

UNITED STATES INTERNATIONAL TRADE COMMISSION

Washington, D.C.

In the Matter of

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

Inv. No. 337-TA-1411

**INITIAL DETERMINATION ON VIOLATION OF SECTION 337 AND
RECOMMENDED DETERMINATION ON REMEDY AND BOND**

Administrative Law Judge Bryan F. Moore

(September 30, 2025)

Appearances:

For Complainant Sun Pharmaceutical Industries, Inc.:

Betty Chen; Gabrielle Higgins; and Maximillian McDonald of DESMARAIS LLP of San Francisco, CA

Tuhin Ganguly; David J. Shaw; and Atifah Safi of DESMARAIS LLP of Washington, DC

Raymond Habbaz and Paul Macri of DESMARAIS LLP of New York, NY

For Respondents Biofrontera Inc.; Biofrontera Pharma GmbH; Biofrontera AG; and Biofrontera Bioscience GmbH:

Deanna Tanner Okun; Chad A. Landmon; Lauren E. Peterson; Chris Jones; and Sean M. Wesp of Polsinelli P.C. of Washington, DC

Brian J. Larivee of Polsinelli P.C. of Boston, MA

Elton F. Dean III and Megan Hart of Polsinelli P.C. of St. Louis, MO

Corey M. Casey of Polsinelli P.C. of Kansas City, MO

Kendall K. Gurule of Polsinelli P.C. of Denver, CO

Dominique E. Smith of Polsinelli P.C. of Los Angeles, CA

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Table of Abbreviations

The following abbreviations may be used in this Initial Determination:

CDX	Complainant's demonstrative exhibit
CPX	Complainant's physical exhibit
CX	Complainant's exhibit
CIB	Complainant's initial post-hearing brief
CRB	Complainant's reply post-hearing brief
CPHB	Complainant's pre-hearing brief
JX	Joint Exhibit
RDX	Respondents' demonstrative exhibit
RPX	Respondents' physical exhibit
RX	Respondents' exhibit
RIB	Respondents' initial post-hearing brief
RRB	Respondents' reply post-hearing brief
RPHB	Respondents' pre-hearing brief
RWS	Rebuttal witness statement
Tr.	Transcript
WS	Witness statement

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Administrative Law Judge Bryan F. Moore

(September 30, 2025)

Pursuant to the Notice of Investigation, this is the final initial determination in *Certain Photodynamic Therapy Systems, Components Thereof, and Pharmaceutical Products Used in Combination with the Same*, United States International Trade Commission Investigation No. 337-TA-1411.

For the reasons stated herein, I have determined that there is a violation of section 337 of the Tariff Act of 1930, as amended, in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain photodynamic therapy systems, components thereof, and pharmaceutical products used in combination with the same based on infringement of U.S. Patent Nos. 11,446,512 and 11,697,028.

I. INTRODUCTION

A. Procedural History

On June 26, 2024, Sun Pharmaceutical Industries, Inc. (“Complainant” or “Sun Pharma”) filed a complaint alleging violations of section 337 based on the importation, sale for importation, or sale within the United States after importation of certain photodynamic therapy systems, components thereof, and pharmaceutical products used in combination with the same that purportedly infringe U.S. Patent Nos. 11,446,512 (“the ’512 patent”) and 11,697,028 (“the ’028 patent”) (collectively, “the Asserted Patents”).¹ 89 Fed. Reg. 62790 (Aug. 1, 2024); *see* EDIS Doc. ID 827991. A supplement to the complaint was filed on July 9, 2024. *Id.*

The Notice of Investigation named the following parties as respondents: Biofrontera Inc.; Biofrontera Pharma GmbH (“Biofrontera Pharma”); Biofrontera Bioscience GmbH (“Biofrontera Bioscience”); and Biofrontera AG (collectively, “Respondents” or “Biofrontera”). *Id.* The Office of Unfair Import Investigations is not a party to this investigation. *Id.*

On August 19, 2024, I issued an initial determination setting the target date at eighteen months. Order No. 5, *not reviewed*, Comm’n Notice (Sept. 16, 2024).

On October 22, 2024, I granted-in-part complainant’s motion to amend the complaint and investigation to add certain claims.² Order No. 8, *not reviewed*, Comm’n Notice (Nov. 20, 2024).

On June 25, 2025, I issued an initial determination granting complainant’s motion for summary determination on the satisfaction of the economic prong of the domestic industry

¹ The investigation was instituted as to the following claims: claims 1, 2, 4-6, 16, 17, and 19-21 of the ’028 patent and claims 1-3, 5, 8, and 20 of the ’512 patent.

² Specifically, claims 17 and 18 of the ’512 patent were added to the Investigation. Thus, Complaint asserts claims 1-5, 8, and 17-20 of the ’512 patent and claims 1-5, 7, 9, and 16-21 of the ’028 patent (collectively, “the Asserted Claims”).

requirement. Order No. 23. The Commission review is pending. Comm’n Notice to Review (July 25, 2025).

The evidentiary hearing was held on June 30 - July 3, 2025.

B. The Parties

1. Complainant

Complainant Sun Pharmaceutical Industries, Inc. is a corporation organized under the laws of Delaware, having its principal place of business in Princeton, New Jersey. Complaint at ¶ 9. Complainant designs, markets, and sells photodynamic therapy (“PDT”) systems, including the BLU-U® Blue Light Photodynamic Therapy Illuminator device, as well as pharmaceutical products, including the Levulan® prescription medicine, used in combination with the BLU-U® Blue Light Photodynamic Therapy Illuminator device. Additionally, Sun Pharma provides technical support for its BLU-U® Blue Light Photodynamic Therapy Illuminator device and Levulan® prescription medicine. *Id.* at ¶ 11.

2. Respondents

a) Biofrontera Inc.

Respondent Biofrontera Inc. is a corporation organized and existing under the laws of Delaware, with a principal place of business located in Woburn, Massachusetts. *Id.* at ¶ 14. It was established in March 2015 as a wholly owned U.S. subsidiary of Biofrontera AG. *Id.* at ¶ 15. Biofrontera Inc. is involved in the importation of the Accused Products into the United States and/or sale of the Accused Products after importation in the United States. *Id.* at ¶ 14.

b) Biofrontera Pharma

Respondent Biofrontera Pharma GmbH is a corporation organized and existing under the laws of Germany, with a principal place of business in Leverkusen, Germany. *Id.* at ¶ 18.

Biofrontera Pharma is a wholly owned subsidiary of Biofrontera AG. *Id.* Biofrontera Pharma is “sufficiently involved with the design, manufacture, sale, and importation of the Accused Products, such that it is an importer for purposes of Section 337” and it “also sells for importation, and/or is involved in sales within the United States after importation, of the Accused Products.” *Id.* at ¶ 17.

c) Biofrontera Bioscience

Respondent Biofrontera Bioscience GmbH is a company located in Leverkusen, Germany. Biofrontera Bioscience is “sufficiently involved with the design, manufacture, and importation of the Accused Products, such that it is an importer for purposes of Section 337” and it “also sells the Accused Products for importation into the United States.” *Id.* at ¶ 26. Biofrontera Bioscience is a wholly owned subsidiary of Biofrontera AG. *Id.* at ¶ 27.

d) Biofrontera AG

Respondent Biofrontera AG is a German corporation organized under the laws of Germany, having a principal place of business in Leverkusen, Germany. *Id.* at ¶ 30. Biofrontera AG is “sufficiently involved with the design, manufacture, and importation of the Accused Products, such that it is an importer for purposes of Section 337” and it “also sells for importation into the United States the Accused Products.” *Id.* at ¶ 29.

C. The Asserted Patents

1. The '512 Patent

U.S. Patent No. 11,446,512, entitled “Adjustable illuminator for photodynamic therapy and diagnosis,” issued on September 20, 2022, from U.S. Patent Application No. 16/791,004, which was filed on February 14, 2020. JX-0001 ('512 patent). The application is a divisional application of U.S. Patent Application No. 15/292,731, filed on October 13, 2016, now granted as U.S. Patent

No. 10,589,122, which claims the benefit of priority to U.S. Provisional Application No. 62/241,902 filed on October 15, 2015, now expired. *Id.* at 1:8-13.

Complainant asserts claims 1, 3, 5, 8, 17-18, and 20 for infringement and claims 1, 2, 4, 5, 8, 19, and 20 for domestic industry, CIB at 7, which recite:

1. [p] A system for photodynamically diagnosing or treating a patient, comprising:
 - [a] an illuminator comprising at least five panels connected by nested hinges on inner side surfaces of adjacent panels,
 - [b] light sources disposed on surfaces of the at least five panels, the illuminator being configured to uniformly illuminate a treatment surface of the patient via the light sources,
 - [c] 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,
 - [d] wherein each of the at least five panels has two first edges and two second edges shorter than the two first edges, and the light sources are arranged such that a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges.
2. [p] The system of claim 1, [a] wherein the illuminator is configured to uniformly illuminate the treatment surface when the treatment surface is at a distance of two to four inches from the illuminator.
3. [p] The system of claim 1, [a] wherein the illuminator is configured to output red light at a dose of about 30 J/cm² to about 150 J/cm².
4. [p] The system of claim 1, [a] wherein the illuminator is configured to output light at an irradiance density of 10 mW/cm² to 30 mW/cm².
5. [p] The system of claim 1, [a] wherein a plurality of the light sources are configured to emit light having a wavelength in a range of 400 nm to 700 nm.
8. [p] A method of photodynamically diagnosing or treating a patient, comprising:
 - [a] administering 5-aminolevulinic acid (ALA) to the patient;
 - [b] positioning an illuminator proximate to the patient, the illuminator comprising at least five panels connected by nested hinges on inner side surfaces of adjacent panels; and
 - [c] uniformly illuminating a treatment surface of the patient with light sources disposed on the at least five panels of the illuminator,

- [d] wherein each of the at least five panels has two first edges and two second edges shorter than the two first edges, and the light sources are arranged such that a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges.
17. [p] The method of claim 8, [a] wherein at least one panel includes a recess configured to receive a flange of one of the nested hinges.
18. [p] The method of claim 17, [a] wherein the recess is positioned at an inner side surface of the at least one panel.
19. [p] The method of claim 8,
- [a] wherein the illuminator comprises at least three first panels having first widths, at least two second panels having second widths, wherein each of the second widths of the at least two second panels is narrower than each of the first widths of the at least three first panels; and
- [b] wherein the at least three first panels and the at least two second panels are connected in an alternating manner such that each of the at least two second panels has a first lateral side connected to a respective one of the at least three first panels and a second lateral side connected to another respective one of the at least three first panels.
20. [p] A system for photodynamically diagnosing or treating a patient, comprising:
- [a] an illuminator comprising at least five panels connected by nested hinges on inner side surfaces of adjacent panels, the nested hinges being configured so as to allow continuous illumination across the at least five panels,
- [b] light sources disposed on surfaces of the at least five panels, the illuminator being configured to uniformly illuminate a treatment surface of the patient via the light sources,
- [c] 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,
- [d] wherein each of the at least five panels has two first edges and two second edges shorter than the two first edges, and the light sources are arranged such that a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges.

'512 patent at claims 1-5, 8, and 17-20.

2. The '028 Patent

U.S. Patent No. 11,697,028, entitled “Adjustable illuminator for photodynamic therapy and diagnosis,” issued on July 11, 2023, from U.S. Patent Application No. 17/942,353, which was filed on September 12, 2022. JX-0002 ('028 patent). The application is a continuation of U.S. Patent Application No. 16/791,004, filed on February 14, 2020, now granted as U.S. Patent No. 11,446,512, which is a divisional application of U.S. Patent Application No. 15/292,731, filed on October 13, 2016, now granted as U.S. Patent No. 10,589,122, which claims the benefit of priority to U.S. Provisional Application No. 62/241,902, filed on Oct. 15, 2015. *Id.* at 1:8-15.

Complainant asserts claims 1, 2, 4, 16, 17, and 19-21 for infringement and claims 1, 3, 4, 5, 7, 9, 16-18, and 21 for domestic industry, CIB at 7, which recite:

1. [p] A system for photodynamically diagnosing or treating a patient, comprising:
 - [a] an illuminator comprising five panels connected by hinged structures on inner side surfaces of adjacent panels; and
 - [b] 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,
 - [c] one of the five panels being positioned as a center panel configured to face the treatment surface, and two or more of the five panels being configured to be angled relative to the center panel,
 - [d] wherein the five panels are positioned to allow treatment within approximately four inches of the treatment surface, and
 - [e] wherein each of the five panels has two first edges and two second edges shorter than the two first edges, and the light sources are arranged such that a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges.
2. [p] The system of claim 1, [a] wherein the illuminator is configured to output red light at a dose of 30 J/cm² to 150 J/cm².
3. [p] The system of claim 1, [a] wherein the illuminator is configured to output light at an irradiance density of 10 mW/cm² to 30 mW/cm².

4. [p] The system of claim 1, [a] wherein a plurality of the light sources are configured to emit light having a wavelength in a range of 400 nm to 700 nm.
5. [p] A method of photodynamically diagnosing or treating a patient, comprising:
 - [a] administering 5-aminolevulinic acid (ALA) to the patient;
 - [b] positioning an illuminator proximate to the patient, the illuminator comprising five panels connected by hinged structures on inner side surfaces of adjacent panels; and
 - [c] uniformly illuminating a treatment surface of the patient with light sources disposed on the five panels of the illuminator, the five panels being positioned to allow treatment within approximately four inches of the treatment surface,
 - [d] wherein each of the five panels has two first edges and two second edges shorter than the two first edges, and the light sources are arranged such that a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges.
7. [p] The method of claim 5, [a] wherein the illuminating comprises outputting blue light during at least part of the time when the treatment surface is illuminated.
9. [p] The method of claim 5, wherein:
 - [a] the illuminator comprises at least three first panels having first widths, at least two second panels having second widths, wherein each of the second widths of the at least two second panels is narrower than each of the first widths of the at least three first panels; and
 - [b] the at least three first panels and the at least two second panels are connected in an alternating manner such that each of the at least two second panels has a first lateral side connected to a respective one of the at least three first panels and a second lateral side connected to another respective one of the at least three first panels.
16. [p] A system for photodynamically diagnosing or treating a patient, comprising:
 - [a] a mobile base supported by at least four wheels;
 - [b] a pillar perpendicular to the base;
 - [c] a controller disposed to be supported by the pillar;
 - [d] an arm mounted to a top portion of the pillar; and
 - [e] an illuminator connected at an end of the arm, [f] the arm being hinged to allow adjustment of a position of the illuminator relative to the base, [g] the illuminator comprising:

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,

[h][a] 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 light sources being configured to output light uniformly during at least part of a time when the treatment surface is illuminated, [h][b] each of the five panels having two first edges and two second edges shorter than the two first edges, the light sources arranged such that a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges, and

[i] one or more fans mounted to at least one of the five panels.

17. [p] The system of claim 16, [a] wherein 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.

18. [p] The system of claim 16, [a] wherein the light sources are configured to output blue light during at least part of the time when the treatment surface is illuminated.

19. [p] The system of claim 16, [a] wherein the light sources are configured to output red light during at least part of the time when the treatment surface is illuminated.

20. [p] A system for photodynamically diagnosing or treating a patient, comprising:

[a] an illuminator comprising five panels connected by hinged structures on inner side surfaces of adjacent panels, wherein the illuminator is configured to output light at a variable irradiance density during treatment; and

[b] 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,

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

[d] wherein the five panels are positioned to allow treatment within approximately four inches of the treatment surface, and

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

21. [p] A system for photodynamically diagnosing or treating a patient, comprising:

[a] an illuminator comprising five panels connected by hinged structures on inner side surfaces of adjacent panels; and

[b] 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,

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

[d] wherein the five panels are positioned to allow treatment within approximately four inches of the treatment surface,

[e] wherein the five panels are individually configurable to control illumination from each of the five panels, and

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

'028 patent at claims 1-5, 7, 9, and 16-21.

D. The Accused Products

Complainant asserts that “RhodoLED® XL, alone or in combination with Ameluz®” are the accused products (“Accused Products”). CIB at iv. RhodoLED® XL and Ameluz® are shown below.



RhodoLED® XL

CDX-0004C.150.

E. The Domestic Industry Products

Complainant asserts that “BLU-U® 4170E, individually or in combination with Levulan®, practices each of the system DI Claims and healthcare providers practice each of the method DI Claims when they use BLU-U® 4170E in combination with Levulan® following Sun Pharma’s instructions.” CIB at 132. BLU-U® 4170E and Levulan® are shown below.



BLU-U® 4170E

CDX-0004C.19.



II. PRELIMINARY ISSUES

A. Statutory Authority

The Commission has statutory authority to investigate an alleged violation of section 337(a)(1)(A) by named respondents when such respondents have allegedly used unfair methods of competition and unfair acts in the importation of articles into the United States, the threat or effect of which is to destroy or substantially injure a domestic industry in the United States or prevent the establishment of an industry in the United States. 19 U.S.C. § 1337(a)(1)(A). Here, Sun Pharma’s complaint states that Respondents violated section 337 by importing the Accused Products by reason of infringement of certain claims of the Asserted Patents. Complaint at ¶¶ 79-87. The Commission thus has statutory authority to conduct this investigation.

Both Sun Pharma and Respondents have actively participated in this investigation. Respondents have not contested the Commission’s statutory authority. RIB at 8. I find that the Commission has statutory authority over Sun Pharma and Respondents in accordance with the Commission’s governing statutes. *See, e.g.*, 19 U.S.C. §§ 1333, 1337(e)-(f).

B. Importation

The statute defines a violation of section 337 as “[t]he importation into the United States, the sale for importation, or the sale within the United States after importation by the owner, importer, or consignee, of articles that . . . infringe a valid and enforceable United State patent.” 19 U.S.C. § 1337(a)(1)(B). Accordingly, “[t]o prevail under section 337, a complainant must prove that a respondent actually imported or sold for [or after] importation the articles at issue.” *Certain Carbon and Alloy Steel Products*, Inv. No. 337-TA-1002, Order No. 103 at 33, *not reviewed*, Comm’n Notice, (Nov. 1, 2017).

Respondents stipulated they import, sell for importation, or sell after importation, RhodoLED® XL. *See* CX-0608C at ¶ 3 (referencing Ex. A); CX-1196C. Biofrontera AG and Biofrontera Inc. also import, sell for importation, or sell after importation, Ameluz®, which is made in Switzerland, and sold by Biofrontera AG (a German company) to Biofrontera Inc. (a U.S. company) for sale in the U.S. Tr. (Foguet) at 371:5-8; RX-0002C (Foguet WS) at Q/A 29-30. I therefore find that the importation requirement of section 337 has been satisfied with respect to Respondents’ accused products.

C. Commission Rule 210.12(a)(7)

Commission Rule 210.12(a)(7) requires that “at least one complainant is the owner or exclusive licensee of the subject intellectual property.” 19 C.F.R. § 210.12(a)(7); *see also Certain Active Matrix Organic Light-Emitting Diode Display Panels & Modules for Mobile Devices, & Components Thereof*, Inv. No. 337-TA-1351, Comm’n Op. at 14 (May 15, 2024).

Respondents do not dispute that the Asserted Patents are assigned to Complainant. *See* RIB at 3 (stating that Complainant purchased DUSA Pharmaceutical, Inc., the assignee of the Asserted Patents). The evidence shows that each of the Asserted Patents has been assigned to Complainant. Complaint, Ex. 2 (Certified Assignment Records for the ’512 patent; Sun Pharma merged with DUSA Pharmaceutical, Inc., the assignee of the Asserted Patents) and Ex. 4 (Certified Assignment Records for the ’028 patent; Sun Pharma merged with DUSA Pharmaceutical, Inc., the assignee of the Asserted Patents), ¶¶ 10, 52, 58 (Complainant Sun Pharma is the assignee and sole owner of the Asserted Patents).

I find that Commission Rule 210.12(a)(7) is satisfied.

III. LEVEL OF ORDINARY SKILL IN THE ART

One of ordinary skill in the art is a hypothetical person who is presumed to be aware of all pertinent prior art. *Custom Accessories, Inc. v. Jeffrey-Allan Industries, Inc.*, 807 F.2d 955, 962 (Fed. Cir. 1992). Determining the appropriate level of skill for this hypothetical person involves considering the types of problems encountered in the art, prior art solutions to those problems, rapidity with which innovations are made, sophistication of the technology at issue, the educational level of active workers in the field, and the level of education of the inventors themselves. *Daiichi Sankyo Co. v. Apotex, Inc.*, 501 F.3d 1254, 1256 (Fed. Cir. 2007).

I previously determined that a person of ordinary skill in the art with respect to the Asserted Patents 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. Order No. 18 at 13.

IV. CLAIM CONSTRUCTION

It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005). “[T]here is no magic formula or catechism for conducting claim construction.” *Id.* at 1324. Instead, weight may be attached to appropriate sources “in light of the statutes and policies that inform patent law.” *Id.*

The terms of a claim are generally given their ordinary and customary meaning which is the meaning they would have to one of skill in the art at the time of the invention. *Id.* at 1312-13. The ordinary meaning of a claim term is its meaning to one of skill in the art after reading the entire patent. *Id.* at 1321. The patent specification “is always highly relevant to the claim

construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term.” *Vitronics Corp. v. Conception, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996).

In addition to the specification, a court “should also consider the patent’s prosecution history, if it is in evidence.” *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 980 (Fed. Cir. 1995), *aff’d*, 517 U.S. 370 (1996). The prosecution history, which is intrinsic evidence, is “the complete record of the proceedings before the PTO and includes the prior art cited during the examination of the patent.” *Phillips*, 415 F.3d at 1317. “[T]he prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be.” *Id.* “[B]ecause the prosecution history represents an ongoing negotiation between the PTO and the applicant, rather than the final product of that negotiation, it often lacks the clarity of the specification and thus is less useful for claim construction purposes.” *Id.*

In some situations, a “court will need to look beyond the patent’s intrinsic evidence and to consult extrinsic evidence in order to understand, for example, the background science or the meaning of a term in the relevant art during the relevant time period.” *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 574 U.S. 318, 331 (2015). Extrinsic evidence is “all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises.” *Markman*, 52 F.3d at 980. While expert testimony can be useful “to ensure that the court’s understanding of the technical aspects of the patent is consistent with that of a person of skill in the art,” such testimony is “generated at the time of and for the purpose of litigation and thus can suffer from bias that is not present in intrinsic evidence.” *Phillips*, 415 F.3d at 1318-19. Further, while extrinsic evidence may be useful, it is less reliable than intrinsic evidence, and

its consideration “is unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence.” *Id.* Where the intrinsic record unambiguously describes the scope of the patented invention, reliance on extrinsic evidence is improper. *See Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1308 (Fed. Cir. 1999) (citing *Vitronics*, 90 F.3d at 1583).

In the *Markman* order, I construed the following terms:

Term & Claims	ALJ's Construction
“uniformly illuminate a treatment surface” / “uniformly illuminating a treatment surface” '512 and '028 Patents: All Asserted Claims	“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”
“a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges” '512 and '028 Patents: All Asserted Claims	Not indefinite. “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”
“photodynamically diagnosing or treating a patient” '512 and '028 Patents: All Asserted Claims	Preamble is limiting
“nested hinges on inner side surfaces” '512 Patent: All Asserted Claims	Not indefinite. “hinges that fit on inner side surfaces of adjacent panels”
“a recess” '512 Patent: Claims 17–18	“indentation, small hollow, or cleft”
“within approximately four inches of the treatment surface” '028 Patent: Claims 1, 2, 4–6, and 20–21	“less than or equal to approximately four inches from the treatment surface”
“the five panels are individually configurable to control illumination from each of the five panels” '028 Patent: Claims 16–17, 19, and 21	Not indefinite. Plain and ordinary meaning, which is “the power output and/or light intensity of each panel can be individually controlled”

Order No. 18 at 13, 23, 29, 35, 40, 45, 47.

V. THE '512 PATENT

A. Infringement

Complainant argues that “Biofrontera, via RhodoLED® XL, alone or in combination with Ameluz®, directly and/or indirectly infringes” asserted claims 1, 3, 5, 8, 17-18, and 20 of the '512 patent. CIB at 10-47. Biofrontera argues that it does not infringe the asserted claims of the '512 patent. RIB at 12-24; RRB at 3-8.

1. Legal Standard

In a section 337 investigation, the complainant bears the burden of proving infringement of the asserted patent claims by a preponderance of the evidence. *Spansion, Inc. v. Int'l Trade Comm'n*, 629 F.3d 1331, 1349 (Fed. Cir. 2010). This standard “requires proving that infringement was more likely than not to have occurred.” *Warner-Lambert Co. v. Teva Pharm. USA, Inc.*, 418 F.3d 1326, 1341 n.15 (Fed. Cir. 2005).

Literal infringement is a question of fact. *Finisar Corp. v. DirecTV Grp., Inc.*, 523 F.3d 1323, 1332 (Fed. Cir. 2008). Literal infringement requires the patentee to prove that the accused device contains each limitation of the asserted claim(s). If any claim limitation is absent, there is no literal infringement of that claim as a matter of law. *Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241, 1247 (Fed. Cir. 2000).

2. Claim 1

a) Limitation 1[p]

Limitation 1[p] recites “A system for photodynamically diagnosing or treating a patient, comprising.” JX-0001 at claim 1. Biofrontera does not dispute that RhodoLED® XL meets this limitation. Respondents' Identification of Undisputed Claim Limitations (EDIS Doc ID No.

856372 (hereinafter, “Respondents’ Undisputed Claim Limitations”) at 8. The evidence shows that this limitation is met. CX-0010C (Jokerst WS) at Q/A 425-36.

a) Limitation 1[a]

Limitation 1[a] recites “an illuminator comprising at least five panels connected by nested hinges on inner side surfaces of adjacent panels.” JX-0001 at claim 1. Complainant argues that this limitation is met. CIB at 11-22; CRB at 1-9. Biofrontera disputes that RhodoLED® XL meets this limitation. RIB at 12-20; RRB at 3-5.

Biofrontera argues that RhodoLED®-XL hinges are not “on” inner side surfaces of adjacent panels because the hinge flanges extend “through” the panel’s shell and bolt to an interior portion of the panel’s support structure. *See* RIB at 12, 19. This argument depends on Dr. Grove’s claim interpretation that “the hinge structures need to be mounted on the inner side surfaces.” Tr. (Grove) at 448:19-24, 455:24-456:11; RX-0009C (Grove RWS) at Q/A 66. I discuss these arguments below, but, as an initial matter, I do not adopt Dr. Grove’s construction.

Dr. Grove derives this additional requirement from the word “on” in “on inner side surfaces.” RX-0009C (Grove RWS) at Q/A 31-34. However, limitation 1[a] does not require “mounting.” Indeed, the construction of “nested hinges on inner side surfaces...” requires only that the hinges fit on inner side surfaces. Order No. 18 at 35. The claims require only that the “panels” be “connected by” hinges; they do not specify where or how the hinges are connected to the panels. Tr. (Jokerst) at 251:12-20. Biofrontera argues mounting is required because “on” must mean “in contact with and supported by the top surface.” RIB at 13; RX-0009C (Grove RWS) at Q/A 32-34. For this construction, Dr. Grove relies on a dictionary definition of “on” (from JX-0029.1), which he then contrasts with “through.” Based on this definition, Dr. Grove opines that the claims require the hinge flanges to be laid on and connected to the inner side surfaces. RX-

0009C (Grove RWS) at Q/A 37. Relying on the patents' Figure 3B, Dr. Grove additionally requires the hinges to be "laid flat against and mounted to the inner side surfaces of panels." *Id.* at Q/A 38-40; Tr. (Grove) at 449:12-25, 449:7-11. He opines that the hinges of the patents' commercial embodiment, BLU-U® 4170E, further supports his construction. RX-0009C (Grove RWS) at Q/A 43-46; Tr. (Grove) at 450:1-5.

Dr. Grove's mounting requirement fails for the following reasons. First, Dr. Grove does not justify why his particular definition of "on," "in contact with and supported by the top surface of," should define the claims' scope. That same dictionary provides multiple definitions for "on," including "in contact with an outer surface" and "the location of something." JX-0029.1. Those other definitions equally apply to the hinges of Figure 3B and 4170E, as both hinges are in contact with and located on the inner side surfaces. RDX-0020C.010. The dictionary definitions ignored by Dr. Grove are more applicable than the one selected by Dr. Grove, because his selected definition requires contact with and support by "the top surface," but the claims recite "on inner side surfaces."

In *Inverness Medical Switzerland v. Warner Lambert*, the Federal Circuit reversed the construction of "on" based on the dictionary definition "used as a function word to indicate position in contact with and supported by the top surface of," the same definition proposed by Dr. Grove. 309 F.3d 1373, 1378-79 (Fed. Cir. 2002). The Federal Circuit found "on" had two pertinent definitions and without a clear intent in the specification or prosecution history to limit the definition to one meaning, the ordinary meaning of the word should encompass both because "a word that has an ordinary meaning encompassing two relevant alternatives may be construed to encompass both alternatives." *Id.* Biofrontera has not shown that the patents must exclude the other definitions of "on."

Dr. Grove's additional requirement from Figure 3B that the hinges must be laid flat against and mounted to the inner side surfaces is also improper, particularly when he admitted hinge flanges do not have to be flat. Tr. (Grove) at 440:20-23. Biofrontera justifies its claim construction through Dr. Jokerst's testimony that the patents do not include any other "picture" of a hinge on an inner side surface besides Figure 3B. RIB at 14. But that figure is but one embodiment of the claimed invention. As Dr. Jokerst explained, the patents describe additional embodiments with hinge flanges received in recesses, arrangements that are not shown in Figure 3B. JX-0001 at 5:1-8; claims 7, 17, 18; Tr. (Jokerst) at 253:6-8. Dr. Grove's reliance on Figure 3B is an improper attempt to read in the "preferred embodiment or import a limitation from the specification into the claims." *Kara Tech. Inc. v. Stamps.com Inc.*, 582 F.3d 1341, 1348 (Fed. Cir. 2009); *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir. 2004) ("Even when the specification describes only a single embodiment, the claims of the patent will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope...").³

Dr. Grove's mounting requirement for hinges "on inner surfaces" also conflicts with additional limitations in dependent claims. Claim 17 requires a recess that is "configured to receive" the nested hinges' flange, meaning the flange's connection point need not be on the panel's outer surface. Claim 18 further requires the recess of claim 17 be positioned at an inner side surface. That supports that the broader recitation in claim 17 of the recess and the hinge flange it receives are not required to be on an inner side surface, and there is certainly no particular

³ Dr. Grove's reliance on Sun Pharma's BLU-U® 4170E's hinges to support his construction is also misguided. "[C]laim construction, from which an infringement analysis depends, focuses on the recited limitation of the *claims*, not on the features of a commercial embodiment of the invention." *Myco Indus., Inc. v. BlephEx, LLC*, 955 F.3d 1, 15 (Fed. Cir. 2009) (emphasis in original).

attachment point required. Tr. (Jokerst) at 262:21-263:5. *Wright Medical Tech., Inc. v. Osteonics Corp.*, 122 F.3d 1440, 1445 (Fed. Cir. 1997) (“[W]e must not interpret an independent claim in a way that is inconsistent with a claim which depends from it...”). For all the reasons above, I do not adopt Dr. Grove’s construction of the term “on.”

Biofrontera asserts several arguments for why the accused hinges cannot be considered “on inner side surfaces.” Biofrontera asserts that hinge holders cannot be a part of the inner side surfaces, that the hinges contact with the panel shell is incidental and is not supportive, and that hinges cannot “fit” on the inner side surface because its flanges extend into the interior of the panel. RIB 16-20.

Biofrontera first asserts that the hinges cannot be “on inner side surfaces” despite the fact that they rest on the exterior portion (tabs) of the panels’ support structure, known as the hinge holder.⁴ RIB at 19. Biofrontera argues the hinge holders cannot be a part of the inner side surfaces because they are a part of a support structure largely housed inside the interior to the panel. *Id.* at 19 (“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.”). However, the fact that the hinge holder is a part of a larger component is not relevant to whether the hinges are “on inner side surfaces.” Both experts agree that “[w]hen the panel is assembled, the inner side surface of the panel is made up of more than one piece.” Tr. (Grove) at 440:15-19; Tr. (Jokerst) at 248:2-7 (testifying that the inner side surface can “be made up of multiple components”). And Dr.

⁴ Biofrontera calls the tabs “Scharnierhalter,” or “hinge holder.” JX-0069C.1. The tabs are part of the panel’s support plate, to which various panel components, like the front and rear shells, are attached. CX-0010C (Jokerst WS) at Q/A 463; CX-0031C.68.

Grove clearly identified portions of larger components as making up the inner side surfaces of the panels.

Inner Side Surfaces of the RhodoLED® XL



RDX-0020C.012; Tr. (Grove) at 439:19-22 (agreeing that he highlighted “a portion of the front black piece of the casing and a portion of the back white piece of the casing”). Therefore, Biofrontera’s argument to exclude the exterior portion of the hinge holder as an “inner side surface” because it is a part of a larger component that has interior portions is not persuasive.

Excluding the hinge holder also contradicts its expert’s testimony. Dr. Grove defined the inner side surfaces as “exterior surfaces or faces of a panel between the front and back of the panel - in other words, the surfaces of the panels that face an adjacent panel.” RX-0009C (Grove RWS) at Q/A 36. Dr. Grove admitted the hinge holder is (1) “exterior” to the panel, Tr. (Grove) at 444:15-19; (2) is “part of the panel,” *id.* at 443:19-21; and (3) is “located between the front and the back of the panel,” *id.* at 445:14-446:1. There is no separate requirement for each portion of the “inner

side surface” to face an adjacent panel, as Dr. Grove admitted the short horizontal piece of the recess shown in CDX-1000.1, is part of the inner side surface, though it does not face the adjacent panel. CDX-1000.1; Tr. (Grove) at 453:20-454:4. Thus, Dr. Grove’s own definition, which is consistent with Dr. Jokerst’s definition, CX-0010C (Jokerst WS) at Q/A 467, supports that the surfaces of the hinge holder are a part of the inner side surfaces of the panel.

Biofrontera also argues that the hinge is on the front surface of the hinge holder. RIB at 20. However, the hinge is on the inner side surface of the panels, as required by limitation 1[a]. The limitation does not require those inner side surfaces to be flat; there can be “portions that stick in... and portions that stick out.” Tr. (Jokerst) at 250:3-12; CX-0010C (Jokerst WS) at Q/A 475; Tr. (Grove) at 441:14-25 (impeached with prior testimony that claims do not require the side surfaces to be planar). Thus, a surface can be an inner side surface regardless of which direction the surface is pointing. Tr. (Jokerst) at 250:3-12 (testifying that the inner side surfaces can be pointed in different directions); Tr. (Grove) at 453:20-454:4 (agreeing that a surface not facing an adjacent panel is still as inner side surface). All surfaces of the hinge holder are exterior to the panel, are part of the panel, and located between the front and back of the panel. Therefore, all exterior surfaces of the hinge holder are part of the inner side surface regardless of which direction they are pointing. Therefore, I do not find this “hinge holder” argument persuasive.

Biofrontera’s second argument is based on the hinges’ contact with the panel’s shell. In addition to resting on the hinge holders, RhodoLED®-XL’s hinges contact the panel’s shell, which Dr. Grove agrees is part of the inner side surfaces. Biofrontera makes an attorney argument based on Dr. Grove’s definition of “on,” (*i.e.*, “in contact with and supported by the top surface of,”) that the contact is incidental and is not supportive and, thus, does not meet the claim limitation. RIB at 20. Dr. Grove never explained why that contact is “incidental.” In contrast, Dr. Jokerst explained

the importance of that contact from a design perspective, as it reduces adverse effects from vibration during operation of the machine. Tr. (Jokerst) at 250:19-251:2. I do not find Biofrontera's argument persuasive.

Finally, Biofrontera argues the hinges cannot "fit" on the inner side surface, as required by my construction, because its flanges extend into the interior of the panel. RIB at 18-19. This argument repeats the prior arguments that the flanges need to be laid flat against and mounted to the inner side surfaces. Dr. Grove provides no explanation why the extension of the flanges into the interior of the panel means they cannot "fit" on the inner side surfaces. *See* RX-0009C (Grove RWS) at Q/A 67. As noted, that argument is also contradicted by claim 17 which permits the flanges of a nested hinge to be received into a recess that is not necessarily located on an inner side surface, without any specific attachment point, and will still be a "nested hinge" that fits on inner side surfaces of adjacent panels. Thus, I do not find this argument persuasive.

The evidence shows that this limitation is met. CX-0010C (Jokerst WS) at Q/A 437-75.

b) Limitation 1[b]

Limitation 1[b] recites "light sources disposed on surfaces of the at least five panels, the illuminator being configured to uniformly illuminate a treatment surface of the patient via the light sources." JX-0001 at claim 1. Biofrontera does not dispute that RhodoLED® XL meets this limitation. Respondents' Undisputed Claim Limitations at 8. The evidence shows that this limitation is met. CX-0010C (Jokerst WS) at Q/A 476-517.

c) Limitation 1[c]

Limitation 1[c] recites "one of the at least five panels positioned as a center panel configured to face the treatment surface, and two or more of the at least five panels being configured to be angled relative to the center panel." JX-0001 at claim 1. Biofrontera does not

dispute that RhodoLED® XL meets this limitation. Respondents' Undisputed Claim Limitations at 8. The evidence shows that this limitation is met. CX-0010C (Jokerst WS) at Q/A 518-28.

d) Limitation 1[d]

Limitation 1[d] recites “wherein each of the at least five panels has two first edges and two second edges shorter than the two first edges, and the light sources are arranged such that a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges.” JX-0001 at claim 1. Biofrontera does not dispute that RhodoLED® XL meets this limitation. Respondents' Undisputed Claim Limitations at 8. The evidence shows that this limitation is met. CX-0010C (Jokerst WS) at Q/A 529-75.

3. Claim 3

Claim 3 recites “The system of claim 1, wherein the illuminator is configured to output red light at a dose of about 30 J/cm² to about 150 J/cm².” JX-0001 at claim 3.

Biofrontera argues that “each dependent claim of each asserted patent remains in dispute as based on an independent claim that does not infringe” but it “does not separately dispute” that RhodoLED® XL meets this claim. Respondents' Undisputed Claim Limitations at 8. For the reasons discussed above, I found that RhodoLED® XL meets independent claim 1. The evidence shows that RhodoLED® XL also meets the additional limitations of dependent claim 3. CX-0010C (Jokerst WS) at Q/A 576-83.

4. Claim 5

Claim 5 recites “The system of claim 1, wherein the illuminator is configured to output light at an irradiance density of 10 mW/cm² to 30 mW/cm².” JX-0001 at claim 5.

Biofrontera argues that “each dependent claim of each asserted patent remains in dispute as based on an independent claim that does not infringe” but it “does not separately dispute” that

RhodoLED® XL meets this claim. Respondents' Undisputed Claim Limitations at 8. For the reasons discussed above, I found that RhodoLED® XL meets independent claim 1. The evidence shows that RhodoLED® XL also meets the additional limitations of dependent claim 5. CX-0010C (Jokerst WS) at Q/A 584-90.

5. Claim 8

a) Limitation 8[p]

Limitation 8[p] recites “A method of photodynamically diagnosing or treating a patient, comprising.” JX-0001 at claim 8. Biofrontera does not dispute that RhodoLED® XL in combination with Ameluz® meets this limitation. Respondents' Undisputed Claim Limitations at 8. The evidence shows that this limitation is met. CX-0010C (Jokerst WS) at Q/A 597-603; CX-0009C (Shmuylovich WS) at Q/A 135-38.

b) Limitation 8[a]

Limitation 8[a] recites “administering 5-aminolevulinic acid (ALA) to the patient.” JX-0001 at claim 8. Biofrontera does not dispute that RhodoLED® XL in combination with Ameluz® meets this limitation. Respondents' Undisputed Claim Limitations at 8. The evidence shows that this limitation is met. CX-0010C (Jokerst WS) at Q/A 604-10; CX-0009C (Shmuylovich WS) at Q/A 139-48.

c) Limitation 8[b]

Limitation 8[b] recites “positioning an illuminator proximate to the patient, the illuminator comprising at least five panels connected by nested hinges on inner side surfaces of adjacent panels; and.” JX-0001 at claim 8. Biofrontera disputes that RhodoLED® XL in combination with Ameluz® meets this limitation. RIB at 12-20; RRB at 3-5.

Biofrontera does not dispute that RhodoLED® XL in combination with Ameluz® meets the first portion of this limitation, *i.e.*, “positioning an illuminator proximate to the patient.” Respondents’ Undisputed Claim Limitations at 8. The evidence shows that using the RhodoLED® XL in accordance with Biofrontera’s instructions performs this step. JX-0086.9 (RhodoLED® XL User Manual); CX-0010C (Jokerst WS) at Q/A 619; CX-0009C(Shmuylovich WS) at Q/A 165-70.

As to the second portion of this limitation “the illuminator comprising at least five panels connected by nested hinges on inner side surfaces of adjacent panels,” the Accused Products comprises at least five panels connected by nested hinges on inner side surfaces of adjacent panels for the same reasons as discussed above with respect to limitation 1[a]. CX-0010C (Jokerst WS) at Q/A 617-21, 649; CX-0009C (Shmuylovich WS) at Q/A 165-72; CX-1009C.4; JX-0073C; JX-0078.6.

d) Limitation 8[c]

Limitation 8[c] recites “uniformly illuminating a treatment surface of the patient with light sources disposed on the at least five panels of the illuminator.” JX-0001 at claim 8. Biofrontera disputes that RhodoLED® XL in combination with Ameluz® meets this limitation. RIB at 22-24; RRB at 6-8.

I find that using the RhodoLED® XL in accordance with Biofrontera’s instructions performs the step of “uniformly illuminating a treatment surface of the patient with light sources disposed on the at least five panels of the illuminator.” JX-0086.9 (RhodoLED® XL User Manual); CX-0010C (Jokerst WS) at Q/A 619; CX-0009C (Shmuylovich WS) at Q/A 165-70 (explaining the User Manual steps that instruct performing photodynamic therapy).

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

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

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

- STEP 1) Plug in the lamp.
- STEP 2) Turn on the lamp and wait for the home screen to appear (see chapter 8.4.3).
- STEP 3) Check the proper functioning of the RhodoLED® XL.
- STEP 4) Treat the affected skin area: Application, incubation, and removal of the topical medication according to the USPI of Ameluz®.
- STEP 5) Position the patient comfortably and equip the patient with protective eyewear (see chapter 6).
- STEP 6) Select active panels (see chapter 8.4.5).
- STEP 7) Position the lamp and adjust the lamp head over the skin area to be treated (distance 4.9 inch /12.5 cm) (see chapter 8.4.6).
- STEP 8) Put on protective eyewear and make sure anyone remaining in the treatment room also wears protective eyewear (see chapter 6).
- STEP 9) Start treatment by pressing **Start**, the illumination period begins (see chapter 8.4.9).
Remind the patient to remain still throughout the illumination period.
If audible indicators during treatment are activated, explain the sounds to the patient.

JX-0086.9 (highlighted). For example, steps 5, 7, and 9 instruct positioning the patient and the lamp, and starting the illumination. *Id.* The User Manual notes that “RhodoLED® XL has 45 LEDs per panel with a total of 5 panels (225 LEDs), which emit a uniform, visible red light.” JX-0086.7.

Biofrontera argues that it does not induce infringement because users may perform a treatment using less than five panels. RIB at 22-24; RRB at 6-8; RX-0011C (Ehrenreich) at Q/A 98. However, the default mode of the RhodoLED® XL activates all five panels:

8.4.5 Selecting Active LED Panels

The device has 5 LED panels which are also displayed by the software (Figure 10). The illustrated panels are visible from the back side and the corresponding panel of the device can be identified via the handles, starting from the left. All panels are activated by default and can be deactivated via the software. To deactivate LED panels, press on the illustrated panel. For easier orientation, the panel number can also be found at the backside of the respective panel (Figure 11).



Figure 10: Software illustration of RhodoLED® XL LED panels (all panels are activated)

JX-0086.16 (highlighted); CX-0009C (Shmuylovich WS) at Q/A 168. If a user attempts to start a treatment with fewer than five panels, a message appears warning the user that not all panels are activated. JX-0066C.29; Tr. (Thompson) at 131:20-132:7 (testifying that JX-0066C.29 is the warning a user receives when less than five panels are active); Tr. (Ehrenreich) at 517:12-20 (confirming affirmative action is necessary to start treatment with less than five panels); Tr. (Shmuylovich) at 181:3-182:19. As Mr. Thompson testified, a warning message is typically included in software to alert the user that they are doing something that is not intended. Tr. (Thompson) at 121:18-122:5, 131:3-132:15.

Biofrontera's customers have used all five panels to uniformly illuminate a patient during treatment. Biofrontera produced a promotional video where its customer performs PDT on a patient using Ameluz® and all five RhodoLED® XL panels. JX-0073C (Ted Lain Video); CX-0009C (Shmuylovich WS) at Q/A 168. Dr. Ehrenreich admitted the same:

6 Q. All right. And in that video, Dr. Lain and his
7 staff apply ALA to a patient, right?

8 A. I'd have to watch the video to confirm that, but
9 that's my recollection. At some point, ALA seems to have
10 been applied.

11 Q. And the ALA they apply is Ameluz, right?

12 A. I believe so.

13 Q. And in that video, Dr. Lain treats the patient
14 with the RhodoLED XL lamp; isn't that right?

15 A. Yes.

16 Q. And in that video, Dr. Lain and his staff
17 position the panels on the RhodoLED XL device to be
18 proximate the patient. That's true, isn't it?

19 A. Yes.

20 Q. And in that video, Dr. Lain treated the patient
21 using all five panels as part of the treatment, right?

22 A. As best as I can recall and tell from the angles
23 of the videos, that seems to be the case.

Tr. (Ehrenreich) at 518:6-23.

The evidence shows that this limitation is met. CX-0010C (Jokerst WS) at Q/A 617-21;
CX-0009C (Shmuylovich WS) at Q/A 165-72.

e) Limitation 8[d]

Limitation 8[d] recites “wherein each of the at least five panels has two first edges and two second edges shorter than the two first edges, and the light sources are arranged such that a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges.” JX-0001 at claim 8. Biofrontera does not dispute that

RhodoLED® XL in combination with Ameluz® meets this limitation. Respondents' Undisputed Claim Limitations at 9. The evidence shows that this limitation is met. CX-0010C (Jokerst WS) at Q/A 529-75.

6. Claims 17 and 18

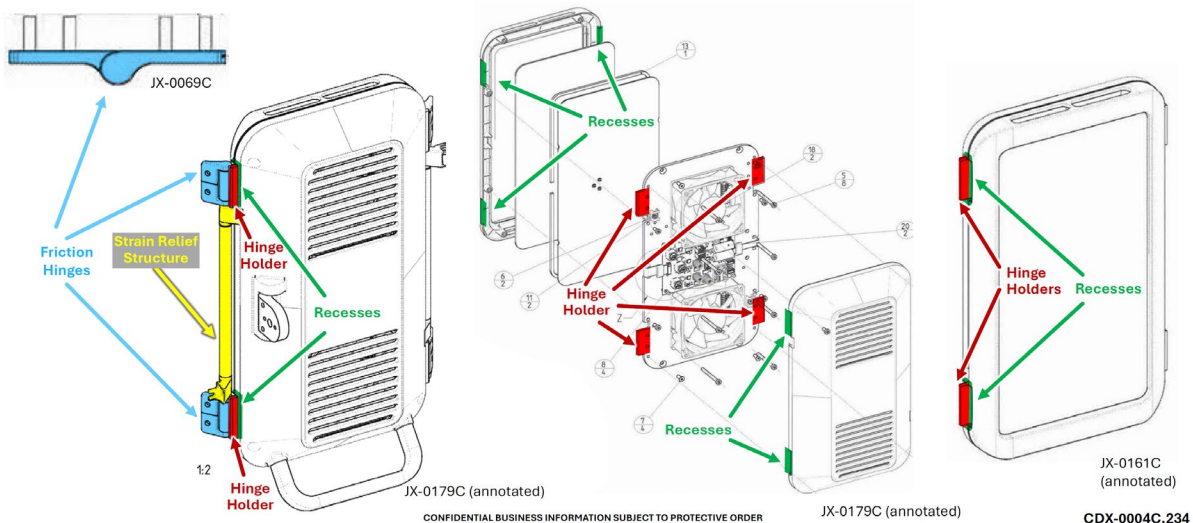
Claim 17 recites “The method of claim 8, wherein at least one panel includes a recess configured to receive a flange of one of the nested hinges.” JX-0001 at claim 17. Claim 18 recites “The method of claim 17, wherein the recess is positioned at an inner side surface of the at least one panel.” JX-0001 at claim 18. Complainant argues that claims 17 and 18 are met. CIB at 46-47; CRB at 9. Biofrontera disputes that RhodoLED® XL in combination with Ameluz® meets claims 17 and 18. RIB at 20-22; RRB at 5-6.

The Accused Products meet claim 17. First, RhodoLED® XL’s friction hinges include a flange, as Biofrontera admits. CX-0022C (RFA Response No. 28). Second, each panel shell has multiple recesses, as shown in the engineering diagrams below.

Claim 17 of the '512 Patent

wherein at least one panel includes a recess configured to receive a flange of one of the nested hinges

Construction: “recess” is “indentation, small hollow, or cleft”



CDX-0004C.234; CX-0010C (Jokerst WS) at Q/A 626-29; JX-0179C; JX-0161C. When assembled, those recesses define an opening configured to receive a flange of the friction hinge. CX-0010C (Jokerst WS) at Q/A 629-32, JX-0069C; JX-0111. Those openings are each a “small hollow” under my construction of “a recess.” CX-0010C (Jokerst WS) at Q/A 631-34.

Biofrontera argues that the opening in RhodoLED®-XL’s panel shell is not a recess because the recess is required to be “in the continuous inner side surface.” RIB at 21. Similarly, Dr. Grove opines the recess for both claims 17 and 18 must be “on inner side surfaces of adjacent panels.” RX-0009C (Grove RWS) at Q/A 103. However, claim 17 recites a recess *without* requiring a location of the recess. In contrast, claim 18 does specify that the recess “is positioned at an inner side surface.” Nevertheless, Dr. Grove’s opinion replaces the claim’s “positioned at” with “on” and further extends his construction of “on,” RX-0009C (Grove RWS) at Q/A 103, as discussed above.

Biofrontera’s requirement for the recess to be “in the continuous inner side surface” was expressly rejected during the *Markman* phase. Order No. 18 at 47 (“I decline to construe the term with the words ‘in a surface.’”). Nevertheless, Biofrontera argues that the accused device only “include[s] an opening **through** which hinge flanges extend for attachment within the interior compartment of the RhodoLED®XL panels.” RIB at 21. Biofrontera’s argument is not persuasive. For example, I construed “recess” to include “an alternative” to “indentation”: “small hollow” or “cleft,” Order No. 18 at 47, which *can* include openings like RhodoLED®-XL’s. Thus, the evidence shows that claim 17 is met. CX-0010C (Jokerst WS) at Q/A 625-35.

As to claim 18, as shown above with respect to claim 17, the recess is positioned at an inner side surface of the panel. CX-0010C (Jokerst WS) at Q/A 641. Thus, the evidence shows that claim 18 is met. CX-0010C (Jokerst WS) at Q/A 641.

7. Claim 20

a) Limitation 20[p]

Limitation 20[p] recites “A system for photodynamically diagnosing or treating a patient, comprising.” JX-0001 at claim 20. Biofrontera does not dispute that RhodoLED® XL meets this limitation. Respondents’ Undisputed Claim Limitations at 9. RhodoLED® XL meets this limitation for the same reasons as discussed above with respect to the limitation 1[p]. The evidence shows that this limitation is met. CX-0010C (Jokerst WS) at Q/A 425-36.

b) Limitation 20[a]

Limitation 20[a] recites “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.” JX-0001 at claim 20. Biofrontera disputes that RhodoLED® XL meets this limitation. RIB at 12-20; RRB at 3-5.

RhodoLED® XL comprises at least five panels connected by nested hinges on inner side surfaces of adjacent panels for the same reasons as limitation 1[a]. Biofrontera’s arguments concerning “nested hinges on inner side surfaces” were addressed in detail above with respect to limitation 1[a]. RhodoLED® XL comprises nested hinges configured to allow continuous illumination across the at least five panels. CX-0010C (Jokerst WS) at Q/A 649-52. The hinges fit between adjacent panels and do not interfere with the continuous illumination across the five panels. *Id.* The hinges do not extend past the plane of the front of the panels and do not block any light from reaching the patient. *Id.* at Q/A 650; JX-0069C. Indeed, Biofrontera’s documents describe how Biofrontera designed the friction hinges on RhodoLED® XL to reduce the distance between the panels, which would allow for continuous illumination across the five panels. JX-0068C.26; CX-0321C.14; CX-0323C.3 [REDACTED]

[REDACTED]; CX-1005C.35 [REDACTED]

[REDACTED]

[REDACTED]; JX-0008C (Luebbert Dep. Tr.) at 82:7-11 (noting that the distance between panels can effect homogeneity). CX-0010C (Jokerst WS) at Q/A 651-52; JX-0068.26; CX-0321C.14; CX-0323C.3; CX-1005.35.

Thus, the evidence shows that this limitation is met. CX-0010C (Jokerst WS) at Q/A 649-52.

c) Limitation 20[b]

Limitation 20[b] recites “light sources disposed on surfaces of the at least five panels, the illuminator being configured to uniformly illuminate a treatment surface of the patient via the light sources.” JX-0001 at claim 20. Biofrontera does not dispute that RhodoLED® XL meets this limitation. Respondents’ Undisputed Claim Limitations at 9. RhodoLED® XL meets this limitation for the same reasons as discussed above with respect to the limitation 1[b]. The evidence shows that this limitation is met. CX-0010C (Jokerst WS) at Q/A 476-517.

d) Limitation 20[c]

Limitation 20[c] recites “one of the at least five panels positioned as a center panel configured to face the treatment surface, and two or more of the at least five panels being configured to be angled relative to the center panel.” JX-0001 at claim 20. Biofrontera does not dispute that RhodoLED® XL meets this limitation. Respondents’ Undisputed Claim Limitations at 9. RhodoLED® XL meets this limitation for the same reasons as discussed above with respect to the limitation 1[c]. The evidence shows that this limitation is met. CX-0010C (Jokerst WS) at Q/A 518-28.

e) Limitation 20[d]

Limitation 20[d] recites “wherein each of the at least five panels has two first edges and two second edges shorter than the two first edges, and the light sources are arranged such that a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges.” JX-0001 at claim 20. Biofrontera does not dispute that RhodoLED® XL meets this limitation. Respondents’ Undisputed Claim Limitations at 9. RhodoLED® XL meets this limitation for the same reasons as discussed above with respect to the limitation 1[d]. The evidence shows that this limitation is met. CX-0010C (Jokerst WS) at Q/A 529-75.

8. Indirect Infringement

Complainant argues that Biofrontera indirectly infringes method claims 8, 17, and 18 by inducement. CIB at 30-38; CRB at 13-17. Biofrontera argues that it does not instruct its customers to use all five panels. RIB at 22-24; RRB at 6-8.

Indirect infringement may be either induced or contributory. Direct infringement must first be established for a claim of indirect infringement to prevail. *BMC Res. v. Paymentech*, 498 F.3d 1373, 1379 (Fed. Cir. 2007).

Section 271(b) of the Patent Act provides: “Whoever actively induces infringement of a patent shall be liable as an infringer.” 35 U.S.C. §271(b). To establish liability, the patent holder must prove that “once the defendants knew of the patent, they ‘actively and knowingly aid[ed] and abett[ed] another’s direct infringement.’” *DSU Med. Corp. v. JMS Co., Ltd.*, 471 F.3d 1293, 1305 (Fed. Cir. 2006) (*en banc*) (citations omitted). A finding of induced infringement requires “evidence of culpable conduct, directed to encouraging another’s infringement, not merely that the inducer had knowledge of the direct infringer’s activities.” *Id.* at 1306. Although § 271(b) requires

knowledge that the induced acts constitute patent infringement, the Supreme Court has held that liability will also attach when the defendant is willfully blind. *Global-Tech Appliances, Inc. v. SEB S.A.*, 131 S. Ct. 2060, 2068-2069 (2011). The burden is on the complainant to prove that the respondent had the specific intent and took action to induce infringement. *DSU*, 471 F.3d at 1305-06. Intent may be proven by circumstantial evidence. *Lucent Techs., Inc. v. Gateway, Inc.*, 580 F.3d 1301, 1322 (Fed. Cir. 2009).

For the reasons discussed below, Biofrontera indirectly infringes method Claims 8, 17, and 18. Biofrontera induces infringement of the Asserted Claims by making, selling, and/or offering for sale the RhodoLED® XL, individually or in combination with Ameluz®, along with promotional, training, and instructional materials instructing the infringing use of the Accused Products. CX-0010C (Jokerst WS) at Q/A 404; CX-0009C (Shmuylovich WS) at Q/A 182 (explaining that dermatologists rely on those materials). Biofrontera indirectly infringes the asserted system claims of the '512 patent by inducing its customers to use the RhodoLED® XL, which infringes those claims as discussed in preceding sections. 35 U.S.C. §271; *ACCO Brands, Inc. v. ABA Locks Mfrs. Co.*, 501 F.3d 1307, 1313-14 (Fed. Cir. 2007).

Knowledge of infringement: Biofrontera knew or should have known of the Asserted Patents and Sun Pharma's infringement assertions since at least when the complaint was filed on June 26, 2024. 35 U.S.C. §271(b); JX-0198; JX-0019-20; CX-0010C (Jokerst WS) at Q/A 405; Tr. (Luebbert) at 327:8- 328:10 ("Q.... when [the Asserted Patents] were brought to your attention, Biofrontera had not yet launched the RhodoLED XL product, right? A. Right."); CX-0014C (Jokerst RWS) at Q/A 629; JX-0011C (Foguet Dep. Tr.) at 41:24-42:2. Biofrontera admits that "RhodoLED® XL has been developed for use in photodynamic therapy in combination with Ameluz® gel." JX-0086.5; see CX-0027C.3 (RFA Response No. 3) (admitting that RhodoLED®

XL can be used for photodynamic therapy); JX-0181.2 (Ameluz® indication for PDT using RhodoLED XL to treat actinic keratosis (“AK”)); JX-0104.4-5; RX-0002C (Foguet WS) at Q/A 40.

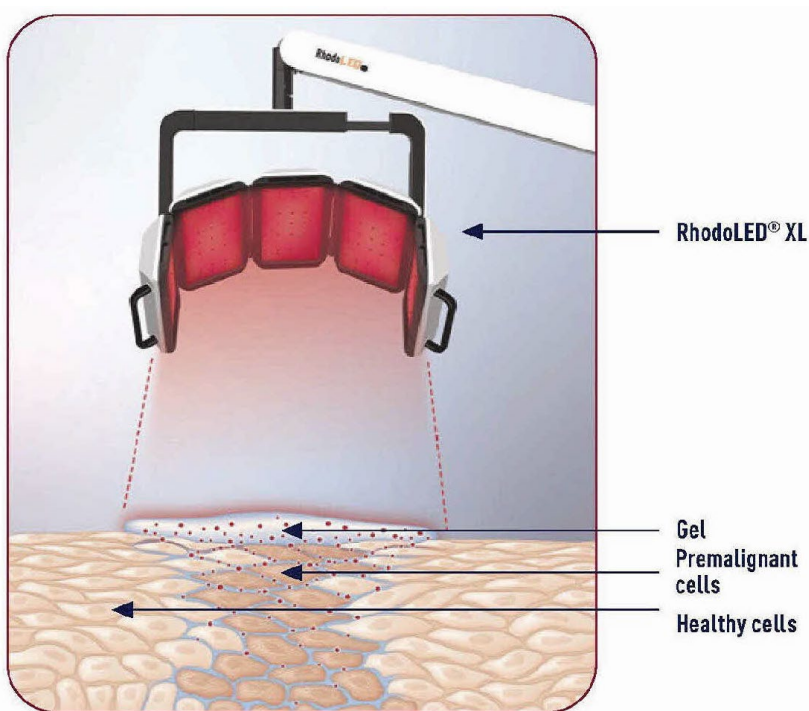
Acts of direct infringement: Biofrontera admitted its customers used RhodoLED® XL with Ameluz® to treat patients. CX-0024C (RFA Response No. 9, 26); CX-0010C (Jokerst WS) at Q/A 419-23; JX-0009C (Lyons Dep. Tr.) at 76:16-77:15 (testifying as to Biofrontera’s customers’ use), 95:20-96:13; JX-0010C (Baldyga Dep. Tr.) at 37:13-42:1, 212:3-22. Customers can use RhodoLED® XL in an infringing manner when sold by Biofrontera—the customer need not alter the default settings to infringe. CX-0010C (Jokerst WS) at Q/A 406. Biofrontera’s marketing team produced a video of a Biofrontera customer using the RhodoLED® XL with Ameluz to treat a patient. JX-0073C (Dr. Lain video); JX-0009C (Lyons Dep. Tr.) at 93:17-94:7; JX-0010C (Baldyga Dep. Tr.) at 184:16-185:3.

Acts of inducement: Biofrontera conducts training to use RhodoLED® XL in accordance with the instructions in the User Manual. CX-0010C (Jokerst WS) at Q/A 407-17; CX-0009C (Shmuylovich WS) at Q/A 184-90; CX-1008C.21 (“[t]he user must be trained prior to using the device.... training is conducted by personnel authorized by Biofrontera.”); JX-0180C.4 (RhodoLED® XL will be “used exclusively by adequately trained health care professionals”); JX-0086.5 (“The user manual must be read carefully prior to using the RhodoLED® XL.”); JX-0010C (Baldyga Dep. Tr.) at 152:19-155:9 (training occurs at customer site), 212:3-14; JX-0009C (Lyons Dep. Tr.) at 95:20-96:13 (discussing customer training), 96:24-97:8, 100:2-101:8, 101:14-20 (discussing training of RhodoLED® XL sales force), 113:1-115:12; CX-0331C.3 (internal training presentation); RX-0002C (Foguet WS) at Q/A 104-07, 114; RX-0004C (Luebbert WS) at Q/A 87-88. Biofrontera’s training includes an illustration of “the basic operation of the RhodoLED XL”

and an overview of device components and instruct using the panels in the curved “C-shape” configuration. CX-0331C.8.

Encouraging infringing uses: Biofrontera encourages, recommends, and promotes infringing uses of RhodoLED® XL. For example, Biofrontera’s presentations and videos are intended to encourage sales and treatments using RhodoLED® XL. JX-0010C (Baldyga Dep. Tr.) at 37:13-42:1, 40:6-11, 44:1-8, 184:16-185:3; JX-0009C (Lyons Dep. Tr.) at 93:17-94:7.

Five-panel treatments are not merely options among many offered to users. Biofrontera specifically designed a five-panel device to address its customers’ need for a full-face illumination. CX-0010C (Jokerst WS) at Q/A 359-60; CX-0009C (Shmuylovich WS) at Q/A 112-16; Tr. (Luebbert) at 338:2-12. Biofrontera’s marketing materials depict full-face illumination using five panels and the only technical data provided is for five-panel treatments:



The treatment process

Your healthcare provider will guide you through therapy with AMELUZ® (aminolevulinic acid HCl) topical gel, 10% and RhodoLED® XL

IMPORTANT SAFETY INFORMATION (selected)

When using this product:

- **Photosensitivity:** Avoid sun exposure on the treated lesion sites and surrounding skin for approximately 48 hours following treatment.
- **Geriatric Warning:** No overall differences in safety or effectiveness were observed between older (65 years and older) and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

AMELUZ®
[aminolevulinic acid
HCl] topical gel, 10%
& RhodoLED®

8

1

Your healthcare provider will prepare the skin and apply AMELUZ® (application area should not exceed 20 cm²).

2

After waiting the recommended time (3 hours) to allow AMELUZ® gel to penetrate the targeted cells, your healthcare provider will illuminate the area with RhodoLED® XL lamp for 13.5 minutes.

Your healthcare provider's staff will provide protective eyewear that must be worn during your RhodoLED® XL lamp treatment.



SAFETY

Adverse reactions and the safety of PDT with AMELUZ®

Most common side effects at the application site were:

- | | | |
|------------------|-----------------------|--------------|
| • skin reddening | • swelling | • scabbing |
| • pain/burning | • itching | • hardening |
| • irritation | • scaling of the skin | • blistering |

Most side effects occurred during illumination or shortly afterwards, were generally of mild to moderate intensity, and lasted for 1 to 4 days in most cases; in some cases, they persisted for 1 to 2 weeks or even longer.

9

JX-0104.4-5.

Trifold- COVER

ARE YOU RED-Y?

Talk to your Biofrontera PDT Consultant about Integrating the RhodoLED® XL into your practice

INDICATION
AMELUZ®, in combination with photodynamic therapy (PDT) using BF-RhodoLED® or RhodoLED® XL lamp, a narrowband, red light illumination source, is indicated for lesion-directed and field-directed treatment of actinic keratosis (AK) of mild-to-moderate severity on the face and scalp.
Please see Important Safety Information inside and accompanying PI.

AMELUZ®
[aminolevulinic acid HCl] topical gel, 10%
& **RhodoLED®**

Are you RED-Y?
- Emphasis on RED light

Image of lamp head:
- Up close image of lamp head- 5 panels; LED positioning, etc.

Indication:
- Reminder of AMELUZ® and BF-RhodoLED®/RhodoLED® XL and indication of lesion/field-directed treatment of AK face/scalp

AMELUZ®
[aminolevulinic acid HCl] topical gel, 10%
& **BF-RhodoLED®**

JX-0105C.3.

RhodoLED® XL

Emission spectrum of LEDs

Peak wavelength of ~635 nm

5 Panels with 225 LEDs in total (45 LEDs/panel) emit a uniform light

Allows for full-face of full-scalp illumination treatment

Biofrontera

Treating with RhodoLED® XL:

- 13.5 minutes illumination time
- 37 J/cm² of energy delivery
- Total illumination area of 9.06 x 11.42 in (23 cm x 29 cm) when all 5 panels are used in curved configuration
- Treatment distance of 4.9 ± 0.59 in (12.5 cm ± 1.5 cm)

JX-0078.7; JX-0010C (Baldyga Dep. Tr.) at 38:19-39:7, 45:7-46:5. Though Dr. Luebbert testified that JX-0078 was “an internal document,” Tr. (Luebbert) at 346:4-14, Mr. Baldyga, the document’s author, testified that it was presented to third-party customers to advertise the device’s features, including five panels. JX-0010C (Baldyga Dep. Tr.) at 44:18-21, 45:7-11.

Biofrontera ships the illuminator with five panels activated “by default,” and with a warning dialog that stops a user if any panel is deactivated. JX-0066C.29; Tr. (Thompson) at 133:20-134:7. Biofrontera does not provide examples in its promotional and instructional materials where fewer panels are recommended, it does not provide illumination area data for fewer panels, and it never depicts a treatment with fewer panels illuminated.

Dr. Ehrenreich’s opinion that Biofrontera’s label never “recommends” using five panels is contradicted by that label—it instructs, “Position the lamp head” at a distance which “usually allows a full-face illumination with the use of 5 panels” and states “[t]he smallest recommended number of panels to be used are 3 adjacent panels”:

- RhodoLED XL has a curved configuration with an effective treatment area up to 23 x 29 cm. Position the lamp head of the RhodoLED XL 11-14 cm from the skin’s surface. This usually allows a full-face illumination with the use of 5 panels. The smallest recommended number of panels to be used are 3 adjacent panels (see chapter 8.4.6 of RhodoLED XL user manual).

JX-0074.4 (highlighted). Three is the minimum and five is within the “recommended number of panels.”

Moreover, Biofrontera’s focus on the label alone is misplaced. Unlike Biofrontera’s cited ANDA cases where no marketing has occurred beyond a proposed label, here Biofrontera produced marketing graphics, presentations, and videos, all actively promoting using five panels. CX-0010C (Jokerst WS) at Q/A 621; JX-0078.6-7 (presentation to customers); JX-0104.4-5; JX-0073C (Dr. Lain video); JX-0105C.5. “[A]dvertising an infringing use” can evidence inducement. *Takeda Pharms. U.S.A., Inc. v. W.-Ward Pharm. Corp.*, 785 F.3d 625, 630-31 (Fed. Cir. 2015). The fact that users can deviate from the “default” and illuminate fewer panels does not mean that Biofrontera does not induce infringing acts: inducement liability attaches “even if the product has

substantial noninfringing uses.” *Sanofi v. Watson Lab’ys Inc.*, 875 F.3d 636, 646 (Fed. Cir. 2017) (noting “[t]here is no basis for a different inducement rule for drug labels”).

Biofrontera argues, RIB at 23, that Sun Pharma’s experts considered an “internal” presentation, JX-0105C, that is not shown to users. However, Biofrontera’s VP of sales and marketing testified the presentation shows Biofrontera marketing materials alongside “notes from marketing individuals at Biofrontera about why certain things were included in the marketing materials.” JX-0010C (Baldyga Dep. Tr.) at 22:20-23:8, 20:4-14. One “talking point[]” for marketing personnel is to “recommend to start treatment with 5 panels.” JX-0105C.5.

Biofrontera argues that JX-0067C is irrelevant because it’s an FDA communication. RIB at 23. But that communication confirms the “default configuration” of the illuminator: “all panels are activated,” and demonstrates Biofrontera’s intent in designing a five-panel device. “[M]any patients with AK lesions scattered through face and scalp will require illumination with all five panels.” JX-0067C.5; CX-0010C (Jokerst WS) at Q/A 516-17.

B. Technical Prong

Complainant argues that “BLU-U® 4170E, individually or in combination with Levulan®, practices” claims 1, 2, 4, 5, 8, 19, and 20 of the ’512 patent. CIB at 132-47. Biofrontera argues that complainant has not carried its burden to show that the technical prong of the domestic industry requirement has been met. RIB at 105-06; RRB at 54-56.

1. Legal Standard

For a patent-based complaint, a violation of section 337 can be found “only if an industry in the United States, relating to the articles protected by the patent . . . concerned, exists or is in the process of being established.” 19 U.S.C. § 1337(a)(2). This domestic industry requirement of section 337 is often described as having an economic prong and a technical prong. *InterDigital*

Commc'ns, LLC v. Int'l Trade Comm'n, 707 F.3d 1295, 1298 (Fed. Cir. 2013); *Certain Stringed Musical Instruments & Components Thereof*, Inv. No. 337-TA-586, USITC Pub. 4120, 2009 WL 5134139 (Dec. 2009), Comm'n Op. at 12-14. The complainant bears the burden of establishing that the domestic industry requirement is satisfied. *See Certain Set-Top Boxes & Components Thereof*, Inv. No. 337-TA-454, FID at 294, 2002 WL 31556392 (June 21, 2002) (unreviewed by Commission in relevant part).

The technical prong of the domestic industry requirement is satisfied when the complainant in a patent-based section 337 investigation establishes that it is practicing or exploiting the patents at issue. *See* 19 U.S.C. § 1337(a)(2) and (3); *Certain Microsphere Adhesives, Process for Making Same & Prods. Containing Same, Including Self-Stick Repositionable Notes*, Inv. No. 337-TA-366, Comm'n Op. at 8, 1996 WL 1056095 (Jan. 16, 1996). “The test for satisfying the ‘technical prong’ of the industry requirement is essentially [the] same as that for infringement, *i.e.*, a comparison of domestic products to the asserted claims.” *Alloc, Inc. v. Int'l Trade Comm'n*, 342 F.3d 1361, 1375 (Fed. Cir. 2003). To prevail, the patentee must establish by a preponderance of the evidence that the domestic product practices one or more claims of the patent. It is sufficient to show that the products practice any claim of that patent, not necessarily an asserted claim of that patent. *See Certain Male Prophylactic Devices*, Inv. No. 337-TA-546, Comm'n Op. at 38 (Aug. 1, 2007).

2. Biofrontera's Conclusory Arguments

Biofrontera argues, in a single paragraph, that Sun Pharma has not carried its burden with respect to the system claims. RIB at 105-06. That is insufficient to meet the standard set forth in my Ground Rules. G.R. 14.2. Biofrontera failed to set forth its contentions as to why the system claims are not practiced by BLU-U® 4170E. I find that those contentions are abandoned or

withdrawn with respect to each limitation of the Asserted Claims. *Id.* (“Any contentions that are not set forth in detail in the post-hearing initial brief shall be deemed abandoned or withdrawn.”).

As to the method claims, Biofrontera offers no rebuttal expert analysis. *See* RIB at 105-06; RRB at 54-56. Regarding the evidence of BLU-U® 4170E’s use, Biofrontera’s argument fails to take into account [REDACTED]

[REDACTED]. The unrebutted expert analysis showed that following BLU-U® 4170E’s Operating Manual practices the method domestic industry claims. *See* CIB at 141-47, 159-60. Sworn testimony that was subject to cross-examination suffices “without further corroboration by underlying documentation.” *Certain Raised Garden Beds*, Inv. No. 337-TA-1334, Comm’n Op. (Apr. 1, 2024) at 45.

3. Claim 1

a) Limitation 1[p]

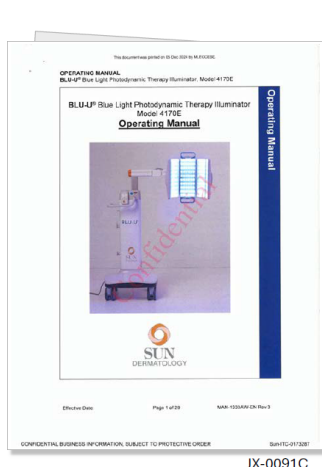
Limitation 1[p] recites “A system for photodynamically diagnosing or treating a patient, comprising.” JX-0001 at claim 1. Biofrontera disputes that BLU-U® 4170E meets this limitation (Respondents’ Undisputed Claim Limitations at 2) but offers no specific substantive argument (RIB at 105-06; RRB at 54-56).

BLU-U® 4170E meets this limitation. CX-0010C (Jokerst WS) at Q/A 85-91. For example, the Operating Manual describes how the device is indicated for the treatment of AK, and is intended to provide phototherapeutic light to the body as a “Photodynamic Therapy Illuminator.” JX-0091C.4, .7.

Claim 1 of the '512 Patent – Preamble

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

Construction – the preamble is limiting



JX-0091C

The **BLU-U®** Blue Light Photodynamic Therapy Illuminator Model 4170E, in combination with the Levulan® Kerastick® (aminolevulinic acid HCl) for Topical Solution, 20%, is indicated for the treatment of minimally to moderately thick actinic keratoses (AK) of the face, scalp or upper extremities.

JX-0091C.4

The **BLU-U®** Blue Light Photodynamic Therapy Illuminator Model 4170E is intended to provide phototherapeutic light to the body. The **BLU-U®** 4170E is generally indicated to treat dermatological indications. The **BLU-U®** 4170E is specifically indicated to treat moderate inflammatory acne vulgaris.

JX-0091C.4

The **BLU-U®** is a compact light source designed to provide a uniform distribution of blue light to areas of the patient's face, scalp or upper extremities for the use stated above. It is comprised of 5 individual LED panels connected by hinges. The panels are covered by a protective shield, the center panel directs cooling airflow to the patient to improve comfort during the treatment.

JX-0091C.7

CDX-0004C.24

CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER

CDX-0004C.24; CX-0010C (Jokerst WS) at Q/A 86-91; JX-0091C, .4, .7; CX-0011C (Lundahl WS) at Q/A 53-59 (describing how the Operating Manual instructs users how to treat AK with PDT using BLU-U® 4170E in combination with Levulan®). BLU-U® 4170E is a system for photodynamically treating a patient.

b) Limitation 1[a]

Limitation 1[a] recites “an illuminator comprising at least five panels connected by nested hinges on inner side surfaces of adjacent panels.” JX-0001 at claim 1. Biofrontera does not dispute that BLU-U® 4170E meets this limitation. Respondents’ Undisputed Claim Limitations at 2. The evidence shows that this limitation is met. CX-0010C (Jokerst WS) at Q/A 92-103.

c) Limitation 1[b]

Limitation 1[b] recites “light sources disposed on surfaces of the at least five panels, the illuminator being configured to uniformly illuminate a treatment surface of the patient via the light sources.” JX-0001 at claim 1. Biofrontera does not dispute that BLU-U® 4170E meets this

limitation. Respondents' Undisputed Claim Limitations at 2. The evidence shows that this limitation is met. CX-0010C (Jokerst WS) at Q/A 104-26.

d) Limitation 1[c]

Limitation 1[c] recites “one of the at least five panels positioned as a center panel configured to face the treatment surface, and two or more of the at least five panels being configured to be angled relative to the center panel.” JX-0001 at claim 1. Biofrontera does not dispute that BLU-U® 4170E meets this limitation. Respondents' Undisputed Claim Limitations at 2. The evidence shows that this limitation is met. CX-0010C (Jokerst WS) at Q/A 127-33.

e) Limitation 1[d]

Limitation 1[d] recites “wherein each of the at least five panels has two first edges and two second edges shorter than the two first edges, and the light sources are arranged such that a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges.” JX-0001 at claim 1. Biofrontera does not dispute that BLU-U® 4170E meets this limitation. Respondents' Undisputed Claim Limitations at 2. The evidence shows that this limitation is met. CX-0010C (Jokerst WS) at Q/A 134-48.

4. Claim 2

Claim 2 recites “The system of claim 1, wherein the illuminator is configured to uniformly illuminate the treatment surface when the treatment surface is at a distance of two to four inches from the illuminator.” JX-0001 at claim 2. Biofrontera disputes that BLU-U® 4170E meets this limitation (Respondents' Undisputed Claim Limitations at 3) but offers no specific substantive argument (RIB at 105-06; RRB at 54-56).

BLU-U® 4170E meets this limitation. CX-0010C (Jokerst WS) at Q/A 155-61. The Operating Manual instructs users to use BLU-U® 4170E at treatment distances of two-to-four

inches. JX-0091C.18-20. Sun Pharma tests BLU-U® 4170E to ensure it meets internal standards for uniformity, including that the measured power output at any point on the active emitting surface shall not be less than 60% of the maximum when measured over all operational distances, including at two and four inches from the panels to the treatment surface. CX-1021C; CX-1216C.3.

5. Claim 4

Claim 4 recites “The system of claim 1, wherein the illuminator is configured to uniformly illuminate the treatment surface when the treatment surface is at a distance of two to four inches from the illuminator.” JX-0001 at claim 4.

Biofrontera argues that “each dependent claim of each asserted patent remains in dispute as based on an independent claim that is not practiced by the domestic industry products” but it “does not separately dispute” that BLU-U® 4170E meets this claim. Respondents’ Undisputed Claim Limitations at 2. I found that BLU-U® 4170E meets independent claim 1. The evidence shows that BLU-U® 4170E also meets the additional limitations of dependent claim 4. CX-0010C (Jokerst WS) at Q/A 162-68.

6. Claim 5

Claim 5 recites “The system of claim 1, wherein a plurality of the light sources are configured to emit light having a wavelength in a range of 400 nm to 700 nm.” JX-0001 at claim 5. Biofrontera argues that “each dependent claim of each asserted patent remains in dispute as based on an independent claim that is not practiced by the domestic industry products” but it “does not separately dispute” that BLU-U® 4170E meets this claim. Respondents’ Undisputed Claim Limitations at 2. For the reasons discussed above, I found that BLU-U® 4170E meets independent claim 1. The evidence shows that BLU-U® 4170E also meets the additional limitations of dependent claim 5. CX-0010C (Jokerst WS) at Q/A 169-73.

7. Claim 8**a) Limitation 8[p]**

Limitation 8[p] recites “A method of photodynamically diagnosing or treating a patient, comprising.” JX-0001 at claim 8. Biofrontera disputes that BLU-U® 4170E in combination with Levulan® meets this limitation (Respondents’ Undisputed Claim Limitations at 3) but offers no specific substantive argument (RIB at 105-06; RRB at 54-56).

Using BLU-U® 4170E in combination with Levulan® in accordance with Sun Pharma’s instructions performs this limitation. CX-0010C (Jokerst WS) at Q/A 178-82; CX-0009C (Shmuylovich WS) at Q/A 74-75. As discussed for Element 1[p], BLU-U® 4170E is indicated for the treatment of minimally to moderately thick AK of the face, scalp, or upper extremities and intended to provide phototherapeutic light to the body. *See* JX-0091C.4, .7; CX-0011C (Lundahl WS) at Q/A 55, 59; see also CDX-0005C.13.

b) Limitation 8[a]

Limitation 8[a] recites “administering 5-aminolevulinic acid (ALA) to the patient.” JX-0001 at claim 8. Biofrontera does not dispute that BLU-U® 4170E in combination with Levulan® meets this limitation. Respondents’ Undisputed Claim Limitations at 3. The evidence shows that this limitation is met. CX-0010C (Jokerst WS) at Q/A 76-78.

c) Limitation 8[b]

Limitation 8[b] recites “positioning an illuminator proximate to the patient, the illuminator comprising at least five panels connected by nested hinges on inner side surfaces of adjacent panels; and.” JX-0001 at claim 8. Biofrontera disputes that BLU-U® 4170E in combination with Levulan® meets this limitation (Respondents’ Undisputed Claim Limitations at 3) but offers no specific substantive argument (RIB at 105-06; RRB at 54-56).

Using BLU-U® 4170E following Sun Pharma’s instructions performs this limitation. CX-0010C (Jokerst WS) at Q/A 190-93; CX-0009C (Shmuylovich WS) at Q/A 79-89.

BLU-U® 4170E comprises an illuminator comprising at least five panels connected by nested hinges on inner side surfaces of adjacent panels for the same reasons as Element 1[a]. The Operating Manual explains the procedures for treating lesions on the face, scalp, and upper extremities, where BLU-U® 4170E must be positioned such that the entire surface area to be treated lies between two and four inches from BLU-U® 4170E’s surface. JX-0091C.18-20; CX-0010C (Jokerst WS) at Q/A 192-93; JX-0183C.2; CX-0009C (Shmuylovich WS) at Q/A 80.

d) Limitation 8[c]

Limitation 8[c] recites “uniformly illuminating a treatment surface of the patient with light sources disposed on the at least five panels of the illuminator.” JX-0001 at claim 8. Biofrontera does not dispute that BLU-U® 4170E in combination with Levulan® meets this limitation. Respondents’ Undisputed Claim Limitations at 3. The evidence shows that this limitation is met. CX-0010C (Jokerst WS) at Q/A 194-97.

e) Limitation 8[d]

Limitation 8[d] recites “wherein each of the at least five panels has two first edges and two second edges shorter than the two first edges, and the light sources are arranged such that a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges.” JX-0001 at claim 8. Biofrontera does not dispute that BLU-U® 4170E in combination with Levulan® meets this limitation. Respondents’ Undisputed Claim Limitations at 3. The evidence shows that this limitation is met. CX-0010C (Jokerst WS) at Q/A 194-97.

8. Claim 19

Claim 19 recites “[p] The method of claim 8, [a] wherein the illuminator comprises at least three first panels having first widths, at least two second panels having second widths, wherein each of the second widths of the at least two second panels is narrower than each of the first widths of the at least three first panels; and [b] wherein the at least three first panels and the at least two second panels are connected in an alternating manner such that each of the at least two second panels has a first lateral side connected to a respective one of the at least three first panels and a second lateral side connected to another respective one of the at least three first panels.” JX-0001 at claim 19.

Biofrontera argues that “each dependent claim of each asserted patent remains in dispute as based on an independent claim that is not practiced by the domestic industry products” but it “does not separately dispute” that BLU-U® 4170E in combination with Levulan® meets this claim. Respondents’ Undisputed Claim Limitations at 2. For the reasons discussed above, I found that BLU-U® 4170E in combination with Levulan® meets independent claim 8. The evidence shows that BLU-U® 4170E in combination with Levulan® the additional limitations of dependent claim 19. CX-0010C (Jokerst WS) at Q/A 200-06.

9. Claim 20

a) Limitation 20[p]

Limitation 20[p] recites “A system for photodynamically diagnosing or treating a patient, comprising.” JX-0001 at claim 20. Biofrontera disputes that BLU-U® 4170E meets this limitation (Respondents’ Undisputed Claim Limitations at 4) but offers no specific substantive argument (RIB at 105-06; RRB at 54-56).

BLU-U® 4170E meets this limitation for the same reasons as discussed above with respect to the '512 patent limitation 1[p]. CX-0010C (Jokerst WS) at Q/A 86-91.

b) Limitation 20[a]

Limitation 20[a] recites “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.” JX-0001 at claim 20. Biofrontera does not dispute that BLU-U® 4170E meets this limitation. Respondents’ Undisputed Claim Limitations at 4. The evidence shows that this limitation is met. BLU-U® 4170E meets this limitation for the same reasons as discussed above with respect to the '512 patent limitation 1[a]. CX-0010C (Jokerst WS) at Q/A 212-15.

c) Limitation 20[b]

Limitation 20[b] recites “light sources disposed on surfaces of the at least five panels, the illuminator being configured to uniformly illuminate a treatment surface of the patient via the light sources.” JX-0001 at claim 20. Biofrontera does not dispute that BLU-U® 4170E meets this limitation. Respondents’ Undisputed Claim Limitations at 4. The evidence shows that this limitation is met. BLU-U® 4170E meets this limitation for the same reasons as discussed above with respect to the '512 patent limitation 1[b]. CX-0010C (Jokerst WS) at Q/A 104-26.

d) Limitation 20[c]

Limitation 20[c] recites “one of the at least five panels positioned as a center panel configured to face the treatment surface, and two or more of the at least five panels being configured to be angled relative to the center panel.” JX-0001 at claim 20. Biofrontera does not dispute that BLU-U® 4170E meets this limitation. Respondents’ Undisputed Claim Limitations at 4. The evidence shows that this limitation is met. BLU-U® 4170E meets this limitation for the

same reasons as discussed above with respect to the '512 patent limitation 1[c]. CX-0010C (Jokerst WS) at Q/A 127-33.

e) Limitation 20[d]

Limitation 20[d] recites “wherein each of the at least five panels has two first edges and two second edges shorter than the two first edges, and the light sources are arranged such that a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges.” JX-0001 at claim 20. Biofrontera does not dispute that BLU-U® 4170E meets this limitation. Respondents’ Undisputed Claim Limitations at 4. The evidence shows that this limitation is met. BLU-U® 4170E meets this limitation for the same reasons as discussed above with respect to the '512 patent limitation 1[d]. CX-0010C (Jokerst WS) at Q/A 134-48.

VI. THE '028 PATENT

A. Infringement

Complainant argues that “Biofrontera, via RhodoLED® XL, alone or in combination with Ameluz®, directly and/or indirectly infringes” claims 1, 2, 4, 16, 17, and 19-21 of the '028 patent. CIB at 48-75. Biofrontera argues that it does not infringe the asserted claims of the '028 patent. RIB at 24-30; RRB at 9-12.

1. Claim 1

a) Limitation 1[p]

Limitation 1[p] recites “A system for photodynamically diagnosing or treating a patient, comprising.” JX-0002 at claim 1. Biofrontera does not dispute that RhodoLED® XL meets this limitation. Respondents’ Undisputed Claim Limitations at 9. RhodoLED® XL meets this

limitation for the same reasons as discussed above with respect to the '512 patent limitation 1[p]. The evidence shows that this limitation is met. CX-0010C (Jokerst WS) at Q/A 425-36.

b) Limitation 1[a]

Limitation 1[a] recites “an illuminator comprising five panels connected by hinged structures on inner side surfaces of adjacent panels; and.” JX-0002 at claim 1. Biofrontera disputes that RhodoLED® XL meets this limitation. RIB at 24-27; RRB at 9.

As discussed above with respect to '512 patent limitation 1[a], each of the five panels of RhodoLED® XL are connected by one or more hinged structures on inner side surfaces of adjacent panels. Specifically, two friction hinges and one strain relief structure are rotatable and connects adjacent panels. CX-0010C (Jokerst WS) at Q/A 665-79; JX-0179C.1. In all other respects, RhodoLED® XL meets this limitation for the same reasons as discussed above with respect to the '512 patent limitation 1[a].

c) Limitation 1[b]

Limitation 1[b] recites “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.” JX-0002 at claim 1. Biofrontera does not dispute that RhodoLED® XL meets this limitation. Respondents' Undisputed Claim Limitations at 9. RhodoLED® XL meets this limitation for the same reasons as discussed above with respect to the '512 patent limitation 1[b]. The evidence shows that this limitation is met. CX-0010C (Jokerst WS) at Q/A 476-517.

d) Limitation 1[c]

Limitation 1[c] recites “one of the five panels being positioned as a center panel configured to face the treatment surface, and two or more of the five panels being configured to be angled relative to the center panel.” JX-0002 at claim 1. Biofrontera does not dispute that RhodoLED®

XL meets this limitation. Respondents' Undisputed Claim Limitations at 10. RhodoLED® XL meets this limitation for the same reasons as discussed above with respect to the '512 patent limitation 1[c]. The evidence shows that this limitation is met. CX-0010C (Jokerst WS) at Q/A 518-28.

e) Limitation 1[d]

Limitation 1[d] recites “wherein the five panels are positioned to allow treatment within approximately four inches of the treatment surface, and.” JX-0001 at claim 1. Complainant argues that this limitation is met. CIB at 49-56; CRB at 10-11. Biofrontera disputes that RhodoLED® XL meets this limitation. RIB at 27-29; RRB at 9-11.

The five RhodoLED® XL panels are positioned, and capable of being positioned, to allow treatment within approximately four inches of the treatment surface. CX-0010C (Jokerst WS) at Q/A 684-751.

When Biofrontera designed RhodoLED® XL, it positioned the device's five panels in a row with hinges in between the panels at the end of the spring arm, allowing the panels to be placed in a curved shape proximate the patient. CX-0010C (Jokerst WS) at Q/A 687. The manual states that the “panels should only be used in [a] curved shape” to ensure the proper light dose:

The orientation of the panels can be changed from a curved shape to an unfolded form by pulling the holding bracket apart (Figure 5).

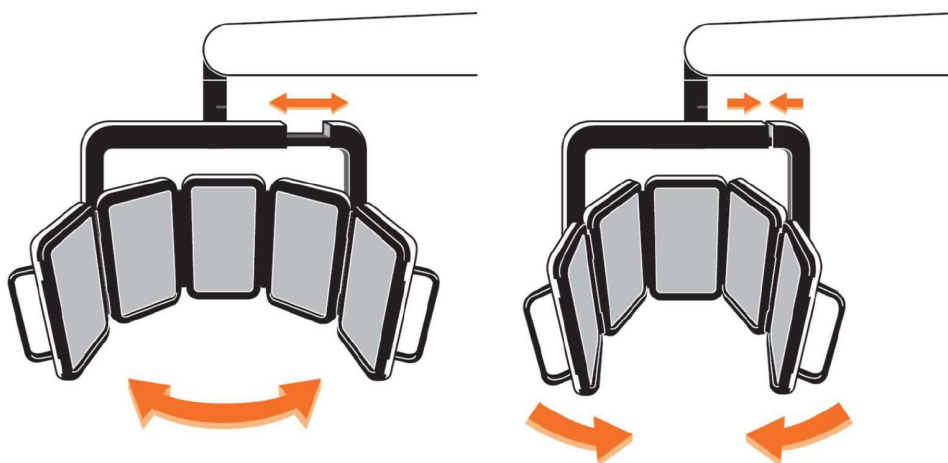


Figure 5: Movement range of the lamp head.

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

JX-0086.12. This design permits placing the panels in a curved shape, so that all five panels are within approximately four inches of the treatment surface. CX-0010C (Jokerst WS) at Q/A 687.

RhodoLED® XL is configured to provide treatment at less than or equal to four inches. Biofrontera admits that it will operate when each of the five panels is positioned at a treatment distance of 4.0 inches. CX-0024C.4 (First Suppl. RFA Response No. 18). The manual notes if the panels are too close or too far, they still light up:

8.4.8 Adjustment Light

If the correct treatment distance of 4.9 inch (12.5 cm) is set the LEDs of the panel light up at a low light intensity to allow an easy adjustment of the distance and the target treatment area.

The size of the treatment area is 9.06 x 11.42 inch (23 cm x 29 cm) for all panels in a curved shape.

Note: When starting the treatment, the LED panels that are too close or too far away from the treatment area will nevertheless also light up. To disable an LED panel during the treatment it must be switched off on the display (see Figure 12).

JX-0086.18; CX-0017C (Thompson WS) at Q/A 68; Tr. (Thompson) at 130:10-131:5. Biofrontera could have designed the RhodoLED® XL to only illuminate within the recommended range, but

chose not to. Tr. (Thompson) at 131:9-25. JX-0008C (Luebbert Dep. Tr.) at 163:21-165:13 (Biofrontera designed the device without an automatic shutoff based on distance). Even Biofrontera’s documents reflect that it is “common” for a user to not follow the recommended range. CX-0010C (Jokerst WS) at Q/A 724; JX-0083C.81, .86, .130, .211, .271.

Dr. Jokerst tested RhodoLED® XL to show it uniformly illuminates a treatment surface at 4.3 and 3.9 inches:

Claim 1 of the '028 Patent – Fourth Element

wherein the five panels are positioned to allow treatment within approximately four inches of the treatment surface

Construction: “within approximately four inches of the treatment surface” is “less than or equal to approximately four inches from the treatment surface.”

		January 9, 2025	January 17, 2025												
		Measurement Distance: 3.9 inches <table><tr><td>Max:</td><td>71.72</td></tr><tr><td>Min:</td><td>56.03</td></tr><tr><td>Min % of Max:</td><td>78.12%</td></tr></table>	Max:	71.72	Min:	56.03	Min % of Max:	78.12%	Measurement Distance: 3.9 inches <table><tr><td>Max:</td><td>81.68</td></tr><tr><td>Min:</td><td>55.22</td></tr><tr><td>Min % of Max:</td><td>67.61%</td></tr></table>	Max:	81.68	Min:	55.22	Min % of Max:	67.61%
Max:	71.72														
Min:	56.03														
Min % of Max:	78.12%														
Max:	81.68														
Min:	55.22														
Min % of Max:	67.61%														
		Measurement Distance: 4.3 inches <table><tr><td>Max:</td><td>61.34</td></tr><tr><td>Min:</td><td>48.94</td></tr><tr><td>Min % of Max:</td><td>79.78%</td></tr></table> CX-1152C	Max:	61.34	Min:	48.94	Min % of Max:	79.78%	Measurement Distance: 4.3 inches <table><tr><td>Max:</td><td>79.65</td></tr><tr><td>Min:</td><td>52.92</td></tr><tr><td>Min % of Max:</td><td>66.44%</td></tr></table> CX-1153C	Max:	79.65	Min:	52.92	Min % of Max:	66.44%
Max:	61.34														
Min:	48.94														
Min % of Max:	79.78%														
Max:	79.65														
Min:	52.92														
Min % of Max:	66.44%														
CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER		CDX-0004C.264													

CDX-0004C.264; CX-0010C (Jokerst WS) at Q/A 375-95, 723; CX-1152C; CX-1153C. That testing is consistent with Biofrontera’s calculations of uniformity at approximately four inches or less. CX-0010C (Jokerst WS) at Q/A 700-22; JX-0067C; JX-0082C.3; JX-0083C.272-73; CX-1005C.120; CX-1109C. Biofrontera found that there is likely no effect on the patient if the reduced treatment distance leads to an increased light dose. CX-0010C (Jokerst WS) at Q/A 726-27; JX-0063C.13; JX-0071C.28. No expert has rebutted Dr. Jokerst’s testing or analysis.

As another example, even if infringement requires considering only the recommended treatment distances, RhodoLED® XL's approved treatment distance includes 4.3 inches:

Claim 1 of the '028 Patent – Fourth Element

wherein the five panels are positioned to allow treatment within approximately four inches of the treatment surface

Construction: "within approximately four inches of the treatment surface" is "less than or equal to approximately four inches from the treatment surface."



Figure 9: Home screen

JX-0086.15

CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER

The RhodoLED® XL LEDs are calibrated such that the skin being treated receives a light dose of approximately 37 J/cm² under the following conditions:

- Illumination time of 13.5 minutes
- Treatment distance of 4.9 ± 0.6 inch (12.5 cm ± 1.5 cm)

JX-0086.7

8.4.7 Adjusting the Treatment Distance

The correct treatment distance for the RhodoLED® XL is 4.9 ± 0.6 inch (12.5 ± 1.5 cm). Each LED panel is equipped with a distance sensor to allow individual adjustment of all panels. The distance sensor is automatically switched on if the panel is switched on. The current distance of each panel is shown on the control unit display above the panel illustration. The following table summarizes the visualization of the treatment distance.

Note: When starting the treatment, the LED panels that are too close or too far away from the treatment area will nevertheless also light up. To disable an LED panel during the treatment it must be switched off on the display (see Figure 12).

JX-0086.17

Typical irradiance	approx. 46 mW/cm² ± 20 % at 4.9 inch (12.5 cm) distance
Max irradiance	approx. 55 mW/cm² at 4.9 inch (12.5 cm) distance
Illuminated area	An area of 9.06 x 11.42 inch (23 cm x 29 cm) is illuminated using all panels in curved shape.
Max. deviation of the intensity over the treatment area	Approx. 20 %
Treatment distance	4.9 ± 0.6 inch (12.5 cm ± 1.5 cm)
	Measuring accuracy ± 0.3 cm (0.1 inch)

JX-0086.27

CDX-0004C.260

CDX-0004C.260; CX-0010C (Jokerst WS) at Q/A 685-92; JX-0086.7, .15, .17, .27; JX-0082C.3 (Biofrontera's treatment range started at 10.5-14.5 cm (4.1-5.7 in), with a safety margin added for the sensor); CX-0010C (Jokerst WS) at Q/A 692 (even when a panel is at 4.3 inches, a correct-distance checkmark is shown, see JX-0086.18 below):

Table 1: Adjusting the treatment distance

Pictogram	Meaning
	Treatment distance is correct for this LED panel (4.9 ± 0.6 inch / 12.5 ± 1.5 cm), adjustment light is/turns on
	Treatment distance is too small for this LED panel. LED panel must be further away from treatment area, adjustment light is/turns off
	Treatment distance is too large for this LED panel. LED panel must be closer to the treatment area, adjustment light is/turns off
	This LED panel is switched off

A distance of 4.3 inches meets the construction of “within approximately four inches.” CX-0010C (Jokerst WS) at Q/A 728. Terms like “approximately” and “about” must be interpreted in their technological context. *Par Pharm., Inc. v. Hospira, Inc.*, 835 F. App’x 578, 584 (Fed. Cir. 2020); *Pall Corp. v. Micron Separations, Inc.*, 66 F.3d 1211, 1217 (Fed. Cir. 1995) (“about” avoids a “strict numerical boundary” and the “range must be interpreted in its technologic and stylistic context”). Dr. Jokerst testified that “approximately” is commonly used in engineering to refer to $\pm 10\%$, absent other information, and here, the Asserted Patents and technology provide additional information and context. CX-0010C (Jokerst WS) at Q/A 728; Tr. (Jokerst) at 206:18-24.

The Asserted Patents provide treatment distances in single-digit whole numbers, conveying that “approximately four inches” includes distances which would round to four inches, such as 3.7 and 4.4 inches (in accordance with the common engineering understanding of “approximately”). CX-0010C (Jokerst WS) at Q/A 728. Thus, in the context of the Asserted Patents, the RhodoLED® XL’s listed treatment distance of 4.3 inches is “within approximately four inches.” *Id.*

Also, a distance of 4.3 inches is “within approximately four inches” in the context of PDT illuminators, the technology at issue, because PDT treatment distances convey how to place panels in a curved configuration around contoured treatment surfaces, like the human face. Those contoured surfaces have protrusions (such as the nose) on the order of about an inch. CX-0009C (Shmuylovich WS) at Q/A 88; Tr. (Ehrenreich) at 527:17-528:7. That degree of approximation is supported by documents both Biofrontera and Sun Pharma considered in designing their PDT illuminators. For example, “The Measure of Man and Woman,” was considered during BLU-U® 4170E development and shows that the nose protrudes about an inch from the face. CX-0009C (Shmuylovich WS) at Q/A 83-88; JX-0203.26; CX-0010C (Jokerst WS) at Q/A 739-43. Biofrontera used a similar document, [REDACTED] in designing the RhodoLED® XL. CX-0010C (Jokerst WS) at Q/A 732-34 (noting the RhodoLED® XL Design Review Report (JX-0071C.2) references [REDACTED] (JX-0071C.222)); CX-0009C (Shmuylovich WS) at Q/A 83-88.

The devices’ placement instructions account for facial variations. Sun Pharma instructs users to position all surfaces between two and four inches, implying a two-inch range (*i.e.*, 3 ± 1 in). JX-0091C.18 (4170E Operating Manual); CX-0010C (Jokerst WS) at Q/A 729-30, 743; CX-0009C (Shmuylovich WS) at Q/A 82. Biofrontera chose a 1.2-inch range for the RhodoLED® XL (4.9 inches $\pm$ 0.6). JX-0086.27, CX-0010C (Jokerst WS) at Q/A 731-34; RX-0004C (Luebbert WS) at Q/A 107-08. Because PDT illuminators have treatment distance ranges of 1-2 inches around a center point to account for physiological variations, “approximately” must encompass that wide degree of variation. CX-0010C (Jokerst WS) at Q/A 745. In practice, dermatologists like Dr. Ehrenreich “don’t use a ruler to measure” the distance from the patient to the treatment surface,

they “just eyeball” it. Tr. (Ehrenreich) at 528:24-529:5. PDT’s technological context confirms that 4.3 inches, 0.3 inches above 4, is “within approximately four inches.”

Biofrontera relies only on Dr. Ehrenreich, not Dr. Grove, to argue noninfringement of this limitation. Dr. Ehrenreich has two noninfringement opinions.

First, Dr. Ehrenreich opines that “positioned to allow treatment” is a “method step” that must be performed by someone treating a patient—and Biofrontera does not treat patients. RX-0011C (Ehrenreich RWS) at Q/A 21, 66, 68, 139. However, these are system claims—“wherein the five panels are positioned to allow treatment within approximately four inches” describes a capability of the claimed system. *See Finjan, Inc. v. Secure Computing Corp.*, 626 F.3d 1197, 1204 (Fed. Cir. 2010) (“[T]o infringe a claim that recites capability and not actual operation, an accused device ‘need only be capable of operating’ in the described mode.”). Thus, Dr. Ehrenreich’s first opinion fails because it is legally misguided—there is no requirement of use to infringe. *R.A.C.C. Indus., Inc. v. Stun-Tech, Inc.*, 1998 WL 834329, at *3 (Fed. Cir. 1998) (“This court has never determined that functional language in a claim converts an apparatus claim into a method of use or hybrid claim.”).

Moreover, though Dr. Ehrenreich never considered the structural aspects of RhodoLED® XL, *see* RX-0011C (Ehrenreich RWS) at Q/A 30, Dr. Grove did. He agreed with Dr. Jokerst that Biofrontera positions the five panels in a row, connected by hinges, to allow panels to be placed in a curved shape. Tr. (Grove) at 435:23-438:4. Indeed, he admitted Biofrontera positions the panels that way because “that curved shape allows each of the panels to be approximately the same distance from the treatment surface.” Tr. (Grove) at 438:5-10.

Second, Dr. Ehrenreich opines that the RhodoLED® XL is not configured to allow treatment within approximately four inches of a treatment surface, but that is factually incorrect.

As explained above, Biofrontera enables using RhodoLED® XL at treatment distances of less than or equal to 4.0 inches, and 4.3 inches meets the construction of “within approximately four inches.” Dr. Ehrenreich opines that “approximately” implies only a “minimal” or “de minimus” variation excluding 4.3 inches. RX-0011C (Ehrenreich RWS) at Q/A 152. Dr. Ehrenreich, however, does not explain what “minimal” or “de minimus” means in context or why a variation of just 0.3 inches does not qualify. Because this limitation is structural, RhodoLED®-XL infringes before actual use. *Finjan*, 626 F.3d at 1204 (“[T]o infringe a claim that recites capability and not actual operation, an accused device ‘need only be capable of operating’ in the described mode.”).

Biofrontera’s brief ignores its own expert’s admissions. Instead, it argues the limitation should be re-construed as a method step that Biofrontera does not infringe, citing *IPXL* and *Lyda*. RIB at 27-28. *IPXL*, however, found clear and convincing evidence of indefiniteness where a system claim recited “wherein...the user uses the input means...” because it was unclear when infringement occurred. *IPXL Holdings, L.L.C. v. Amazon.com, Inc.*, 430 F.3d 1377, 1384 (Fed. Cir. 2005). In *Lyda*, the system claims were re-interpreted as methods because the patentee duplicated “the same method steps” e.g., “providing a program identifier code” under a system preamble. *Lyda v. CBS Corp.*, 838 F.3d 1331, 1335 (Fed. Cir. 2016). Here, there is no signal for a method step because “positioned” is structural. Biofrontera agrees that the recitation of “positioned” earlier in the same claims, the panel “being positioned as a center panel,” is structural—the same is true for this limitation.

RhodoLED®-XL “allows” treatment within approximately four inches because the device is configured “to allow treatment” at 4.0 inches. CIB at 49-50. Even if infringement requires considering the device’s recommended distances, Dr. Jokerst testified how PDT’s technological context supports considering “approximately four inches” to cover 4.3 inches. CX-0010C (Jokerst

WS) at Q/A 728. There is no evidentiary support for Dr. Ehrenreich’s contrary “de minimus” opinion. As noted, he never explains why 4.3 inches is outside the claims’ scope, just that it exceeds his asserted “de minimus” requirement. Indeed, in my *Markman* Order, I rejected Biofrontera’s argument that reads out “approximately” from the claims. Order No. 18 at 42-45.

The evidence shows that this limitation is met.

Doctrine of Equivalents: For the reasons discussed below, even if Biofrontera does not literally infringe this limitation, Biofrontera infringes limitation 1[d] “wherein the five panels are positioned to allow treatment within approximately four inches of the treatment surface” under the doctrine of equivalents.

“[A] product or process that does not literally infringe upon the express terms of a patent claim may nonetheless be found to infringe if there is ‘equivalence’ between the elements of the accused product or process and the claimed elements of the patented invention.” *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 21 (1997). “[T]he proper time for evaluating equivalency . . . is at the time of infringement, not at the time the patent issued.” *Id.* at 37.

“The ‘essential inquiry’ in determining whether there has been infringement under this doctrine is whether ‘the accused product or process contains elements identical or equivalent to each claimed element of the patented invention.’” *Am. Calcar, Inc. v. Am. Honda Motor Co.*, 651 F.3d 1318, 1338 (Fed. Cir. 2011) (quoting *Warner-Jenkinson*, 520 U.S. at 40). An element in the accused device is equivalent to a claim limitation if the only differences between the two are insubstantial to one of ordinary skill in the art. *Wavetronix LLC v. EIS Elec. Integrated Sys.*, 573 F.3d 1343, 1360 (Fed. Cir. 2009); *AquaTex Indus. v. Techniche Sols.*, 419 F.3d 1374, 1382 (Fed. Cir. 2005). In order to assess insubstantiality, a court considers whether an element of the accused product “performs substantially the same function in substantially the same way to obtain the same

result” as the patented invention. *Am. Calcar*, 651 F.3d at 1338; *see also Voda v. Cordis Corp.*, 536 F.3d 1311, 1326 (Fed. Cir. 2008). A patentee alleging infringement under the doctrine of equivalents must submit particularized evidence as to equivalence and must explain specifically why the difference between the claimed invention and what the accused product actually does is “insubstantial.” *Am. Calcar*, 651 F.3d at 1338.

Prosecution history estoppel can prevent a patentee from relying on the doctrine of equivalents when the patentee relinquished subject matter during prosecution of the patent, either by amendment or argument. *AquaTex*, 419 F.3d at 1382. In particular, “[t]he doctrine of prosecution history estoppel limits the doctrine of equivalents when an applicant makes a narrowing amendment for purposes of patentability, or clearly and unmistakably surrenders subject matter by arguments made to an examiner.” *Id.*

Both the purportedly claimed distance range under Biofrontera’s interpretation and the RhodoLED® XL’s recommended treatment distance range perform the same function, because panels positioned in both ranges are capable of illuminating the treatment surface to activate ALA. CX-0010C (Jokerst WS) at Q/A 746-51. These distances perform in the same way because RhodoLED® XL panels positioned at those distances deliver an adequate light dose to the treatment area. *Id.* These distances achieve the same result because RhodoLED® XL delivers uniform light at those distances to allow photodynamic diagnosis (“PD” or “PDD”). *Id.* The equivalence of distances such as 4.3 inches and 4.0 inches is further supported by Biofrontera’s own broad treatment range, encompassing 1.2 inches, significantly more than the difference of 0.3 inches between what Biofrontera purports is the maximum claimed distance (4.0 inches plus a “de minimus” amount) and the minimum distance Biofrontera recommends (4.3 inches). *Id.* And, as discussed above, Biofrontera’s documents detail that decreasing the treatment distance has no

adverse or beneficial effects. *Id.* Thus, Biofrontera infringes limitation 1[d] under the doctrine of equivalents.

f) Limitation 1[e]

Limitation 1[e] recites “wherein each of the five panels has two first edges and two second edges shorter than the two first edges, and the light sources are arranged such that a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges.” JX-0002 at claim 1. Biofrontera does not dispute that RhodoLED® XL meets this limitation. Respondents’ Undisputed Claim Limitations at 10. The evidence shows that this limitation is met for the same reasons as discussed above with respect to the ’512 patent limitation 1[d]. CX-0010C (Jokerst WS) at Q/A 529-75.

2. Claim 2

Claim 2 recites “The system of claim 1, wherein the illuminator is configured to output red light at a dose of 30 J/cm² to 150 J/cm².” JX-0002 at claim 2. Biofrontera argues that “each dependent claim of each asserted patent remains in dispute as based on an independent claim that does not infringe” but it “does not separately dispute” that RhodoLED® XL meets this claim. Respondents’ Undisputed Claim Limitations at 8. For the reasons discussed above, I found that RhodoLED® XL meets independent claim 1. The evidence shows that RhodoLED® XL also meets the additional limitations of dependent claim 2 for the same reasons as discussed above with respect to the ’512 patent claim 3. CX-0010C (Jokerst WS) at Q/A 576-83.

3. Claim 4

Claim 4 recites “The system of claim 1, wherein a plurality of the light sources are configured to emit light having a wavelength in a range of 400 nm to 700 nm.” JX-0002 at claim 4. Biofrontera argues that “each dependent claim of each asserted patent remains in dispute as

based on an independent claim that does not infringe” but it “does not separately dispute” that RhodoLED® XL meets this claim. Respondents’ Undisputed Claim Limitations at 8. For the reasons discussed above, I found that RhodoLED® XL meets claim independent 1. The evidence shows that RhodoLED® XL also meets the additional limitations of dependent claim 4 for the same reasons as discussed above with respect to the ’512 patent claim 5. CX-0010C (Jokerst WS) at Q/A 584-90.

4. Claim 16

a) Limitation 16[p]

Limitation 16[p] recites “A system for photodynamically diagnosing or treating a patient, comprising.” JX-0002 at claim 16. Biofrontera does not dispute that RhodoLED® XL meets this limitation. Respondents’ Undisputed Claim Limitations at 10. The evidence shows that this limitation is met for the same reasons as discussed above with respect to the ’512 patent limitation 1[p]. CX-0010C (Jokerst WS) at Q/A 425-36.

b) Limitation 16[a]

Limitation 16[a] recites “a mobile base supported by at least four wheels.” JX-0002 at claim 16. Biofrontera does not dispute that RhodoLED® XL meets this limitation. Respondents’ Undisputed Claim Limitations at 10. The evidence shows that this limitation is met. CX-0010C (Jokerst WS) at Q/A 767-69.

c) Limitation 16[b]

Limitation 16[b] recites “a pillar perpendicular to the base.” JX-0002 at claim 16. Biofrontera does not dispute that RhodoLED® XL meets this limitation. Respondents’ Undisputed Claim Limitations at 10. The evidence shows that this limitation is met. CX-0010C (Jokerst WS) at Q/A 770-72.

d) Limitation 16[c]

Limitation 16[c] recites “a controller disposed to be supported by the pillar.” JX-0002 at claim 16. Biofrontera does not dispute that RhodoLED® XL meets this limitation. Respondents’ Undisputed Claim Limitations at 10. The evidence shows that this limitation is met. CX-0010C (Jokerst WS) at Q/A 773-78.

e) Limitation 16[d]

Limitation 16[d] recites “an arm mounted to a top portion of the pillar; and.” JX-0002 at claim 16. Biofrontera does not dispute that RhodoLED® XL meets this limitation. Respondents’ Undisputed Claim Limitations at 10. The evidence shows that this limitation is met. CX-0010C (Jokerst WS) at Q/A 779-81.

f) Limitation 16[e]

Limitation 16[e] recites “an illuminator connected at an end of the arm.” JX-0002 at claim 16. Biofrontera does not dispute that RhodoLED® XL meets this limitation. Respondents’ Undisputed Claim Limitations at 10. The evidence shows that this limitation is met. CX-0010C (Jokerst WS) at Q/A 782-88.

g) Limitation 16[f]

Limitation 16[f] recites “the arm being hinged to allow adjustment of a position of the illuminator relative to the base.” JX-0002 at claim 16. Biofrontera does not dispute that RhodoLED® XL meets this limitation. Respondents’ Undisputed Claim Limitations at 10. The evidence shows that this limitation is met. CX-0010C (Jokerst WS) at Q/A 789-94.

h) Limitation 16[g]

Limitation 16[g] recites “the illuminator comprising: 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.” JX-0002 at claim 16. Biofrontera disputes that RhodoLED® XL meets this limitation. RIB at 29-30; RRB at 12.

RhodoLED® XL contains “five panels connected by hinged structures to allow continuous illumination across the five panels.” Claim 16 does not require the hinged structures to be “on inner side surfaces of adjacent panels.” Biofrontera admitted that “the five LED panels of the RhodoLED® XL include hinges that connects [sic] adjacent panels.” CX-0022C (RFA Response No. 27). The hinges allow continuous illumination across the five panels for the same reasons as ’512 patent limitation 20[a]. Biofrontera does not dispute that RhodoLED® XL meets this portion of the limitation. Respondents’ Undisputed Claim Limitations at 10.

Biofrontera, however, disputes that “the five panels are individually configurable to control illumination from each of the five panels.” RhodoLED® XL meets this limitation because “the power output and/or light intensity of each panel can be individually controlled,” as required by the construction. This capability is demonstrated in several features, but overall, each RhodoLED® XL panel has its own LED controller that runs its own code which individually controls the power output and light intensity from each panel. CX-0017C (Thompson WS) at Q/A 40-46, 77-87; Tr. (Thompson) at 108:6-12; 124:21-125:15.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] CX-0010C (Jokerst WS) at Q/A 809-16; CX-0017C (Thompson WS) at Q/A 35-36; CDX-0006C.10; JX-0066C.24; JX-0065C.21; JX-0066C.18; JX-0065C.21; CX-1185C. [REDACTED]

[REDACTED] CX-0017C (Thompson WS) at Q/A 37. [REDACTED]

[REDACTED] CDX-0004C.296; CX-0010C (Jokerst WS) at Q/A 810-14; JX-0066C.24; CX-0017C (Thompson WS) at Q/A 40. *See* CX-1261 (00:33) [REDACTED]

[REDACTED]. Dr. Jokerst performed [REDACTED] on a RhodoLED® XL. CX-0010C (Jokerst WS) at Q/A 813-14; *see* CX-1122; CX-1123 [REDACTED]

[REDACTED] CDX-0004C.297; CX-0010C (Jokerst WS) at Q/A 812; JX-0109C.4. [REDACTED]

[REDACTED] Tr. (Thompson) at 126:17-127:1. [REDACTED]

[REDACTED] Tr. (Foguet) at 387:17-388:5.

Activating/Deactivating Panels: Each panel can be individually turned on or off, such that the power output and light intensity for a given panel can be set to either an activated state, where the default power and light intensity is output, or to a deactivated state, where no power and no light intensity is output. CX-0010C (Jokerst WS) at Q/A 817-23; CDX-0004C.299; JX-0086.16; CX-1267; CX-1241; CX-1112 (video showing panel deactivation during treatment); [REDACTED]

The ability to individually adjust the LED intensities of the panels is not in dispute. CX-0024C.5 (First Suppl. RFA Response No. 24) [REDACTED]

[REDACTED]

[REDACTED] *see also* Tr. (Luebbert), 343:13-21 [REDACTED]

[REDACTED] The ability to deactivate individual panels during a treatment session is also not in dispute. CX-0024C.5 (First Suppl. RFA Response No. 19) [REDACTED]

[REDACTED]

Dr. Grove offers no opinions regarding this limitation. *See, generally*, RX-0009C (Grove RWS). Rather, Biofrontera, through its medical expert, argues that this limitation is not met because: (1) access to the service menus is protected by a password, which is not given to healthcare professionals, RX-0011C (Ehrenreich RWS) at Q/A 177-78, 186, and (2) this limitation is a method step which Biofrontera does not induce healthcare providers to perform during a treatment. *Id.* at Q/A 176-78.

Biofrontera misreads this limitation to require actual adjustment of panel output “as part of treatment.” RIB at 30. That is contrary to the construction of “individually configurable” that requires only that the panels “can be individually controlled.” There is also no specification support for Biofrontera’s new construction. As I noted in the *Markman* order, the disclosures in the specification for this limitation relate to the capability of the light sources to be adjusted, not actual adjustment during treatment. Order No. 18 at 37-38 (citing ’028 patent at 3:14-21, 4:15-22, 6:18-33, 6:43-50).

The preamble cannot convert the limitation to a quasi-“method step” requiring configuration during treatment. The preamble is met because RhodoLED®-XL is a system for

photodynamically treating patients, and the limitation is met because its panels are individually configurable. *Jazz Pharms., Inc. v. Avadel CNS Pharms., LLC*, 60 F.4th 1373, 1380 (Fed. Cir. 2023) (“That the claimed systems can be used in the course of treating patients suffering from narcolepsy does not alter the fact that these are system claims.”) (citing *MasterMine Software, Inc. v. Microsoft Corp.*, 874 F.3d 1307, 1315-16 (Fed. Cir. 2017) (finding that inclusion of functional language describing capabilities of claimed system does not transform system claim into method claim)).

Further, there is no dispute that each panel’s output—the intensity during treatment—can be set on a panel-by-panel basis through Biofrontera’s software without user modification. Tr. (Thompson) at 126:17-127:1 (maintenance menu allows for each panel’s brightness during treatment to be adjusted); CX-0017C (Thompson WS) at Q/A 88-91 (panel deactivation sets that panel’s intensity to zero).

The evidence shows that this limitation is met.

i) Limitation 16[h][a]

Limitation 16[h][a] recites “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 light sources being configured to output light uniformly during at least part of a time when the treatment surface is illuminated.” JX-0002 at claim 16. Biofrontera does not dispute that RhodoLED® XL meets this limitation. Respondents’ Undisputed Claim Limitations at 10. The evidence shows that this limitation is met. CX-0010C (Jokerst WS) at Q/A 476-517.

j) Limitation 16[h][b]

Limitation 16[h][b] recites “each of the five panels having two first edges and two second edges shorter than the two first edges, the light sources arranged such that a higher intensity of

light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges, and.” JX-0002 at claim 16. Biofrontera does not dispute that RhodoLED® XL meets this limitation. Respondents’ Undisputed Claim Limitations at 10-11. The evidence shows that this limitation is met. CX-0010C (Jokerst WS) at Q/A 529-75.

k) Limitation 16[i]

Limitation 16[i] recites “one or more fans mounted to at least one of the five panels.” JX-0002 at claim 16. Biofrontera does not dispute that RhodoLED® XL meets this limitation. Respondents’ Undisputed Claim Limitations at 11. The evidence shows that this limitation is met. CX-0010C (Jokerst WS) at Q/A 831-37.

5. Claim 17

Claim 17 recites “The system of claim 16, wherein 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.” JX-0002 at claim 17. Biofrontera argues that “each dependent claim of each asserted patent remains in dispute as based on an independent claim that does not infringe” but it “does not separately dispute” that RhodoLED® XL meets this claim. Respondents’ Undisputed Claim Limitations at 8. For the reasons discussed above, I found that RhodoLED® XL meets independent claim 16. The evidence shows that RhodoLED® XL also meets the additional limitations of dependent claim 17 for the same reasons as discussed above with respect to the ’512 patent limitation 1[c]. CX-0010C (Jokerst WS) at Q/A 518-28.

6. Claim 19

Claim 19 recites “The system of claim 16, [a] wherein the light sources are configured to output red light during at least part of the time when the treatment surface is illuminated.” JX-0002 at claim 19. Biofrontera argues that “each dependent claim of each asserted patent remains in

dispute as based on an independent claim that does not infringe” but it “does not separately dispute” that RhodoLED® XL meets this claim. Respondents’ Undisputed Claim Limitations at 8. For the reasons discussed above, I found that RhodoLED® XL meets independent claim 16. The evidence shows that RhodoLED® XL also meets the additional limitations of dependent claim 19 for the same reasons as discussed above with respect to the ’512 patent claim 3. CX-0010C (Jokerst WS) at Q/A 576-83.

7. Claim 20

a) Limitation 20[p]

Limitation 20[p] recites “A system for photodynamically diagnosing or treating a patient, comprising.” JX-0002 at claim 20. Biofrontera does not dispute that RhodoLED® XL meets this limitation. Respondents’ Undisputed Claim Limitations at 11. The evidence shows that this limitation is met for the same reasons as discussed above with respect to the ’512 patent limitation 1[p]. CX-0010C (Jokerst WS) at Q/A 425-36.

b) Limitation 20[a]

Limitation 20[a] recites “an illuminator comprising five panels connected by hinged structures on inner side surfaces of adjacent panels, wherein the illuminator is configured to output light at a variable irradiance density during treatment; and.” JX-0002 at claim 20. Biofrontera disputes that RhodoLED® XL meets this limitation. RIB at 24-27; RRB at 9.

RhodoLED® XL meets the “hinged structures” portion of the limitation for the same reasons as ’028 patent limitation 1[a]. The evidence shows that the “variable irradiance density” portion is met. CX-0010C (Jokerst WS) at Q/A 850.

c) Limitation 20[b]

Limitation 20[b] recites “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.” JX-0002 at claim 20. Biofrontera does not dispute that RhodoLED® XL meets this limitation. Respondents’ Undisputed Claim Limitations at 11. The evidence shows that this limitation is met for the same reasons as discussed above with respect to the ’512 patent limitation 1[b]. CX-0010C (Jokerst WS) at Q/A 476-517.

d) Limitation 20[c]

Limitation 20[c] recites “one of the five panels being positioned as a center panel configured to face the treatment surface, and two or more of the five panels being configured to be angled relative to the center panel.” JX-0002 at claim 20. Biofrontera does not dispute that RhodoLED® XL meets this limitation. Respondents’ Undisputed Claim Limitations at 11. The evidence shows that this limitation is met for the same reasons as discussed above with respect to the ’512 patent limitation 1[c]. CX-0010C (Jokerst WS) at Q/A 518-28.

e) Limitation 20[d]

Limitation 20[d] recites “wherein the five panels are positioned to allow treatment within approximately four inches of the treatment surface, and.” JX-0002 at claim 20. Biofrontera disputes that RhodoLED® XL meets this limitation. RIB at 27-29; RRB at 9-11. The evidence shows that this limitation is met for the same reasons as discussed above with respect to the ’028 patent limitation 1[d]. CX-0010C (Jokerst WS) at Q/A 684-751.

f) Limitation 20[e]

Limitation 20[e] recites “wherein each of the five panels has two first edges and two second edges shorter than the two first edges, and the light sources are arranged such that a higher intensity

of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges.” JX-0002 at claim 20. Biofrontera does not dispute that RhodoLED® XL meets this limitation. Respondents’ Undisputed Claim Limitations at 11. The evidence shows that this limitation is met for the same reasons as discussed above with respect to the ’512 patent limitation 1[d]. CX-0010C (Jokerst WS) at Q/A 529-75.

8. Claim 21

a) Limitation 21[p]

Limitation 21[p] recites “A system for photodynamically diagnosing or treating a patient, comprising.” JX-0002 at claim 21. Biofrontera does not dispute that RhodoLED® XL meets this limitation. Respondents’ Undisputed Claim Limitations at 11. The evidence shows that this limitation is met for the same reasons as discussed above with respect to the ’512 patent limitation for the same reasons as discussed above with respect to the ’512 patent limitation 1[p]. CX-0010C (Jokerst WS) at Q/A 425-36.

b) Limitation 21[a]

Limitation 21[a] recites “an illuminator comprising five panels connected by hinged structures on inner side surfaces of adjacent panels; and.” JX-0002 at claim 21. Biofrontera disputes that RhodoLED® XL meets this limitation. RIB at 24-27; RRB at 9. The evidence shows that this limitation is met for the same reasons as discussed above with respect to the ’028 patent limitation 1[a]. CX-0010C (Jokerst WS) at Q/A 865-66.

c) Limitation 21[b]

Limitation 21[b] recites “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.” JX-0002 at claim 21. Biofrontera does not dispute that RhodoLED® XL meets this

limitation. Respondents' Undisputed Claim Limitations at 11-12. The evidence shows that this limitation is met for the same reasons as discussed above with respect to the '512 patent limitation 1[b]. CX-0010C (Jokerst WS) at Q/A 476-517.

d) Limitation 21[c]

Limitation 21[c] recites "one of the five panels being positioned as a center panel configured to face the treatment surface, and two or more of the five panels being configured to be angled relative to the center panel." JX-0002 at claim 21. Biofrontera does not dispute that RhodoLED® XL meets this limitation. Respondents' Undisputed Claim Limitations at 12. The evidence shows that this limitation is met for the same reasons as discussed above with respect to the '512 patent limitation 1[c]. CX-0010C (Jokerst WS) at Q/A 518-28.

e) Limitation 21[d]

Limitation 21[d] recites "wherein the five panels are positioned to allow treatment within approximately four inches of the treatment surface." JX-0002 at claim 21. Biofrontera disputes that RhodoLED® XL meets this limitation. RIB at 27-29; RRB at 9-11. The evidence shows that this limitation is met for the same reasons as discussed above with respect to the '028 patent limitation 1[d]. CX-0010C (Jokerst WS) at Q/A 871-72.

f) Limitation 21[e]

Limitation 21[e] recites "wherein the five panels are individually configurable to control illumination from each of the five panels, and." JX-0002 at claim 21. Biofrontera disputes that RhodoLED® XL meets this limitation. RIB at 29-30; RRB at 12. The evidence shows that this limitation is met for the same reasons as discussed above with respect to the '028 patent limitation 16[g]. CX-0010C (Jokerst WS) at Q/A 808-23.

g) Limitation 21[f]

Limitation 21[f] recites “wherein each of the five panels has two first edges and two second edges shorter than the two first edges, and the light sources are arranged such that a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges.” JX-0002 at claim 21. Biofrontera does not dispute that RhodoLED® XL meets this limitation. Respondents’ Undisputed Claim Limitations at 12. The evidence shows that this limitation is met for the same reasons as discussed above with respect to the ’512 patent limitation 1[d]. CX-0010C (Jokerst WS) at Q/A 529-75.

B. Technical Prong

Complainant argues that “BLU-U® 4170E, individually or in combination with Levulan®, practices” claims 1, 3, 4, 5, 7, 9, 16-18, and 21 of the ’028 patent. CIB at 147-60. Biofrontera argues that complainant has not carried its burden to show that the technical prong of the domestic industry requirement has been met. RIB at 105-06; RRB at 54-56.

1. Claim 1**a) Limitation 1[p]**

Limitation 1[p] recites “A system for photodynamically diagnosing or treating a patient, comprising.” JX-0002 at claim 1. Biofrontera disputes that BLU-U® 4170E meets this limitation (Respondents’ Undisputed Claim Limitations at 4) but offers no specific substantive argument (RIB at 105-06; RRB at 54-56).

BLU-U® 4170E meets this limitation for the same reasons as discussed above with respect to the ’512 patent limitation 1[p]. The evidence shows that this limitation is met. CX-0010C (Jokerst WS) at Q/A 86-91.

b) Limitation 1[a]

Limitation 1[a] recites “an illuminator comprising five panels connected by hinged structures on inner side surfaces of adjacent panels; and.” JX-0002 at claim 1. Biofrontera does not dispute that BLU-U® 4170E meets this limitation. Respondents’ Undisputed Claim Limitations at 4. BLU-U® 4170E meets this limitation for the same reasons as discussed above with respect to the ’512 patent limitation 1[a]. The evidence shows that this limitation is met. CX-0010C (Jokerst WS) at Q/A 92-103.

c) Limitation 1[b]

Limitation 1[b] recites “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.” JX-0002 at claim 1. Biofrontera does not dispute that BLU-U® 4170E meets this limitation. Respondents’ Undisputed Claim Limitations at 4. BLU-U® 4170E meets this limitation for the same reasons as discussed above with respect to the ’512 patent limitation 1[b]. The evidence shows that this limitation is met. CX-0010C (Jokerst WS) at Q/A 104-26.

d) Limitation 1[c]

Limitation 1[c] recites “one of the five panels being positioned as a center panel configured to face the treatment surface, and two or more of the five panels being configured to be angled relative to the center panel.” JX-0002 at claim 1. Biofrontera does not dispute that BLU-U® 4170E meets this limitation. Respondents’ Undisputed Claim Limitations at 4. BLU-U® 4170E meets this limitation for the same reasons as discussed above with respect to the ’512 patent limitation 1[c]. The evidence shows that this limitation is met. CX-0010C (Jokerst WS) at Q/A 127-33.

e) Limitation 1[d]

Limitation 1[d] recites “wherein the five panels are positioned to allow treatment within approximately four inches of the treatment surface, and.” JX-0001 at claim 1. Biofrontera disputes that BLU-U® 4170E meets this limitation (Respondents’ Undisputed Claim Limitations at 4) but offers no specific substantive argument (RIB at 105-06; RRB at 54-56).

BLU-U® 4170E comprises wherein the five panels are positioned to allow treatment within approximately four inches of the treatment surface. CX-0010C (Jokerst WS) at Q/A 237-42. BLU-U® 4170E was designed such that the five panels are positioned to allow treatment within approximately four inches of the treatment surface, where the five panels are at the end of 4170E’s pivoting arm and connected by hinges; that enables the panels to assume a circular, curved configuration where the panels are positioned less than or equal to approximately four inches from the treatment surface. JX-0183C; *see* JX-0091C.7 (describing how the “Five Panel LED treatment array” connects to the end of the pivoting arm); CX-1038C.2; JX-0091C.13; CX-1243C.1. The Operating Manual requires placing 4170E such that the entire surface area to be treated lies between two and four inches from 4170E’s surface. JX-0091C.18-20.

f) Limitation 1[e]

Limitation 1[e] recites “wherein each of the five panels has two first edges and two second edges shorter than the two first edges, and the light sources are arranged such that a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges.” JX-0002 at claim 1. Biofrontera does not dispute that BLU-U® 4170E meets this limitation. Respondents’ Undisputed Claim Limitations at 4. BLU-U® 4170E meets this limitation for the same reasons as discussed above with respect to the ’512 patent

limitation 1[d]. The evidence shows that this limitation is met. CX-0010C (Jokerst WS) at Q/A 134-48.

2. Claim 3

Claim 3 recites “The system of claim 1, [a] wherein the illuminator is configured to output light at an irradiance density of 10 mW/cm² to 30 mW/cm².” JX-0002 at claim 3. Biofrontera argues that “each dependent claim of each asserted patent remains in dispute as based on an independent claim that is not practiced by the domestic industry products” but it “does not separately dispute” that BLU-U® 4170E meets this claim. Respondents’ Undisputed Claim Limitations at 2. I found that BLU-U® 4170E meets independent claim 1. The evidence shows that BLU-U® 4170E also meets the additional limitations of dependent claim 3 for the same reasons as discussed above with respect to the ’512 patent claim 4. CX-0010C (Jokerst WS) at Q/A 162-68.

3. Claim 4

Claim 4 recites “The system of claim 1, wherein a plurality of the light sources are configured to emit light having a wavelength in a range of 400 nm to 700 nm.” JX-0002 at claim 4. Biofrontera argues that “each dependent claim of each asserted patent remains in dispute as based on an independent claim that is not practiced by the domestic industry products” but it “does not separately dispute” that BLU-U® 4170E meets this claim. Respondents’ Undisputed Claim Limitations at 2. For the reasons discussed above, I found that BLU-U® 4170E meets independent claim 1. The evidence shows that BLU-U® 4170E also meets the additional limitations of dependent claim 4 for the same reasons as discussed above with respect to the ’512 patent claim 5. CX-0010C (Jokerst WS) at Q/A 169-73.

4. Claim 5**a) Limitation 5[p]**

Limitation 5[p] recites “A method of photodynamically diagnosing or treating a patient, comprising.” JX-0002 at claim 5. Biofrontera disputes that BLU-U® 4170E in combination with Levulan® meets this limitation (Respondents’ Undisputed Claim Limitations at 5) but offers no specific substantive argument (RIB at 105-06; RRB at 54-56).

BLU-U® 4170E in combination with Levulan® meets this limitation for the same reasons as discussed above with respect to the ’512 patent limitation 8[p]. The evidence shows that this limitation is met. CX-0010C (Jokerst WS) at Q/A 178-82; CX-0009C (Shmuylovich WS) at Q/A 74-75.

b) Limitation 5[a]

Limitation 5[a] recites “administering 5-aminolevulinic acid (ALA) to the patient.” JX-0002 at claim 5. Biofrontera does not dispute that BLU-U® 4170E in combination with Levulan® meets this limitation. Respondents’ Undisputed Claim Limitations at 5.

BLU-U® 4170E in combination with Levulan® meets this limitation for the same reasons as discussed above with respect to the ’512 patent limitation 8[a]. The evidence shows that this limitation is met. CX-0010C (Jokerst WS) at Q/A 183-89; JX-0183C.2; CX-0009C (Shmuylovich WS) at Q/A 76-78.

c) Limitation 5[b]

Limitation 5[b] recites “positioning an illuminator proximate to the patient, the illuminator comprising five panels connected by hinged structures on inner side surfaces of adjacent panels; and.” JX-0002 at claim 5. Biofrontera disputes that BLU-U® 4170E in combination with

Levulan® meets this limitation (Respondents' Undisputed Claim Limitations at 5) but offers no specific substantive argument (RIB at 105-06; RRB at 54-56).

BLU-U® 4170E in combination with Levulan® meets this limitation for the same reasons as discussed above with respect to the '512 patent limitation 8[b]. The evidence shows that this limitation is met. CX-0010C (Jokerst WS) at Q/A 192-93; JX-0183C.2; CX-0009C (Shmuylovich WS) at Q/A 80.

d) Limitation 5[c]

Limitation 5[c] recites “uniformly illuminating a treatment surface of the patient with light sources disposed on the five panels of the illuminator, the five panels being positioned to allow treatment within approximately four inches of the treatment surface.” JX-0002 at claim 5. Biofrontera disputes that BLU-U® 4170E in combination with Levulan® meets this limitation (Respondents' Undisputed Claim Limitations at 5) but offers no specific substantive argument (RIB at 105-06; RRB at 54-56).

BLU-U® 4170E in combination with Levulan® meets this limitation for the same reasons as discussed above with respect to the '512 patent limitation 8[c]. The evidence shows that this limitation is met. CX-0010C (Jokerst WS) at Q/A 194-97; CX-0009C (Shmuylovich WS) at Q/A 90-94.

e) Limitation 5[d]

Limitation 5[d] recites “wherein each of the five panels has two first edges and two second edges shorter than the two first edges, and the light sources are arranged such that a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges.” JX-0002 at claim 5. Biofrontera does not dispute that BLU-U®

4170E in combination with Levulan® meets this limitation. Respondents' Undisputed Claim Limitations at 5.

BLU-U® 4170E in combination with Levulan® meets this limitation for the same reasons as discussed above with respect to the '512 patent limitation 8[d]. The evidence shows that this limitation is met. CX-0010C (Jokerst WS) at Q/A 194-97; CX-0009C (Shmuylovich WS) at Q/A 90-94.

5. Claim 7

Claim 7 recites “The method of claim 5, wherein the illuminating comprises outputting blue light during at least part of the time when the treatment surface is illuminated.” JX-0002 at claim 7. Biofrontera argues that “each dependent claim of each asserted patent remains in dispute as based on an independent claim that is not practiced by the domestic industry products” but it “does not separately dispute” that BLU-U® 4170E in combination with Levulan® meets this claim. Respondents' Undisputed Claim Limitations at 2.

I found that BLU-U® 4170E in combination with Levulan® meets independent claim 5. BLU-U® 4170E in combination with Levulan® meets the additional limitations of dependent claim 7. CX-0010C (Jokerst WS) at Q/A 268-70.

6. Claim 9

Claim 9 recites “The method of claim 5, wherein: [a] the illuminator comprises at least three first panels having first widths, at least two second panels having second widths, wherein each of the second widths of the at least two second panels is narrower than each of the first widths of the at least three first panels; and [b] the at least three first panels and the at least two second panels are connected in an alternating manner such that each of the at least two second panels has a first lateral side connected to a respective one of the at least three first panels and a second lateral

side connected to another respective one of the at least three first panels.” JX-0002 at claim 9. Biofrontera argues that “each dependent claim of each asserted patent remains in dispute as based on an independent claim that is not practiced by the domestic industry products” but it “does not separately dispute” that BLU-U® 4170E in combination with Levulan® meets this claim. Respondents’ Undisputed Claim Limitations at 2.

I found that BLU-U® 4170E in combination with Levulan® meets independent claim 5. BLU-U® 4170E in combination with Levulan® meets the additional limitations of dependent claim 9 for the same reasons as discussed above with respect to the ’512 patent claim 19. CX-0010C (Jokerst WS) at Q/A 203-06.

7. Claim 16

a) Limitation 16[p]

Limitation 16[p] recites “A system for photodynamically diagnosing or treating a patient, comprising.” JX-0002 at claim 16. Biofrontera disputes that BLU-U® 4170E meets this limitation (Respondents’ Undisputed Claim Limitations at 6) but offers no specific substantive argument (RIB at 105-06; RRB at 54-56).

BLU-U® 4170E meets this limitation for the same reasons as discussed above with respect to the ’512 patent limitation 1[p]. The evidence shows that this limitation is met. CX-0010C (Jokerst WS) at Q/A 86-91.

b) Limitation 16[a]

Limitation 16[a] recites “a mobile base supported by at least four wheels.” JX-0002 at claim 16. Biofrontera does not dispute that BLU-U® 4170E meets this limitation. Respondents’ Undisputed Claim Limitations at 6. The evidence shows that this limitation is met. CX-0010C (Jokerst WS) at Q/A 282-84.

c) Limitation 16[b]

Limitation 16[b] recites “a pillar perpendicular to the base.” JX-0002 at claim 16. Biofrontera does not dispute that BLU-U® 4170E meets this limitation. Respondents’ Undisputed Claim Limitations at 6. The evidence shows that this limitation is met. CX-0010C (Jokerst WS) at Q/A 285-87.

d) Limitation 16[c]

Limitation 16[c] recites “a controller disposed to be supported by the pillar.” JX-0002 at claim 16. Biofrontera does not dispute that BLU-U® 4170E meets this limitation. Respondents’ Undisputed Claim Limitations at 6. The evidence shows that this limitation is met. CX-0010C (Jokerst WS) at Q/A 288-90.

e) Limitation 16[d]

Limitation 16[d] recites “an arm mounted to a top portion of the pillar; and.” JX-0002 at claim 16. Biofrontera does not dispute that BLU-U® 4170E meets this limitation. Respondents’ Undisputed Claim Limitations at 6. The evidence shows that this limitation is met. CX-0010C (Jokerst WS) at Q/A 291-93.

f) Limitation 16[e]

Limitation 16[e] recites “an illuminator connected at an end of the arm.” JX-0002 at claim 16. Biofrontera does not dispute that BLU-U® 4170E meets this limitation. Respondents’ Undisputed Claim Limitations at 6. The evidence shows that this limitation is met. CX-0010C (Jokerst WS) at Q/A 294-98.

g) Limitation 16[f]

Limitation 16[f] recites “the arm being hinged to allow adjustment of a position of the illuminator relative to the base.” JX-0002 at claim 16. Biofrontera does not dispute that BLU-U®

4170E meets this limitation. Respondents' Undisputed Claim Limitations at 6. The evidence shows that this limitation is met. CX-0010C (Jokerst WS) at Q/A 299-301.

h) Limitation 16[g]

Limitation 16[g] recites “the illuminator comprising: 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.” JX-0002 at claim 16. Biofrontera disputes that BLU-U® 4170E meets this limitation (Respondents' Undisputed Claim Limitations at 6) but offers no specific substantive argument (RIB at 105-06; RRB at 54-56).

BLU-U® 4170E meets “the illuminator comprising: five panels connected by hinged structures” portion for the same reasons as discussed above with respect to the '512 patent limitation 1[a]. CX-0010C (Jokerst WS) at Q/A 92-103. BLU-U® 4170E meets “the illuminator comprising: five panels connected by hinged structures to allow continuous illumination across the five panels” portion for the same reasons as discussed above with respect to the '512 patent limitation 20[a]. CX-0010C (Jokerst WS) at Q/A 212-15.

BLU-U® 4170E also meets the last portion “wherein the five panels are individually configurable to control illumination from each of the five panels.” CX-0010C (Jokerst WS) at Q/A 306-13. The power output and/or light intensity of each panel can be individually controlled, as each panel has addressable LEDs whose power output and light intensities are individually controlled, and each panel sets its power configuration independently. CX-1244C; *see* CX-1266C.14; CX-0017C (Thompson WS) at Q/A 93-109 (reviewing how each panel sets its power configuration); CX-1248C.1; CX-0011C (Lundahl WS) at Q/A 84-91.

i) Limitations 16[h][a]-[b]

Limitations 16[h][a]-[b] recite “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 light sources being configured to output light uniformly during at least part of a time when the treatment surface is illuminated, each of the five panels having two first edges and two second edges shorter than the two first edges, the light sources arranged such that a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges, and.” JX-0002 at claim 16. Biofrontera does not dispute that BLU-U® 4170E meets these limitations. Respondents’ Undisputed Claim Limitations at 6. The evidence shows that these limitations are met. CX-0010C (Jokerst WS) at Q/A 314-19.

j) Limitation 16[i]

Limitation 16[i] recites “one or more fans mounted to at least one of the five panels.” JX-0002 at claim 16. Biofrontera does not dispute that BLU-U® 4170E meets this limitation. Respondents’ Undisputed Claim Limitations at 6. The evidence shows that this limitation is met. CX-0010C (Jokerst WS) at Q/A 320-25.

8. Claim 17

Claim 17 recites “The system of claim 16, wherein 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.” JX-0002 at claim 17. Biofrontera argues that “each dependent claim of each asserted patent remains in dispute as based on an independent claim that is not practiced by the domestic industry products” but it “does not separately dispute” that BLU-U® 4170E meets this claim. Respondents’ Undisputed Claim Limitations at 2. I found that BLU-U® 4170E meets independent claim 16. The evidence shows that BLU-U® 4170E also

meets the additional limitations of dependent claim 17 for the same reasons as discussed above with respect to the '512 patent limitation 1[c]. CX-0010C (Jokerst WS) at Q/A 127-33.

9. Claim 18

Claim 18 recites “The system of claim 16, wherein the light sources are configured to output blue light during at least part of the time when the treatment surface is illuminated.” JX-0002 at claim 18. Biofrontera argues that “each dependent claim of each asserted patent remains in dispute as based on an independent claim that is not practiced by the domestic industry products” but it “does not separately dispute” that BLU-U® 4170E meets this claim. Respondents’ Undisputed Claim Limitations at 2. I found that BLU-U® 4170E meets independent claim 16. The evidence shows that BLU-U® 4170E also meets the additional limitations of dependent claim 18. CX-0010C (Jokerst WS) at Q/A 328-31.

10. Claim 21

a) Limitation 21[p]

Limitation 21[p] recites “A system for photodynamically diagnosing or treating a patient, comprising.” JX-0002 at claim 21. Biofrontera disputes that BLU-U® 4170E meets this limitation (Respondents’ Undisputed Claim Limitations at 7) but offers no specific substantive argument (RIB at 105-06; RRB at 54-56).

BLU-U® 4170E meets this limitation for the same reasons as discussed above with respect to the '512 patent limitation 1[p]. The evidence shows that this limitation is met. CX-0010C (Jokerst WS) at Q/A 86-91.

b) Limitation 21[a]

Limitation 21[a] recites “an illuminator comprising five panels connected by hinged structures on inner side surfaces of adjacent panels; and.” JX-0002 at claim 21. Biofrontera does

not dispute that BLU-U® 4170E meets this limitation. Respondents' Undisputed Claim Limitations at 7. BLU-U® 4170E meets this limitation for the same reasons as discussed above with respect to the '512 patent limitation 1[a]. The evidence shows that this limitation is met. CX-0010C (Jokerst WS) at Q/A 92-103.

c) Limitation 21[b]

Limitation 21[b] recites “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.” JX-0002 at claim 21. Biofrontera does not dispute that BLU-U® 4170E meets this limitation. Respondents' Undisputed Claim Limitations at 7. BLU-U® 4170E meets this limitation for the same reasons as discussed above with respect to the '512 patent limitation 1[b]. The evidence shows that this limitation is met. CX-0010C (Jokerst WS) at Q/A 104-26.

d) Limitation 21[c]

Limitation 21[c] recites “one of the five panels being positioned as a center panel configured to face the treatment surface, and two or more of the five panels being configured to be angled relative to the center panel.” JX-0002 at claim 21. Biofrontera does not dispute that BLU-U® 4170E meets this limitation. Respondents' Undisputed Claim Limitations at 7. BLU-U® 4170E meets this limitation for the same reasons as discussed above with respect to the '512 patent limitation 1[c]. The evidence shows that this limitation is met. CX-0010C (Jokerst WS) at Q/A 127-33.

e) Limitation 21[d]

Limitation 21[d] recites “wherein the five panels are positioned to allow treatment within approximately four inches of the treatment surface.” JX-0002 at claim 21. Biofrontera disputes

that BLU-U® 4170E meets this limitation (Respondents' Undisputed Claim Limitations at 7) but offers no specific substantive argument (RIB at 105-06; RRB at 54-56).

BLU-U® 4170E meets this limitation for the same reasons as discussed above with respect to the '512 patent limitation 1[d]. The evidence shows that this limitation is met. CX-0010C (Jokerst WS) at Q/A 134-48.

f) Limitation 21[e]

Limitation 21[e] recites “wherein the five panels are individually configurable to control illumination from each of the five panels, and.” JX-0002 at claim 21. Biofrontera disputes that BLU-U® 4170E meets this limitation (Respondents' Undisputed Claim Limitations at 7) but offers no specific substantive argument (RIB at 105-06; RRB at 54-56).

BLU-U® 4170E meets this limitation for the same reasons as discussed above with respect to the '028 patent limitation 16[g]. The evidence shows that this limitation is met. CX-0010C (Jokerst WS) at Q/A 92-103, 212-15, 306-13.

g) Limitation 21[f]

Limitation 21[f] recites “wherein each of the five panels has two first edges and two second edges shorter than the two first edges, and the light sources are arranged such that a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges.” JX-0002 at claim 21. Biofrontera does not dispute that BLU-U® 4170E meets this limitation. Respondents' Undisputed Claim Limitations at 7. BLU-U® 4170E meets this limitation for the same reasons as discussed above with respect to the '512 patent limitation 1[d]. The evidence shows that this limitation is met. CX-0010C (Jokerst WS) at Q/A 134-48.

VII. VALIDITY

A. Legal Standard

A patent is presumed valid. *See* 35 U.S.C. § 282; *Microsoft Corp. v. i4i Ltd. P’ship*, 564 U.S. 91, 95 (2011). A respondent who has raised patent invalidity as an affirmative defense has the burden of overcoming this presumption by clear and convincing evidence. *See Microsoft*, 564 U.S. at 95.

1. 35 U.S.C. § 103 (Obviousness)

Under 35 U.S.C. §103, a patent may be found invalid for obviousness if “the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains.” 35 U.S.C. §103. Because obviousness is determined at the time of invention, rather than the date of application or litigation, “[t]he great challenge of the obviousness judgment is proceeding without any hint of hindsight.” *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 655 F.3d 1364, 1375 (Fed. Cir. 2011) (“*Star II*”).

When a patent is challenged as obvious, the critical inquiry in determining the differences between the claimed invention and the prior art is whether there is an apparent reason to combine the known elements in the fashion claimed by the patent at issue. *KSR Int’l Co. v. Teleflex, Inc.*, 550 U.S. 398, 417-418 (2007). The Federal Circuit has since held that when a patent is challenged as obvious, based on a combination of several prior art references, “the burden falls on the patent challenger to show by clear and convincing evidence that a person of ordinary skill in the art would have had reason to attempt to make the composition or device, or carry out the claimed process,

and would have had a reasonable expectation of success in doing so.” *PharmaStem Therapeutics, Inc. v. ViaCell, Inc.*, 491 F.3d 1342, 1360 (Fed. Cir. 2007) (citations omitted).

Obviousness is a determination of law based on underlying determinations of fact. *Star II*, 655 F.3d at 1374. The factual determinations behind a finding of obviousness include: (1) the scope and content of the prior art, (2) the level of ordinary skill in the art, (3) the differences between the claimed invention and the prior art, and (4) secondary considerations of non-obviousness. *KSR*, 550 U.S. at 399 (citing *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966)). These factual determinations are referred to collectively as the “*Graham* factors.” Secondary considerations of non-obviousness include commercial success, long felt but unresolved need, and the failure of others. *Id.* When present, secondary considerations “give light to the circumstances surrounding the origin of the subject matter sought to be patented,” but they are not dispositive on the issue of obviousness. *Geo. M. Martin Co. v. Alliance Mach. Sys. Int’l.*, 618 F.3d 1294, 1304-06 (Fed. Cir. 2010). A court must consider all the evidence from the *Graham* factors before reaching a decision on obviousness. For evidence of secondary considerations to be given substantial weight in the obviousness determination, its proponent must establish a nexus between the evidence and the merits of the claimed invention. *W. Union Co. v. MoneyGram Payment Sys. Inc.*, 626 F.3d 1361, 1372-73 (Fed. Cir. 2010) (citing *In re GPAC Inc.*, 57 F.3d 1573, 1580 (Fed. Cir. 1995)).

B. Obviousness

Respondents argue that all Asserted Claims are invalid as obvious in view of the following four alleged pieces of prior art:

- U.S. Patent No. 6,223,071 (RX-0065) (“Lundahl”);

- U.S. Patent Application Publication No. 2005/0075703 (RX-0057 or RX-0099) (“Larsen”);⁵
- U.S. Patent Application Publication No. 2010/0118522 (RX-0576) (“Hente”); and
- U.S. Patent No. 4,823,858 (RX-0607) (“Perutz”).

RIB at 30-90.

Lundahl was filed on May 1, 1998, and issued on April 24, 2001. RX-0065 at cover page. Lundahl qualifies as prior art under §102(a)(1) because it was published before the earliest effective filing date of the Asserted Patents.

Larsen was published on April 7, 2005, and claims priority to January 22, 2001. RX-0057 at cover page. Larsen qualifies as prior art under §102(a)(1) because it was published before the earliest effective filing date of the Asserted Patents.

Hente was published on May 13, 2010, and claims priority to May 2, 2007. RX-0576 at cover page. Hente qualifies as prior art under §102(a)(1) because it was published before the earliest effective filing date of the Asserted Patents.

Perutz was filed on June 2, 1987, and issued on April 25, 1989. RX-0607 at cover page. Perutz qualifies as prior art under §102(a)(1) because it was published before the earliest effective filing date of the Asserted Patents.

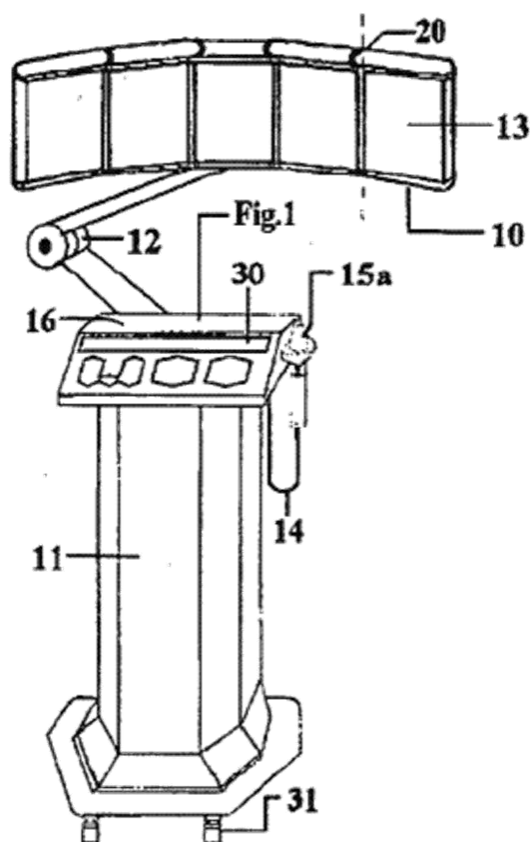
⁵ In their respective post-hearing briefs, Biofrontera cites to RX-0099 for Larsen, but Complainant cites to RX-0057. *See e.g.*, RIB at 35 and CIB at 79.

1. Larsen and Hente**a) Hinges**

Each of claims 1, 16, 20, and 21 of the '028 patent and claims 1, 8, and 20 of the '512 patent recites “nested hinges” or “hinged structures.” JX-0002 at claims 1, 16, 20, 21; JX-0001 at claims 1, 8, 20.

Biofrontera argues that “Larsen individually, or Larsen further in view of Hente, teaches and renders obvious” the “nested hinges” or “hinged structures” limitation. RIB at 40-47; RRB at 13-18. Complainant disagrees because Larsen refers to hinges on the bottom of the panels and even if one reads Larsen as having hinges between the panels, the disclosure is insufficient to teach “nested hinges.” CIB at 83-85; CRB at 18-24.

I find that Larsen does not disclose or render obvious the claimed hinges. CX-0014C (Jokerst RWS) at Q/A 196, 231. As an initial matter, in its only disclosure of hinges, Larsen cites Figure 1 and explains that “several applicators 13 are flexibly connected to each other through hinges 10.” RX-0057 at [0072]; CX-0014C (Jokerst RWS) at Q/A 197. As shown in Figure 1 below, element “10” points to the bottom of applicator 13, not the inner side surfaces of adjacent panels. CX-0014C (Jokerst RWS) at Q/A 197-98.



RX-0057 at Fig. 1, [0027], [0040], [0069], [0071], [0072].

Larsen's express disclosure of hinges on the bottom of the applicator, not on the inner side surfaces, is corroborated by the prosecution histories of the Asserted Patents and related applications. CX-0014C (Jokerst RWS) at Q/A 197-231; JX-0004.1731 (Examiner allowing claims of the '512 patent over Larsen stating "the art of record neither anticipates nor renders obvious 'nested hinges on inner side surfaces of adjacent panels'"); RX-0059 (Larsen '381 patent); JX-0003.130 (during the '028 patent prosecution, Same Examiner recognizing Larsen '381 patent discloses "Hinged Structures 10" in reference to same Figure 1); CDX-0018C.64; JX-0003.446-52 (allowing claims of the '028 patent over the prior art of record, which included the Larsen '381 patent (that contains the same Figure 1 disclosure as the Larsen publication)). Larsen used the

same convention in another application, where he identified “individual [sic] hinged (27) flat elements (26)” in reference to hinges on the bottom of the panels:

Figure 1 of Larsen

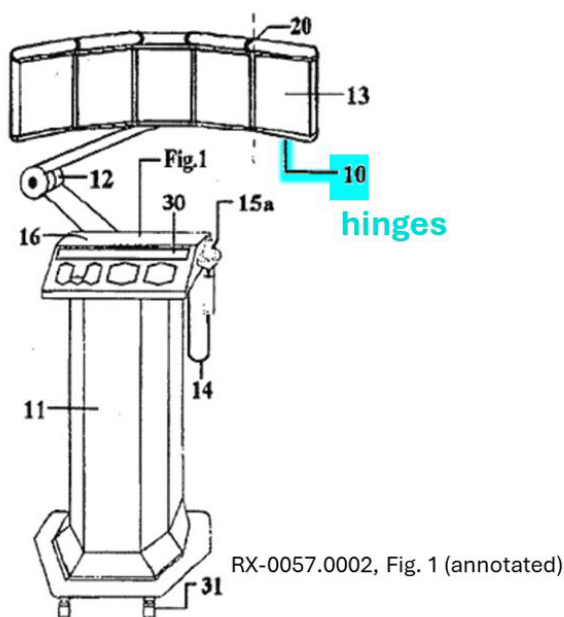
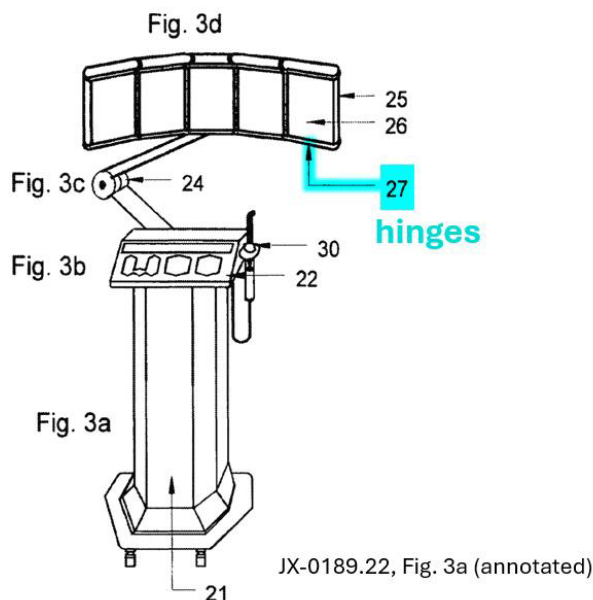


Figure 3d of the Larsen Australian Application

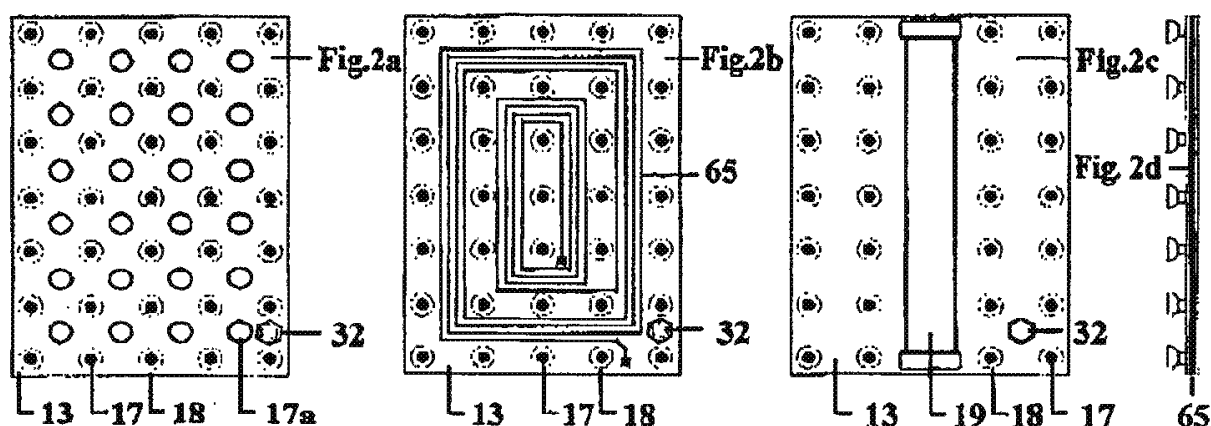


CDX-0018C.65, .67; RX-0057.0002; JX-0189.17, .22 (identifying “27” as “individual [sic] hinged”); JX-0191 at 8:27-30, 8:42-43 (U.S. Patent No. 7,311,722 issuing from U.S. Larsen patent application disclosing “applicators 13 are flexibly connected to each other through hinges 10”); Tr. (Jokerst) at 761:7-764:19.

Larsen discloses 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-0057 at [0072]. Larsen also discloses that element 10 as “the invented device 10.” RX-0057 at [0069]. In view of those disclosures, Biofrontera argues that “it is clear that one of these passages must contain a typographical error.” RIB at 42. The issue of typographical errors in prior art was recently explained by the Federal Circuit. “[W]here a prior art reference includes an obvious error of a typographical or similar nature that would be apparent to one of ordinary skill in the art who would

mentally disregard the errant information as a misprint or mentally substitute it for the correct information, the errant information cannot be said to disclose subject matter.” *LG Elecs. Inc. v. ImmerVision, Inc.*, 39 F.4th 1364, 1372 (Fed. Cir. 2022). Here, Biofrontera urges me to correct the alleged error.

If Biofrontera is correct that Larsen’s “hinges 10,” RX-0057 at [0072], should read “20,” then element 20, “the light sources 17 are placed in regular row arrangements, i.e., 20,” *id.* at [0071], is likely another typographical error. Contrary to Biofrontera’s arguments, element 20 refers not to the location “between the panels.” Rather, it is the location of the “regular row arrangement” of light sources, which are “mounted in” the applicators 13. CX-0014C (Jokerst RWS) at Q/A 159, 197-201. While Dr. Jokerst agreed there is no label “20” in Figures 2b-c, a skilled artisan would not expect there to be because Figure 1’s dotted line indicates a more detailed view shown in those figures. RX-0057 at [0041] (Figs. 2a-2d “illustrate details of the machine applicator”); CX-0014C (Jokerst RWS) at Q/A 225-30. Figure 2d shows a cross-sectional view with the light sources “in regular row arrangements, i.e., 20.” *Id.* Figures 2a-2d are reproduced below.



RX-0057 at Figs. 2a-2d. It may be arguable that Larsen has typographical errors as to both elements “10” and “20,” but the combined typographical errors make “hinges 10” less likely to be an obvious error amenable to being “mentally substituted” for the correct information.

Larsen discloses “according to FIG. 1,” the applicators are connected “through hinges 10.” RX-0057 at [0072]. Biofrontera suggests that “the most likely scenario is that the ‘10’ illustrated in Figure 1 refers to the [entire] invented device.” RIB at 42. Complainant argues that, although “10” is used once with “the invented device,” that appears to be a clear error because “invented device” is used several times without “10,” *id.* at [0074], [0079], [0111-17], whereas “hinges” appears once and it is labeled “10.” *Id.* at [0072]. Moreover, Larsen describes Figure 1 as “a perspective drawing of the invented device,” and the label “Fig. 1” points to the entire device. *Id.* at [0040]; CX-0014C (Jokerst RWS) at Q/A 227-29. “Fig. 1” does not point to anything that could be hinges or regular row arrangements. Thus, according to Complainant, element “10” is not “preserved” for, or used only to refer to, the invented device. There is no basis for Dr. Grove’s re-write of Larsen’s disclosure in [0072]. He never opined that hinges 10 on the panels’ bottom would be so unusual to persons of ordinary skill that they would assume it to be an obviously correctable typographical error. Also, Larsen’s other publications identify hinges on the bottom using nearly identical figures. CX-0014C (Jokerst RWS) at Q/A 212-24; JX-0189.17, .22; JX-0191 at 8:27-30, 8:41-47; RIB at 79-81.

Finally, Biofrontera points to Examiner comments made during the ’512 patent prosecution. RIB at 43. But that same Examiner allowed the patent over Larsen, stating: “the art of record neither anticipates nor renders obvious ‘nested hinges on inner side surfaces of adjacent

panels’.” CX-0014 (Jokerst RWS) at Q/A 207; JX-0004.1731.⁶ Biofrontera has not shown persuasively that Larsen’s disclosure of hinges “respectively connecting one edge with the other” requires hinges on the inner side surface. For example, Figure 1 shows hinges on the bottom and this disclosure combined with the disclosure of “connecting one edge” would not make it obvious to one of ordinary skill that the hinges must be on inner side surfaces. CX-0014C (Jokerst RWS) at Q/A 236-37. In sum, I find that there is no persuasive evidence that one of ordinary skill would recognize the label “10” as a typographical error and disregard it and mentally “correct” Larsen by assuming label “20” refers to the location of the hinges as on the inner side surface of the panel. My conclusion is further supported especially given that Dr. Grove admitted that “Larsen does not describe in any detail the hinges...,” Tr. (Grove) at 563:1-20, and “Hente does not disclose hinges in any detail,” Tr. (Grove) at 585:8-12.

Given that the references do not describe the hinges in any detail, Biofrontera’s second argument is that even absent a disclosure, it was obvious to place hinges located on inner side surfaces. RIB at 44. Biofrontera argues “Figure 1 of Larsen shows that the inner edges of each of the panels (13) are nearly flush with each other.” *Id.* I find Larsen’s panels are not “nearly flush.” CX-0014C (Jokerst RWS) at Q/A 232. For example, Biofrontera’s expert, Dr. Bretschneider, admitted Larsen has “lower irradiance regions at the junction of two of Larsen’s panels,” JX-0188.66, contradicting a flush arrangement. Further, even if the panels are “nearly flush,” that is no motivation to place hinges on inner side surfaces, as opposed to another location. CX-0014C (Jokerst RWS) at Q/A 233. Biofrontera ignores that persons of ordinary skill would be discouraged from placing hinges on the inner side because that would impede the panels from being flush,

⁶ During the ’028 patent prosecution, that same Examiner corrected the earlier error and pointed to “Hinged Structures 10” in reference to Figure 1 with hinges 10 on the bottom. JX-0003.130.

create gaps, and affect uniformity. CX-0014C (Jokerst RWS) at Q/A 233-37; Tr. (Jokerst) at 765:3-25. Dr. Bretschneider concluded the same: “A person of ordinary skill in the art would understand that the gaps between adjacent panels could lead to regions of low irradiance on the patient’s skin.” JX-0188.66.⁷

Dr. Grove opines that hinges between PDT panels are “the most logical location for hinges.” RIB at 42. However, Biofrontera’s only support for this is Dr. Grove’s conclusory statement at the hearing about butt hinges, Tr. (Grove) at 592:2-5, but that is absent from his witness statement. Further, there is no evidence butt hinges that fit on side surfaces were known before 2015. CX-0014C (Jokerst RWS) at Q/A 237 (explaining butt hinges sit on the tops of surfaces). I find that given the fact that, as Dr. Grove testified, there is no detail about the hinges, there is not sufficient evidence to show that one of ordinary skill would assume that the hinge would be on the inner side surface of the panel.

Biofrontera also argues that there are only a “finite number of identified, predictable solutions” for connecting panels that make this limitation obvious. RIB at 44-45. However, Dr. Jokerst testified that “[a] person of ordinary skill would have understood that there were numerous designs to connect the panels of a PDT device flexibly, including without hinges or with different hinge designs, including overlay hinges, strap hinges, and knife hinges, on the top, bottom, and back of the panels.” CX-0014C (Jokerst RWS) at Q/A 236. Biofrontera fails to identify a single illuminator with hinges on inner side surfaces of panels—the only references of record with that

⁷ Biofrontera represented to the USPTO Larsen needed other references “to further reduce unirradiated gaps on the skin and make illumination more uniform.” JX-0190.22. Biofrontera’s new claim that Larsen alone teaches panels for “prevention of gaps in irradiance of the skin,” RIB at 35, may suggest Biofrontera has changed its interpretation of Larsen. However, neither party appears to be arguing that this creates a res judicata or prosecution history estoppel.

arrangement are the Asserted Patents. Before 2015, persons of ordinary skill designing PDT illuminators to output uniform light were discouraged from placing hinge between the LED panels because that arrangement was thought to negatively impact the illuminator's uniformity by creating gaps between the panels, interfering with the panels' wiring, and causing panel alignment issues. CX-0014C (Jokerst RWS) at Q/A 233-37; Tr. (Jokerst) at 765:3-25; JX-0008C (Luebbert Dep. Tr.) at 82:7-11, 84:10-86:9; *Arctic Cat Inc. v. Bombardier Recreational Prods. Inc.*, 876 F.3d 1350, 1363 (Fed. Cir. 2017) (one must consider evidence that “suggests reasons that a skilled artisan would be discouraged from pursuing such a combination,” even when not rising to the level of teaching away).

Biofrontera's reliance on *Teva Pharms. U.S.A., Inc. v. Sandoz, Inc.*, 906 F.3d 1013, 1026 (Fed. Cir. 2018) is misplaced because there, the prior art focused on two variables, dose size and injection frequency, and provided clear direction as to choices likely to be successful. *Id.* at 1025. Here, the prior art provides no direction for successfully connecting PDT panels to achieve uniform illumination—Biofrontera's expert says his cited art lacks a depiction of hinges, a description of their physical structure, and “does not disclose hinges in any detail.” Tr. (Grove) at 563:1-9, 585:5-12.⁸

⁸ I am also not persuaded by Dr. Grove's invalidity analysis because it conflicts with his noninfringement testimony on hinges “on inner side surfaces.” For example, Dr. Grove identified “nested hinges on inner side surfaces” in Larsen, even as he admits that the reference provides no visual depiction or any description of the physical structure of hinges. Tr. (Grove) at 562:7-563:9. However, in his noninfringement analysis, Dr. Grove determined which hinges fell within the claims (BLU-U® 4170E, Fig. 3B), and which did not (RhodoLED®-XL), through examining the panels' internal structure and the points of attachment. *Id.* at 450:1-451:1. He has not explained how he can determine whether Larsen's or Hente's hinges disclose this limitation when those hinges are never shown, and he has no information on their structure or connection points. *Id.* at 562:7-563:9; 584:18-585:12. Meaning, Dr. Grove never explains how he knows that Larsen's hinges are “between panels” but do not “extend through” to connect to an interior structure—which would place them outside the claims under his interpretation of the claims.

As to Hente, Biofrontera fails to address that the reference only identifies hinges “at the outer ends of each section 20, 30” and “outer rims of the light emitting device respectively sections,” not on an inner side surface of adjacent panels. CX-0014C (Jokerst RWS) at Q/A 340; RX-0576.0011, .0013,[0015],[0037]; CIB at 83-85. Additionally, Hente’s disclosure regarding “rims” that “fac[e] each other” does not meet this limitation. CX-0014C (Jokerst RWS) at Q/A 347-49. Dr. Grove ignores Hente’s disclosures that artificial light leaves the sections through the rims and side surfaces, with hinges that impede light from the front surface. *Id.*; CIB at 84-85. Biofrontera has not shown by clear and convincing evidence that Larsen individually, or Larsen in view of Hente, renders obvious the “nested hinges” or “hinged structures” limitations.

b) Continuous illumination

Biofrontera argues that “[t]he 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.” RIB at 45; *see* RRB at 15-18. Complainant disagrees. CIB at 101-03; CRB at 24-25.

Biofrontera’s claim that Larsen discloses this limitation is without support or evidence in the reference. Larsen never teaches that its hinges “allow for minimization of the gap between panels” to “allow continuous illumination.” Biofrontera’s attorney argument fails to cite Larsen for this alleged teaching. RIB at 45. Biofrontera’s attorneys claim this configuration is “illustrated in Figure 1,” *id.*, but its expert admitted the opposite: “in Figure 1 of Larsen, you can’t actually see what Larsen’s hinges look like.” Tr. (Grove) at 563:1-5.

Because “Larsen doesn’t provide a description of the physical structure of the hinges...,” Tr. (Grove) at 563:1-23, Larsen cannot teach those hinges “allow continuous illumination across the five panels.” CX-0014C (Jokerst RWS) at Q/A 317-19. Moreover, Biofrontera’s expert

confirmed Larsen cannot have “continuous illumination” because it has “lower irradiance regions at the junction of two of Larsen’s panels.” JX-0188.66.

Biofrontera has not shown by clear and convincing evidence that “the nested hinges be[] configured so as to allow continuous illumination across the at least five panels” is disclosed by Larsen.

2. Lundahl and Larsen

a) Uniformly illuminate

Biofrontera argues that “[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.’” RIB at 33; *see* RIB at 31, 33, 50; RRB at 18-20. Complainant disagrees. CIB at 97-100; CRB at 25-29.

Biofrontera admits that the claims require uniform illumination “via the light sources” which are “disposed on the surfaces of the five panels.” RIB at 30. However, throughout its analysis, Biofrontera relies on separate disclosures from Lundahl (lacking five panels) and Larsen (lacking uniform illumination) for pieces of this limitation and never demonstrates that the combination—Lundahl’s light distribution with Larsen’s five LED panels—teaches the whole “uniformly illuminate” limitation. *Unigene Labs., Inc. v. Apotex, Inc.*, 655 F.3d 1352, 1360 (Fed. Cir. 2011) (“Obviousness requires more than a mere showing that the prior art includes separate references covering each separate limitation in a claim....”). Biofrontera’s analysis fails to sufficiently show that it is free of improper hindsight.

Biofrontera argues that “the level of uniformity required by the claims is not high.” RIB at 31. That is contradicted by Lundahl, which states there are “biological requirements imposed on a

PDT light source” that meant conventional illuminators were insufficient; instead, the invention was required to provide “a highly uniform output irradiance.” RX-0065 at 4:11-22, 2:27-30, 6:55-57. The inventors explained the difficulty in achieving uniform illumination at the level required for PDT. JX-0015C (Carota Dep. Tr.) at 73:20-74:14 (“[U]niformity was a big one... It was one of the more difficult challenges that we had.”); JX-0014C (Boyajian Dep. Tr.) at 87:3-89:12, 100:7-12, 100:22-101:15. Dr. Grove even opined that the claimed uniformity requires “undue experimentation.” Tr. (Grove) at 579:15-25.

As construed, “uniformly illuminate” requires a measurement—“such that the measured irradiance at a treatment surface of the patient is at least within 60% of the measured maximum.” Lundahl offers a singular uniformity measurement of a “preferred embodiment of the present invention” that achieved this uniformity level only with Lundahl’s integrated fluorescent system. RX-0065 at 15:22-27, 4:11-22. That preferred embodiment’s uniformity relies on U-shaped tubes with precise spacing, reflectors, and the specific cooling and electrical system. CX-0014C (Jokerst RWS) at Q/A 153-55, 289-91. But in its hypothetical combination, Biofrontera (1) replaces Lundahl’s fluorescent tubes with Larsen’s LEDs, (2) adds Larsen’s panels, (3) strips away Lundahl’s cooling system, the electrical system, the reflectors, but (4) keeps Lundahl’s vertical tube spacing for the LEDs. First, “hindsight reconstruction to pick and choose among isolated disclosures in the prior art” is improper. *In re Fine*, 837 F.2d 1071, 1075 (Fed. Cir. 1988). Fundamentally, however, Dr. Grove never measured any irradiance values for the resultant combination, and, thus, Biofrontera cannot prove the combination maintained the measured uniformity of Lundahl’s integrated fluorescent system. Biofrontera has not shown sufficiently that a skilled artisan would reasonably expect success in achieving the claimed uniformity given those modifications all affect uniformity. CX-0014C (Jokerst RWS) at Q/A 235, 294, 479-89. There is

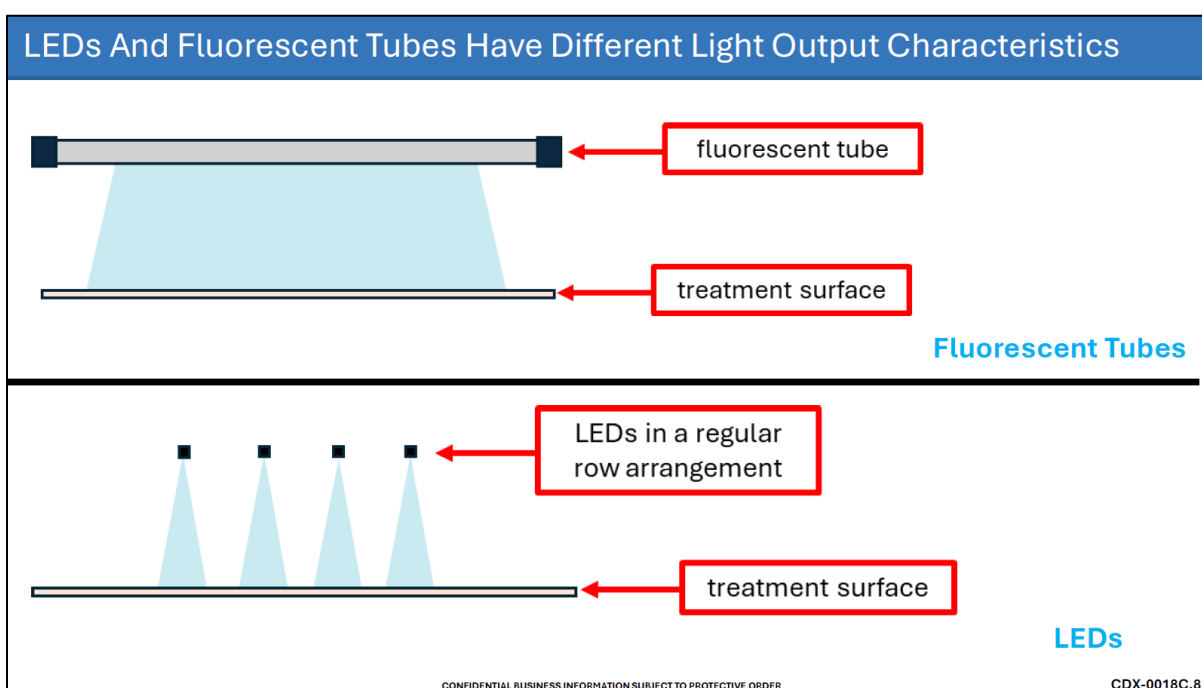
no reasonable expectation of success where an expert merely relies on the theory that “the prior art combinations were simple and would have led to predictable results,” and there is contrary expert testimony. *Juniper Networks, Inc. v. Correct Transmission, LLC*, 2024 WL 3517862, at *6 (Fed. Cir. July 24, 2024).

Biofrontera asserts “[t]he spacing of lights” alone “provided the ‘desired uniformity.’” RIB at 33. But Lundahl warns that his components required a “much higher degree of precision and integration” to control the “irradiance uniformity” to “assure that the properties of the device are suitable to deliver light to the target lesions and drive the photodynamic reaction.” RX-0065 at 4:11-22. Nevertheless, Biofrontera argues “Lundahl states that other design elements were not needed to achieve the desired uniform illumination.” RIB at 33. That statement is not persuasive because it relies on a single sentence where Lundahl says, “an additional diffusing element” was not needed—because of the other enumerated components. RX-0065 at 6:54-57. Lundahl’s Abstract lists several components for improving uniformity; there is no disclosure that the spacing alone achieves “the desired uniform illumination,” as Biofrontera argues.⁹ RX-0065 at Abstract.

Biofrontera asserts that all features other than the U-shape and spacings are “rendered unnecessary once fluorescent tubes are replaced by superior LED technology.” RIB at 50. This is attorney argument not supported by any record evidence. CX-0014C (Jokerst RWS) at Q/A 294. Moreover, it is a waived theory because it is not in Biofrontera’s pre-hearing brief. G.R. 11.2. That theory assumes that (1) Lundahl’s vertical spacing of fluorescent tubes is unrelated to fluorescent technology, and (2) LEDs illuminate uniformly with that same spacing. These assumptions are not

⁹ Biofrontera’s reliance on *PGS Geophysical AS v. Iancu* (RIB at 52) is misplaced. There, the Board found the risk of smearing would not teach away from the combination, not that a skilled artisan can parse the reference and disregard its teachings. 891 F.3d 1354, 1365-66 (Fed. Cir. 2018).

persuasive, as the different light sources have different optical emission properties. One cannot assume identical illumination given Lundahl's spacing but different light sources. Fluorescent tubes are continuous, diffuse light sources, whereas LEDs are directional point-source with Lambertian outputs. Thus, switching to LEDs would create gaps and would completely change the light distribution pattern emitted from the illuminator. CX-0014C (Jokerst RWS) at Q/A 273-74, 310, 506.



CDX-0018C.81. In fact, Mr. Boyajian testified on the differences in light output between LEDs and fluorescent tubes and the challenges that this brought when he achieved uniform illumination with LEDs in the patented system.

Q. What challenges did you face when you were trying to achieve uniformity of illumination with LEDs?

A. There were a lot of challenges. So they are a point source of light. As everyone has already mentioned, a fluorescent tube, very contiguous, very diffuse. LEDs, just one spot. And when you're talking about uniformity, you're talking about the difference between high intensity and low intensity and the delta between them.

Tr. (Boyajian) at 76:15-77:21. Biofrontera acknowledges the optical differences affecting illumination. RIB at 50 (reviewing Dr. Grove's testimony on how tubes' 360-degree output differ from unidirectional LEDs). However, Biofrontera ignores these differences when it concluded uniform illumination is the necessary outcome of maintaining Lundahl's spacing of fluorescent tubes when using "superior LED technology," RIB at 50. CX-0014C (Jokerst RWS) at Q/A 313.

Biofrontera also ignores the optical dead spaces created by breaking Lundahl's device into five panels. CX-0014C (Jokerst RWS) at Q/A 310-13. Dr. Luebbert, Biofrontera's CEO, testified that multiple-panel illuminators had known issues in homogeneity because of "gaps between individual connected panels" that are not present in a "single curved structure." JX-0008C (Luebbert Dep. Tr.) at 199:12-200:14. Neither Lundahl nor Larsen teaches how to maintain uniformity when introducing multi-panel gaps. CX-0014C (Jokerst RWS) at Q/A 297-98, 470; JX-0188.66 (Biofrontera's expert confirming Larsen has "lower irradiance regions at the junction of two of Larsen's panels.").

Biofrontera also argues that "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." RIB at 77 (citing Tr. (Jokerst) at 739:20-23; CX-0010C (Jokerst WS) at Q/A 107).

Biofrontera’s reliance on BLU-U® 4170E and XL is irrelevant because they use different spacing and neither is prior art. I decline to rely on Complainant’s own device and any evidence of ability to combine references or motivation to combine references. “It is black letter law that ‘[t]he inventor's own path itself never leads to a conclusion of obviousness; that is hindsight.’ *Otsuka Pharmaceutical Co., Ltd. v. Sandoz, Inc.*, 678 F.3d 1280, 1296 (Fed. Cir. 2012); *see also*, *Geospatial Tech. Assocs., LLC v. United States*, 164 Fed. Cl. 267, 272 (2023) (“an invention which combines known elements is novel if there is no known motivation to combine them *at the time of the invention* . . . the fact [that] a POSITA might or even would be able to combine certain references does not mean they would have had a reason or motivation to do so.”) (emphasis added); *Nat’l Steel Car, Ltd. v. Canadian Pac. Ry., Ltd.*, 357 F.3d 1319, 1337 (Fed. Cir. 2004) (“a claimed invention would not be obvious without a demonstration of the existence of a motivation to combine those references *at the time of the invention*.) (emphasis added). Biofrontera’s “uniformity” analysis is based on the wrong assumption that spacing LEDs according to Lundahl’s fluorescent tube spacing leads to the claimed 60% uniformity. Biofrontera offers only speculation in support because it did no analysis and provided no evidence showing spacing alone is enough. CX-0014C (Jokerst RWS) at Q/A 309-13, 503-06. I am not persuaded by Biofrontera’s reliance on a single conclusory statement that it would “adapt[] an existing device to achieve the same goal.” *Juniper Networks*, 2024 WL 3517862, at *6.¹⁰

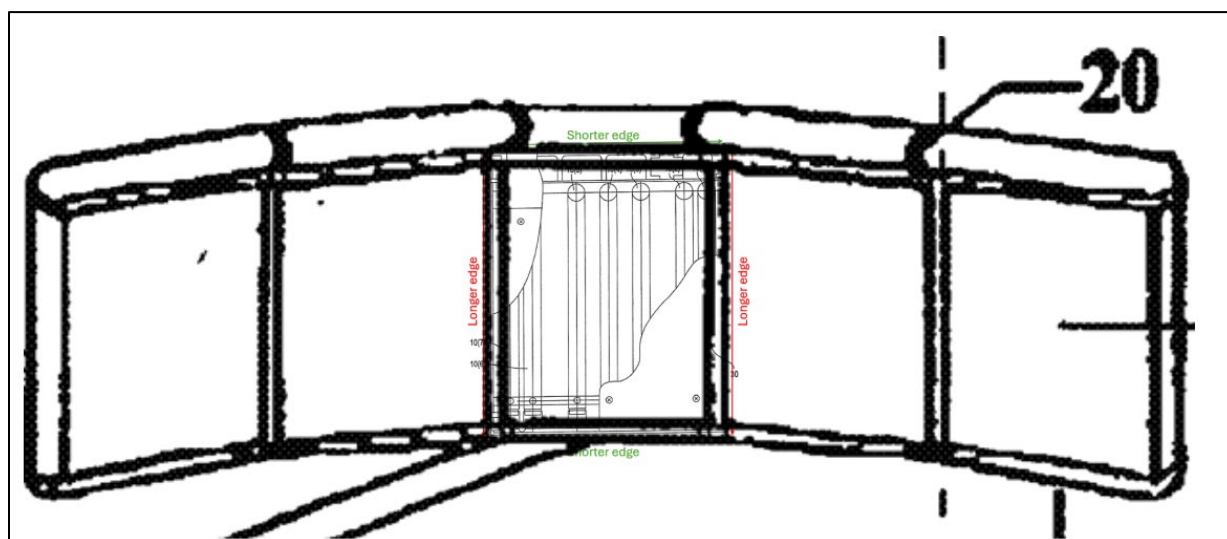
Biofrontera has not shown by clear and convincing evidence that the combination of Lundahl and Larsen renders “uniformly illuminate” obvious.

¹⁰ Biofrontera’s reliance on *Muniauction, Inc. v. Thompson Corp.*, 532 F.3d 1318 (Fed. Cir. 2008), RIB at 31, is misplaced. There, the patent itself described using “a conventional internet browser,” *id.* at 1326, but here, there is no evidence that a skilled artisan would reasonably expect the combination to achieve “measured irradiance... at least within 60% of the measured maximum.”

b) Higher intensity of light

All of the Asserted Claims recite the “higher intensity proximate second edges” limitation. JX-0002 at claims 1, 16, 20, 21; JX-0001 at claims 1, 8, 20. Biofrontera argues that “Lundahl discloses the ‘higher intensity proximate second edges’ limitation[] and it would be obvious to incorporate this teaching in combination with Larsen.” RIB at 57; *see* RIB at 56-61; RRB at 21-25. Complainant disagrees. CIB at 86-97; CRB at 30-34.

It is undisputed that neither Larson nor Lundahl teaches the full limitation. Instead, Biofrontera argues that Lundahl teaches “arranging light sources in a higher density near the top and bottom edges of its device” and applies that to each of Larsen’s panels. RIB at 57. However, the “top and bottom edges” that Biofrontera alleges emit a higher intensity of light, are the longer edges, not the shorter second edges, as required by the claims. CX-0014C (Jokerst RWS) at Q/A 249-55. Applying Lundahl’s light distribution to Larsen’s five panels yields a higher intensity of light on the longer edges of each panel. CX-0014C (Jokerst RWS) at Q/A 258-59.



CDX-0018C.77.

Biofrontera asserts that Lundahl discloses “a higher intensity of light is emitted proximate the second [shorter] edges,” because Sun asserted the RhodoLED®-XL met this claim limitation. RIB at 57 n.6. As discussed above, the LED spacing of the RhodoLED®-XL is very different. Moreover, Biofrontera is wrong to rely on the spacing in Figure 2 of Lundahl because that is not the spacing that provides Lundahl’s uniformity—Figure 2’s distances between the three center tubes are not evenly spaced. CX-0014C (Jokerst RWS) at Q/A 279. The specification’s precise measurements lead to uniformity. RX-0065 at 6:16-30, 6:43-45. They are not only “exemplary values” as argued by Biofrontera. CX-0014C (Jokerst RWS) at Q/A 142. In sum, Biofrontera’s reading of Lundahl requires improper hindsight, and, thus, “cannot constitute clear and convincing evidence of invalidity.” *Zenith Elecs. Corp. v. PDI Commc’n Sys., Inc.*, 522 F.3d 1348, 1363 (Fed. Cir. 2008).

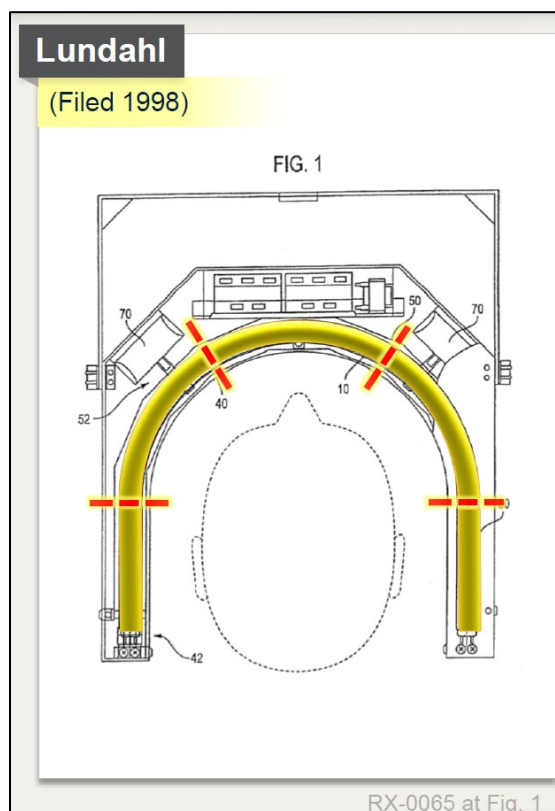
Biofrontera further argues that insisting on a precise disclosure for this limitation “ignores a POSA’s capacity for basic creativity and common sense.” RIB at 59. But the Federal Circuit warned that “‘common sense’...cannot be used as a wholesale substitute for reasoned analysis and evidentiary support especially when dealing with a limitation missing from the prior art references specified.” *Arendi S.A.R.L. v. Apple Inc.*, 832 F.3d 1355, 1362 (Fed. Cir. 2016) (endorsing common sense only where “the limitation in question was unusually simple and the technology particularly straightforward”). Here, the inventors testified this LED arrangement helped them solve the hardest problem in an LED five-panel illuminator, uniformity. JX-0014C (Boyajian Dep. Tr.) at 87:3-89:12, 99:15-101:15; JX-0015C (Carota Dep. Tr.) at 73:20-74:14.

By breaking the Lundahl device into five panels, Biofrontera introduces additional edges and gaps which create optical dead spaces that in turn reduce uniformity of light. CX-0014C (Jokerst RWS) at Q/A 310, 469-71. Biofrontera never considers this problem and never explains

why a skilled artisan would not accommodate the optical dead space with higher intensity of light at the longer edge—like Lundahl teaches. *DSS Tech. Mgmt., Inc. v. Apple Inc.*, 885 F.3d 1367, 1376 (Fed. Cir. 2018) (after identifying several technical gaps in the expert’s testimony, explaining “[t]he similarities in transmission hardware cannot close these gaps without additional, reasoned analysis”). It is improper to cherry pick parts of the art such that hindsight “be[comes] the thread that stitches together prior art patches into something that is the claimed invention.” *Metalcraft of Mayville, Inc. v. The Toro Co.*, 848 F.3d 1358, 1367 (Fed. Cir. 2017).

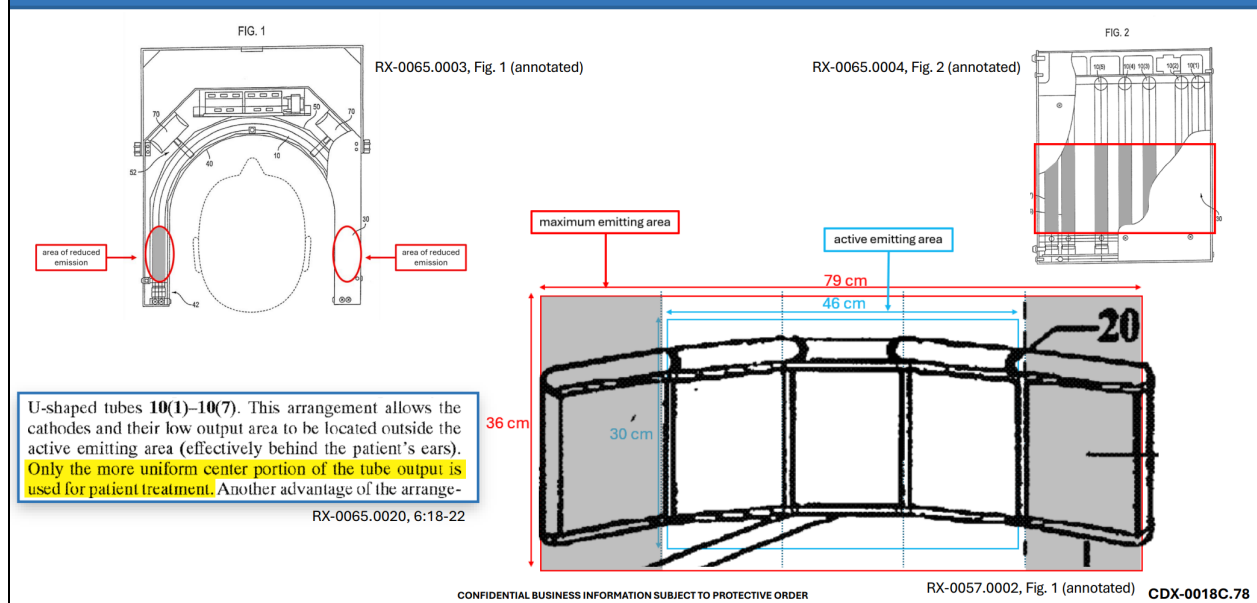
Biofrontera’s hindsight combination fails to meet the whole limitation. Each of the five panels needs higher intensity near the shorter edges. The proposed combination with Lundahl’s light distribution does not have higher intensity for each panel because Lundahl teaches areas of reduced emission. CX-0014C (Jokerst RWS) at Q/A 264.

Biofrontera asserts Lundahl would be broken up into five panels, including the straight arms on the left and right:



RIB at 60. But Lundahl's curved center is the only portion with higher intensity at the top and bottom as "[o]nly the more uniform center portion of the tube output is used for patient treatment." RX-0065 at 6:10-22. Nor is this just a matter of tube spacing, as Lundahl tuned the cooling system to increase output in the "generally arcuate region." *Id.* at 3:8-21. Biofrontera cites Dr. Jokerst's testimony explaining this point. Tr. (Jokerst) at 740:25-741:5 (answering Lundahl teaches a higher intensity, "in the curved region, which would be near the forehead and chin..."); CX-0014C (Jokerst RWS) at Q/A 256-60, 270-71. Combining Lundahl's light distribution with Larsen's five panels yields higher intensity at the shorter edges only in the center of the device, not on each of the five panels. CX-0014C (Jokerst RWS) at Q/A 262-72; CX-1053C; Tr. (Jokerst) at 750:21-752:9.

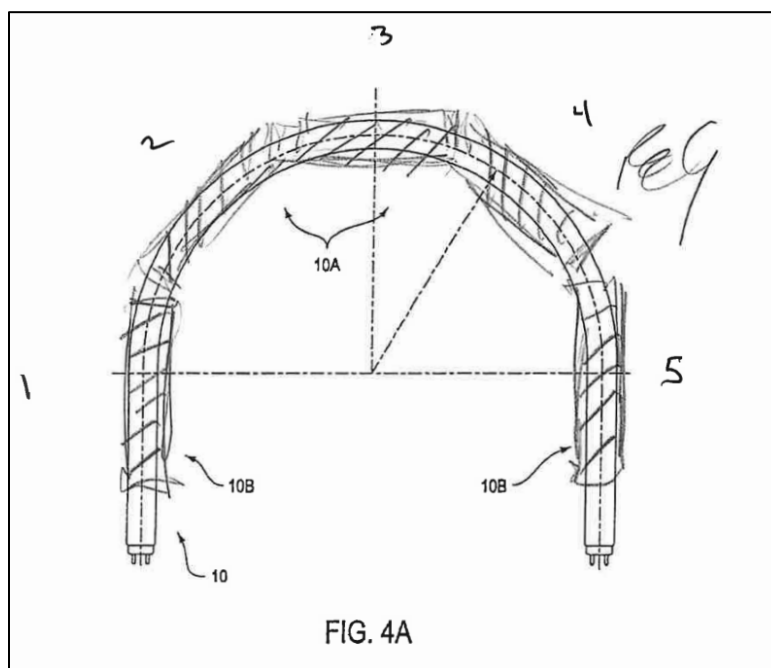
Dr. Grove Reads Out “Wherein *Each* Of The Five Panels...” From The “Higher Intensity” Limitation



CDX-0018C.78.

Dr. Grove ignores these teachings and attempts to avoid the problems above by only (partially) incorporating Lundahl's regions of unknown intensity into his five-panel combination.

Tr. (Grove) at 560:13-562:4.



CDX-1001. Dr. Grove’s incorporation of components-of-components to arrive at the claimed invention is further evidence of impermissible hindsight. Biofrontera never explains how combining Lundahl’s disclosures with Larsen would satisfy the full limitation. Additionally, incorporating Larsen’s scan engine in the Lundahl/Larsen combination would lead to higher intensity of light emitted from the center of the panels, not near the second shorter edges as claimed. *See* CIB at 90-92.¹¹

Biofrontera has not shown by clear and convincing evidence that the combination of Lundahl and Larsen renders “higher intensity” of light obvious.

c) Individually configurable:

Claims 16 and 21 of the ‘028 patent recite the “individually configurable” limitation. JX-0002 at claims 16, 21. Biofrontera argues that “Larsen discloses the individually configurable

¹¹ References to IPR institution decisions are irrelevant, and ignores that the Board’s preliminary decision lacked a full evidentiary record, including multiple distinct arguments Complainant made here.

limitation.” RIB at 63; *see* RIB at 62-64; RRB at 25-26. Complainant disagrees. CIB at 100-01; CRB at 35.

Larsen at [0074] discloses that “the control mechanism is equipped with a switch select system for operating different types of semiconductor diodes 17 and/or with laser diodes.” Claim 5 recites “wherein the light sources are individually selected—switched ON or OFF” in context of independent claim 1 (“the light sources consists of at least one semiconductor diode and/or at least one laser diode”). Persons of ordinary skill would understand that claim 5 refers to switching between the light source types recited in Claim 1, not illuminating or darkening light sources on individual panels. CX-0014C (Jokerst RWS) at Q/A 436-37. “Individually” in claim 5 does not refer to panels, and Biofrontera has no support to show that the output from each panel can be individually controlled. *Id.* at Q/A 441. Moreover, Larsen states that “[w]ith the help of the control mechanism 16, the invented device is adjustable.” RX-0057 at [0074]. The entire device is adjustable, not that each of the five applicators is individually configurable to control illumination from each panel.

Biofrontera has not shown by clear and convincing evidence that Larsen discloses the individually configurable limitation.

d) Center Panel

Claims 1, 17, 20, and 21 of the ‘028 patent and claims 1 and 20 of the ’512 patent recite the “center panel” limitation. JX-0002 at claims 1, 17, 20, and 21. Biofrontera argues that “Larsen discloses the center panel limitation” and that “Larsen clearly depicts two or more panels angled around a center panel in its Figure 1.” RIB at 53; *see* RIB at 53-54; RRB at 20-21. Complainant disagrees. CIB at 103-04; CRB at 29.

Biofrontera ignores the full limitation, relying only on Dr. Jokerst’s testimony that Figure 1’s panels are angled relative to the center panel. Tr. (Jokerst) at 738:13-739:2. But Larsen does not disclose “a center panel configured to face the treatment surface,” CX-0014C (Jokerst RWS) at Q/A 327-29, and Biofrontera makes no assertion to the contrary.

Biofrontera has not shown by clear and convincing evidence that Larsen discloses the center panel limitation.

e) Four wheels

Claim limitation 16[a] of the ’028 patent recites “a mobile base supported by at least four wheels.” ’028 patent at claim 16. Complainant argues that “there is no express disclosure in Larsen of four wheels—Dr. Grove points to Figure 1, but shows two wheels.” CIB at 107. Complainant argues that “Biofrontera does not address the failing articulated in Sun Pharma’s Post-Hearing Brief for this limitation.” CRB at 36 (citing CIB at 107-08). Indeed, Biofrontera did not address this issue in its post-hearing brief.

Because Biofrontera has the burden on invalidity, I find that Biofrontera has abandoned or withdrawn this argument. G.R. 14.2 (“Any contentions that are not set forth in detail in the post-hearing initial brief shall be deemed abandoned or withdrawn.”).

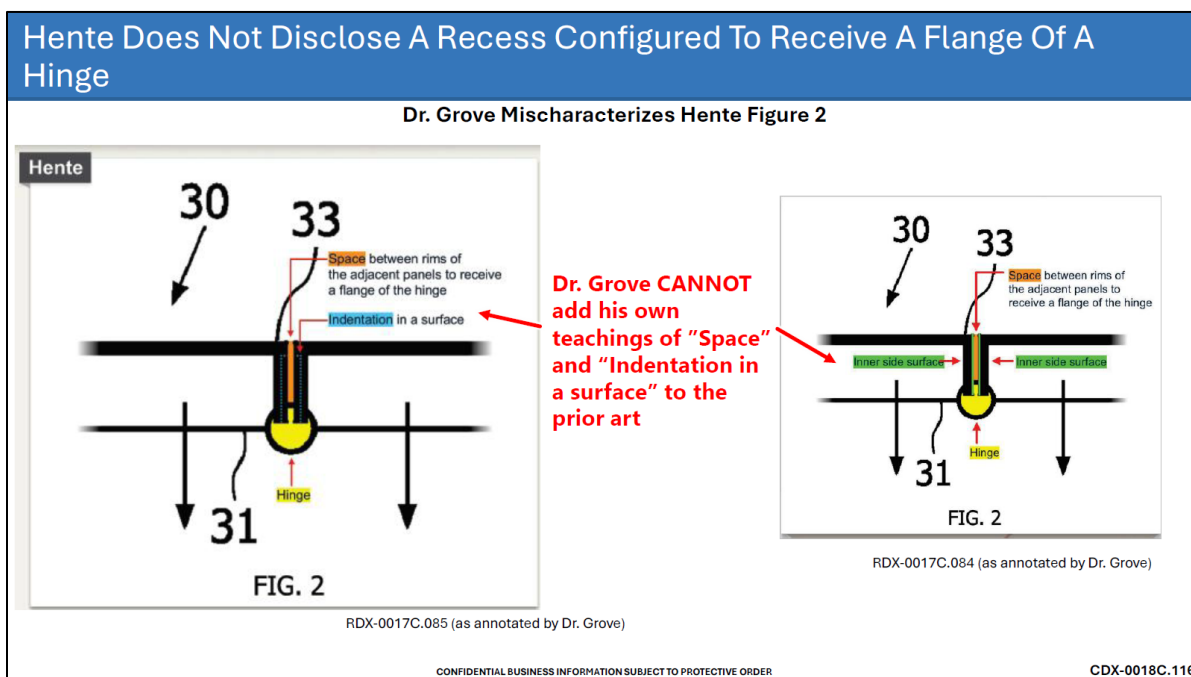
3. Lundahl, Larsen, Hente and Perutz

a) Recess and flange

Claim 17 of the ’512 patent recites “[t]he method of claim 8, wherein at least one panel includes a recess configured to receive a flange of one of the nested hinges.” JX-0001 at claim 17. Claim 18 of the ’512 patent recites “[t]he method of claim 17, wherein the recess is positioned at an inner side surface of the at least one panel.” *Id.* at claim 18. Biofrontera argues that Perutz and

Hente disclose “the recess limitation and recess location limitations.” RIB at 69; *see* RIB at 69-71; RRB at 27-28. Complainant disagrees. CIB at 104-06; CRB at 35-36.

Dr. Grove admits that Hente does not disclose hinges “in any detail.” Tr. (Grove) at 563:14-20. Yet, Biofrontera argues that Hente “would have motivated a POSA to place the flange of the hinges in an indentation at the inner side surfaces of panels....” RIB at 70-71. That is conclusory and unsupported. CX-0014C (Jokerst RWS) at Q/A 374-75, 388. Dr. Grove opines, with no support, concerning a “space between the rims of adjacent panels of Hente to receive a flange of the hinge,” (contradicting his statement that Hente’s sections are “nearly flush.”). *Id.*



CDX-0018C.116.

Hente does not disclose a nearly flushed arrangement, nested hinges that fit on inner side surfaces of adjacent panels, a flange, or a recess. CX-0014C (Jokerst RWS) at Q/A 375-78, 388; Tr. (Grove) at 585:13-586:18. Biofrontera asserts these are design elements known to predictably decrease the space between the panels, but that assertion is conclusory. Even if Hente’s connection

means were hinges, and those hinges were connected by flanges, a skilled artisan would not place them on Hente's rims or side surfaces because that would block light flowing through them, contrary to Hente's explicit teachings. CX-0014C (Jokerst RWS) at Q/A 376, 382, 388.

Biofrontera has not shown by clear and convincing evidence that the combination of Lundahl, Larsen, Hente and Perutz renders recess and flange obvious.

4. Motivation and Reasonable Expectation of Success

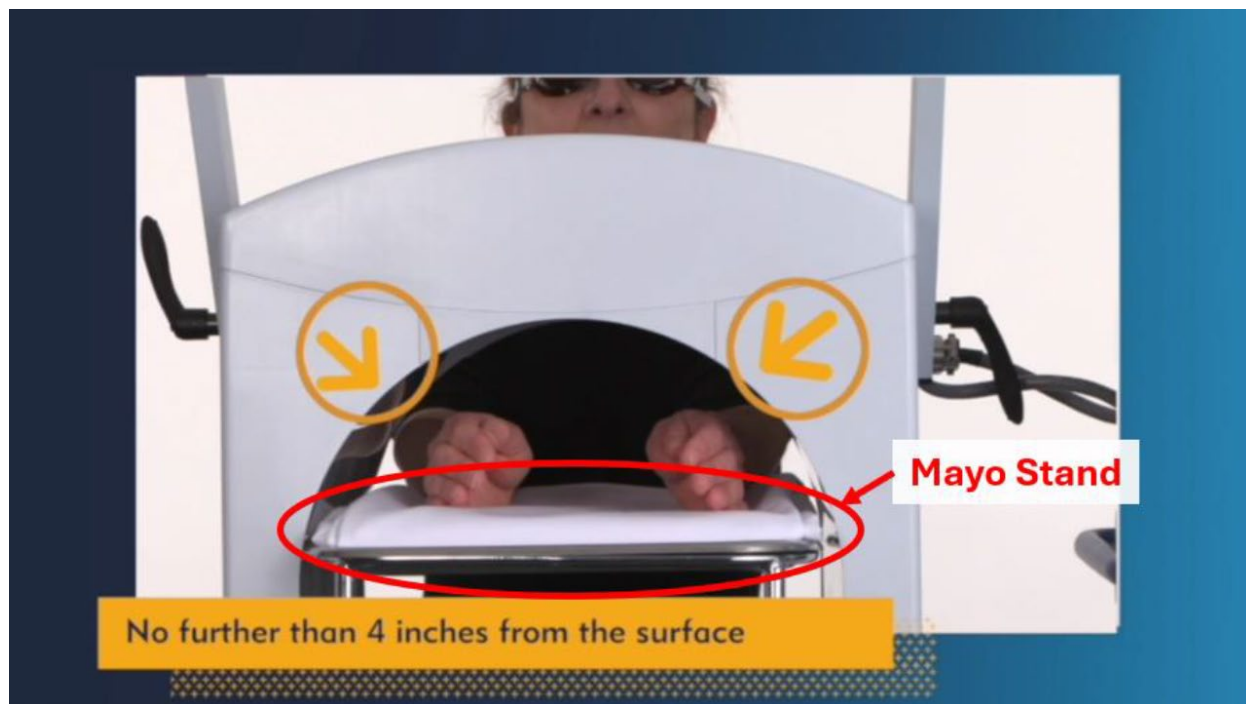
a) Lundahl and Larsen

(1) Lack of Motivation to Increase Flexibility

Biofrontera asserts that BLU-U® 4170D¹² “illustrates the real-world advantages and drawbacks of the device disclosed in Lundahl,” arguing that its fixed U-shape made treatment of some head sizes and some body parts challenging enough to motivate a skilled artisan to develop a more flexible device. RIB at 74-76. Biofrontera cites Dr. Ehrenreich's “17 years of real-world experience using the 4170D” for support. *Id.* at 75. But the size of a patient's body part never prevented Dr. Ehrenreich from doing a PDT treatment. Tr. (Ehrenreich) at 648:1-17. While Dr. Grove “envisioned many scenarios where the shape and dimensions of the patient would not allow for the proper 2-4” treatment distance,” RIB at 75, Dr. Ehrenreich had not encountered one such scenario in his 17-year history with BLU-U® 4170D, Tr. (Ehrenreich) at 648:1-17. Another dermatologist, Dr. Roberts, uses BLU-U® 4170D for treating patients' faces, necks, arms, hands, chests, and backs without issues. CX-1063.15.

¹² Biofrontera never identified BLU-U® 4170D as a prior art system in its contentions or in its prehearing brief. Therefore, I give little weight to arguments that rely on that system, including any disclosures of claim limitations or shortcomings that provide an alleged motivations to combine.

Biofrontera argues Lundahl’s statement about treating arms is “more aspirational than practical,” RIB at 75, but that is contrary to the evidentiary record because BLU-U® 4170D is indicated to treat arms, JX-0197C.1. Dr. Ehrenreich confirmed so on cross-examination. Tr. (Ehrenreich) at 663:12-665:18; CX-1355. Indeed, he has treated arms and hands with BLU-U® 4170D for years with no plans to stop. Tr. (Ehrenreich) at 640:10-18. “Jury-rigging” with a Mayo stand does not indicate a problem motivating increased flexibility because (1) it is standard PDT practice, and (2) it is still used with flexible hinged devices. Tr. (Ehrenreich) at 642:9-647:8, 663:12-665:18; CX-0013C (Shmuylovich RWS) at Q/A 210; CX-1330C.69, 69:12-18.



CX-1355 at 3:15 (annotated).



CX-1351 at 1:42 (annotated).

Further, Biofrontera’s proposal to modify Lundahl with hinges for increased flexibility reflects hindsight bias because it ignores “that there were numerous other designs to connect the panels of a PDT device flexibly, including without hinges...” CX-0014C (Jokerst RWS) at Q/A 236.

Biofrontera acknowledges hinged panels would introduce gaps but argues it cannot defeat a motivation to increase flexibility. However, Biofrontera’s citation of *Medichem, S.A. v. Rolabo, S.L.*, 437 F.3d 1157, 1165 (Fed. Cir. 2006) omits the next sentence, “the benefits, both lost and gained, should be weighed against one another.” Moreover, introducing gaps would destroy Lundahl’s goal of uniform illumination, undermining any motivation for flexibility. *Medtronic, Inc. v. Teleflex Innovations S.a.r.l.*, 69 F.4th 1341, 1350-52 (Fed. Cir. 2023) (the “the destruction of Ressemann’s entire purpose, shared with the challenged claims, was probative of whether Medtronic’s modifications would have been obvious.”); *Polaris Indus. v. Arctic Cat, Inc.*, 882 F.3d

1056, 1061, 1067-69 (Fed. Cir. 2018) (failing to consider whether modifications would undermine the art’s goal, shared with the challenged claims, warranted vacatur). Without uniformity, Lundahl is not an effective medical device. RX-0065 at 4:11-22. Without effective treatment, there is no point in fitting someone into the device. *See* CX-0014C (Jokerst RWS) at Q/A 511. Therefore, it is not a matter of trade-offs. There is no motivation to increase flexibility at the expense of uniformity.

Finally, Biofrontera’s assumption that incorporating hinge panels but maintaining uniformity would be easy or routine is contradicted by inventor testimony—those who built the first PDT hinged-panel device that achieved the required uniformity—and Dr. Grove’s admission that achieving uniform illumination would require undue experimentation. Tr. (Grove) at 579:18-25; JX-0015C (Carota Dep. Tr.) at 73:20-74:14; JX-0014C (Boyajian Dep. Tr.) at 87:3-89:12, 100:7-12, 100:22-101:15. Biofrontera has provided no evidence that simply positioning panels at angles would eliminate or minimize gaps such that one would achieve uniform illumination.

(2) Lack of Motivation to Replace Fluorescent Tubes

For the first time in its post-hearing brief, Biofrontera argues there was a motivation to replace fluorescent tubes because of supposed safety concerns. RIB at 77-79. The citations to Dr. Grove’s testimony do not support this new theory. This argument is waived. G.R.11.2. Regardless, fluorescent tubes did not “become obsolete by the 2015 priority date”—BLU-U® 4170D is still sold ten years later, and Dr. Ehrenreich and Dr. Roberts still use it to this day. Tr. (Ehrenreich) at 640:10-16; CX-1063.15; CX-0016C (Vander Veen WS) at Q/A 244.

(3) Reasonable Expectation of Success

Biofrontera must show a reasonable expectation of success “in combining references to meet the limitations of the claimed invention.” *Intelligent Bio-Sys., Inc. v. Illumina Cambridge*

Ltd., 821 F.3d 1359, 1367 (Fed. Cir. 2016); *Teva Pharmaceuticals v. Corcept Therapeutics*, 18 F.4th 1377, 1381-82 (Fed. Cir. 2021). Biofrontera fails to show a reasonable expectation that its combination of Lundahl and Larsen would meet the uniform illumination limitation as discussed above. Biofrontera asserts that its “modifications to Lundahl’s device are simple and straightforward,” RIB at 79, but that ignores the challenges of achieving uniform illumination using LEDs and hinged panels, as discussed above.¹³ Its expert previously claimed achieving uniformity would require “undue experimentation.” Tr. (Grove) at 579:15-25.

b) Lundahl, Larsen, and Hente

Because its expert admitted to not “relying on Hente for teachings related to PDT,” Tr. (Grove) at 587:9-11, Biofrontera argues that Hente is relevant “for its teaching of hinge positioning.” RIB at 84. But to be analogous art, Hente’s solution must be “reasonably pertinent,” meaning, “a person of ordinary skill would reasonably be expected to look for a solution to the problem facing the inventor.” *In re Oetiker*, 977 F.2d 1443, 1447 (Fed. Cir. 1992). Biofrontera defines the problem very broadly and improperly. The problem the inventors faced was uniform illumination with a multi-panel PDT device utilizing LEDs for “photodynamically diagnosing or treating a patient” as required by all claims. CX-0014C (Jokerst RWS) at Q/A 536. If a skilled artisan would look to the entire field of illuminators “that can adjust the size of the illuminated area,” then the field invention would be enormous. Biofrontera has not shown that a person of

¹³ Biofrontera’s reliance on *Tyco* and *Fisher*, RIB at 80-81, is misplaced. This is not simply a case of combining familiar prior art elements to achieve the same functions. Nor is this a case of combining predictable mechanical or electrical elements. The inventors achieved the difficult task of uniform illumination with a PDT device in a new way. Tr. (Boyajian) at 76:15-77:21; JX-0014C (Boyajian Dep. Tr.) at 73:21-74:9 (“I invented something that could do what was on label in a way that wasn’t done before.”) Moreover, unlike the Davison patent in *Tyco*, the prior art here discouraged claim limitations. CX-0014C (Jokerst RWS) at Q/A 233-37.

ordinary skill seeking to solve the problem of delivering uniform illumination with a multi-panel PDT device utilizing LEDs would reasonably be expected to look to a workbench illuminator to learn where to position a hinge.¹⁴ CX-0014C (Jokerst RWS) at Q/A 524; CIB at 114-16; *Oetiker*, 977 F.2d at 1447 (“It has not been shown that a person of ordinary skill, seeking to solve a problem of fastening a hose clamp, would reasonably be expected or motivated to look to fasteners for garments”).

Moreover, a skilled artisan would not be motivated to combine Lundahl and Larsen with Hente because the hinges in Hente are not designed to uniformly illuminate. CX-0014C (Jokerst RWS) at Q/A 237, 346-49, 363. Biofrontera is using Hente “for its teaching of hinge positioning,” but the hinges stick out in front of the device obstructing illumination. CX-0014C (Jokerst RWS) at Q/A 346. Furthermore, there is no reasonable expectation of success because Hente is not “suitable” for combination with Lundahl and Larsen as required. *Intel Corp. v. Qualcomm Inc.*, 21 F.4th 784, 800 (Fed. Cir. 2021). Hinges suitable for a very thin stretchable device like Hente’s would not be suitable for connecting rigid, thick panels in the alleged combined PDT device of Lundahl and Larsen. CX-0014C (Jokerst RWS) at Q/A 533-36; CIB at 83-84, 114-16.

c) Lundahl, Larsen, Hente and Perutz

Perutz is further afield and has nothing to do with illuminators. It is simply a connection of display panels. For that reason, Perutz would not “have commended itself to an inventor’s attention in considering his problem.” RIB at 85; CX-0014C (Jokerst RWS) at Q/A 557-59.

¹⁴ *Sci. Plastic Prods. v. Biotage AB*, 766 F.3d 1355, 1359 (Fed. Cir. 2014), RIB at 82, is not on point. There, prior art references addressing the problem of providing a fluid tight seal was sufficiently close to the claimed invention’s problem. *Sci. Plastic Prods.*, 766 F.3d at 1359-60. Here, the problem addressed by the claimed invention is uniform illumination and Hente discloses nothing about that problem. CX-0014C (Jokerst RWS) at Q/A 536.

There are numerous differences that make Hente and Perutz unsuitable, including the size of features they connect. CX-0014C (Jokerst RWS) at Q/A 554-56. Biofrontera never demonstrates a known industry need to motivate combining the prior art to arrive at the “recess” limitations. *Id.* at Q/A 527-33, 553-56, 560. Here, unlike *Adapt Pharma Operations Ltd. v. Teva Pharms. USA, Inc.*, 25 F.4th 1354, 1365 (Fed. Cir. 2022), where the FDA “encouraged the industry to ‘develop an intranasal naloxone product that could be FDA approved,’” there was no known need for a recess configured to receive a flange of one of the nested hinges or recesses positioned at an inner side surface of the at least one panel. Unlike *Paulsen*, 30 F.3d 1475, 1481-82 (Fed. Cir. 1994), the problem here is not as narrow as simply connecting two panels. The inventors’ problem was specific to achieving uniform illumination in a medical setting. Perutz says nothing about how to solve that problem. CX-0014C (Jokerst RWS) at Q/A 552.

C. Secondary Considerations

Secondary considerations of nonobviousness may rebut a prima facie case of obviousness. *Merck Sharp & Dohme Corp. v. Hospira, Inc.*, 874 F.3d 724, 733 (Fed. Cir. 2017) (“[once it is established] a prima facie case [of obviousness is shown] we turn to [a party’s] attempt to rebut this prima facie case with secondary considerations of nonobviousness.”) (quoting *Muniauction, Inc. v. Thomson Corp.*, 532 F.3d 1318, 1327 (Fed. Cir. 2008)). Here, where Respondents have not made out a prima facie case of obviousness, there is no showing to rebut. Accordingly, I need not consider any secondary considerations of nonobviousness.

D. Written Description

Biofrontera argues that the Asserted Patents do not demonstrate that “the inventors actually invented, or ‘possessed,’ the concept of photodynamic diagnosis,” and that “[t]he 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.” RIB at 90-91; *see* 90-102; RRB at 40-48. Complainant disagrees. CIB at 130-31; CRB at 46-55.

The specification must provide a written description of the claimed invention that “reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date.” *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (*en banc*). Determining whether the written description requirement has been satisfied “requires an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art[]” to determine whether the specification “show[s] that the inventor actually invented the invention claimed.” *Id.* Compliance with the written description requirement is a question of fact and “the level of detail required to satisfy the written description requirement varies depending on the nature and scope of the claims and on the complexity and predictability of the relevant technology.” *Id.*

The written description inquiry must be analyzed on a claim-by-claim basis. *In re Hunter*, 1995 WL 364375, at *5 (Fed. Cir. 1995) (“[O]ne must analyze each claim for compliance with the written description requirement.”). Biofrontera, however, never separately considers the claims, and combines system and method claims which have different written description requirements. *EVM Sys., LLC v. Rex Med., L.P.*, 2015 WL 4911090, at *6 (E.D. Tex. Aug. 17, 2015) (“Imposing a standard for the written description requirement as it applies to method claims would be improper for apparatus claims”); *Crown Packaging Tech., Inc. v. Ball Metal Beverage Container Corp.*, 635 F.3d 1373, 1382 (Fed. Cir. 2011) (district court erred where it “failed to distinguish in its written description analysis between... product claim... and... method claims”). The correct inquiry is whether a skilled artisan reading the Asserted Patents’ disclosure in light of the knowledge in the art would understand that the inventors possessed (1) an improved illuminator that can be used for

PD, and (2) a specific method of using that illuminator in combination with ALA to photodynamically diagnose.¹⁵

The inventors never claimed to have invented photodynamic diagnosis, which was a well-known concept in 2015. Tr. (Foguet) at 372:4-14. Rather, the inventors invented an adjustable illuminator that provides uniform illumination and “is suitable for use in photodynamic dynamic therapy and diagnosis.” JX-0001 at 1:17-20. PD uses steps well-known in 2015: (1) administering a photosensitizer such as ALA; (2) illuminating the area with visible light at an appropriate wavelength, and (3) detecting resulting fluorescence. Tr. (Foguet) at 372:4-14; Tr. (Shmuylovich) at 697:19-699:5, CX-0013C (Shmuylovich RWS) at Q/A 107. This mechanism is disclosed in the specification. JX-0001 at 1:34-47. It was also known that PDT and PD share the same basic mechanism. Tr. (Shmuylovich) at 697:19-699:5, CX-0013C (Shmuylovich RWS) at Q/A 92-93. Thus, the specification discloses the same overall mechanism for “PDT or PD” and discloses that that mechanism can be used to selectively “destroy” (PDT) or “locate” (PD) the target tissue. JX-0001 at 1:39-43. The only real difference between PDT and PD is the exposure time: PDT requires minutes to result in cell death whereas fluorescence used for PD is nearly instantaneous. *Id.* at 8:64-9:52; CX-0013C (Shmuylovich RWS) at Q/A 93; Tr. (Shmuylovich) at 697:19-699:5, 701:2-8. This is the “state of knowledge” that forms the context that “must be applied” for written description. *Capon v. Eshhar*, 418 F.3d 1349, 1358 (Fed. Cir. 2005).

¹⁵ Biofrontera argues Mr. Boyajian testified he doesn’t understand his patent. RIB at 91. Inventors are not presumed to understand patent particulars. *Estech Sys. IP, LLC v. Mitel Networks, Inc.*, 2023 WL 2695093, at *8 (E.D. Tex. Mar. 28, 2023). Biofrontera never cross-examined Mr. Boyajian on PD at trial. In any event, Mr. Carota, another named inventor, testified regarding his knowledge of PD. JX-0015C (Carota Dep. Tr.) at 89:22-90:20.

Biofrontera argues that the patents encompass a “generic invention.” RIB at 92. The system Asserted Claims recite an illuminator with specific features, such as (1) five panels; (2) connected by hinges; (3) a center panel configured to face a treatment surface while the others are angled; (4) emitting a higher intensity of light near the shorter edges of the panels; (5) achieving uniform illumination that is 60% of the measured maximum; and (6) individually configurable panels. The method Asserted Claims recite using an illuminator with many of those specific features, with a specific photosensitizer, ALA. The law requires disclosures consistent with what is claimed. There is no requirement for a separate disclosure for PD of every possible disease because the claims do not recite any disease or condition. *United Therapeutics Corp. v. Liquidia Techs., Inc.*, 74 F.4th 1360, 1371 (Fed. Cir. 2023) (“It would be incorrect to fractionate a disease or condition that a method of treatment claim is directed to, and to require a separate disclosure in the specification for each individual variant of the condition... in order to satisfy the enablement and written description provisions of 35 U.S.C. § 112, unless these variants are specified in the claims.”).

The patents disclose an improvement to conventional illuminators that provided inadequately uniform light. JX-0001 at 2:5-20. Skilled artisans knew that uniform light is beneficial for both PDT and PD. CX-0013C (Shmuylovich RWS) at Q/A 43. The claimed illuminator eliminates optical dead spaces, providing more uniform light through the above structural features “in an adjustable illuminator designed for PDT or PD.” JX-0001 at 2:50-61 3:9-19, 6:22-38, 6:49-51, 8:39-60. The specification provides an exemplary method of using the claimed illuminator with ALA. JX-0001 at 9:1-43. While the specification references PDT at the start, it concludes by confirming that the method is also for photodynamic diagnosis using the illuminator, JX-0001 at 9:44-48, consistent with the known overlap between photodynamic therapy and photodynamic diagnosis. A person skilled in the art reading the specification would

understand that the inventors possessed an illuminator suitable for PD, as recited in the system claims, and method using the illuminator with ALA, as recited in the method claims. CX-0013C (Shmuylovich RWS) at Q/A 186-92.

Biofrontera divides PDT and PD, ignoring that persons of ordinary skill would readily apply PDT disclosures to implement PD using the disclosed illuminator.¹⁶ Indeed, PD is often the first step of PDT, used to confirm sufficient accumulation of Protoporphyrin IX (“PpIX”) in the cells before treatment. CX-0013C (Shmuylovich RWS) at Q/A 33 (“Monitoring fluorescent activity during treatments is a great way to confirm the uptake of the photosensitizing agent by the damaged tissue that the dermatologist is treating—here, PD during PDT acts as further diagnostic confirmation of the disease.”), 168-69; CX-0343.11. Biofrontera argues that certain “parameters” should have been disclosed.¹⁷ Biofrontera is misguided. *Ariad Phams.*, 598 F.3d at 1352 (“We

¹⁶ Biofrontera’s expert Dr. Ehrenreich failed to properly analyze knowledge in the art. Tr. (Ehrenreich) at 605:24-606:23. He contradicted himself about whether he had ever performed PD (Tr. (Ehrenreich) at 605:24-606:20) and overlooked foundational articles published in the Journal of the American Academy of Dermatology—widely regarded as the dermatology “bible”—(CX-0013C (Shmuylovich RWS) at Q/A 190) which establishes that all parameters he criticizes the specification for not disclosing were well-known to a person of ordinary skill by 2015.

¹⁷ Most cases cited by Biofrontera involve pharmaceutical claims and are not instructive here. See RIB at 91-95. *Ariad Phams., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (“[L]evel of detail required to satisfy the written description requirement varies depending on the nature and scope of the claims and on the complexity and predictability of the relevant technology.”). *LizardTech* is distinguishable as the patentee there disclosed one method for performing image compression but tried to claim all methods of achieving the same result, without sufficient guidance for the full claim scope. The Asserted Patents do not claim all possible methods of PD; they claim a specific illuminator and a method using that illuminator. 424 F.3d at 1345. In *Flash-Control v. Intel Corp.*, patentee relied on expert testimony to argue person of ordinary skill would understand the invention from prior art, with no support in the specification itself. 2021 WL 2944592 (Fed. Cir. 2021) at *4. The Asserted Patents expressly describe the use of visible light with photoactivatable agents like ALA, with the claimed illuminator. In *Nuvo Pharmaceuticals (Ireland) Designated Activity Co. v. Dr. Reddy’s Labs*, the patentee claimed efficacy but did not disclose what amount would be effective. 923 F.3d 1368, 1373, 1380-81 (Fed. Cir. 2019). The Asserted Patents do not claim efficacy. In *Regents of Univ. of Cal. v. Eli Lilly*, the patentee

have made clear that the written description requirement does not demand either examples or an actual reduction to practice...”); *LizardTech, Inc. v. Earth Res. Mapping, Inc.*, 424 F.3d 1336, 1345 (Fed. Cir. 2005) (no requirement for the specification to “contain examples explicitly covering the full scope of the claim language” as “it is unnecessary to spell out every detail of the invention”). Regardless, each parameter is disclosed commensurate with the knowledge in the art, *Capon*, 418 F.3d at 1358, because “[a] patent need not teach, and preferably omits, what is well known in the art.” *Spectra-Physics, Inc. v. Coherent, Inc.*, 827 F.2d 1524, 1534 (Fed. Cir. 1987); *Streck, Inc. v. Rsch. & Diagnostic Sys., Inc.*, 665 F.3d 1269, 1285 (Fed. Cir. 2012) (“patentee can rely on information that is ‘well-known in the art’ to satisfy written description”).

Disclosures of each of the parameters are discussed below.

Wavelength: The specification discloses visible light in the 400-700 nm range, with specific reference to blue, green, and red light—all within the known excitation spectrum of PpIX as Dr. Ehrenreich admits. JX-0001 at 4:2-13, Tr. (Ehrenreich) 613:9-614:12. Biofrontera’s argument that PpIX’s peak absorption wavelength of 405 nm is not specifically listed, RIB at 100-01, is not persuasive. As Dr. Ehrenreich admitted, it is known to use light “generally near the peak to excite the agent,” Tr. (Ehrenreich) at 615:3-8, and the patents disclose emitting “blue light having wavelengths at or above 400 nanometers (nm), for example, about 430 nm, about 420 nm

generically claimed human insulin-encoding cDNA without disclosing the structure or characteristics of the cDNA. 119 F.3d 1559, 1567 (Fed. Cir. 1997). The Asserted Claims are not generic; they claim, and the specification discloses, a specific illuminator and a method using that illuminator with a specific photosensitizer. Unlike *Purdue Pharma L.P. v. Faulding Inc.*, where patentee disclosed a broad class of formulations without guiding a skilled artisan to the claimed invention, the Asserted Patents provide structural detail of the five-panel illuminator for PD and PDT and provides “blaze marks,” *i.e.*, disclosed wavelengths suitable for PD and PDT. 230 F.3d 1320, 1326 (Fed. Cir. 2000).

or, for example, 417 nm” to excite ALA. JX-0001 at 4:3-7; CX-0013C (Shmuylovich RWS) at Q/A 28-31; CX-1081.4.

Illumination Time: Skilled artisans understand that the difference between PD and PDT is the duration of illumination, with PD requiring very little illumination time to fluoresce.¹⁸ The specification instructs illuminating for a “prescribed period” to “selectively locate, destroy, or alter the target tissue.” JX-0001 at 1:39-43, 9:16-21. Dr. Shmuylovich testified fluorescence in PD can be visualized within milliseconds, and there is no requirement to instantly turn it off, as Biofrontera suggests. Tr. (Shmuylovich) at 713:2-16 (“Q. How long does it take to take a picture or to look with your eyes? A. You can push the button and look... You don’t have to turn it off within a millisecond.”).

Incubation Time: Biofrontera argues that the 14-18 hour incubation period for ALA¹⁹ disclosed for PDT is unsuitable for PD. RIB at 94. That contention is not found in Biofrontera’s prehearing brief, which says nothing about longer incubation time interfering with PD. RPHB at 199-201. Nor did Dr. Ehrenreich testify that PD is impossible after 14 hours. Instead, Biofrontera offered this attorney argument through its fact witness who inserted the new theory in response to a closed-ended question. Tr. (Foguet) at 375:2-14. The only expert testimony on point is from Dr. Shmuylovich, who explained how the specification teaches “[f]ormation of photosensitive porphyrin and photosensitization of the treated lesions occurs over the next 14-18 hours”—which

¹⁸ Contrary to Biofrontera’s argument, RIB at 94, this opinion was fully disclosed in Dr. Shmuylovich’s rebuttal witness statement (CX-0013C (Shmuylovich RWS) at Q/A 169), and Biofrontera had ample opportunity to examine Dr. Shmuylovich about his opinion at the evidentiary hearing, and indeed asked multiple questions about the difference in illumination time between PD and PDT. Tr. (Shmuylovich) at 712:9-23, 695:2-697:10.

¹⁹ Use of ALA is required only in the method claims.

includes detectable fluorescence.” CX-0013C (Shmuylovich RWS) at Q/A 91-92 (citing JX-0001 at 8:64-9:52). Consistent with the teaching that fluorescence occurs over time, persons of ordinary skill were aware that fluorescence can be detected following shorter incubation times, *e.g.*, 3 hours (CX-1084.4, CX-1076.2, CX-1079.3), and 4-6 hours (CX-0342.2, CX-0343.11). CX-0013C (Shmuylovich RWS) at Q/A 36, 117, 123, 130-32. A person of ordinary skill would not extend incubation beyond what is known in the art to be appropriate for a photosensitizer, *e.g.*, beyond 14-18 hours for ALA: doing so would be inconsistent with established scientific understanding and produce inoperative results. *In re Smythe*, 480 F.2d 1376, 1385 (C.C.P.A. 1973) (“[R]equiring an applicant to be so specific in his claims ‘as to exclude materials known to be inoperative and [which] even those not skilled in the art would not try’” for written description “would result in claims which would fail to comply with 35 U.S.C. § 112, second paragraph...”); *In re Cook*, 439 F.2d 730, 735 (C.C.P.A. 1971) (“There is nothing wrong with” claims that “read on inoperative embodiments in the trivial sense that they can and do omit ‘factors which must be presumed to be within the level of ordinary skill in the art...’”).

Fluence: The patents expressly disclose fluence values suitable for PDT. JX-0001 at 9:1-42 (*e.g.*, low intensity (0.1-2 J/cm²), high intensity (*e.g.*, 30-150 J/cm²)). Because visualizing fluorescence requires only seconds of light exposure, CX-0013C (Shmuylovich RWS) at Q/A 168-69, a skilled artisan would understand that the PDT-sufficient fluence applied for a shorter duration would activate PpIX for PD. CX-0013C (Shmuylovich RWS) at Q/A 170; Tr. (Shmuylovich) at 713:2-16.

Cameras and Filters to Visualize Fluorescence: Biofrontera argues that filters or cameras may be required to visualize fluorescence and that such visualization is not possible with a five-panel device that wraps around the treatment surface. RIB at 101-02. Both arguments

misstate the science and the record. First, filters are not necessary to see fluorescence. Fluorescing PpIX produces “a pink glow...with a blue illumination.” Tr. (Shmuylovich) at 708:1-12. Fluorescence with a device like BLU-U® 4170E or 4170D can be visualized by turning off the ambient lights and looking at the skin which will fluoresce pinkish-red that diagnostically confirms ALA uptake. CX-0013C (Shmuylovich RWS) at Q/A 29; Tr. (Foguet) at 372:4-14. Second, Biofrontera’s argument that the panels would impede a physician’s view is without citation to its expert’s testimony and is deemed abandoned because it was not raised in its pre-hearing brief. G.R. 11.2 (“Any contentions not set forth in detail in the pre-hearing brief shall be deemed abandoned or withdrawn.”). In any event, Sun Pharma’s videos for positioning BLU-U® 4170E demonstrate how the treatment area is visible and not completely obscured:



CDX-1100.1; CX-1351 at 1:39.

This is further seen in the photo below, offered as Complainant's demonstrative exhibit to rebut Biofrontera's untimely argument, demonstrating that one can look above or below the device to see the pink fluorescence:²⁰



Persons of ordinary skill knew how to incorporate filters when needed for fluorescence visualization, as extensively documented in the art. CX-0013C (Shmuylovich RWS) at Q/A 29; CX-1079.3.

Biofrontera has not shown by clear and convincing evidence that the asserted claims are invalid for failure to comply with the written description requirement of 35 U.S.C. § 112.

²⁰ <https://www.ocregister.com/2017/02/14/this-blue-light-zap-can-save-lives-from-skin-cancer/>

E. Enablement

Biofrontera argues that “[t]he 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.” RIB at 102; *see* 102-05; RRB at 48-54. Complainant disagrees. CIB at 122-30; CRB at 55-57.

The enablement requirement necessitates that the patentee disclose “the manner and process of making and using [the invention], in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same . . .” pre-AIA 35 U.S.C. § 112, ¶ 1. The requirement “is met when at the time of filing the application one skilled in the art, having read the specification, could practice the invention without ‘undue experimentation.’” *Cephalon, Inc. v. Watson Pharms., Inc.*, 707 F.3d 1330, 1336 (Fed. Cir. 2013) (quoting *In re Wands*, 858 F.2d 731, 736-37 (Fed. Cir. 1988)). Thus, the relevant inquiry is “whether, with [the patentee’s] patent specification as an initial guide, the hypothetical skilled artisan’s knowledge of the surrounding art and ability to modestly experiment would have been sufficient to enable him to make and use [the claimed invention].” *AK Steel Corp. v. Sollac and Ugine*, 344 F.3d 1234, 1244 (Fed. Cir. 2003). Factors to be considered in determining whether a disclosure would require undue experimentation include: “(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. Enablement is a question of law based on

underlying factual findings and must be shown by clear and convincing evidence. *MagSil Corp. v. Hitachi Global Storage Techs., Inc.*, 687 F.3d 1377, 1380 (Fed. Cir. 2012).

The preamble of the Asserted Claims includes “photodynamically diagnosing or treating a patient.” Biofrontera, through Dr. Ehrenreich, asserts that the Asserted Claims are not enabled because “undue experimentation would have been required to use the claimed illuminator to photodynamically diagnose a patient across the full scope of the asserted claims.” RIB at 102, 104; RRB at 48, 52-54; RX-0007C (Ehrenreich WS) at Q/A 206. Biofrontera does not assert that a skilled artisan would be unable to build an illuminator with the structural components of the claims. Indeed, Biofrontera’s expert expressly opined that a skilled artisan would not require undue experimentation to practice the claims when photodynamically treating a patient. RX-0007C (Ehrenreich WS) at Q/A 209; Tr. (Ehrenreich) at 616:8-19.

Biofrontera failed to establish by clear and convincing evidence that the Asserted Claims are invalid for lack of enablement, because a person skilled in the art reading the Asserted Patents would understand how to use the claimed illuminator for photodynamically diagnosing a patient, *i.e.*, apply a photoactivatable agent and then turn on the claimed illuminator to uniformly illuminate the treatment surface, without undue experimentation. CX-0013C (Shmuylovich RWS) at Q/A 55.

Biofrontera argues that “[t]he prior art shows PD had been used with a narrow number of dermatological conditions and relied on specific diagnostic parameters,” RIB at 103, and that PD was poorly understood for certain conditions, RX-0007C (Ehrenreich WS) at Q/A 244-45. However, the scope of the Asserted Claims do not require an enabling disclosure of diagnosing specific conditions not known to be amenable to PD and the claims do not recite any disease or condition. CX-0013C (Shmuylovich RWS) at Q/A 75-78.

The *Wands* factors are discussed below.

1. Nature of the Invention and Breadth of the Claims

The system Asserted Claims recite an improved illuminator with specific, structural characteristics that make it suitable for use in PD or PDT and the method claims recite steps for using that improved illuminator with ALA for PD or PDT. The Asserted Patents disclose the breadth of those claims. JX-0001 at 1:17-20 (the “invention relates generally to an adjustable illuminator that provides a uniform distribution of visible light in a number of configurations and is suitable for use in photodynamic therapy and diagnosis”), 9:44-48 (“The invention thus provides a method for photodynamically diagnosing...a patient, which includes providing the adjustable illuminator described above, placing the patient in the illuminator, and illuminating the patient to diagnose...the patient”); JX-0002 at 9:48-52; CX-0013C (Shmuylovich RWS) at Q/A 56-85.

The Asserted Claims relate to photodynamic diagnosis of dermatological conditions, as the claimed five-panel illuminator is used in PDT or PD by illuminating the exterior of a patient, as opposed to internal body parts. JX-0001 at 9:44-52; CX-0013C (Shmuylovich RWS) at Q/A 75-78.

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

The specification teaches a skilled artisan to make the claimed illuminator, which is suitable for use in PD. The specification also teaches a skilled artisan how to use that illuminator to photodynamically diagnose a patient. CX-0013C (Shmuylovich RWS) at Q/A 94. The specification includes many disclosures about using the claimed illuminator for PD, including a general procedure for performing PD with an illuminator. JX-0001 at 1:34-45, 2:50-54; CX-0013C (Shmuylovich RWS) at Q/A 86-97. That procedure is applicable to any dermatological condition amenable to PD. CX-0013C (Shmuylovich RWS) at Q/A 90. The specification also incorporates

by reference several patents specifically for the techniques, methods, compositions, and devices related to both PDT and PD. *Id.* at Q/A 97; JX-0001 at 1:48-55. The specification further includes procedures for conducting PDT using the claimed illuminator. JX-0001 at 8:64-9:52; CX-0013C (Shmuylovich RWS) at Q/A 91. Biofrontera agrees that those procedures enable a skilled artisan to perform PDT using the claimed illuminator. RX-0007C (Ehrenreich WS) at Q/A 209; CX-0013C (Shmuylovich RWS) at Q/A 47; Tr. (Ehrenreich) at 616:3-19 (Dr. Ehrenreich admitting that undue experimentation would not be required to practice the PDT aspect of the Asserted Claims).

Those procedures also direct a skilled artisan how to photodynamically diagnose using the illuminator, as the difference between PD and PDT for these steps is simply the length of illumination time (what the specification refers to as the “prescribed time”) and the act of detecting fluorescence. JX-0001 at 1:39-43 (changes caused by exposing photosensitizing agent to light “allow the agent to then selectively locate...the target tissue”); CX-0013C (Shmuylovich RWS) at Q/A 93; Tr. (Shmuylovich) at 705:4-707:25, *id.* at 708:23-709:6. The “prescribed period” of illumination required for PD is nearly instantaneous, whereas tissue destruction requires minutes of illumination, as the specification describes. JX-0001 at 8:64-9:52; CX-0013C (Shmuylovich RWS) at Q/A 93; Tr. (Shmuylovich) at 697:19-699:5, 701:2-8. Therefore, those steps disclosed for PDT inform a person of ordinary skill how to perform PD. CX-0013C (Shmuylovich RWS) at Q/A 92-93; CX-1081.1; Tr. (Shmuylovich) at 703:14-704:19.

The specification reiterates the overlapping steps for PD/PDT:

The invention thus provides a method for photodynamically diagnosing or treating a contoured surface of a patient, which includes providing the adjustable illuminator described above, placing the patient in the illuminator, and illuminating the patient to diagnose or treat the patient.

JX-0001 at 9:44-48.

The specification appropriately directs a person skilled in the art regarding the novel aspects of the inventions, including how to build the claimed illuminator and how to use that illuminator in PD and PDT. CX-0013C (Shmuylovich RWS) at Q/A 97. The specification discloses that one can use the claimed illuminator to uniformly illuminate a patient's treatment area during both PD and PDT, using the standard procedures for PD and PDT at the time. *Id.* at Q/A 97. The general mechanics and procedures for PD using such illuminators were understood in the art. *Id.* at Q/A 97. For example, the specification discloses emitting "light at an appropriate wavelength ... to activate the particular photoactivatable agent used in treatment or diagnosis." JX-0001 at 3:66-4:2.

3. Level of Skill in the Art

The level of skill in the art is high, particularly with respect to PD of dermatological conditions using various photosensitizing agents. CX-0013C (Shmuylovich RWS) at Q/A 98-103; RX-0007C (Ehrenreich WS) at Q/A 239.

4. State of the Prior Art and Predictability of the Field

Experts from both parties agree that the general concepts of PD were well-understood by 2015. CX-0013C (Shmuylovich RWS) at Q/A 106; RX-0007C (Ehrenreich WS) at Q/A 245; Tr. (Ehrenreich) at 617:3-6. While the Asserted Patents disclose a novel illuminator that is configured to output a uniform light across five panels, it was also known in the art at the time of the asserted patents that illuminators could be used for both photodynamic therapy and diagnosis. Tr. (Ehrenreich) at 621:5-624:2 (reviewing disclosures in RX-0065 at 376:8-379:5; Tr. (Foguet) at 376:16-377:8 (admitting her patent disclosed a PDT light that "may further be capable to induce red fluorescence of accumulated porphyrins"). Both experts agree that it was known that applying

a fluorophore/photosensitizer, exposing it to light, and detecting resulting fluorescence could identify abnormal tissue, including certain cancers. CX-0013C (Shmuylovich RWS) at Q/A 104-48; Tr. (Ehrenreich) at 617:3-618:1.

The knowledge of PD by those skilled in the art is not in dispute. CX-0011C (Lundahl WS) at Q/A 60; CX-0013C (Shmuylovich RWS) at Q/A 107. Dr. Foguet admitted on cross-examination that it was known before 2015 that “irradiation of a photosensitizer could give rise to a characteristic fluorescence radiation which could be used for diagnostic purposes.” Tr. (Foguet) at 372:4-14. Biofrontera’s expert admits that “photodynamic diagnosis was generally known as of the priority date of the asserted patents.” Tr. (Ehrenreich) at 617:4-6. Biofrontera’s expert, Dr. Ehrenreich, testified in reference to CDX-1100.4 that PD involves applying a photosensitizer like ALA (Step A), its accumulation in abnormal cells (Step B), conversion to PpIX (Step C), and illumination with light of the appropriate wavelength (Step D) will induce fluorescence that is detectable by human eye or a camera (Step E). Tr. (Ehrenreich) at 617:7-618:16.

A skilled artisan using a known photosensitizer and the claimed illuminator would understand how to configure the device to match the photosensitizer’s absorption spectrum. CX-0013C (Shmuylovich RWS) at Q/A 109; Tr. (Ehrenreich) at 612:25-613:8. Dr. Ehrenreich admitted that “if a dermatologist is using an agent known to absorb light at a particular wavelength, that dermatologist can use an illuminator that emits light at a wavelength generally near the peak to excite the agent.” Tr. (Ehrenreich) at 615:3-8. There is nothing in the use of the claimed illuminator for PD that would confuse a skilled artisan as compared to other illuminators used in PD at the time of the invention. CX-0013C (Shmuylovich RWS) at Q/A 110, 125; JX-0001 at 1:48-60; RX-0622.0018, 1:23-31; CX-1085.2-3. Once built according to the Asserted Patents, the illuminator’s use in PD would be readily understood by persons of ordinary skill based on the state

of the art and the patent disclosures. CX-0013C (Shmuylovich RWS) at Q/A 106-36; CX-0342; CX-0343; CX-1076; CX-1081; CX-1084; CX-1085; RX-0622; Tr. (Shmuylovich) at 708:23-709:6.

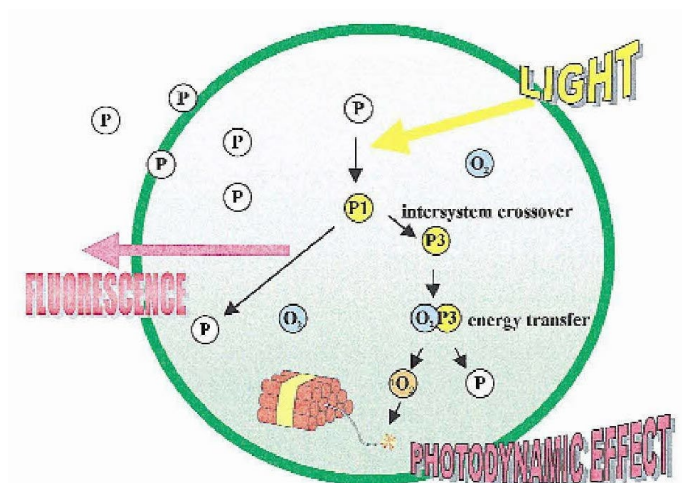


Fig 3. Mechanism of fluorescence and type II reaction pathway during PDT. O₂, Ground state oxygen; ¹O₂, singlet oxygen; P, photosensitizer; P1, singlet excited photosensitizer; P3, triplet excited photosensitizer.

CX-0343.7.



Fig 4. A, PDT of large squamous cell carcinoma on the left external ear in a patient in poor general condition resulting from acute lymphatic leukemia. B, The intense PpIX fluorescence 5 hours after topical application of 20% ALA delineates the actual margins of the tumor. C, Clinical result 5 months after multiple treatments with topical ALA and 80 to 120 J/cm² of red light, showing minimal residual erythema.

CX-0343.11; CX-0342.2 (providing exemplary instructions for a “technique of PDD [photodynamic diagnosis]”); JX-0015C (Carota Dep. Tr.) at 93:6-16, 94:10-95:8; JX-0011C (Foguet Dep. Tr.) at 189:22-191:17; RX-0007C (Ehrenreich WS) at Q/A 239 (recognizing

knowledge at the time of the patents for diagnosing certain conditions using known photosensitizing agents); Tr. (Foguet) at 375:17-25 (disclosed example of PD using 405 nm light).

5. Quantity Of Experimentation Needed To Make Or Use The Invention

The knowledge of a skilled artisan, combined with the disclosures of the Asserted Patents and the state of the art at the time would enable a skilled artisan to practice the full scope of the claims without undue experimentation. CX-0013C (Shmuylovich RWS) at Q/A 149-75. None of the parameters identified by Biofrontera, RIB at 92-96 and 103, qualify as undue experimentation to practice the scope of the claims, including selecting the 1) wavelength to use for PD, 2) type and amount of photosensitizer to use, and 3) light dose and fluence. *Id.* at Q/A 150; Tr. (Shmuylovich) at 705:4-706:19.

A skilled artisan would understand that PDT and PD require a photosensitizer or fluorophore, and a light source. CX-0013C (Shmuylovich RWS) at Q/A 152; Tr. (Shmuylovich) at 705:4-706:19. Photosensitizers have well-studied absorption and emission spectra, with known particular wavelengths for efficient activation. CX-0013C (Shmuylovich RWS) at Q/A 152. A person skilled in the art seeking to use the claimed methods and systems with a particular photosensitizer could easily look up which wavelengths of light to use to excite that photosensitizer for fluorescence activity. *Id.*, *id.* at Q/A 172 (example of ALA); Tr. (Shmuylovich) at 705:22-706:19 (“Depending on which fluorophore you have, you know which wavelength you need...But if you had another fluorophore, it is pretty simple to either look up the fluorescence peaks or just measure them.”).

A skilled artisan would not need to test every visible wavelength to determine the appropriate one for PD. CX-0013C (Shmuylovich RWS) at Q/A 153. Testing absorption spectra for fluorophores is routine, *id.* at Q/A 152, 175, and testing at 10 nm intervals is unnecessary. *Id.*

at Q/A 172, 153; Tr. (Shmuylovich) at 706:2-3 (appropriate wavelength depends on the known properties of the fluorophore). Moreover, types of photosensitizers, their activation wavelengths, administration routes, and dosages were well-known in the art by 2015. CX-0013C (Shmuylovich RWS) at Q/A 160-66; CX-1084.6. Topical application was standard for PD of dermatological indications, and effective photosensitizer doses were documented and could be adjusted as needed for patient specific factors. CX-0013C (Shmuylovich RWS) at Q/A 165.

Biofrontera has not shown by clear and convincing evidence that the asserted claims are invalid for failure to comply with the enablement requirement of 35 U.S.C. § 112.

VIII. ECONOMIC PRONG

As noted, on June 25, 2025, I issued an initial determination granting complainant's motion for summary determination on the satisfaction of the economic prong of the domestic industry requirement. Order No. 23. The Commission review is pending. Comm'n Notice to Review (July 25, 2025).

IX. CONCLUSIONS OF LAW

1. The Commission has statutory authority with respect to this investigation.
2. Sun Pharma is the owner by assignment of the Asserted Patents.
3. The importation requirement is satisfied for the Accused Products.
4. Claims 1, 3, 5, 8, 17-18, and 20 of the '512 patent have been shown to be infringed.
5. Claims 1, 2, 4, 16, 17, and 19-21 of the '028 patent have been shown to be infringed.
6. The technical prong of the domestic industry requirement for the '512 patent has been satisfied.
7. The technical prong of the domestic industry requirement for the '028 patent has been satisfied.
8. The '512 patent is not invalid under 35 U.S.C § 103 for obviousness.

9. The '028 patent is not invalid under 35 U.S.C § 103 for obviousness.
10. The '512 patent is not invalid under 35 U.S.C § 112 for lack of written description.
11. The '028 patent is not invalid under 35 U.S.C § 112 for lack of written description.
12. The '512 patent is not invalid for failure to comply with the enablement requirement of 35 U.S.C. § 112.
13. The '028 patent is not invalid for failure to comply with the enablement requirement of 35 U.S.C. § 112.

X. RECOMMENDED DETERMINATION ON REMEDY AND BOND

The Commission has broad discretion in selecting the form, scope, and extent of any remedy. *Viscofan, S.A. v. Int'l Trade Comm'n*, 787 F.2d 544, 548 (Fed. Cir. 1986); *see also Hyundai Electronics Industries Co. Ltd. v. Int'l Trade Comm'n*, 899 F.2d 1204, 1209 (Fed. Cir. 1990). By Commission rule, the administrative law judge must issue a recommended determination on the appropriate remedy if the Commission finds a violation of section 337 and on the amount of bond to be posted by respondents during Presidential review of any Commission remedy. *See* 19 C.F.R. § 210.42(a)(1)(ii). I address these issues below.

A. Limited Exclusion Order

Section 337(d)(1) provides that “[i]f the Commission determines, as a result of an investigation under this section, that there is a violation of this section, it shall direct that the articles concerned, imported by any person violating the provision of this section, be excluded from entry into the United States, unless, after considering the [public interest], it finds that such articles should not be excluded from entry.” 19 U.S.C. § 1337(d)(1). The Commission is required to issue an exclusion order upon the finding of a section 337 violation absent a finding that the effects of any of the statutorily-enumerated public interest factors counsel otherwise. *Spansion*, 629 F.3d at 1358.

Biofrontera argues that an LEO should not cover Ameluz® because it can be used in a non-infringing manner with the RhodoLED®. RIB at 107-08 (“Ameluz® may be used with non-accused products, *i.e.*, the RhodoLED®, which is not within the scope of the Investigation.”). Complainant states that “it does not seek to exclude Ameluz® imported for non-infringing uses” but “seeks exclusion of Ameluz® for use in conjunction with the infringing RhodoLED®-XL.” CRB at 58.

Biofrontera argues that an LEO would unfairly harm customers who already own RhodoLED®-XL by preventing them from obtaining Ameluz®. RIB at 107. The Commission has, however, consistently rejected the notion that non-infringing uses can shield products from exclusion where there is a predominant infringing use—Biofrontera can certify which imports are for non-infringing uses. *Certain Baseband Processor Chips and Chipsets*, Inv. No. 337-TA-543, Comm’n Op. (June 7, 2007) at 2-3 (ordering a limited exclusion order with importer certification of non-infringing exempt models). Complainant states that it “does not oppose a narrowly tailored exemption to LEO for legitimate service and repair functions covered by warranty for existing users, consistent with Commission precedent.” CRB at 58. I agree.

I recommend entry of an LEO. I further recommend that the LEO should include a certification provision. *See Certain Multiple Mode Outdoor Grills & Parts Thereof*, Inv. No. 337-TA-895, Comm’n Op. at 56 (Feb. 20, 2015) (“[I]t has been Commission practice for the past several years to include certification provisions in all exclusion orders to aid . . . CBP in enforcing the Commission’s remedial orders.”). I also recommend an exemption for service and repair functions covered by warranty for existing users.

Additionally, I recommend the standard certification provision in any limited exclusion order such that, at the discretion of Customs and Border Patrol and pursuant to procedures it

establishes, persons seeking to import articles that are potentially subject to any limited exclusion order may be required to certify that they are familiar with the terms of the limited exclusion order, that they have made appropriate inquiry, and thereupon state that, to the best of their knowledge and belief, the products being imported are not excluded from entry under the limited exclusion order. *See Tobacco Heating Articles*, 337-TA-1199, Comm’n Op. at 45-46.

B. Cease and Desist Order

Section 337(f)(1) provides that in addition to, or in lieu of, the issuance of an exclusion order, the Commission may issue a cease and desist order as a remedy for violation of section 337. 19 U.S.C. § 1337(f)(1). A cease and desist order is generally issued when a respondent maintains commercially significant inventories in the United States or has significant domestic operations that could undercut the remedy provided by an exclusion order. *Certain Table Saws Incorporating Active Injury Mitigation Technology and Components Thereof*, Inv. No. 337-TA-965, Comm’n Op. at 4-6 (Feb. 1, 2017). “A complainant seeking a cease and desist order must demonstrate, based on the record, that this remedy is necessary to address the violation found in the investigation so as to not undercut the relief provided by the exclusion order.” *Id.* at 5.

Complainant argues that respondents maintain a commercially significant U.S. inventory of RhodoLED® XL. CIB at 161. Biofrontera argues that (1) a CDO “should not include Ameluz®, which is not an Accused Product,” (2) “Biofrontera should be permitted to sell Ameluz® for non-infringing uses, including with customers’ RhodoLED® and previously-purchased RhodoLED®XL lamps,” and (3) “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.” RIB at 109-10; *see* RRB at 56-57. Complainant responds that it “does not oppose a narrowly tailored exemption for legitimate service and repair

functions covered by warranty, consistent with Commission precedent” and that “Ameluz® should be included in the CDO to the same extent as the LEO given its infringing use with RhodoLED®-XL units already in the market, subject to certification.” CRB at 58-59.

The evidence shows that Biofrontera maintains a commercially significant U.S. inventory of RhodoLED® XL. Biofrontera held [REDACTED] RhodoLED® XL units in U.S. inventory as of November 30, 2024, with an additional [REDACTED] units on order. *See* Tr. at 423:8-25; CX-0608C (Jan. 2, 2025 Joint Stipulation of Importation and Inventory); RX-0003C (Leffler WS) at Q/A 38 (Biofrontera had 160 units in U.S. inventory as of April 18, 2025). With estimated sales of 140-[REDACTED] units in 2025, Biofrontera held [REDACTED] months’ worth of sales of RhodoLED® XL in inventory as of November 30, 2024, which is commercially significant. *See* CX-0016C (Vander Veen WS) at Q/A 325-28; CX-1334C at 49:6-16; CX-1335C at 139:4-21; CX-1329C at 79:17-80:5. Biofrontera sells from its inventory. *See* CX-1336C at 106:9-25.

I agree with complainant’s reasonable approach with respect to putting in place a narrowly tailored exemption. Such tailored relief balances stopping infringement with any equitable concerns raised by Biofrontera. *Certain Automated Put Walls*, Inv. No. 337-TA-1293, Comm’n Op. at 37-8 (including such exemption in CDO). I recommend that CDOs issue with exemption for service and repair functions covered by warranty. I also recommend that Ameluz® should be included in the CDO to the same extent as the LEO given its infringing use with RhodoLED®-XL units already in the market, subject to certification.

C. Bond

When the Commission enters an exclusion order or a cease and desist order, a respondent may continue to import and sell its products during the 60-day Presidential review period under an amount determined by the Commission to be “sufficient to protect the complainant from any

injury.” 19 U.S.C. § 1337(j)(3); *see also* 19 C.F.R. § 210.50(a)(3); and *Certain Automated Put Walls and Automated Storage and Retrieval Systems, Associated Control Software, and Component Parts Thereof*, Inv. No. 337-TA-1293, Comm’n Op. at 46 (July 31, 2023). Complainant bears the burden of establishing the need for a bond. *Id.* at 47.

When reliable price information is in the record, the Commission often sets the bond by eliminating the differential between the domestic product and the imported product. *Id.* at 46. The Commission may also use a reasonable royalty rate to set the bond amount where one can be determined from the record. *Id.* Where the record establishes that the calculation of a price differential is impractical or there is insufficient evidence in the record to determine a reasonable royalty, the Commission has imposed a 100 percent bond. *Id.*

Complainant argues that “a price comparison is impractical,” that “neither the average price nor the ‘floor price’ account for Biofrontera’s aggressive trade-in discounts on RhodoLED® XL,” and “the majority of RhodoLED® XL placements in the U.S.—over 55% as of December 2024—are leased for [REDACTED] for up to six months.” CIB at 161-62; *see* CRB at 59.

Biofrontera argues that no bond should be imposed during Presidential Review because (1) the RhodoLED®-XL is priced higher than Complainant’s BLU-U® 4170E device; (2) Biofrontera has not sold any RhodoLED®-XL units below [REDACTED]; and (3) [REDACTED] [REDACTED] RIB at 110-12; *see* RRB at 57-59.

I agree with Biofrontera that there is no record evidence to support setting 100% bond as argued by Complainant. The law instructs that a bond should be set to protect Complainant from any injury. 19 U.S.C. § 1337(j)(3); 19 C.F.R. §§ 210.42(a)(1)(ii), 210.50(a)(3). But Complainant

never argues that the price of the BLU-U® 4170E is higher than the RhodoLED® XL. *See* CIB at 161-62; CRB at 59.

I recommend the Commission set the bond rate for the Presidential review period at 0%.

XI. INITIAL DETERMINATION ON VIOLATION

It is my initial determination that a violation of section 337 of the Tariff Act, as amended, has occurred by the importation into the United States, the sale for importation, or the sale within the United States after importation of certain photodynamic therapy systems, components thereof, and pharmaceutical products used in combination with the same based on infringement of U.S. Patent No. 11,446,512 and U.S. Patent No. 11,697,028. I hereby certify this Initial Determination and Recommended Determination to the Commission.

The Secretary shall serve the confidential version of this Initial Determination and Recommended Determination upon counsel who are signatories to the Protective Order (Order No. 1) issued in this investigation. A public version will be served on all parties of record later.

Under 19 C.F.R. § 210.42(h), this Initial Determination shall become the determination of the Commission unless a party files a petition for review under 19 C.F.R. § 210.43(a) or the Commission orders on its own motion a review of the Initial Determination or certain issues therein under 19 C.F.R. § 210.44. 19 C.F.R. § 210.42(d).

XII. ORDER

Within seven days of the date of this document, the parties shall jointly submit a single proposed public version of this document with any proposed redactions indicated in red. If the parties submit excessive redactions, they may be required to provide declarations from individuals with personal knowledge, justifying each proposed redaction and specifically explaining why the information sought to be redacted meets the definition for confidential business information set

forth in 19 C.F.R. § 201.6(a). To the extent possible, the proposed redactions should be made electronically in a single PDF file with the proposed redactions submitted as “marked” but not yet “applied.” The proposed redactions should be submitted via email to Moore1411@usitc.gov and not filed on EDIS.

SO ORDERED.


Bryan F. Moore
Administrative Law Judge

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

Inv. No. 337-TA-1411

CONFIDENTIAL CERTIFICATE OF SERVICE

I, Lisa R. Barton, hereby certify that the attached **INITIAL DETERMINATION** has been served via EDIS upon the following parties as indicated, on **September 30, 2025**.



Lisa R. Barton, Secretary
U.S. International Trade Commission
500 E Street, SW, Room 112
Washington, DC 20436

**On Behalf of Complainant Sun Pharmaceutical Industries,
Inc:**

Betty Chen, Esq.
DESMARAIS LLP
101 California Street, Suite 3000
San Francisco, CA 94111
Email: bchen@desmaraisllp.com

- ☐ Via Hand Delivery
- ☐ Via Express Delivery
- ☐ Via First Class Mail
- ☒ Other: Email Notification
of Availability for Download

**On Behalf of Respondents Biofrontera Inc., Biofrontera
Pharma GMBH, Biofrontera Bioscience GMBH, and
Biofrontera AG:**

Deanna Tanner Okun, Esq.
POLSINELLI P.C.
1401 Eye Street N.W., Suite 800
Washington, D.C. 20005
Email: dtokun@polsinelli.com

- ☐ Via Hand Delivery
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