

PUBLIC VERSION

**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**

Investigation No. 337-TA-1411

COMMISSION OPINION

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I. INTRODUCTION

On July 25, 2025, the Commission determined to review Order No. 23, in which the presiding administrative law judge (“ALJ”) granted in part complainant Sun Pharmaceutical Industries, Inc.’s (“Complainant”) motion for summary determination that the economic prong of the domestic industry (“DI”) requirement is satisfied. Comm’n Notice at 2 (July 25, 2025). On January 28, 2026, the Commission determined to review in part the final initial determination (“FID”) issued by the presiding administrative law judge (“ALJ”) on September 30, 2025. 91 Fed. Reg. 4630-31 (Feb. 2, 2026).

Upon consideration of the issues under Commission review, the Commission affirms the ALJ’s construction of “nested hinges on inner side surfaces” with modified reasoning. The Commission also affirms with modified and additional reasoning the FID’s finding that none of the asserted claims are invalid as obvious under 35 U.S.C. § 103. Furthermore, the Commission affirms with modified reasoning the ALJ’s finding that Complainant has satisfied the economic prong of the DI requirement under 19 U.S.C. § 1337(a)(3)(B).

Therefore, the Commission has determined that there has been a violation of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337 (“section 337”), with respect to asserted claims 1, 3, 5, 8, 17, 18, and 20 of U.S. Patent No. 11,446,512 (“the ’512 Patent”) and asserted claims 1, 2, 4, 16, 17, and 19-21 of U.S. Patent No. 11,697,028 (“the ’028 Patent”) (collectively, “the Asserted Patents”).

Having found a violation of section 337, the Commission has determined to issue a limited exclusion order (“LEO”) against respondents Biofrontera Inc. of Woburn, Massachusetts; Biofrontera Pharma GmbH of Leverkusen, Germany; Biofrontera AG of Leverkusen, Germany; and Biofrontera Bioscience GmbH of Leverkusen, Germany (collectively, “Respondents”). The Commission has also determined to issue cease and desist orders (“CDOs”) against each

Respondent. The Commission finds that the public interest factors do not preclude the issuance of these remedial orders. The Commission has determined to set a bond of zero percent (0%) during the period of Presidential review. This opinion sets forth the Commission’s reasoning in support of that determination.

II. BACKGROUND

A. Procedural History

On August 1, 2024, the Commission instituted this investigation based on a complaint filed by Complainant. 89 Fed. Reg. 62790 (Aug. 1, 2024). The complaint, as supplemented, alleges a violation of section 337, based on the importation into the United States, the sale for importation, and the sale within the United States after importation of certain photodynamic therapy systems, components thereof, and pharmaceutical products used in combination with the same by reason of infringement of certain claims of the ’028 patent and the ’512 patent. The notice of investigation named Respondents as respondents. The Office of Unfair Import Investigations is not a party to this investigation.

On November 20, 2024, the Commission amended the complaint and notice of investigation to add infringement allegations as to claims 17 and 18 of the ’512 patent. Order No. 8 (Oct. 22, 2024), *unreviewed by Comm’n* Notice (Nov. 20, 2024).

On March 4, 2025, the ALJ issued an order construing certain claim terms (Order No. 18). As relevant here, the ALJ construed the disputed claim term “nested hinges on inner side surfaces” to mean “hinges that fit on inner side surfaces.” Order No. 18 at 29-35.

On June 25, 2025, the ALJ issued an initial determination (Order No. 23) granting in part

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Complainant's motion¹ pursuant to Commission Rule 210.18 (19 C.F.R. § 210.18) that it has satisfied the economic prong of the DI requirement under subsections 337(a)(3)(B) and (C). The ALJ granted the motion only as to subsection (B), finding that Complainant's investment of approximately \$ [REDACTED] in internal labor expenditures is significant. Order No. 23 at 3-6. The ALJ declined to reach Complainant's motion for a finding that the economic prong is satisfied under subsection (C) or that Complainant had shown a DI in the process of being established. *Id.* at 11, n. 2, 11-12.

On June 26, 2025, Complainant submitted a letter to the ALJ, explaining that Order No. 23 inadvertently relies on an incorrect investment-to-revenue percentage that has since been corrected. Complainant Letter Regarding Order No. 23 at 1 (June 26, 2025). Complainant explained that its expert had recently corrected his Opening Witness Statement (CX-0016C) and Direct Demonstratives (CDX.0007C) to reflect that "[t]he correct percentage is [REDACTED]%, not [REDACTED]%." *Id.* Complainant further explained that it "inadvertently overlooked that this issue also impacted the pending summary determination brief until after receiving Order No. 23." *Id.*

On July 3, 2025, Respondents filed a petition for review of Order No. 23.² Respondents sought review of the following issues: (1) the significance and cognizability of Complainant's claimed investments under section 337(a)(3)(B); (2) the ALJ's failure to consider and analyze whether Complainant has a DI in the process of being established or a DI under subsection (C);

¹ Complainant Sun Pharmaceutical Industries, Inc.'s Motion and Memorandum of Points and Authorities on Satisfaction of the Economic Prong of Domestic Industry ("Compl. Mot.") (May 2, 2025).

² Respondents' Petition for Review of the Initial Determination Granting Motion for Summary Determination on Satisfaction of the Economic Prong of Domestic Industry (July 3, 2025) ("DI-PFR").

and (3) the ALJ's finding of satisfaction of the economic prong despite lack of a commercialized DI product. DI-PFR at 2. On July 11, 2025, Complainant filed a response to Respondents' petition.³

On July 25, 2025, the Commission determined to review Order No. 23.Comm'n Notice at 2 (July 25, 2025).

The ALJ held an evidentiary hearing from June 30 to July 3, 2025.

On September 30, 2025, the ALJ issued the FID, finding a violation of section 337 with respect to each of the asserted claims. FID at 143-44. Specifically, the FID finds that the accused product, the RhodoLED XL, alone or in combination with the pharmaceutical product Ameluz, infringes claims 1, 3, 5, 8, 17-18, and 20 of the '512 patent and claims 1, 2, 4, 16, 17, and 19-21 of the '028 patent. *Id.* at 143. The FID further finds that neither of the Asserted Patents are invalid under 35 U.S.C. § 103 for obviousness or under 35 U.S.C. § 112 for lack of written description or enablement. *Id.* at 143-44. Finally, the FID finds that Complainant has satisfied the technical prong of the DI requirement for both Asserted Patents. *Id.* at 143.

The FID also includes the ALJ's Recommended Determination ("RD") on remedy and bond, should the Commission find a violation of section 337. RD at 144-49. The RD recommends issuing an LEO barring entry of the RhodoLED XL and Ameluz that is used in conjunction with the RhodoLED XL. *Id.* at 145. The RD further recommends that the LEO includes a standard certification provision and an exemption for service and repair functions for the RhodoLED XL covered by warranty for existing users. *Id.* The RD also recommends entering a CDO against each of the Respondents based on Respondents maintaining a commercially significant U.S. inventory of RhodoLED XL, with an exemption for service and

³ Complainant's Response to Respondents' Petition for Review of Order No. 23 (July 11, 2025).

repair functions covered by warranty. *Id.* at 147. Finally, the RD recommends that the Commission set a bond of zero percent (0%) for any importations of infringing products during the period of Presidential review. *Id.* at 147-49.

On November 17, 2025, Respondents filed a petition for review of certain claim constructions set forth in Order No. 18, several findings related to infringement and invalidity in the FID, and a pre-hearing ruling set forth in Order No. 25.⁴ Also on November 17, 2025, Complainant filed a petition requesting review of the ALJ's construction of the preamble "photodynamically diagnosing or treating a patient" as limiting.⁵ On November 25, 2025, Complainant and Respondents filed their respective responses to the petitions for review.⁶

On January 28, 2026, the Commission determined to review the FID in part. 91 Fed. Reg. at 4630. Specifically, the Commission determined to review: (1) the construction of the claim term "nested hinges" and (2) whether the asserted claims of the Asserted Patents are invalid as obvious. *Id.* The notice also reiterates that Order No. 23 remains under review. *Id.* The Commission did not request briefing on any of the issues under review. The notice also requested submissions on remedy, the public interest, and bonding. *Id.* at 4631.

On February 11, 2026, Complainant and Respondents filed their initial briefs on remedy,

⁴ Respondents Biofrontera Inc., Biofrontera Pharma GmbH, Biofrontera Bioscience GmbH, and Biofrontera AG's Petition for Review of the Initial Determination Finding Violation of Section 337 (Nov. 17, 2025) ("RPFR").

⁵ Complainant Sun Pharmaceutical Industries, Inc.'s Petition and Contingent Petition for Review of Initial Determination on Violation of Section 337 and Recommended Determination on Remedy and Bond (Nov. 17, 2025).

⁶ Complainant's Response to Respondents' Petition for Review of the Initial Determination (Nov. 25, 2025) ("CRPFR"); Respondents Biofrontera Inc., Biofrontera Pharma GmbH, Biofrontera Bioscience GmbH, and Biofrontera AG's Response to Complainant's Petition and Contingent Petition for Review of Initial Determination Finding Violation of Section 337.

bonding, and the public interest.⁷ On February 18, 2026, Complainant and Respondents filed their respective responses.⁸

On February 24, 2026, Respondents submitted a letter requesting that the Commission take judicial notice of a final written decision (“FWD”) issued by the U.S. Patent and Trademark Office Patent Trial and Appeal Board (“PTAB”) finding claims 1, 2, 4-6, 16, 17, and 19-21 of the ’028 patent unpatentable as obvious.⁹ IPR Letter at 1. On March 5, 2026, the Commission requested additional briefing from the parties on “whether, and to what extent, the FWD should impact the Commission’s determination regarding the validity of the asserted claims of both the ’028 patent and the ’512 patent.” Comm. Not. at 3 (Mar. 5, 2026). On March 12, 2026, the parties submitted their initial responses.¹⁰ On March 19, 2026, the parties submitted their responsive submissions.¹¹

⁷ Complainant Sun Pharmaceutical Industries, Inc.’s Submission in Response to Commission’s Notice of Review (Feb. 11, 2026) (“Compl. RBPI”); Respondents’ Written Submission on Remedy, Bond, and Public Interest (Feb. 11, 2026) (“Resp. RBPI”).

⁸ Complainant Sun Pharmaceutical Industries, Inc.’s Response to Respondents’ Submission on Remedy, Bond, and Public Interest (Feb. 18, 2026) (“Compl. RBPI Response”); Respondents’ Reply to Complainant Sun Pharma’s Submission in Response to Commission’s Notice of Review (Feb. 18, 2026) (“Resp. RBPI Response”).

⁹ Letter to the Commission Requesting Judicial Review of IPR Final Written Decision Regarding U.S. Patent No. 11,697,028 (Feb. 24, 2026) (“IPR Letter”).

¹⁰ Complainant Sun Pharmaceutical Industries, Inc.’s Submission in Response to Commission’s Notice Requesting Additional Briefing (Mar. 12, 2026) (“Compl. PTAB”); Respondents Biofrontera Inc., Biofrontera Pharma GmbH, Biofrontera Bioscience GmbH, and Biofrontera AG’s Response to the Commission’s Request for Additional Briefing (Mar. 12, 2026) (“Resp. PTAB”).

¹¹ Complainant Sun Pharmaceutical Industries, Inc.’s Response to Respondents Biofrontera Inc., Biofrontera Pharma GmbH, Biofrontera Bioscience GmbH, and Biofrontera AG’s Response to the Commission’s Request for Additional Briefing (Mar. 19, 2026) (“Compl. PTAB Response”); Respondents Biofrontera Inc., Biofrontera Pharma GmbH, Biofrontera Bioscience GmbH, and Biofrontera AG’s Responsive Submission to Complainant’s Response to the Commission Request for Additional Briefing (Mar. 19, 2026) (“Resp. PTAB Response”).

B. The Parties

1. Complainant

Complainant Sun Pharmaceutical Industries, Inc. is a Delaware corporation with its principal place of business in Princeton, New Jersey. FID at 2.

2. Respondents

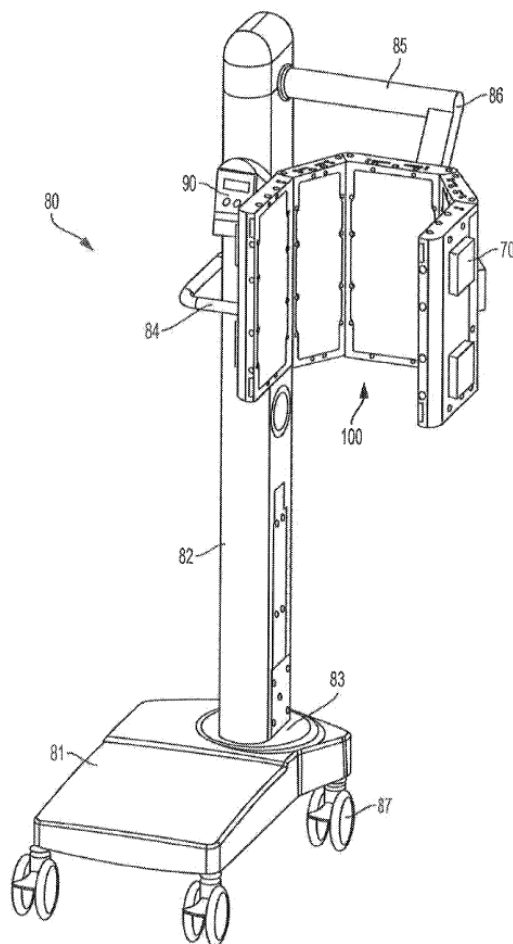
Respondent Biofrontera AG is a German corporation with its principal place of business in Leverkusen, Germany. *Id.* Respondent Biofrontera, Inc. is a Delaware corporation with a principal place of business in Woburn, Massachusetts and is a wholly owned U.S. subsidiary of Biofrontera AG. *Id.* Respondent Biofrontera Pharma is a German corporation with its principal place of business in Leverkusen, Germany and is a wholly owned subsidiary of Biofrontera AG. *Id.* at 3. Biofrontera Bioscience is a German company located in Leverkusen, Germany. *Id.*

C. The Asserted Patents

1. The '512 Patent¹²

The '512 patent is titled “Adjustable Illuminator for Photodynamic Therapy and Diagnosis.” The patent issued on September 20, 2022, and has an effective priority date of October 15, 2015. JX-0001; FID at 3. The '512 patent is directed to an adjustable illuminator for both photodynamic therapy (“PDT”) and photodynamic diagnosis (“PD”) using “specific and highly uniform intensity and color of light” to more effectively treat certain dermatologic conditions, such as actinic keratosis, on various areas of the body. JX-0001 at 2:21-49. Figure 4 illustrates one embodiment of the claimed invention:

¹² The '512 patent issued from an application filed after March 16, 2013, the effective date of the America Invents Act (“AIA”), and thus must be evaluated under the AIA statute.



Id. at FIG. 4.

Complainant asserts claims 1, 3, 5, 8, 17, 18, and 20 of the '512 patent for infringement, which recite as follows (with the disputed limitations emphasized):

Claim #	Limitation
1[p]	A system for photodynamically diagnosing or treating a patient , comprising:
1[a]	an illuminator comprising at least five panels connected by nested hinges on inner side surfaces of adjacent panels ,
1[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,

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1[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,
1[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.
3[p]– 3[a]	The system of claim 1, wherein the illuminator is configured to output red light at a dose of about 30 J/cm ² to about 150 J/cm ² .
5[p]– 5[a]	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.
8[p]	A method of photodynamically diagnosing or treating a patient , comprising:
8[a]	administering 5-aminolevulinic acid (ALA) to the patient;
8[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
8[c]	uniformly illuminating a treatment surface of the patient with light sources disposed on the at least five panels of the illuminator,
8[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]– 17[a]	The method of claim 8, wherein at least one panel includes a recess configured to receive a flange of one of the nested hinges.

18[p]– 18[a]	The method of claim 17, wherein the recess is positioned at an inner side surface of the at least one panel.
20[p]	A system for photodynamically diagnosing or treating a patient , comprising:
20[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,
20[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,
20[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 ,
20[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.

JX-0001 at cls. 1, 3, 5, 8, 17, 18, and 20 (emphasis added).

2. The '028 Patent¹³

The '028 patent is entitled “Adjustable Illuminator for Photodynamic Therapy and Diagnosis,” also issued on July 11, 2023, and also has an effective priority date of October 15, 2015. JX-0002; FID at 6. The '028 patent is a continuation of and shares a specification with

¹³ The '028 patent issued from an application filed after March 16, 2013, the effective date of the AIA, and thus must be evaluated under the AIA statute.

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the '512 patent. JX-0002 at [60]. The claim scope of the '028 patent substantially overlaps with the claims of the '512 patent; the material difference between the two patents is that the '028 patent claims the use of blue light in addition to red light during at least a portion of treatment. JX-0002 at cl. 7. Like the '512 patent, the '028 patent is directed to an adjustable illuminator for both PD and PDT using “specific and highly uniform intensity and color of light” to more effectively treat certain dermatologic conditions, such as actinic keratosis, on various areas of the body. JX-0002 at 2:23-51. The '028 patent contains the same Figure 4 as the '512 patent, above.

Complainant asserts claims 1, 2, 4, 16, 17, and 19-21 of the '028 patent for infringement, which recite as follows (with the disputed limitations emphasized):

Claim #	Limitation
1[p]	A system for photodynamically diagnosing or treating a patient , comprising:
1[a]	an illuminator comprising five panels connected by hinged structures on inner side surfaces of adjacent panels ; and
1[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,
1[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 ,
1[d]	wherein the five panels are positioned to allow treatment within approximately four inches of the treatment surface, and
1[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.

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2[p]– 2[a]	The system of claim 1, wherein the illuminator is configured to output red light at a dose of 30 J/cm ² to 150 J/cm ² .
4[p]– 4[a]	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.
16[p]	A system for photodynamically diagnosing or treating a patient , comprising:
16[a]	a mobile base supported by at least four wheels ;
16[b]	a pillar perpendicular to the base;
16[c]	a controller disposed to be supported by the pillar;
16[d]	an arm mounted to a top portion of the pillar; and
16[e]	an illuminator connected at an end of the arm,
16[f]	the arm being hinged to allow adjustment of a position of the illuminator relative to the base,
16[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,
16[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,
16[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
16[i]	one or more fans mounted to at least one of the five panels.

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17[p]– 17[a]	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 .
19[p]– 19[a]	The system of claim 16, 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:
20[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
20[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,
20[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 ,
20[d]	wherein the five panels are positioned to allow treatment within approximately four inches of the treatment surface, and
20[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:

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21[a]	an illuminator comprising five panels connected by hinged structures on inner side surfaces of adjacent panels ; and
21[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,
21[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 ,
21[d]	wherein the five panels are positioned to allow treatment within approximately four inches of the treatment surface,
21[e]	wherein the five panels are individually configurable to control illumination from each of the five panels, and
21[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 .

JX-0002 at cls. 1, 2, 4, 16, 17, and 19-21 (emphasis added).

D. The Accused Products

The accused products in this investigation are “the RhodoLED XL, alone or in combination with Ameluz®.” FID at 9. The accused products are shown below:



CDX-0004C.150. Complainant explained that RhodoLED XL is a “red light-emitting LED lamp, which is used exclusively in combination with Ameluz for lesion-directed and field directed treatment of actinic keratoses of mild-to-moderate severity on the face and scalp.” Complainant’s Pre-Hearing Brief at 14. Ameluz is a prescription gel containing 5-aminolevulinic acid that can amplify the effects of the RhodoLED XL. *Id.* at 20; *see also* JX-0104.4.

E. The DI Product

The DI product is Complainant’s BLU-U® Blue Light Photodynamic Therapy Illuminator Model 4170E (“BLU-U 4170E”). Compl. Mot. at 1-2. The BLU-U 4170E is a photodynamic therapy (“PDT”) lamp that can be used alone or in combination with Levulan®, a topical prescription medication, to treat non-hyperkeratotic actinic keratosis of the face, scalp, and upper extremities. *Id.* at 2. Complainant alleges that that the BLU-U 4170E practices the system claims of both the ’512 and ’028 patents. *Id.* at 2 n.2. The BLU-U 4170E is awaiting

FDA approval and, accordingly, has not been commercialized. Currently on the market is an earlier version of Complainant's PDT lamp, the BLU-U® 4170D ("BLU-U 4170"¹⁴) device.

III. COMMISSION REVIEW OF THE FINAL ID

When the Commission reviews an initial determination, in whole or in part, it reviews the determination *de novo*. *Certain Electronic Stud Finders, Metal Detectors and Electrical Scanners*, Inv. No. 337-TA-1221, Comm'n Op. at 9 (Feb. 15, 2022) (citations omitted), *aff'd*, *Zircon Corp. v. Int'l Trade Comm'n*, 101 F.4th 817 (Fed. Cir. 2024). Upon review, the "Commission has 'all the powers which it would have in making the initial determination,' except where the issues are limited on notice or by rule." *Certain Electronic Devices, Including Streaming Players, Televisions, Set Top Boxes, Remote Controllers, and Components Thereof* ("Streaming Players"), Inv. No. 337-TA-1200, Comm'n Op. at 7 (Nov. 10, 2021) (citations omitted), *aff'd*, *Roku, Inc. v. Int'l Trade Comm'n*, 90 F.4th 1367 (Fed. Cir. 2024). With respect to the issues under review, "the Commission may affirm, reverse, modify, vacate, or remand for further proceedings, in whole or in part, the initial determination of the administrative law judge." 19 C.F.R. § 210.45(c). The Commission also "may take no position on specific issues or portions of the initial determination," and "may make any finding or conclusions that in its judgment are proper based on the record in the proceeding." *Id.*; *see also Beloit Corp. v. Valmet Oy*, 742 F.2d 1421, 1423 (Fed. Cir. 1984).

¹⁴ Complainant explained that the BLU-U® 4170 is also referred to as the BLU-U-® 4170D because the D "designates that the BLU-U® 4170 device is shipped fully assembled." Compl. Mot. at 1 n.1.

IV. ANALYSIS

The Commission's findings, conclusions, and supporting analysis follow. The Commission affirms and adopts the FID's findings, conclusions, and supporting analysis that are not inconsistent with the Commission's opinion.

The issues under Commission review are: (1) the construction of the claim term "nested hinges on inner side surfaces," which appears in independent claims 1, 8, and 20 of the '512 patent; (2) whether any asserted claims of the '512 patent or the '028 patent are invalid as obvious under 35 U.S.C. § 103; and (3) whether Complainant has satisfied the economic prong of the DI requirement under section 337(a)(3)(B). As noted, the ALJ addressed issues 1 and 3 in orders 18 and 23, respectively, and issue 2 in the FID.

A. Claim Construction: "Nested Hinges on Inner Side Surfaces of Adjacent Panels"

Claim terms are normally construed according to their ordinary and customary meaning in the art, as understood by a skilled artisan in the context of the entire patent. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-13 (Fed. Cir. 2005), *cert. denied*, 546 U.S. 1170 (2006). Claim construction focuses mainly on the intrinsic evidence, which consists of the claims themselves, the specification, and the prosecution history. *Id.* at 1313-1317. If the intrinsic evidence does not establish the meaning of a claim, then extrinsic evidence may be considered. Extrinsic evidence consists of all evidence external to the patent and the prosecution history, and includes inventor testimony, expert testimony, and learned treatises, and it may be considered if a court deems it helpful in determining the true meaning of language used in the patent claims. *Id.* at 1317.

The Commission determined to review the construction of the claim term "nested hinges on inner side surfaces of adjacent panels" which appears in every asserted independent claim of

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the '512 patent (claims 1, 8, and 20). Order No. 91 Fed. Reg. at 4630; Order No. 18 at 29.

During claim construction, the parties proposed the following constructions of this term:

SUN PHARMA	BIOFRONTERA
Plain and ordinary meaning.	Indefinite
Hinges that fit on inner side surfaces of adjacent panels.	

Order No. 18 at 30. The ALJ found that the term is not indefinite and adopted Complainant's construction. *Id.* at 35.

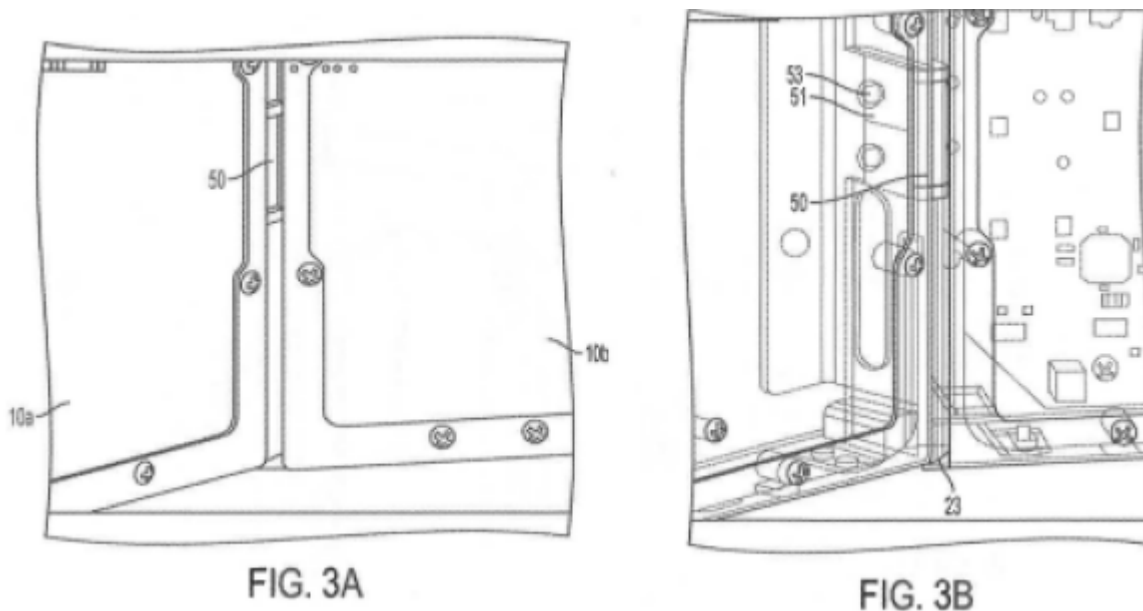
The ALJ found that there is redundancy between “nested” and “on inner side surfaces of adjacent panels,” but that “this redundancy does not prevent one of ordinary skill from understanding the scope of the invention.” *Id.* at 31. The ALJ further found that while “neither party introduces evidence that ‘nested hinges’ is a term that has a plain meaning to either laypersons or a person of ordinary skill in the art,” the word “nested” has a plain and ordinary meaning, which is “to fit compactly together within one another.” *Id.* The ALJ explained that the specification “establishes that the redundant construction is correct,” and that the Federal Circuit has not entirely foreclosed redundant constructions. *Id.* (citing *VLSI Tech. LLC v. Intel Corp.*, 53 F.4th 646, 653 (Fed. Cir. 2022) (holding that “a construction that introduces redundancy into a claim is disfavored, [but] it is not foreclosed . . . particularly . . . where . . . intrinsic evidence makes it clear that the ‘redundant’ construction is correct”)). For example, the ALJ explained that the specification states that “[t]he hinges **50** may take the form of nested hinges, which may include hinges that substantially reduce or eliminate optical dead spaces.” *Id.* at 32 (citing JX-0001 at 4:46-48). The ALJ also relied on Figures 3A and 3B, and based on these figures, the ALJ concluded that “the nested hingers [sic] fit on the inner side surfaces of the adjacent panels. Thus, the patent figures support an understanding that ‘nested hinges’ are

hinges that hinges that [sic] fit on inner side surfaces of adjacent panels.” *Id.* at 32-33 (citing JX-0001 at 4:63-5:12). The ALJ also noted that this construction is supported by the prosecution history, because the claim term was revised following an initial rejection for indefiniteness and the revised construction was found to not be indefinite during prosecution. *Id.* at 34.

In their petition for review, Respondents argued that the ALJ’s construction “reads out the now superfluous word nested from the literal claim language,” such that the claim now reads: “~~nested~~ hinges **that fit** on inner side surfaces of adjacent panels.” RPFR at 19. Respondents argued that “[t]his type of construction is strongly disfavored because it cripples the notice function of patent claims.” *Id.* (citing *Bicon, Inc. v. Straumann Co.*, 441 F.3d 954, 950 (Fed. Cir. 2006)). Complainant responded that the ALJ’s construction is correct, and that the ALJ’s construction is based on analysis from Respondents’ own expert. CRPFR at 15 (citing Grove Claim Construction Declaration at ¶ 83 (“[T]he Merriam-Webster Dictionary’s second definition of the verb ‘nest’ defines it as ‘to fit compactly together or within one another.’”). Complainant also explained that the specification explains the purpose of “nested hinges,” which is for “the outside vertical edges of adjoining panels to be positioned closer to one another.” *Id.* (citing JX-0001 at 4:63-5:10). Complainant also argued that Respondents misinterpret the ALJ’s construction because of the statements regarding redundancy: “[Respondents’ argument] . . . ignores that the ALJ gave ‘nested’ meaning in his final construction, construing it as ‘fit’ in accordance with its ordinary meaning.” *Id.* at 17. Complainant further argued that Respondents did not petition for review of this particular portion of the construction. *See generally* RPFR at 19-24.

On review, the Commission finds that the ALJ's construction of "nested hinges on inner side surfaces" to mean "hinges that fit on inner side surfaces" is correct, but that the ALJ erred in finding that "nested" and "on inner side surfaces" are redundant.

As the ALJ correctly explained, both the intrinsic evidence in Figures 3A and 3B of the '512 patent and Respondents' expert testimony show that "nested" has a plain and ordinary meaning, which is "to fit compactly together within one another." Order No. 18 at 31; *see also* JX-0001 at 4:64-66. Complainant also explained that Respondents' expert did not dispute the plain and ordinary meaning of "nested." CRPFR at 15 (citing Grove Claim Construction Declaration at ¶ 83). The Commission notes that Respondents did not petition for review of the ALJ's findings regarding the plain and ordinary meaning of "nested." *See generally* RPFR at 19-24. As shown in Figures 3A and 3B, the hinges (element 50) are placed on inner side surfaces to fit in such a way as to reduce or eliminate optical dead space:



JX-0001 at Figs. 3A, 3B; *see* 5:1-10.

Separately, the claim language recites that the "nested hinges" are located "on inner side surfaces of the adjacent panels." Order No. 18 at 31; *see also* JX-0001 at cl. 1; FIGS. 3A-3B;

4:63-5:12. The phrase “on inner side surfaces” refers to the location of where the hinges fit, and does not address how the hinges fit. The specification explains that the nested hinges “are mounted to the inner side surfaces of the adjacent panels . . . to allow for rotation of the panels.” JX-0001 at 4:64-66. The specification also explains, referring to Figures 3A and 3B reproduced above, that:

[t]he inner side surface of a panel may include a recess in which the flange **51** may be placed. The inner side surface of the panel may also include an additional recess to accommodate the joint of the hinge **50** such that the joint of the hinge **50** becomes substantially flush with an outer front surface of the panel. Such configurations may allow for the outside vertical edges of adjoining panels to be positioned closer to one another. By spacing the vertical edges of adjoining panels closer, optical dead space may be further reduced or eliminated.

Id. at 5:1-10. This passage identifies where the nested hinges should be placed between the adjacent panels, and explains that placing the hinges on inner side surfaces allows the hinges to fit in a way that reduces optical dead space between the panels.

Putting these together, “nested” refers to *how* the hinges must fit so as to reduce or eliminate optical dead space, and “on the inner side surfaces of the adjacent panels” explains *where* those hinges are located. While both “nested” and “on inner side surface” relate to the hinges, they are not redundant because they address different properties of the claimed hinges. Thus, the ALJ’s reasoning that “nested” and “on inner side surfaces” are redundant is not supported by the record. *See Wasica Fin. GmbH v. Cont’l Auto. Sys., Inc.*, 853 F.3d 1272, 1288 n.10 (Fed. Cir. 2017) (“It is highly disfavored to construe terms in a way that renders them void, meaningless, or superfluous.”). The Commission finds that both the intrinsic and extrinsic evidence supports finding that “nested” and “on inner side surfaces” address different characteristics of the hinges as claimed, and accordingly, those terms are not redundant. Nevertheless, the ALJ’s construction does ultimately give meaning to each term in the claim and

is supported by the record. The ALJ's construction addresses both that the hinges must "fit," and also specifies where the hinges must fit. Accordingly, the Commission affirms the construction of "nested hinges on inner side surfaces" to mean "hinges that fit on inner side surfaces."

B. Validity of the '028 Patent and the '512 Patent

A party cannot be held liable for infringement if the patent claim is invalid. *See Pandrol USA, LP v. AirBoss Railway Prods., Inc.*, 320 F.3d 1354, 1365 (Fed. Cir. 2003). A patent is presumed valid, and a respondent who raises patent invalidity as an affirmative defense has the burden of overcoming this presumption by clear and convincing evidence. 35 U.S.C. § 282; *Microsoft Corp. v. i4i Ltd. P'ship*, 131 S. Ct. 2238, 2242 (2011).

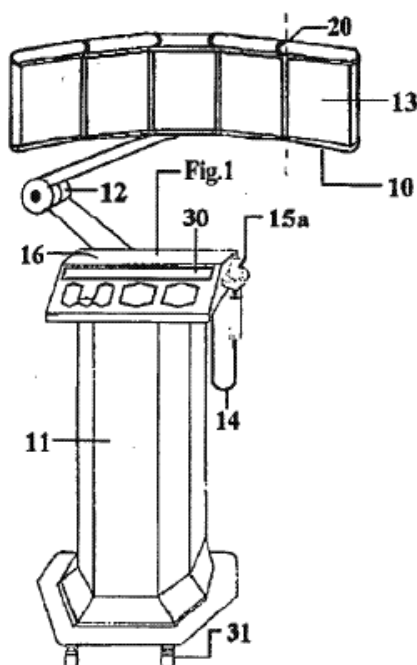
A patent may be found invalid for obviousness if "the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains." 35 U.S.C. § 103. Obviousness is evaluated by considering the *Graham* factors: (1) the scope and content of the prior art; (2) the difference between the prior art and the claimed invention; (3) the level of ordinary skill in the field of the invention; and (4) any relevant objective considerations. *Graham v. John Deere Co.*, 383 U.S. 1 at 17-18 (1966). Obviousness is a question of law based on underlying facts. *Soverain Software LLC v. NewEgg, Inc.*, 705 F.3d 1333, 1336 (Fed. Cir. 2013), discussing *Graham*, 383 U.S. at 17-18.

The Commission determined to review the FID's finding that none of the asserted claims of either the '028 patent or the '512 patent are invalid as obvious. 91 Fed. Reg. at 4630. The PTAB subsequently issued an FWD finding claims 1, 2, 4-6, 16, 17, and 19-21 of the '028 patent invalid as obvious. FWD at 3. Upon review of the FID, the parties' submissions, and the evidence of record, the Commission has determined to affirm the FID's finding that Respondents

failed to meet their burden to show by clear and convincing evidence that any asserted claims of either the '028 patent or the '512 patent are invalid as obvious, as modified and supplemented below.¹⁵

1. “Four wheels”

Claim 16 of the '028 patent recites “a mobile base supported by at least four wheels.” JX-0002 at cl. 16. Respondents argued that Figure 1 of Larsen¹⁶ discloses “four wheels **31**” as shown below:



Respondents' Post-Hearing Brief at 65; RX-0057 at FIG. 1. In particular, Respondents asserted that Figure 1 is a perspective view, such that there could be two wheels behind the wheels

¹⁵ The FID finds that a skilled artisan “would have an 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.” FID at 14.

¹⁶ U.S Patent Publication No. 2005/0075703 to Larsen.

labeled “31” rather than only the two wheels shown in the figure. *Id.*

The FID finds that Larsen does not expressly disclose four wheels because Figure 1 of Larsen shows only two wheels. FID at 116. The FID further finds that Respondents have abandoned or withdrawn their argument that Larsen discloses four wheels because they did not address this issue in their post-hearing brief. *Id.* The FID notes that Complainant argued that Larsen does not expressly disclose four wheels, and that Respondent failed to “address the failing articulated in [Complainant’s] Post-Hearing Brief for this limitation.” FID at 116. The FID then concludes that Respondents “did not address this issue in its post-hearing brief,” and accordingly abandoned or withdrew this argument. *Id.*; 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.”).

Respondents argued that the FID commits a “blatant error” by concluding that Respondents failed to address this limitation in their post-hearing brief. RPFR at 26. For example, Respondents’ Petition notes that they argued in their initial post-hearing brief that Figure 1 of Larsen “suggests that the device may incorporate four wheels, in order to provide stability,” and that a skilled artisan “would have been motivated with a reasonable expectation of success to use four wheels, since the resultant stability was a well-known outcome. *Id.* (citing Respondents’ Post-Hearing Brief at 65-66). In response, Complainant did not dispute that Respondents argued that Larsen “[s]uggests that the device may incorporate four wheels,” but instead argued that Respondents ignored Complainant’s counter-argument that the image in Larsen is “silent as to how many wheels it has.” CRPFR at 52. Complainant explained that its expert testified that the perspective figure in Larsen would not necessarily lead a skilled artisan to conclude that Larsen discloses four wheels, because a person of ordinary skill “would have understood that the device would have been stable and freely movable on only three wheels.” *Id.*

(citing CX-0014C at Q449). Complainant argued that “[i]n its petition, [Respondents] again ignore[] Dr. Jokerst’s analysis of why three wheels would be entirely consistent with Larsen’s disclosure and would provide stability and mobility.” *Id.* at 53.

On review, the Commission affirms the FID’s finding that Respondents did not meet their burden to show that Larsen discloses four wheels, but rejects the FID’s finding that Respondents waived their argument.¹⁷

Specifically, the Commission agrees with the FID and Complainant that Respondents did not meet their burden to show that Larsen either explicitly or implicitly discloses four wheels, or that it would be obvious to modify Larsen to have four wheels. FID at 116; CRPFR at 52-53. Although Respondents argued that “it is inherent that there are at least two more wheels” behind the two wheels shown in Larsen’s Figure 1 (*see* Respondents’ Post-Hearing Brief at 65), Respondents failed to address Complainant’s argument that Larsen’s Figure 1 could just as feasibly disclose only three wheels. CRPFR at 52; *see* Respondents’ Post-Hearing Brief at 65; Complainant’s Post-Hearing Brief at 107; Respondents’ Responsive Post-Hearing Brief at 26-27.¹⁸

Accordingly, the Commission affirms the FID’s finding that Respondents have failed to show by clear and convincing evidence that Larsen discloses the “four wheels” limitation recited

¹⁷ The Commission concludes that Respondents preserved in their post-hearing brief their argument that Larsen suggests that the depicted device may have at least two more wheels for a total of four wheels. Respondents’ Post-Hearing Brief at 65-66.

¹⁸ In light of Complainant’s un rebutted argument that Figure 1 of Larsen could just as feasibly disclose three wheels, the Commission is not persuaded by Respondents’ citation to the prosecution history of the ’028 patent, which does not appear to consider the possibility that the device could be stable with three wheels. *See* JX-0003.130-31. Respondents’ expert testimony is similarly unavailing, as it merely confirms what is stated in the prosecution history. *See* RX-0006C.0055-56, Q/A 249-52. The Commission further notes that the statement from the prosecution history provides no explanation for why the examiner stated it is “inherent” that Figure 1 of Larsen includes four wheels. *See* JX-0003.130-31.

in claim 16 of the '028 patent.

2. “Center panel”

Claims 1, 17, 20, and 21 of the '028 patent and claims 1 and 20 of the '512 patent require that “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.”

The FID finds that Respondents did not meet their burden to show that Larsen discloses this limitation because Respondents “ignore[] the full limitation, relying only on Dr. Jokerst’s testimony that Figure 1’s [of Larsen] panels are angled relative to the center panel.” FID at 116 (citing Tr. (Jokerst) at 738:13-739:2); *see* Respondents’ Initial Post-Hearing Brief at 53-54. Rather, the FID finds, Larsen does not disclose a “center panel configured to face the treatment surface,” and that Respondents made no assertion to the contrary. *Id.* Accordingly, the FID finds that Respondents failed to meet their burden on this limitation. *Id.*

On review, the Commission affirms the FID’s finding that Respondents failed to meet their burden to prove by clear and convincing evidence that the “center panel” limitation is disclosed by Larsen. In their post-hearing briefs, Respondents focused on only the “angled panels” portion of the claim limitation but neglected to explain how Larsen discloses a “center panel configured to face the treatment surface.” Respondents’ Post-Hearing Brief at 53-54; Respondents’ Responsive Post-Hearing Brief at 20-21. In their petition for review, Respondents argue only that “[a]ll of [Larsen’s] panels, including the center panel, are necessarily configured to face the treatment surface,” but they do not point to any arguments they made before the ALJ or explain why they did not waive their arguments for this portion of the limitation. RPFR at 28. Even if the Commission were to agree that “[a]ll of [Larsen’s] panels, including the center panel, are necessarily configured to face the treatment surface,” Respondents did not explain this

connection until their petition for review, thereby waiving that argument.

The Commission acknowledges that the FWD finds otherwise. FWD at 30. However, the FWD indicates that Complainant did not dispute this limitation before the PTAB (*Id.*), which is not the case here. In addition, the FWD specifically notes that its determination differs from the FID based on the lower standard of proof before the PTAB. *Id.* at 30 n.12 (noting that the FWD’s finding under a preponderance of evidence standard differs from the FID’s finding under a clear and convincing evidence standard). Moreover, Respondents did not address whether the Commission should consider the FWD’s findings on the “center panel” limitation in either their initial or responsive submission in response to the Commission’s request for additional briefing regarding the FWD. Thus, based on the record before the Commission, the Commission affirms the FID’s finding that Respondents did not meet their burden as to the “center panel” limitation under a clear and convincing evidence standard.

3. “Nested Hinges”/ “Hinged Structures”

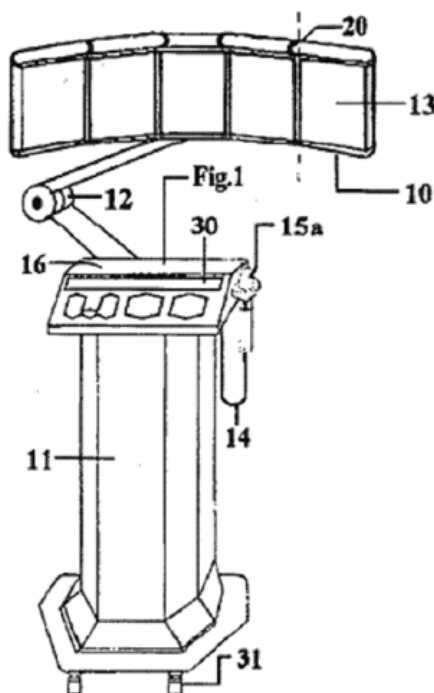
Claims 1, 8, and 20 of the ’512 patent recite “an illuminator comprising at least five panels connected by nested hinges on inner side surfaces of adjacent panels.” JX-0001 at cls. 1, 8, and 20. Claims 1, 20, and 21 of the ’028 patent¹⁹ recite a similar limitation, “an illuminator comprising five panels connected by hinged structures on inner side surfaces of adjacent panels.” JX-0002 at cls. 1, 20, and 21. Respondents argued before the ALJ that Larsen individually or in view of Hente²⁰ discloses this limitation. Respondents’ Post-Hearing Brief at 41-47.

¹⁹ The FID erroneously includes claim 16 of the ’028 patent in the list of independent claims that contain one of the “hinges on inner side surfaces” limitation. However, as Complainant correctly points out, claim 16 recites only “hinged structures to allow continuous illumination across the five panels.” CRPFR at 19-20 n.4.

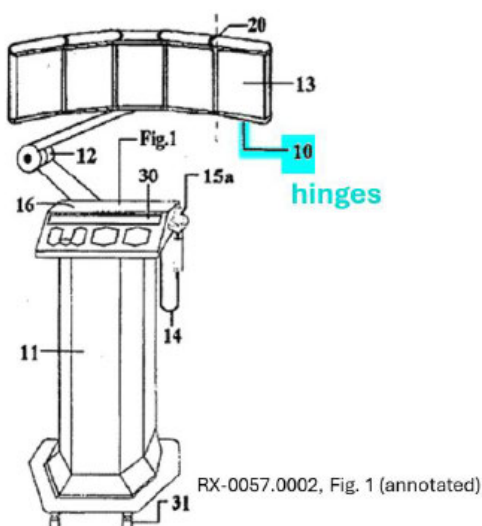
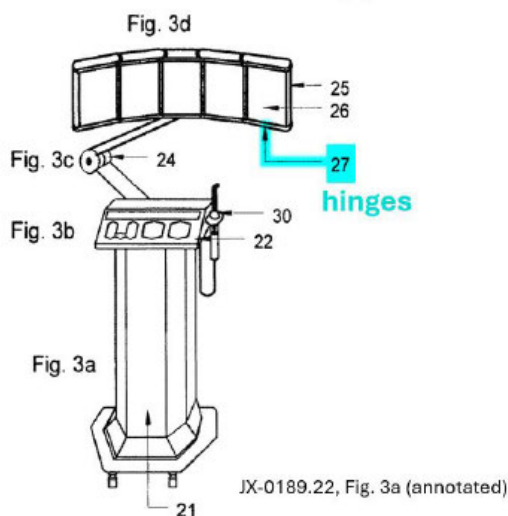
²⁰ U.S. Patent Publication No. 2010/0118522 to Hente.

PUBLIC VERSION

The FID first finds that Larsen individually does not disclose this limitation. FID at 94. The FID explains that in Figure 1 of Larsen, which Respondents rely on for this limitation, element “10” is identified as “hinges,” but the hinges are located on the bottom of the panels, not on inner side surfaces:

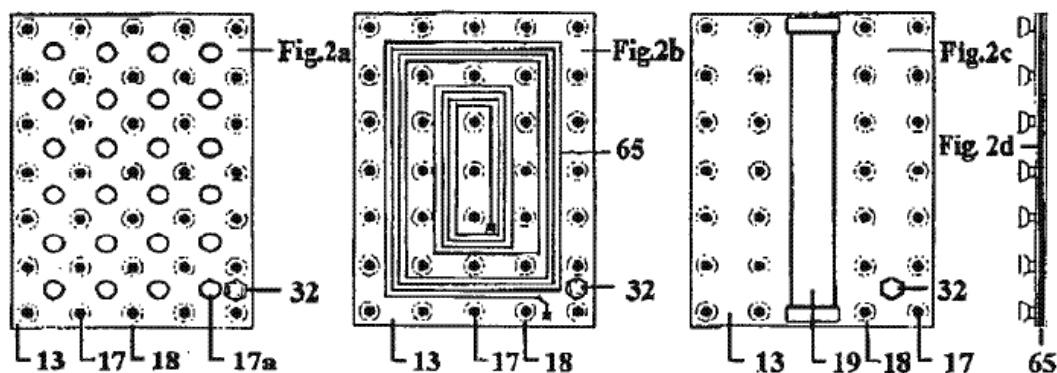


Id. at 94-95 (citing RX-0057 at FIG. 1). Respondents argued that element “10” is a typographical error, and that the patent application meant to identify element “20” as the nested hinges on inner side surfaces of adjacent panels. Respondents’ Post-Hearing Brief at 96. However, the FID finds this argument unpersuasive, because in another patent application, Larsen identifies the exact same structure at the bottom of the panels as “hinges”:

Figure 1 of Larsen**Figure 3d of the Larsen Australian Application**

Id. at 96 (citing RX-0057.9992 and JX-0189.22, Fig. 3A).

The FID also explains that element “20” in Figure 1 of Larsen cannot be the hinges, because the dotted lines in Figure 1 indicate that there is a more detailed view of that portion of the claimed invention, which is depicted in Figures 2A through 2D:



Id. at 97 (citing RX-0057 at FIGS. 2A-2D). While none of the structures in these four images are labeled “20,” the FID explains that “a skilled artisan would not expect there to be, because Figure 1’s dotted line indicates a more detailed view shown in those figures.” *Id.* at 97-98. The FID acknowledges that both “10” and “20” could be typos, but in that case, the combined typographical errors make “hinges 10” less likely to be an obvious error amenable to be

“mentally substituted” for the correct information. *Id.* at 98. The FID also notes that Respondents’ expert “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.” *Id.* This is further underscored by the FID’s observation that Respondents’ expert “admitted that Larsen does not describe in detail any hinges.” *Id.* at 99. The FID also rejects Respondents’ expert testimony that “the most logical location for hinges” is between the panels of the PDT device, characterizing that testimony as “conclusory” and “absent from [the expert’s] witness statement. *Id.* at 100.

Regarding the combination of Larsen in view of Hente, the FID notes that Respondents’ expert also admitted that “Hente does not disclose hinges in any detail.” *Id.* (citing Tr. (Grove) at 585:8-12). The FID rejects Respondents’ argument that “even absent a disclosure, it was obvious to place hinges located on inner side surfaces,” because Respondents did not explain any motivation to “place hinges on inner side surfaces, as opposed to another location.” *Id.* On the contrary, the FID finds that “persons of ordinary skill would be discouraged from placing hinges on the inner side because that would impede the panels from being flush, create gaps, and affect uniformity.” *Id.* at 99-100. The FID also finds Respondents’ expert testimony unpersuasive because “it conflicts with [the expert’s] noninfringement testimony on hinges ‘on inner side surfaces.’” FID at 101 n.8 (citing Tr. (Grove) at 562:7-563:9).

Finally, as to Hente, the FID finds that Respondents “fail[] 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,’” not on inner side surfaces of adjacent panels. *Id.* at 102. The FID explains that these hinges, which are slightly in front of the panels, would “impede light from the front surfaces” and block the claimed invention’s aim of uniform lighting. *Id.* The hinges in



On review, the Commission affirms the FID’s finding that Respondents did not meet their burden to show by clear and convincing evidence that the “hinges” limitations are disclosed by Larson individually or by the combination of Larsen and Hente. The Commission acknowledges that the FWD finds otherwise. FWD at 22-26. However, there are several material differences in the record before the Commission and the record before the PTAB. First, the FID’s findings are based in part on finding that Respondents’ expert testimony was both conclusory and absent from his witness statement (FID at 100), which does not appear to have been an issue in the FWD. Second, Hente was not before the PTAB, and Respondents did not meaningfully dispute that Hente discloses hinges only on the outer edges of the panels, rather than on inner side surfaces as required. RPFR at 38. Third, the FID’s findings are based in part on finding that Respondents’ expert testimony regarding invalidity conflicts with his testimony regarding infringement (FID at 101 n.8), which was not (and could not be) an issue in the FWD. As Complainant explained in its submission regarding the FWD, this particular testimony was obtained during the cross-examination of Respondents’ expert, whereas the PTAB considered

only written declarations from the experts, rather than live testimony subject to cross-examination. Compl. PTAB at 8-9. Finally, Respondents provided supplemental testimony before the PTAB to refute Complainant's argument that hinges on the inner side surfaces would introduce gaps, and as the FWD acknowledged, this supplemental testimony was not presented before the Commission. FWD at 25 n.9. Thus, based on the record before the Commission, the Commission affirms the FID's finding that Respondents did not meet their burden as to the "hinges" limitations by clear and convincing evidence.

4. "Continuous Illumination"

Claim 20 of the '512 patent and claim 16 of the '028 patent require that the hinges be configured to "allow continuous illumination across the at least five panels." JX-0001 at cl. 20; JX-0002 at cl. 16. The FID rejects Respondents' argument that Larsen discloses this limitation, finding instead that Larsen "never teaches that its hinges 'allow for minimization of the gap between panels' to 'allow continuous illumination.'" FID at 102. The FID characterizes Respondents' arguments as "attorney argument," noting that Respondents' expert admitted that "in Figure 1 of Larsen, you can't actually see what Larsen's hinges look like." *Id.* (citing Tr. (Grove) at 563:1-5). Without a description of the hinges, the FID concludes that "Larsen cannot teach those hinges 'allow continuous illumination across the five panels.'" *Id.* Furthermore, the FID notes, Respondents' expert in the '028 patent *inter partes* review ("IPR") proceeding, Dr. Bretschneider, confirmed that "Larsen cannot have 'continuous illumination' because it has 'lower irradiance regions at the junction of two of Larsen's panels.'" *Id.* at 103 (citing JX-0188.66 (Bretschneider IPR Declaration)). Accordingly, the FID finds that Respondents failed to meet its burden as to this limitation. *Id.*

On review, the Commission affirms the FID's finding that Respondents did not meet their burden to prove by clear and convincing evidence that Larson teaches the "continuous

illumination” limitation. The Commission acknowledges that the FWD finds otherwise. FWD at 44-47. However, the FID’s findings are based on testimony that was presented during live cross-examination of Respondents’ expert during the hearing; this testimony was not available to the PTAB. FID at 102. Similarly, the FWD relies in large part on testimony from the oral argument held before the PTAB, which was not available to the Commission. FWD at 44-45. Thus, applying the clear and convincing standard of proof required for a finding of obviousness before the Commission, the Commission affirms the FID’s finding that Respondents did not satisfy their burden to prove by clear and convincing evidence the “continuous illumination” limitation.

5. “Recess” and “recess location”

Claim 17 of the ’512 patent requires that “at least one panel includes a recess configured to receive a flange of one of the nested hinges.” JX-0001 at cl. 17. Claim 18 further requires that “the recess is positioned at an inner side surface of the at least one panel.” *Id.* at cl. 18. Respondents argued before the ALJ that the combination of Lundahl,²¹ Larsen, Hente, and Perutz²² disclose these two limitations.²³ FID at 116-17.

The FID finds that Respondents’ expert, Dr. Grove, “admits that Hente does not disclose hinges ‘in any detail.’” *Id.* at 117. Furthermore, the FID finds that “Hente does not disclose a nearly flushed arrangement, nested hinges that fit on inner side surfaces of adjacent panels, a flange, or a recess.” *Id.* Furthermore, the FID states that “a skilled artisan would not place

²¹ U.S. Patent No. 6,223,071.

²² U.S. Patent No. 4,823,858.

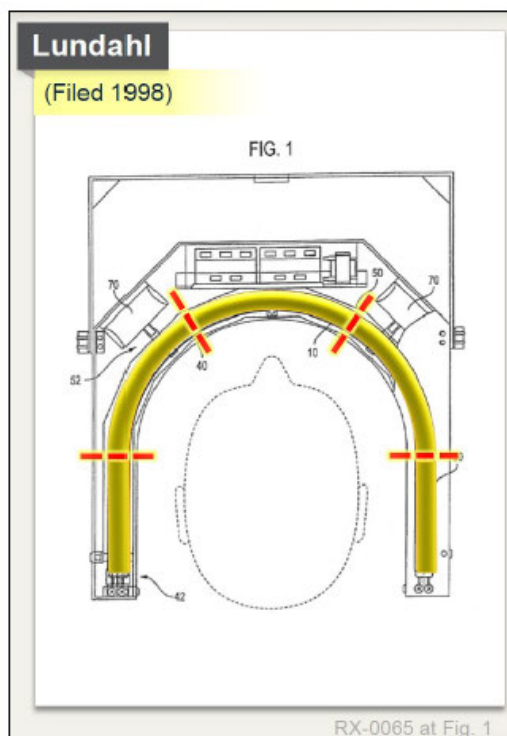
²³ Respondents initially argued that the combination of Lundahl, Larsen, and Hente (without Perutz) disclose these claim limitations, but indicated in their petition for review that they are withdrawing this ground. RPFR at 41.

[hinges] on Hente's rims or side surfaces because that would block light flowing through them, contrary to Hente's explicit teachings." *Id.* at 118. Although the FID is silent as to whether Perutz discloses this limitation, the FID also finds that claims 17 and 18 are not obvious in view of the combination of Lundahl, Larsen, Hente, and Perutz because: (1) Hente and Perutz are not analogous art; (2) the hinge design in Hente is not suitable for combination with medical devices such as those disclosed in Lundahl and Larsen; and (3) Respondents failed to establish a "known industry need" for recesses on the inner side surfaces of the panels. *Id.* at 122-24.

On review, the Commission affirms the FID's finding that Respondents failed to meet their burden to prove that the combination of Lundahl, Larsen, Hente, and Perutz discloses the "recess" and "recess location" limitations. The Commission clarifies that the parties do not dispute that Perutz discloses these limitations. *See* Complainant's Identification of Undisputed Claim Limitations Pursuant to Ground Rule 14.1 at 4. However, the Commission agrees with the FID's finding that Respondents nonetheless failed to meet their burden because Respondents did not show by clear and convincing evidence that there is a motivation to combine these four references to arrive at the "recess" and "recess location" limitations. As the FID correctly explains, Perutz is not analogous art because "[i]t is simply a connection of display panels," and "has nothing to do with illuminators." FID at 123. Furthermore, the problem the inventors of the '512 patent were addressing "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." *Id.* at 123 (citing CX-0014C (Jokerst Rebuttal Witness Statement) at Q/A 552). Accordingly, the Commission affirms the FID's finding that Respondents have failed to show by clear and convincing evidence that the combination of Lundahl, Larsen, Hente, and Perutz discloses the "recess" and "recess location" limitations.

6. “Higher intensity proximate”

Claims 1, 16, 20, and 21 of the '028 patent and claims 1, 8, and 20 of the '512 patent (*i.e.*, all asserted independent claims) contain the limitation “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.” FID at 109. Respondents argued that Lundahl discloses the “higher intensity proximate second edges” portion of the limitation, and Larsen discloses the “five panels” portion of the limitation. *Id.* (citing Respondents’ Post-Hearing Brief at 56-61). Respondents proposed that this combination involves breaking the single curved panel of Lundahl into five individual panels:



Respondents’ Post-Hearing Brief at 60.

The FID finds that “[i]t is undisputed that neither Larsen nor Lundahl teaches the full limitation.” FID at 109. The FID also finds that this combination does not disclose the claim

limitation for several reasons. *Id.* First, the FID credits the testimony of Complainant’s expert, Dr. Jokerst, that, in Larsen, it is the longer edges, not the shorter edges, that emit a higher intensity of light. *Id.* Second, the FID finds that breaking Lundahl’s device into five panels “introduces additional edges and gaps which create optical dead spaces that in turn reduce uniformity of light.” *Id.* at 110. The FID further finds that Respondents arguments amount to improper hindsight because they “cherry pick parts of the art” without considering the impact of combining the two references, such as the additional optical dead space that would result from breaking Lundahl into five pieces. *Id.* at 111. Third, the FID finds that the combination fails to meet the whole limitation of “each of the five panels” having higher intensity near the shorter edges, because only the center panel would have higher intensity at the top and bottom (*i.e.*, shorter edges). *Id.* at 112. The FID explains that in Lundahl, “only the more uniform center portion of the tube output is used for patient treatment,” and accordingly, only the center panel meets the requirement of higher intensity at the top and bottom, rather than a higher intensity of light along the shorter edges of each of the five panels, as required by the claims. *Id.* The FID also points to the “scan engine” in Larsen, which would also contribute to a higher intensity of light only at the center of the device. *Id.* at 114. Accordingly, the FID finds that the combination of Larsen and Lundahl does not disclose the entire scope of the claim limitation. *Id.*

On review, the Commission affirms the FID’s finding that Respondents failed to show by clear and convincing evidence that the combination of Lundahl and Larsen discloses the “higher intensity proximate” limitation. The Commission acknowledges that the FWD finds otherwise. FWD at 31-33. As Complainant explained, Respondents presented different arguments before the PTAB and before the ALJ regarding this limitation. Compl. PTAB at 18. For example, before the Commission, Respondents relied on Larsen’s “scan engine,” but Respondents did not

raise this argument before the PTAB. In addition, the FWD's findings are based in part on testimony that was not presented before the Commission. FWD at 31 n.13 (referencing additional testimony regarding reduced emission areas). Accordingly, based on the record before the Commission and considering the higher standard of proof for a finding of obviousness before the Commission, the Commission affirms the FID's finding that Respondents did not show by clear and convincing evidence that Larsen and Lundahl disclose the "higher intensity proximate" limitation.

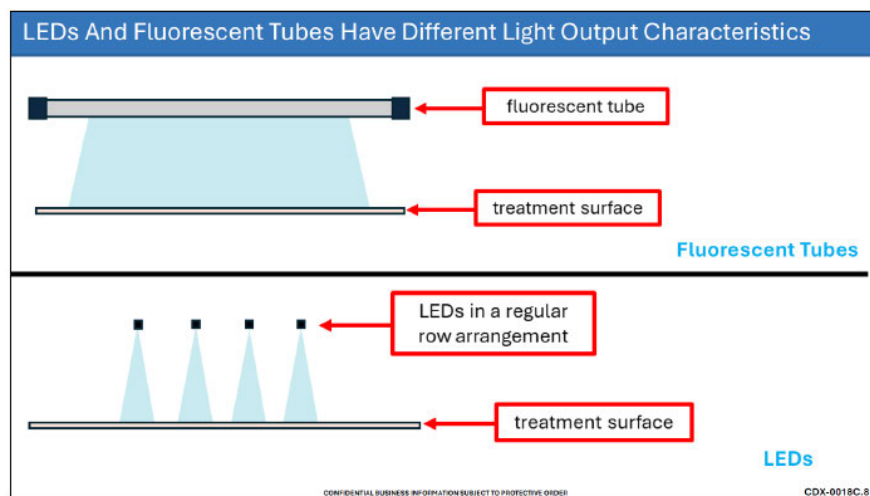
7. "Uniform illumination"

Claims 1, 16, 20, and 21 of the '028 patent and claims 1, 8, and 20 of the '512 patent (*i.e.*, all asserted independent claims) require that the panels of the claimed invention "uniformly illuminate the treatment surface." The ALJ construed (and neither party disputes) "uniformly illuminate" to mean "irradiating light over the active emitting area such that the measured irradiance at a treatment surface of the patient is at least within 60 percent of the measured maximum." Order No. 18 at 13.

The FID finds that Lundahl and Larsen do not disclose the "uniform illumination" limitation. FID at 103. The FID finds that Lundahl offers a "single uniformity measurement of a 'preferred embodiment of the present invention' that achieved this uniformity level only with Lundahl's integrated fluorescent system." *Id.* at 104. The FID also finds that the uniformity measurement of Lundahl relies on "U-shaped tubes with precise spacing, reflectors, and the specific cooling and electrical system" disclosed in Lundahl. *Id.* However, the FID notes that the hypothetical combination of Lundahl and Larsen makes several changes to the system disclosed in Lundahl, such as replacing Lundahl's fluorescent tubes with Larsen's LED lights, dividing Lundahl's single U-shaped tube into five separate panels, and removing Lundahl's cooling system, electrical system, and reflectors, while keeping Lundahl's vertical tube spacing

for the LEDs. *Id.* The FID finds that the combination improperly amounts to hindsight reconstruction to “pick and choose among isolated disclosures in the prior art.” *Id.* (citing *In re Fine*, 837 F.2d 1071, 1075 (Fed. Cir. 1988)). Furthermore, the FID notes that Respondents’ expert could not prove that the combined system satisfied the 60 percent illumination requirement. *Id.*

The FID also rejects Respondents’ argument that “the spacing of lights alone provided the desired uniformity.” *Id.* at 105 (citing Respondents’ Post-Hearing Brief at 33). Specifically, the FID finds that “one cannot assume identical illumination” in the resultant combination of Lundahl (with fluorescent lights) and Larsen (with LED lights) because the two light sources have different light distribution patterns, as shown below:



Id. at 106 (citing CDX-0018C.81). As the FID explains, “[f]luorescent 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.” *Id.* (citing CX-0014C at Q/A 273-74). The FID also finds that inventor testimony underscores how challenging it was to achieve uniform illumination with LED lights. *Id.* at 107 (citing Tr. (Boyajian) at 76:15-77:21). The FID finds that Respondents

ignored these challenges in the resultant combination and did not provide any evidence to show that changing several of the properties of Lundahl would still maintain 60 percent uniformity. *Id.* at 108. Furthermore, the FID finds that Respondents waived their argument that “all other features other than the U-shape and spacings are ‘rendered unnecessary once fluorescent tubes are replaced by superior LED technology.’” *Id.* at 105.

The FID also finds that Respondents provided no motivation to combine Lundahl and Larsen, or a reasonable expectation of success in being able to combine Lundahl and Larsen, to increase flexibility. The FID finds that there were numerous structural differences between Lundahl and Larsen that would make it challenging to combine the two references. *Id.* at 118-22. The FID also finds that there was no reasonable expectation of success in combining Lundahl and Larsen, because Respondents “ignore the challenges of achieving uniform illumination using LEDs” and because Respondents’ expert “previously claimed achieving uniformity would require ‘undue experimentation.’” *Id.* at 122 (citing Tr. (Grove) at 579:15-25).

On review, the Commission affirms the FID’s finding that Respondents failed to show by clear and convincing evidence that the combination of Lundahl and Larsen discloses the “uniform illumination” limitation. The Commission acknowledges that the FWD finds otherwise. FWD at 26-29. However, as Complainant explained, the FWD “expressly acknowledge[s] its divergence from the [FID] on this element based on the lower standard of proof at the PTAB.” Compl. PTAB at 12; FWD at 27 n.10. Furthermore, the FWD considers an additional declaration from Respondents’ expert, as well as additional testimony during the hearing, that is not in the record before the Commission. Compl. PTAB Response at 8; Compl. PTAB at 14. The Commission has reviewed the FWD’s findings and notes that this additional evidence was presented in response to Complainant’s argument about the light distribution

patterns. *See* FWD at 27-29. By contrast, Complainant’s argument and evidence regarding the light distribution pattern remains unrefuted before the Commission, and, accordingly, the evidence in the record before the Commission supports the FID’s finding that incorporating LED lights would result in a light distribution pattern that is not uniform. FID at 106. Finally, the ALJ expressly construed the “uniform illumination” limitation, and the FID’s analysis is based on that undisputed construction. By contrast, the FWD declined to expressly construe claim terms, including the “uniform illumination” claim term. FWD at 13 n.7. Thus, based on the record before the Commission and considering the higher standard of proof for a finding of obviousness before the Commission, the Commission affirms the FID’s finding that Respondents failed to show by clear and convincing evidence that the combination of Lundahl and Larsen discloses the “uniform illumination” limitation.

8. Motivation to Replace Fluorescent Tubes with LED Lights

The combination of Lundahl and Larsen requires replacing the fluorescent tubes in Lundal with the LED lights disclosed in Larsen. FID at 105-07; 121. The FID finds that Respondents argued for the first time in their post-hearing brief that there was a motivation to replace the fluorescent tubes of Lundahl with the LED lights of Larsen “because of supposed safety concerns,” and accordingly waived that argument. FID at 121 (citing Respondents’ Post-Hearing Brief at 77-79). The FID also finds that Respondents’ cited expert testimony does not support this new theory. *Id.*

On review, the Commission affirms with supplemental reasoning the FID’s finding that a skilled artisan would not have been motivated to replace Lundahl’s fluorescent tubes with Larsen’s LED lights. The Commission agrees with the FID that Respondents waived their argument regarding safety concerns, but Respondents made several other arguments that the FID does not address.

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Respondents presented four arguments in their pre-hearing brief concerning why a person of ordinary skill would be motivated to switch Lundahl's fluorescent lights for Larsen's LED lights: (1) LEDs have a lower cost and last longer than fluorescent lights; (2) fluorescent lights have inconsistent output; (3) the narrower output spectrum of LEDs allows for an illuminator with an output wavelength ideally matched to an absorption band of the photosensitizer; and (4) fluorescent lights were becoming obsolete in response to "regulatory pressures." *See* Respondents' Pre-Hearing Brief at 160-61. However, in their post-hearing brief, Respondents advanced a somewhat different set of arguments: (1) as to performance, fluorescent tubes have low output areas (*i.e.*, inconsistent output); (2) fluorescent tubes are temperature sensitive and lose output when they get too hot or cold; (3) there were numerous safety issues with fluorescent lamps that were known at least as early as 2008; (4) fluorescent lights were becoming obsolete due to the increased safety concerns; and (5) several factors were leading to LEDs becoming favored alternatives, including "higher efficiencies, longer lifetimes . . . the relatively narrow output spectrum of LEDs [that] allows more precise tailoring of output wavelength to the absorption band of a photosensitizer," in addition to "their costs came down and had become the industry preferred light source . . . by the early 2010s." *See* Respondents' Post-Hearing Brief at 77-78. Accordingly, Respondents have preserved their arguments that persons of skill in the art would have been motivated to replace the fluorescent lights with LEDs due to longer lifespan, lower cost, improved performance regarding low output areas, and the narrow output spectrum of LEDs.

Nevertheless, the Commission finds that Respondents failed to meet their burden with respect to these arguments. Respondents' arguments about lifespan, cost, improved performance, and the output spectrum of LEDs are conclusory and underdeveloped. Even if

these factors could be seen as motivating factors, Respondents did not meaningfully discuss why any of these factors would outweigh the light distribution issue that Complainant raised, and Respondents discussed these factors only in passing. Respondents have ignored the different light distribution patterns of fluorescent lights and LEDs. *See* CRPFR at 59-60. This difference is critical to the claimed invention of the Asserted Patents, where one of the primary goals was to design a device that maintains uniform illumination across all five panels. *See, e.g.,* JX-0001 at 2:50-62 (“[I]t is an object of some embodiments of the present invention to reduce or eliminate these dead spaces and provide for a more uniform light distribution in an adjustable illuminator designed for PDT or PD of a variety of areas . . . Thus, a uniform light may be delivered to a targeted treatment area regardless of the shape and location of the contoured surface of the body.”). Given the shortcomings in Respondents’ arguments, including their failure to address the light distribution issue, the Commission is not persuaded that Respondents have shown by clear and convincing evidence that a person of ordinary skill would have been motivated to replace Lundahl’s fluorescent lights with Larsen’s LED lights.

The Commission acknowledges that the FWD finds otherwise. FWD at 19-21. However, before the PTAB, Complainant did not dispute that Respondents showed by a preponderance of evidence that a skilled artisan would be motivated to combine Lundahl and Larsen, which contributed to the FWD’s findings on motivation to combine. *Id.* at 21. That is not the case here, where Complainant has consistently disputed motivation to combine. Furthermore, the FID’s finding relies on cross-examination testimony from the hearing before the ALJ; by contrast, Respondents’ expert testimony was not subject to cross-examination before the PTAB. Compl. PTAB at 10-11.

In addition, the motivation to replace fluorescent lights with LEDs is only a portion of the

overall determination as to whether a person of ordinary skill would have been motivated to combine Larsen and Lundahl. For example, another aspect of combining Larsen and Lundahl involves breaking Lundahl's single U-shaped panel into the five separate panels disclosed in Larsen. FID at 107. The Commission agrees with the FID's finding that a skilled artisan would not have been motivated to break Lundahl's panel into five separate panels, which would introduce gaps and impact uniform illumination. *Id.*; *see also id.* at 118-121 (discussing a lack of motivation to increase flexibility); 121-22 (discussing no reasonable expectation of success in combining Lundahl and Larsen). Accordingly, the Commission affirms the FID's finding that Respondents have not shown by clear and convincing evidence that a skilled artisan would have been motivated to combine Lundahl and Larsen based on a motivation to replace fluorescent tubes with LEDs.

The Commission adopts the remainder of the FID's findings regarding obviousness that are not inconsistent with this opinion. Accordingly, the Commission affirms the FID's overall finding that none of the asserted claims of the '028 patent and the '512 patent are invalid as obvious under 35 U.S.C. § 103.

C. Economic Prong of the Domestic Industry Requirement

When a section 337 investigation is based on allegations of patent infringement, the complainant must show that "an industry in the United States, relating to the articles protected by the patent . . . exists or is in the process of being established." 19 U.S.C. § 1337(a)(2). "[A]n industry is considered to exist if there is in the United States, with respect to the articles protected by the patent . . . concerned –

- (A) significant investment in plant and equipment;
- (B) significant employment of labor or capital; or

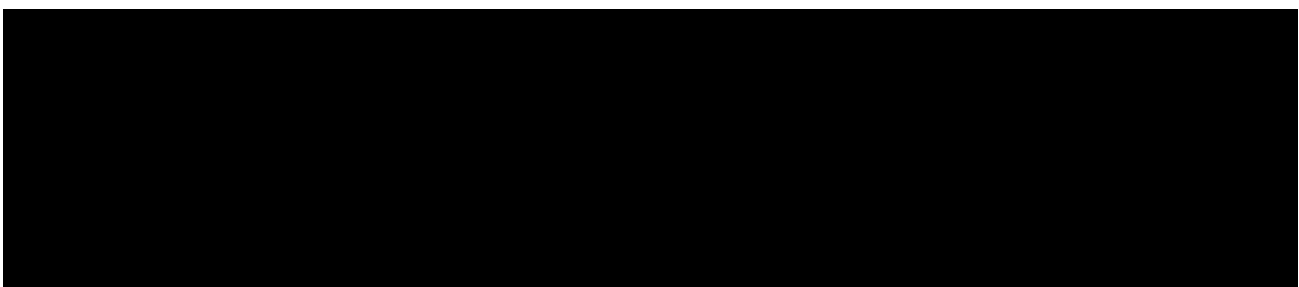
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(C) substantial investment in its exploitation, including engineering, research and development, or licensing.” 19 U.S.C. § 1337(a)(3).

The ALJ granted in part Complainant’s motion for summary determination that it satisfied the economic prong of the DI requirement under section 337(a)(3)(B).²⁴ Order No. 23 at 3. The ALJ found that Complainant has satisfied the economic prong of the DI requirement based on “internal labor expenditures, including regulatory (\$ [REDACTED]) and research and development (\$ [REDACTED]) labor,” totaling approximately \$ [REDACTED] between January 2021 and June 25, 2024. Order No. 23 at 3. The ALJ further found that Complainant’s “R&D employees perform product engineering, electronics technician work, medical science liaison, medical information and medical affairs work, and publications work, and [Complainant’s] regulatory employees perform FDA compliance work, including preparation and submission of documentation to the FDA and facilitating FDA approval for product release.” *Id.* The ALJ also found that “no[ne of Complainant’s] employee[s] that works on the BLU-U® 4170E is located outside of the United States.” *Id.* Although the ALJ found that Complainant’s internal labor expenditures alone satisfy the economic prong of the DI requirement under subparagraph 337(a)(3)(B), the ALJ also considered contractor expenses related to activities in the United States that included design, development, manufacturing, testing, and regulatory activities. *Id.* at 7-11.

Complainant’s expert provided the following breakdown of internal labor expenditures:

²⁴ The ALJ did not reach whether Complainant satisfied the economic prong of the DI requirement under subparagraph 337(a)(3)(C). Order No. 23 at 11 n.2. However, elsewhere in the order, the ALJ stated that Complainant has satisfied the economic prong of the DI requirement under both subparagraphs 337(a)(3)(B) and (C). *Id.* at 3. The latter statement appears to be in error, and the Commission clarifies that it takes no position on whether Complainant satisfied the economic prong of the DI requirement under subparagraph 337(a)(3)(C).



Compl. Mot. at 8. To calculate these figures, each employee's time was allocated based on time spent on the BLU-U 4170E, and that percentage was applied to the respective employees' compensation. Order No. 23 at 3-4.

The ALJ first found that Complainant's investments are significant because 100 percent of those investments are made in the United States and 100 percent of the value added to the DI product is created by domestic investments. *Id.* at 6-7. As the ALJ explained:

[t]here is no genuine dispute with respect to the significance of [Complainant's] investments in research and development, testing, manufacturing services, and regulatory work for the BLU-U 4170E. All of [Complainant's] investments related to the BLU-U 4170E are made in the United States. All of [Complainant's] employees working on R&D and regulatory functions related to the BLU-U 4170E device are located in the United States. All of the [research and development], testing, and regulatory services undertaken by third party contractors . . . that [Complainant] paid for occurs in the United States. All of the manufacturing services [Complainant] paid for . . . occurs in the United States. Thus, 100 [percent] of the value added to the BLU-U 4170E is created by [Complainant's] domestic investments.

Id. (citations omitted). The ALJ indicates separately that Complainant's investments in labor and capital represent a [REDACTED] percent²⁵ reinvestment of revenues from the current BLU-U 4170 device into R&D for the next generation BLU-U 4170E device.

The ALJ also noted that "Respondents do not raise any genuine factual issues concerning [Complainant's] internal labor expenditures related to the BLU-U® 4170E." *Id.* at 5. Rather,

²⁵ Complainant submitted a letter after the ALJ issued its order granting summary determination to correct this percentage. Complainant represents that the correct investment-to-revenue ratio should be [REDACTED] percent, not [REDACTED] percent, as the ALJ inadvertently stated.

Respondents argued only that Complainant's internal labor investments are not significant when compared to Complainant's overall R&D expenditures or when compared to Complainant's investments in its pharmaceutical product Levulan®. *Id.* (citing Resp. Opp. at 14-21). The ALJ rejected both arguments. As to the former, the ALJ explained that a comparison to all of Complainant's R&D expenditures "is not appropriate where a company has a diversified product portfolio[.]" *Id.* at 5. As to the latter, the ALJ noted that "[w]hile Levulan® can be used with the BLU-U® lamps, they are different types of products—one is a pharmaceutical while the other is a medical device. Thus, Levulan ® and the BLU-U® lamps have different revenue structure (recurring versus one-time cost) and development costs." *Id.* at 5-6. Instead, the ALJ explained that "[t]he relevant comparison to determine whether the market for PDT illuminators is significant to [Complainant] is to determine how much of the revenue from the older lamp [Complainant] is reinvesting in its next generation lamp." *Id.* at 6. Based on this method, the ALJ found that Complainant "spent [REDACTED] percent] of its revenues from the BLU-U 4170 on R&D for the BLU-U 4170E, representing a substantial reinvestment of revenues in its next-generation device." *Id.* Based on these findings, the ALJ found that Complainant has satisfied the economic prong of the DI requirement under subsection (B). *Id.* at 8.

On review, the Commission affirms the ALJ's finding that Complainant satisfies the economic prong of the DI requirement for the asserted patents under section 337(a)(3)(B) based on the facts as summarized in Order No. 23, supplementing the ALJ's analysis to consider those facts together based on a holistic review of the record. *Wuhan Healthgen Biotechnology Corp. v. Int'l Trade Comm'n*, 127 F.4th 1334, 1338 (Fed. Cir. 2025) (citing *Lelo Inc. v. Int'l Trade Comm'n*, 786 F.3d 879, 883 (Fed. Cir. 2015)). The ALJ properly considered the record evidence as part of a holistic analysis of whether the Complainant's asserted domestic industry

investments in employment of labor were significant, including by considering the nature of Complainant's regulatory and research and development labor as it relates to the BLU-U 4170E, and that Complainant invested over \$ [REDACTED] in regulatory and research and development work between January 2021 and June 2024. Order No. 23 at 3. Moreover, as the ALJ further found, all of Complainant's employees working on both regulatory and research and development functions related to the BLU-U 4170E and all contractor activities, including manufacturing, are located in the United States, such that "100 [percent] of the value added to the BLU-U 4170E is created by [Complainant's] domestic investments." *Id.* at 7.

Considering these facts together, including that 100 percent of the value added to the BLU-U 4170E is due to Complainant's domestic investments, the Commission finds, consistent with the Federal Circuit's holding in *Wuhan*, that Complainant has satisfied the DI requirement under section 337(a)(3)(B). Specifically, the Federal Circuit has held that, when all investments related to a DI product are made in the United States, such that the domestic value added is 100 percent, that can support a finding that those investments are significant. *Wuhan Healthgen*, 127 F.4th at 1338-39. In *Wuhan*, the Court stated:

It is undisputed that all of [the complainant's] investments and activities related to researching, developing, and commercially producing [the DI product] occurred within the United States Comparing the cost of foreign to domestic manufacturing to determine the percentage of additional value created by DI operations in the final product yields a value added of 100% The investment-to-revenue ratio can indicate whether an investment is significant and substantial. A high ratio signals the company is investing heavily in the industry despite comparatively low revenue, highlighting the industry's importance and value to the company, which can be predictive of a significant market.

Id. (internal citations omitted).

The Commission notes that Respondents did not specifically petition for review of the ALJ's finding that Complainant's investments are significant because all of its investments were

made in the United States, nor do Respondents dispute any of the facts on which the ALJ's analysis relies.

In view of the ALJ's quantitative and qualitative findings, including that Complainant made over \$ [REDACTED] in domestic investments in employment of labor related to regulatory and research and development activities related to the BLU-U 4170E, and that all of Complainant's investments were made in the United States such that 100 percent of the value added is created by Complainant's domestic investments, the Commission finds that Complainant has satisfied the economic prong of the DI requirement based upon significant investment in employment of labor under subsection 337(a)(3)(B). The Commission takes no position on the ALJ's additional finding that Complainant's [REDACTED] percent investment-to-revenue ratio between the old BLU-U 4170 device and the next generation BLU-U 4170E device is significant.²⁶

D. Summary

On review, the Commission affirms the ALJ's construction of "nested hinges" with modified reasoning. The Commission also affirms, with modified and additional reasoning, the FID's findings that none of the asserted claims of either the '028 patent or the '512 patent are invalid as obvious. The Commission further affirms the ALJ's finding with modified reasoning that Complainant has satisfied the economic prong of the DI requirement under section 337(a)(3)(B).

²⁶ Chair Karpel further finds that the ALJ's additional finding regarding the [REDACTED] percent investment-to-revenue ratio supports finding that Complainant satisfied the economic prong of the DI requirement under a holistic approach. As the ALJ found, Complainant reinvested [REDACTED] percent of its revenue from the BLU-U 4170 device into the next generation 4170E device. Chair Karpel finds that fact together with other relevant facts as reviewed above supportive, under a holistic approach, of a finding that Complainant has satisfied the economic prong under section 337(a)(3)(B). Additionally, Chair Karpel observes that Respondents did not argue that Complainant's [REDACTED] percent investment-to-revenue ratio is insignificant or that such a comparison is inappropriate. Rather, Respondents argued only that other comparisons should be used, but the ALJ properly rejected those arguments. Order No. 23 at 5-7.

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The Commission previously determined not to review the FID’s findings that: (1) the RhodoLED XL, alone or in combination with Ameluz, infringes all asserted claims of both the ’028 patent and the ’512 patent (FID at 18-26; 53-77); (2) the asserted claims of the Asserted Patents have written description support and are enabled (FID at 124-142); and (3) Complainant has satisfied the technical prong of the DI requirement for both Asserted Patents (FID at 43-53; 77-90). 91 Fed. Reg. at 4630-31. Accordingly, the Commission finds that Complainant has shown a violation of section 337 by each of the Respondents with respect to claims 1, 3, 5, 8, 17-18, and 20 of the ’512 patent and claims 1, 2, 4, 16, 17, and 19-21 of the ’028 patent.

V. REMEDY, THE PUBLIC INTEREST, AND BONDING

A. Remedy

The Commission has “broad discretion in selecting the form, scope, and extent of the remedy.” *Philip Morris Products S.A. v. Int’l Trade Comm’n*, 63 F.4th 1328, 1339-1340 (Fed. Cir. 2023).

1. 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).

Here, the RD recommends issuing an LEO as to Respondents, and further recommends that the LEO include Ameluz. RD at 145. The RD further recommends that the LEO include a “narrowly tailored exemption . . . for legitimate service and repair functions covered by warranty for existing users[.]” *Id.* The RD also recommends including a standard certification provision

to allow Respondents to import Ameluz for non-infringing purposes, such as use with their non-infringing PDT device. *Id.* at 145-46.

Complainant supports the RD's recommendation for an LEO that includes Ameluz used in conjunction with the RhodoLED XL. Compl. RBPI at 3. Complainant also agrees with a narrowly tailored exemption for legitimate service and repair functions covered by warranty for existing users, as well as the inclusion of a standard certification provision. *Id.* at 3-4.

Respondents agree the Commission should issue an LEO including a standard certification provision and a service, warranty, and repair exemption. Resp. RBPI at 5. However, Respondents argued that Ameluz should be excluded entirely from the LEO. *Id.* Respondents explained that "Ameluz is used with non-accused products, *i.e.*, the BF-RhodoLED, which is not within the scope of the investigation." *Id.* at 6; *see also* Resp. RBPI Response at 2.

Complainant contended that the proper response to Respondents' argument regarding non-infringing uses of Ameluz is to include a standard certification provision, rather than exclude Ameluz from remedial orders entirely. Compl. RBPI at 3-4.

As to the service and repair exemption, Respondents explained that they provide a "three-year warranty including replacement, service, and repair of their RhodoLED XL," and Respondents' "warranty covers any issue during the warranty period." Respondents' Post-Hearing Brief at 109; Resp. RBPI at 8. Respondents' Chief Financial Officer also testified that Respondents offer both a "manufacturer's warranty" and an "extended warranty," and further testified that Respondents are "obligated to repair or replace defective equipment" under warranty. RX-0003C at Q/A 54-55. As part of their process for a repair or replacement, Respondents "will determine if the unit is under warranty—either manufacturer's warranty or extended warranty." *Id.*

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The Commission has determined to issue an LEO against each of the Respondents that includes Ameluz intended for use with RhodoLED XL. The Commission has further determined to include a standard certification provision and a narrowly-tailored exemption to allow the importation of infringing devices and components necessary for service and repair functions, as well as replacements covered by warranty, for devices that have been purchased by U.S. consumers before the expiration of the period of Presidential review of the orders (19 U.S.C. § 1337(j)).²⁷ As the Commission has previously explained, a standard certification provision “allows an importer to certify to Customs that such product has been adjudicated as not excluded from entry under the terms of the LEO.” *See Certain Composite Aerogel Insulation Materials & Methods for Manufacturing the Same*, Inv. No. 337-TA-1003, Comm’n Op., 2018 WL 8648369, at *40 (Feb. 22, 2018). If Respondents intend to import Ameluz for non-infringing purposes, such as for use with its non-infringing PDT device, it may do so by certifying that any such imports of Ameluz are intended for use in a non-infringing manner, which addresses Respondents’ concern that it would be barred from importing Ameluz for use with its non-infringing device.

²⁷ Consistent with his views in past investigations, including Investigation Nos. 337-TA-1400 and 337-TA-1398, Commissioner Kearns would limit the exemption to repair of those devices that were purchased by U.S. consumers prior to the issuance of the remedial orders. *See Certain Cameras, Camera Systems, and Accessories Used Therewith*, Inv. No. 337-TA-1400, Comm’n Op., 2026 WL 747236, *22 n.24 (Mar. 12, 2026); *Certain Smart Wearable Devices, Sys., & Components Thereof*, Inv. No. 337-TA-1398, Comm’n Op., 2025 WL 2603366, *4 n.4 (Sept. 5, 2025). Commissioner Kearns notes that Respondents are on notice of the remedial orders upon issuance of the orders, and therefore, if Respondents sell infringing devices to U.S. consumers after that date, including during the period of Presidential review, they should bear the risk that they may later be unable to repair any defective devices or that they may have to replace them with non-infringing alternatives.

2. Cease and Desist Orders

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 (“CDO”) as a remedy for violation of section 337. *See* 19 U.S.C. § 1337(f)(1). CDOs are generally issued when, with respect to the imported infringing products, respondents maintain commercially significant inventories in the United States or have significant domestic operations that could undercut the remedy provided by an exclusion order. *See, e.g., Certain Tobacco Heating Articles and Components Thereof*, Inv. No. 337-TA-1199, Comm’n Op. at 49 (Sept. 29, 2021), *aff’d*, *Philip Morris Products S.A.*, 63 F.4th at 1332; *Certain Audio Players and Controllers, Components Thereof, and Products Containing Same*, Inv. No. 337-TA-1191, Comm’n Op. at 26 (Jan. 6, 2022), *aff’d*, *Sonos, Inc. v. Int’l Trade Comm’n*, 2024 WL 1507605 (Fed. Cir. Apr. 8, 2024). Complainants bear the burden on this issue. “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.” *Tobacco Heating Articles*, Comm’n Op. at 49-50 (citations omitted); *Audio Players*, Comm’n Op. at 26-27 (citations omitted); *see also* H.R. REP. No. 100-40, at 160 (1987).

The RD recommends issuing a CDO to each Respondent. RD at 147. The RD finds that “[t]he evidence shows that [Respondents maintain] a commercially significant U.S. inventory of RhodoLED XL.” *Id.* Specifically, the record shows that Respondents held [REDACTED] RhodoLED XL units in U.S. inventory, with an additional [REDACTED] units on order. *Id.* The RD also recommends including a narrowly tailored exemption for functions covered by warranty, as well as including a standard certification provision. *Id.* The RD also recommends 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.” *Id.*

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Complainant agrees with the RD's recommendation to issue CDOs to each Respondent. Compl. RBPI at 4. Complainant also agrees with a narrowly tailored exemption for legitimate service and repair functions covered by warranty. *Id.* at 4-5. Complainant also states that Ameluz should be included in the CDOs, subject to certification, as "[Respondents' chief financial officer] admitted to the commercial significance of Ameluz, stating that in terms of sales, Ameluz is [Respondents'] main product." *Id.* Complainant also stated that Respondents' CFO "admitted the commercial significance of Ameluz, stating that in terms of sales, Ameluz is [Respondents'] main product." Compl. RBPI Response at 6. Similarly, Complainant noted that Respondents admitted that it "maintains inventory for Ameluz," and that it "sells from its existing inventory." *Id.* Respondents argue that a CDO should not issue against any of the Respondents because Complainant "failed to show that one is necessary to avoid circumvention of any issued LEO." Resp. RBPI at 8. Respondents also reiterate their argument that Ameluz should be excluded from the remedial orders. *Id.* at 9.

The Commission has determined to issue CDOs against each of Respondents, and that the CDOs should cover Ameluz intended for use with the RhodoLED XL. The Commission has also determined to include a standard certification provision and a narrowly tailored exemption for service and repair functions, as well as replacements covered by warranty, for devices that have been purchased by U.S. consumers before the expiration of the period of Presidential review of the orders (19 U.S.C. § 1337(j)).²⁸ As with the LEO, the standard certification provision would allow Respondents to import Ameluz intended for non-infringing uses. The Commission also noted that Respondents do not meaningfully dispute that they have a commercially significant

²⁸ As explained *supra* note 27, Commissioner Kearns would limit the exemption to those devices that were purchased by U.S. consumers prior to the issuance of the remedial orders.

U.S. inventory of RhodoLED XL, and admitted that they have U.S. inventory of Ameluz. *See* CX-0608C (Joint Stipulation of Importation and Inventory); RX-0003C.0004; JX-0010C at 87:16-18; JX-0009C at 106:9-25.

B. Public Interest

Section 337 requires the Commission, upon finding a violation of section 337, to issue an LEO “unless, after considering the effect of such exclusion upon the public health and welfare, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, and United States consumers, it finds that such articles should not be excluded from entry.” 19 U.S.C. § 1337(d)(1). Similarly, the Commission must consider these public interest factors before issuing a CDO. 19 U.S.C. § 1337(f)(1).

Under appropriate facts and circumstances, the Commission may determine that no remedy should issue because of the adverse impacts on the public interest. *See, e.g., Certain Fluidized Supporting Apparatus & Components Thereof*, Inv. Nos. 337-TA-182/188, USITC Pub. 1667, Comm’n Op. at 1-2, 23-25 (Oct. 1984) (finding that the public interest warranted denying complainant’s requested relief); *see Philip Morris Products S.A.*, 63 F.4th at 1339-1340 (the Commission has “wide latitude for judgment and the courts will not interfere except where the remedy selected has no reasonable relation to the unlawful practices found to exist”) (citation omitted). Moreover, when the circumstances of a particular investigation require, the Commission has tailored its relief in light of the statutory public interest factors. For example, the Commission has allowed continued importation for ongoing medical research, exempted service parts, grandfathered certain infringing products, and delayed the imposition of remedies to allow affected third-party consumers to transition to non-infringing products. *E.g., Certain Microfluidic Devices*, Inv. No. 337-TA-1068 Comm’n Op. at 1, 22-48, 53-54 (analyzing the public interest, discussing applicable precedent, and ultimately issuing a tailored LEO and a

tailored CDO); *Certain Road Milling Machines & Components Thereof*, Inv. No. 337-TA-1067, Comm’n Op. at 32-33 (July 18, 2019) (exempting service parts); *Certain Baseband Processor Chips & Chipsets, Transmitter, & Receiver (Radio) Chips, Power Control Chips, & Prods. Containing Same, Including Cellular Tel. Handsets*, 337-TA-543, USITC Pub. No. 4258, Comm’n Op. at 150-151 (Oct. 2011) (grandfathering certain products); *Certain Personal Data & Mobile Comm’n Devices & Related Software*, 337-TA-710, USITC Pub. No. 4331, Comm’n Op., at 72-73, 80-81 (June 2012) (delaying imposition of remedy).

The statute requires the Commission to consider and make findings on the public interest in every case in which a violation is found regardless of the quality or quantity of public interest information supplied by the parties. 19 U.S.C. § 1337(d)(1), (f)(1). Thus, the Commission publishes a notice inviting the parties as well as interested members of the public and interested government agencies to gather and present evidence on the public interest at multiple junctures in the proceeding. 19 U.S.C. § 1337(d)(1) & (f)(1).

1. Public Health and Welfare

Complainant argued that multiple non-infringing alternatives are available for the treatment of actinic keratosis in the United States, including Respondents’ older non-infringing device and an older model of Complainant’s DI product. Compl. RBPI at 8-9. Complainant also noted that “the majority of the relevant patient population is currently using non-infringing alternatives,” including Complainant’s older device and Respondents’ older device. *Id.* at 9. Complainant also argued that there would be little to no impact on the public health and welfare because Respondents’ public disclosures show that the Accused Products have “no impact on the U.S. market,” as Respondents have only sold around [REDACTED] RhodoLED XL devices as of the end of 2024. *Id.* at 8. Complainant also claimed that Respondents themselves have characterized their sales as “mediocre” and stated that sales have “decelerated” since the beginning of 2025. *Id.*

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Respondents argued that remedial orders would impact the public health and welfare because “only Ameluz, in combination with the BF-RhodoLED or RhodoLED XL, is FDA-approved for lesion-directed or field-directed treatment of [actinic keratosis].” Resp. RBPI at 15-16.

Respondents also claimed that the RhodoLED XL is “the only large PDT lamp approved to treat a large area of a patient in field-directed therapy across a wider area in one treatment session.”

Id. at 16. Respondents further claimed that, if Complainant’s DI product is made available, “it would not replace the [Accused Products], since it does not share the same capabilities,” such as emitting red light instead of blue light. *Id.* at 17.

The Commission finds that the remedial orders will have minimal impact on public health and welfare because consumers still have numerous choices available to treat actinic keratosis, including both PDT and non-PDT options. As Complainant explained, PDT lamps are not the only way to treat actinic keratosis: “[p]hysicians routinely treat [actinic keratosis] using lesion-directed PDT, topical chemotherapeutics, cryotherapy, and other accepted modalities.” Compl. RBPI at 11-12. Respondents do not dispute this. Even if Respondents are correct that the RhodoLED XL is the only PDT lamp approved for treating larger areas of lesions, that does not foreclose treatment options altogether. Furthermore, as Complainant explained (and Respondents do not dispute), only around [REDACTED] RhodoLED XL lamps have been sold as of the end of 2024, and sales have been decelerating since the beginning of 2025. Compl. RBPI at 8. Accordingly, this is not a situation where a widely-used medical device would suddenly be unavailable. Respondents’ own CEO admitted that PDT as a whole (which includes both parties’ older and newer devices) only makes up [REDACTED] percent of the market for treating actinic keratosis. *Id.* Accordingly, evidence from both parties shows that the public health and welfare

would not be negatively impacted by issuing remedial orders, because consumers needing treatment for actinic keratosis have numerous other treatment options available.

2. Competitive Conditions in the United States

Complainant reiterates its arguments made with respect to public health and welfare that there are multiple non-infringing articles in existence to treat actinic keratosis, including both parties' older PDT products. Compl. RBPI at 9. Respondents did not directly address this factor in their RBPI briefing.

The Commission finds that issuing remedial orders will not impact competitive conditions in the United States. As Complainant argued, there are multiple non-infringing alternatives for the treatment of actinic keratosis such that excluding the RhodoLED XL will not materially impact competitive conditions, including Respondents' older PDT device and several non-PDT options.

3. The Production of Like or Directly Competitive Articles in the United States

Neither party has presented evidence or argument regarding how any domestic production related to the infringing products, the domestic industry products, or any other PDT devices, would be affected by remedial orders. Complainant claims only that there are "multiple non-infringing alternatives" to the infringing products available in the United States, including Respondents' older non-infringing device and Complainant's BLU-U 4170D device. Compl. RBPI at 8-11. Moreover, Respondents argue only that there are no suitable alternatives to the infringing products, which are FDA-approved for "treatment of a large, dispersed field of actinic keratosis." Resp. RBPI at 19. Neither argument is relevant to whether remedial orders will impact the production of like or directly competitive articles in the United States. Accordingly,

based on the record presented, the relief in this case would not adversely affect the production of like or directly competitive products in the United States.

4. United States Consumers

Complainant argued that there are numerous reasonable alternatives to the RhodoLED XL, including Respondents' own older non-infringing lamp and Complainant's BLU-U 4170 device. Compl. RBPI at 11. Respondents argued only that, without the RhodoLED XL lamp, consumers will have fewer options for field-directed treatment of actinic keratosis. Resp. RBPI at 19.

The Commission finds that U.S. consumers would not be adversely impacted by the remedial orders, because there are multiple non-infringing alternatives to the Accused Products, including both parties' older lamps, and several other non-PDT-based therapies that appear to take up a much larger share of the market. As discussed above, the Commission also grants an exemption for the importation of articles and components for the purpose of service and repair, and replacement under warranty (RX-0003C at Q/A 53-55) of infringing devices purchased prior to the expiration of the Presidential review period. The exemption, recognizing the significant expense of the infringing devices (*see* Resp. RBPI at 11 (noting price of infringing device is \$ [REDACTED])) and that customers may expect to have their devices repaired (presumably at their own expense) even when the device is not covered by warranty, extends to components necessary for service and repair functions regardless of whether purchased devices are covered by warranty. Granting this exemption, as part of the Commission's broad discretion to select the form, scope, and extent of the remedy, avoids harm to consumers by ensuring that consumers who purchased an infringing device prior to the expiration of the Presidential review period are able to repair

their devices.²⁹ The exemption for replacements of infringing devices is limited to replacements of devices purchased prior to the expiration of the Presidential review period that are covered under warranty. For devices not under warranty, the record does not support a finding that avoidance of harm to consumers requires permitting purchasers whose devices are unrepairable to purchase an infringing device rather than a non-infringing device as a replacement, nor does it support a finding that, outside of the warranty period, a purchaser would expect that its infringing device that needs service or repair would be replaced with another infringing device. *See* Compl. RBPI at 8-11 (discussing availability of Respondents’ non-infringing PDT device).

C. Bonding

If 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 period of Presidential review under a bond in 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). When reliable price information is available in the record, the Commission has often set the bond in an amount that would eliminate the price differential between the domestic product and the imported, infringing product. *See Streaming Players*, Comm’n Op. at 41-42 (citations omitted); *Tobacco Heating Articles*, Comm’n Op. at 77 (citations omitted). The Commission also has used a reasonable royalty rate to set the bond amount where a reasonable royalty rate could be ascertained from the evidence in the record. *See, e.g., id.* Where the record establishes that the

²⁹ Commissioner Johanson concurs with the finding that public interest considerations – including potential harm to consumers – justify the exception for repair and replacement as discussed herein. He finds that all the relevant public interest factors support modifying the scope of the remedial order to incorporate this exception.

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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. *See, e.g., id.*

The RD recommends setting a bond of zero percent (0%) during the period of Presidential review. RD at 109. The RD notes that “there is no record evidence to support setting a 100% bond as argued by Complainant. *Id.* at 108. The RD notes that Respondents presented evidence that the RhodoLED XL is priced higher than Complainant’s BLU-U 4170E device, and that Complainant [REDACTED] *Id.*

Complainant disagreed with the recommended zero percent (0%) bond because “a price comparison is not *per se* required for imposing a bond.” Compl. RBPI at 5. Complainant claimed that its “inability to definitively determine whether the price of the BLU-U 4170E is higher than the RhodoLED XL, or vice versa, is exactly why a 100% bond is necessary and appropriate.” *Id.* at 5-6. For example, Complainant argued, Respondents offer a leasing program for the RhodoLED XL, which it claimed is impossible to compare to non-leased devices. *Id.* at 6. Complainant also argued that Respondents offer trade-in discounts for sales of the RhodoLED XL and also sells refurbished units with similar discounts, which lowers the price to below \$ [REDACTED]. *Id.* at 6-7. Complainant also noted that “there is nothing that stops [Respondents] from lowering it’s ‘floor price’ or increasing the discounts it offers to further undercut and erode [Complainant’s] market through infringing imports.” *Id.* at 7. In response, Respondents argued that zero percent (0%) is appropriate because Complainant has not proven that its BLU-U 4170E is on sale yet and the available evidence “indicates that, when the [BLU-U 4170E] goes on sale, it will be priced lower than the RhodoLED XL.” Resp. RBPI at 9-10. Respondents explained that the estimated price for the BLU-U 4170E when it goes on sale will be between \$ [REDACTED] and

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\$ [REDACTED] based on testimony from several witnesses and experts. *Id.* at 10. By contrast, the price of the RhodoLED XL is \$ [REDACTED], and generally sells for \$ [REDACTED]-\$ [REDACTED]. *Id.* at 11.

Respondents also explain that both parties offer discounts for their lamps, but even taking the discounts into account, the price for the RhodoLED XL will be higher than the price of the BLU-U 4170E. *Id.* Respondents further argued that the leasing program is not the “price” of the lamp, because at the end of the leasing period, customers either return the lamp or pay the remaining value of the lamp to purchase it. *Id.* at 13.

The Commission agrees with the RD’s recommendation to set the bond at zero percent (0%) during the period of Presidential review. The Commission is not persuaded by Complainant’s argument that calculation of a price differential is impossible: in fact, the evidence on the record clearly establishes that Complainant’s BLU-U 4170E, once it is available for sale, will be less expensive than Respondents’ RhodoLED XL, such that Respondents are not undercutting Complainant’s prices. As Respondents argued, the Commission ordinarily sets the bond at zero percent when the average selling price of the accused product is higher than the average selling price of the DI product. Resp. RBPI at 10 (citing *See Certain Access Control Systems & Components Thereof*, Inv. No. 337-TA-1016, Comm’n. Op. at 39-44 (Aug. 21, 2018); *Certain Table Saws Incorporating Active Injury Mitigation Technology & Components Thereof*, Inv. No. 337-TA-965, Comm’n Op. at 15 (Jan. 27, 2017)). Furthermore, Respondents’ leasing program does not make a price differential impossible, as customers who use the leasing program will either return the lamp at the end of the lease, or pay the remaining (higher) price. Resp. RBPI at 13. Complainant did not meaningfully dispute that its own prices are lower, and thus, Complainant has not demonstrated that a bond is needed during the Presidential review period.

D. Suspension of Orders as to the '028 Patent

The Commission has found a violation and determined that issuance of a LEO and CDOs is warranted. However, the Commission has determined to suspend enforcement of the remedial orders as to the '028 patent, pending any further action before the PTAB and any potential appeals. The Commission has previously suspended enforcement of its remedial orders, at least in part, when the PTAB issued a final written decision finding one or more of the asserted claims unpatentable before the Commission made its determination on violation. *See, e.g., Certain Unmanned Aerial Vehicles and Components Thereof*, Inv. No. 337-TA-1133, Comm'n Op. at 35 (Aug. 20, 2020); *Certain Magnetic Tape Cartridges and Tame Components Thereof*, Inv. No. 337-TA-1058, Comm'n Op. at 62-63 (Apr. 9, 2019); *Certain Three-Dimensional Cinema Systems and Components Thereof*, Inv. No. 337-TA-939, Comm'n Op. at 60 (July 21, 2016). The Commission acknowledges that the FWD is currently pending Director Review and may subsequently be appealed to the Federal Circuit, and so the patent claims have not yet been cancelled. *See* IPR2024-01312, Paper No. 54 (Mar. 25, 2026); IPR2024-01312, Paper No. 55 (Apr. 2, 2026). However, the Commission recognizes that the PTAB has statutory authority to cancel patent claims after its unpatentability decision has been finally resolved on appeal, and any such cancellation is binding on the Commission. *See* 35 U.S.C. § 318(b).

VI. CONCLUSION

For the reasons set forth herein, the Commission determines that Complainant has established a violation of section 337 by Respondents with respect to claims 1, 3, 5, 8, 17, 18, and 20 of the '512 Patent and claims 1, 2, 4, 16, 17, and 19-21 of the '028 Patent. Accordingly, the investigation is terminated with a finding of violation of section 337. The Commission determines that the appropriate remedy is an LEO and CDOs as to each Respondent, the public interest does not preclude that remedy, and the bond during the period of Presidential review is

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set at zero percent of the entered value. The Commission will suspend enforcement of the orders as to the '028 patent pending resolution of the FWD.

By order of the Commission.

A handwritten signature in black ink, appearing to read 'L.R. Barton', enclosed within a thin black rectangular border.

Lisa R. Barton
Secretary to the Commission

Issued: May 20, 2026