importation into the U.S., or sell within the U.S. the specific accused products found to infringe the asserted claims of the asserted patents; and (2) those specific accused products found to infringe the asserted claims of the asserted patents, as the remedy provided must have a "reasonable relation to the unlawful practices found to exist." *Hyundai Elecs. Indus. Co., Ltd. v. U.S. Int'l Trade Comm'n*, 899 F.2d 1204, 1209 (Fed. Cir. 1990); *see also* 19 U.S.C. § 1337(d). Any exclusion order should include a certification provision that "will ease the burden both on legitimate trade and on U.S. Customs' enforcement of the exclusion order." *Certain Optoelectronic Devices, Components Thereof, & Prods.* ("*Optoelectronic Devices*"), Inv. No. 337-TA-669, Comm'n Op. at 7 (Jul. 26,

2010); *Certain Road Construction Machines & Components Thereof* ("*Road Construction Machines*"), Inv. No. 337-TA-1088 (Modification) Comm'n Op. at 14 (Sep. 14, 2020) (calling certification provisions "standard" and stating that they have a "longstanding" form).

Further, per Commission precedent, a CDO is not appropriate for any products imported and provided to customers before the issuance of an LEO. *See Certain Sleep-Disordered Breathing Treatment Systems & Components Thereof* ("*Sleep-Disordered Breathing*"), Inv. No. 337-TA-890, Comm'n. Op. at 47 (Jan. 16, 2015). Finally, as remedial orders should not affect respondents' ability to service existing customers' products, exemptions for warranty and repair are common. *See id*; *see also Certain Digital Video Receivers & Related Hardware & Software Components* ("*Digital Video Receivers*"), Inv. No. 337-TA-1103, Comm'n Op. at 24 (May 13, 2020) (including exemption for replacement parts used to repair previously-imported products under warranty).

A. LEO

1. Certification Provision

If an LEO is issued, it should include "the standard certification provision as typically requested by U.S. Customs and Border Protection ('CBP')" whereby Respondent can certify as to which imported products and/or components are not included within the scope of the order. *Certain Movable Barrier Operator Sys. & Components Thereof* ("*Movable Barriers*"), Inv. No. 337-TA-1209, Comm'n Op. at 68 (Mar. 11, 2022); *Certain Beverage Dispensing Sys. & Components Thereof* ("*Beverage Systems*"), Inv. No. 337-TA-1130, Comm'n Op. at 24-25 (Mar. 26, 2020). Such a certification provision "will ease the burden both on legitimate trade and on U.S. Customs' enforcement of the exclusion order." *Optoelectronic Devices*, Inv. No. 337-TA-669, Comm'n Op. at 7; *Road Construction Machines*, Inv. No. 337-TA-1088 (Modification) Comm'n Op. at 14 (calling certification provisions "standard" and stating that they have a "longstanding" form). If

the Commission issues a remedy, any LEO should not include Ameluz.® Ameluz® may be used with non-accused products, *i.e.*, the RhodoLED®, which is not within the scope of the Investigation. Such a certification provision would be consistent with Sun's Complaint. *See* JX-0198, ¶ 6 ("Sun Pharma does not seek to exclude Biofrontera's pharmaceutical products that Biofrontera certifies are not being sold for use with Biofrontera's accused photodynamic therapy treatments."); Tr (Luebbert) 323:25-324:3; 361:21-362:6; JX-0074.1 (Ameluz® Label). Ameluz® may also be used with RhodoLED®XL lamps sold *before* the remedial orders take effect, especially since the RhodoLED®XL is not indicated for use without Ameluz.® Including Ameluz® in an LEO would unfairly harm customers who would then have an unusable lamp. JX-0011C, 29:17-30:9; RX-1176 (Biofrontera Receives FDA-Approval of RhodoLED®XL); JX-0074.1 (Ameluz® Label); Tr (Luebbert) 322:18-21, 361:21-362:6; Tr.(Foguet) 379:12-380:1. Remedial relief is not intended to punish U.S. consumers that purchased accused products prior to any finding of violation. *Certain Digital Video Receivers & Related Hardware & Software Components*, Inv. No. 337-TA-1103, ID at 314-15 (Jun. 4, 2019); *see also Sleep Disordered Breathing*, Inv. No. 337-TA-890, Comm'n Op. at 51 (Dec. 23, 2014).

2. Service & Repair

Any remedial order should narrowly tailor relief to include a service, warranty, and repair exemption provision for existing customers. *See Movable Barriers*, Inv. No. 337-TA-1209, Comm'n Op. at 67-68. Warranty and repair exemptions, to both LEOs and CDOs, are appropriate where a respondent is obligated to repair or replace defective products. *See id*. at 69-72. They are routinely granted by the Commission under appropriate circumstances. *See, e.g., id*. at 68-69, fn.30; *Certain Motorized Vehicles & Components Thereof*, Inv. No. 337-TA-1132, Comm'n Op. at 34 (Jun 18, 2020); *Digital Video Receivers*, Inv. No. 337-TA-1103, Comm'n Op. at 24. Here, a

warranty and repair exemption is appropriate as Biofrontera provides a three-year warranty including replacement, service, and repair of their RhodoLED®XL. RX-0045C (Purchase Terms & Conditions Agreement); RX-0003C, Q/A53-55. Biofrontera's warranty covers any issue during the warranty period. RX-0003C, Q/A53; RX-0004C, Q/A75; JX-0022C; Tr.(Foguet) 382:6-25. A unit that is under warranty may either be repaired or replaced, depending on the issue. RX-0003C, Q/A55. Additionally, Biofrontera may ship lamps to Germany to fix the lamp head and would potentially need to use such repaired imported lamps for warranty purposes. RX-0002C, Q/A117; Tr.(Foguet) 383:1-9.

B. CDO

A CDO is "generally issued when there is a 'commercially significant' amount of infringing, imported product in the United States that could be sold by an infringing respondent resulting in evasion of the remedy provided by an exclusion order." *Certain Mobile Devices, Associated Software, & Components Thereof*, Inv. No. 337-TA-744, Comm'n Op. at 24 (June 5, 2012); *Certain High-Density Fiber Optic Equipment & Components Thereof*, Inv. No. 337-TA-1194, Comm'n Op. at 82 (Aug. 23. 2021). "Complainants bear the burden of proving that respondents have commercially significant inventories of infringing products in the United States." *Sleep-Disordered Breathing*, Inv. No. 337-TA-890, Comm'n. Op. at 49. As of April 18, 2025, Biofrontera had 160 RhodoLED®XL lamps in inventory. RX-0003C, Q/A38. Sun has failed to establish that this is a commercially significant inventory and that a CDO is required.

If the Commission issues a CDO, then it should not include Ameluz®, which is not an Accused Product. As explained above in Section VIII.A.1, Biofrontera should be permitted to sell Ameluz® for non-infringing uses, including with customers' RhodoLED® and previously-purchased RhodoLED®XL lamps.

Furthermore, any CDO should also include an exemption for RhodoLED®XLs and their components used for repair or replacement under Biofrontera's warranty obligations to existing customers. *See* Section VIII.A.2.

C. Bond

If the Commission finds a violation, it should impose no bond during the Presidential Review Period. The purpose of a bond is to protect the complainant from injury and there is no such injury here. 19 U.S.C. § 1337(j)(3). The complainant bears the burden of establishing that (i) a bond is necessary to prevent injury and (ii) the proposed bond amount is necessary to offset injury. Long standing precedent makes clear that when a complainant fails to demonstrate that a bond is warranted, the Commission should not impose a bond. *See Certain Magnetic Tape Cartridges & Components Thereof*, Inv. No. 337-TA-1058, Comm'n Op. at 73-74 (Apr. 10, 2019) (imposing zero bond); *Certain Coenzyme Q-10 Prods. & Methods of Making Same*, Inv. No. 337-TA-790, ID/RD (Sept. 27, 2012) (recommending no bond where complainant "failed in its burden to demonstrate the appropriate bond amount"). Complainant must demonstrate both the need for a bond and a reasonable bond amount "sufficient to protect the complainant from any injury." *Certain Routers, Access Points, Controllers, Network Management Devices, Other Networking Prods. & Hardware & Software Components Thereof* ("*Routers*"), Inv. No. 337-TA-1227, ID at 317-8 (Dec. 7, 2021); *Certain Rubber Antidegradants*, Inv. No. 337- TA-533, Comm'n Op. at 39-40 (July 21, 2006) "When reliable price information is available, the Commission has often set bond by eliminating the differential between the domestic product and the imported, infringing product," or alternatively, through a "reasonable royalty" to license an asserted patent. *Routers*, Inv. No. 337-TA-1227, ID at 317 (citing *Certain Magnetic Tape Cartridges*, Inv. No. 337-TA-1058, Comm'n Op. at 73-74). If the average selling price of the Accused Products is *greater* than

the average selling price of the DI Product, the appropriate bond is 0%. *See Certain Access Control Systems & Components Thereof*, Inv. No. 337-TA-1016, Comm'n. Op. at 39-44 (Aug. 21, 2018); *Certain Table Saws Incorporating Active Injury Mitigation Technology & Components Thereof*, Inv. No. 337-TA-965, Comm'n Op. at 15 (Jan. 27, 2017) Sun has failed to establish that a bond is necessary, [redacted]

Sun's attempts to justify a bond are insufficient. First, Dr. Vander Veen testified that [redacted] a reasonable royalty rate cannot be used to establish bond in this case." CX-0016C, Q/A333. Second, Dr. Vander Veen concludes that—even though there are just two products to consider—a price comparison is not practical to determine a bond. CX-0016C, Q/A330; Tr.Vander Veen) 270:20-271:5; 277:19-278:5. Dr. Vander Veen disregards that [redacted] Dr. Vander Veen's conclusion that a bond should be set at 100% to "eliminate any price difference" between the products is incorrect. CX-0016C, Q/A332.

While there is [redacted], the evidence shows an anticipated price of [redacted]. CX-0011C, Q/A183 ([redacted]); JX-0016C, 31:12-20 (Sun intended to sell 4170E at [redacted]); Tr.(Lundahl) 94:14-16 (Sun currently plans to sell 4170E at [redacted]), 92:17-24 (admitting to retail price goal of [redacted]). These potential prices are [redacted] and generally

sells for [redacted], but in any case, not less than [redacted] over the full-loaded cost of the unit. RX-0837C (Sales & Inventory Report for Q3-2024); RX-0003C, Q/A43, 50-51 (testifying that MSRP is $18,500 and minimum sales price is [redacted]); RX-0008C (Rowe WS) Q/A27 (calculating average sales price of [redacted]). While Dr. Vander Veen speculated that Biofrontera may lower its price for the Accused Product and, potentially, sell its product at a loss, he admitted that he is unaware of rules that require Biofrontera to sell the RhodoLED®XL at a profit. RX-1381C (Vander Veen Dep. Tr.) 159:12-160:20; RX-0003C, Q/A50; Tr (Vander Veen) 276:3-12. Indeed, Dr. Vander Veen could not identify a single sale of the RhodoLED®XL below [redacted] that was not a refurbished unit or due to a trade-in discount. Tr.(Vander Veen) 302:10-303:6; JX-0229C. The evidence shows that Sun will [redacted] Tr.(Lundahl) 94:14-95:13; Tr.(Vander Veen) 303:11-14.

CERTIFICATE OF COMPLIANCE WITH WORD LIMIT

The foregoing filing complies with the word limits set forth in Ground Rule 11.2 and contains 24,912 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.

/s/ *Lauren E. Peterson*
Lauren E. Peterson

Dated July 21, 2025

Respectfully submitted,

/s/ *Lauren E. Peterson*
Deanna Tanner Okun
Chad A. Landmon
Lauren E. Peterson
Chris Jones

Sean M. Wesp
Polsinelli P.C.
1401 Eye Street N.W., Suite 800
Washington, D.C. 20005
Telephone: (202) 626-8320
Brian J. Larivee
Polsinelli P.C.
One International Place
Suite 3900
Boston, MA 02110
Telephone: (617) 406-0398

Elton F. Dean III
Megan Hart
Polsinelli P.C.
7676 Forsyth Boulevard, Suite 800
St. Louis, MO 63105
Telephone: (314) 622-6632

Corey M. Casey, Pharm.D
Polsinelli P.C.
900 W. 48th Place, Suite 900
Kansas City, MO 64112
Telephone: (816) 572-4439

Kendall K. Gurule
Polsinelli P.C.
1401 Lawrence Street, Suite 2300
Denver, CO 80202
Telephone: (303) 256-1921

Dominique E. Smith
Polsinelli P.C.
2049 Century Park East, Suite 2900
Los Angeles, CA 90067
Telephone: (310) 229-1390

Counsel for Biofrontera Inc., Biofrontera Pharma GMBH, Biofrontera Bioscience GMBH, & Biofrontera AG

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:

Lisa R. Barton Secretary to the Commission **U.S. INTERNATIONAL TRADE COMMISSION** 500 E Street, SW, Room 112 Washington, DC 20436	☒ **VIA EDIS**
Brian F. Moore Administrative Law Judge **U.S. INTERNATIONAL TRADE COMMISSION** 500 E Street, SW Washington, DC 20436	☒ **VIA ELECTRONIC MAIL**
Counsel for Complainant Sun Pharmaceutical Industries, Inc. Betty Chen Kurt Fredrickson **DESMARAIS LLP** 101 California Street, Suite 3000 San Francisco, CA 94111 Telephone: (415) 573-1900 Facsimile: (415) 573-1901 Goutam Patnaik Tuhin Ganguly **DESMARAIS LLP** 1899 Pennsylvania Avenue, NW, Suite 400 Washington, DC 20006 Telephone: (202) 451-4900 Facsimile: (202) 451-4901 Raymond Habbaz **DESMARAIS LLP** 230 Park Avenue, 26th Floor New York, NY 10169 Telephone: (212) 351-3400 Facsimile: (212) 351-3401 Email: Sun-BiofronteraITCService@desmaraisllp.com	☒ **VIA ELECTRONIC MAIL**
Counsel for Respondents Biofrontera Inc.,	

Tyler T. VanHoutan **MCGUIREWOODS LLP** Texas Tower 845 Texas Avenue Suite 2400 Houston, Texas 77002 Tel: (713) 571-9191 Fax: (713) 571-9652 Email: mwbiofronteraitc@mcguirewoods.com David E. Finkelson George B. Davis **MCGUIREWOODS LLP** Gateway Plaza 800 East Canal Street Richmond, VA 23219-3916 Telephone: 804-775-1000 Facsimile: 804-775-1061 Email: mwbiofronteraitc@mcguirewoods.com	☒ **VIA ELECTRONIC MAIL**

/s/ Antoine R. Bland
Antoine R. Bland
Polsinelli PC,
1401 Eye Street N.W., Suite 800
Washington, D.C. 20005
Telephone: (202) 626-8362
Email: abland@polsinelli.com